MATERIALS ON THE LAW OF THE EUROPEAN UNION

Spring 2009: PART 2

Caroline Bradley[1]

FOOD SUPPLEMENTS I: EU RULES AND FOOD SAFETY[2]

INTRODUCTION

This packet of materials is designed to illustrate some examples of EU law and policy as they relate to issues of food safety. The examples deal with two types of food

---

[2] There is a lot of detail in places in this document. This is intentional in order to try to make it clear that the EU has put in place a lot of very complex regulation. And, in case anyone is keen on exploring the BSE issue (in particular) further I have included some quite detailed cites. However you are not expected to look at the text of any of the materials cited unless I ask you to do so expressly.

safety issue: food-borne disease or contamination, and the inherent safety of products sold as food. In relation to food safety issues generally, as with other policy areas, the EU tries to adopt collective measures. The BSE cases illustrate some of the tensions that arise in the context of such collective action.

In a document on consumer rights published in 2005 the Commission says:

3. Look around your local supermarket – you will see products from across the whole of Europe. Are they all safe? Yes, they have to be. The EU has laws to help ensure the products you buy are safe. Though no system of regulation can guarantee consumers zero risk, or 100% safety, EU countries have among the highest safety standards in the world.

Food safety is based on the principle that we need to look at the whole of the "food chain" in order to ensure safety. EU food safety laws therefore regulate how farmers produce food (including what chemicals they use when growing plants and what they feed their animals), how food is processed, what colourings and additives can be used in it and how it is sold. The EU also has laws regulating the safety of food imported into the EU from our trading partners in other parts of the world.

The EU's safety laws on other consumer goods are also strict. It is a general requirement of EU law that all products sold in the EU must be safe. If a company discovers it has placed unsafe products on the market it has a legal duty to inform the authorities in the EU countries affected. If the product poses a significant danger the company has to organise a product recall...

4. How can you find out what's in your food? Just look at the information on the package! EU laws on food labelling enable you to know what you are eating. Full details of the ingredients used to make a food product must be given on the label, along with details of any colouring, preservatives, sweeteners and other chemical additives used. If an ingredient is one to which some consumers may be allergic – for example, nuts – it must be marked on the label even if the quantities used are very small.

EU food labelling laws regulate which products can be called "organic" and the use of names associated with quality products from particular European regions – for example, if it is labelled Prosciutto di Parma you can be sure the ham comes from Parma, if it is labelled Kalamata you can be sure the olives are from Kalamata. EU law also enables you to know if food is genetically modified (GM) or contains GM ingredients. If it is, then it must be labelled as genetically modified.[3]

Food safety involves many different policy areas,[4] including health, consumer protection (in relation to health matters and consumer understanding of the nature of food products available for purchase) and farming. And food policy is related more

[3] EU Commission, Consumer Protection in the European Union: Ten Basic Principles, (Jan. 9, 2006) at http://ec.europa.eu/consumers/cons_info/10principles/en.pdf.

[4] Food is a specific context where many policy areas overlap. Other types of consumer product and service (financial services, toys, cosmetics...) involve similar overlapping of issues.

generally to health, because of concerns relating to obesity.[5] Food labelling also involves issues of competition between different food producers.

The Member States all have their own systems for regulating food, but the details of the different regulatory schemes differ. One characteristic of food products is that traditionally food products generally available in the different Member States have been different. The typical characteristics of types of food in the different Member States may vary. Domestic rules may reflect these differences and act as a barrier to the free movement of food products throughout the EU. Chocolate sold in the UK tends to be different from chocolate sold in the other Member States because it contains higher proportions of vegetable fact which does not come from the cocoa plant than chocolate produced in the other Member States.

If other Member States were to restrict the use of the term "chocolate" to products conforming to their traditional practices (containing a high proportion of cocoa and cocoa butter) this could interfere with the ability of UK chocolate producers to compete with the domestic production. They would be forced to:

1. change the name of their product (to one which did not suggest that the product was like the domestic chocolate and which would therefore interfere with the ability of the imported chocolate to compete with the domestic product) or
2. change the characteristics of their product, at least in so far as they planned to export the chocolate to other Member States.

Having to work out how to comply with different rules in effect in 26 other Member States could be very complex (and expensive) and the UK producer might just decide to give up. If this happened there would be less competition in the EU chocolate market than if the UK products could compete more freely.

Free movement of goods is supposed to ensure that goods lawfully marketed in one Member State can be sold freely throughout the EU unless there is a compelling public policy reason why that should not be the case.

UK chocolate producers could respond to this problem by challenging the rules in effect in the different Member States which would interfere with their ability to sell their product throughout the EU. They would argue that Article 28 of the EC Treaty prohibited the Member States from imposing their rules to restrict the sale of UK chocolate. **Article 28** provides:

> Quantitative restrictions[6] on imports **and all measures having equivalent effect** shall be prohibited between Member States.

Measures having equivalent effect to a quantitative restriction have been defined in

---

[5] *See, e.g.*, EU Commission, Green Paper: Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases, COM(2005) 637 final (Dec. 8, 2005) *available at* http://ec.europa.eu/health/ph_determinants/life_style/nutrition/documents/nutrition_gp_en.pdf .

[6] Quotas. Emphasis added.

Procureur du Roi v Dassonville[7] as follows:

> All trading rules enacted by member states which are capable of hindering, directly or indirectly, actually or potentially, intra-community trade are to be considered as measures having an effect equivalent to quantitative restrictions .

This language is very broad. It covers rules which discriminate against imports on their face and also rules which do not discriminate against imports on their face but which impose an additional burden on imports. The sort of rule described above, restricting the use of the description "chocolate" to products with a high proportion of cocoa and cocoa butter is not a rule which discriminates in its terms against imports but it does have an effect on imports. We call rules of this type **indistinctly applicable rules**.

We'll look at the free movement of goods rules in more detail later. The Member States would be able to argue that they should be able to regulate the use of the term "chocolate" in this way, but they probably shouldn't be able to succeed in justifying the rule. **Article 30** of the EC Treaty lists some justifications the Member States can invoke:

> The provisions of Articles 28... shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

In the context of indistinctly applicable rules the Member States may also invoke justifications based on the public interest (including consumer protection) (we'll look at this in more detail later).

But although the UK chocolate producer should be able to succeed in its challenges, challenging all of the different rules in the different Member States could take a long time and be very expensive.

The EU has addressed the problem of chocolate with a directive which sets out the EU's criteria for chocolate.[8] The recitals to the directive state:

> differences between national laws on several kinds of cocoa and chocolate products could hinder the free movement of this product, and thereby have a direct effect on the establishment and functioning of the common market.

---

[7] Case 8-74.

[8] Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption, OJ No. L 197/19 (Aug. 3, 2000) http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/l_197/l_19720000803en00190025.pdf.

The directive specifies which vegetable fats other than cocoa butter may be used in chocolate and provides in Article 2(2):

Chocolate products which, pursuant to paragraph 1, contain vegetable fats other than cocoa butter may be marketed in all of the Member States, provided that their labelling, as provided for in Article 3, is supplemented by a conspicuous and clearly legible statement: 'contains vegetable fats in addition to cocoa butter'. This statement shall be in the same field of vision as the list of ingredients, clearly separated from that list, in lettering at least as large and in bold with the sales name nearby; notwithstanding this requirement, the sales name may also appear elsewhere.

This regulation of labelling addresses the risk that without such a statement consumers might be misled into buying an arguably inferior product or at least a product which contained cheaper ingredients than cocoa butter. The labelling requirement thus addressed the risk of consumer confusion and unfair competition with a rule that meets the requirement of proportionality (the least restrictive rule to achieve the objective).

FOOD SAFETY: BSE

As well as issues of consumer protection and competition, food involves issues of health. These health issues may involve the need to protect consumers of food products from disease, or to protect them from dangerous substances in food products. Within the Commission a Directorate General on health and consumer protection[9] addresses issues relating to food. In addition there is a European Food Safety Authority (EFSA).[10] The EFSA was established after some dramatic issues arose involving questions about the safety of food in Europe. One of these was the BSE (bovine spongiform encephalopathy) crisis which originated in the UK.[11] The UK's Department for Environment, Food and Rural Affairs, Defra, says:

BSE is a relatively new disease of cattle. It was first recognised and defined in the United Kingdom in November 1986. Over the next few years the epidemic grew considerably and affected all parts of the country but to different degrees. It reached its peak in 1992, when 36,680 cases were confirmed, and since then has shown a steady decline....

---

[9] http://ec.europa.eu/food/index_en.htm.

[10] http://www.efsa.europa.eu/en.html. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, OJ No. L 31/1 (Feb. 1, 2002) available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/l_031/l_03120020201en00010024.pdf established the EFSA.

[11] See, e.g., WHO, Fact Sheet on Bovine Spongiform Encephalopathy at http://www.who.int/mediacentre/factsheets/fs113/en/print.html . On the BSE issue in the US, see, e.g. http://www.aphis.usda.gov/newsroom/hot_issues/bse/index.shtml. See also, e.g. FDA Press Release, FDA Proposes Barring Certain Cattle Material From Medical Products As BSE Safeguard (Jan 11, 2007) *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01545.html .

BSE occurs in adult animals in both sexes, typically in animals aged five years and more. It is a neurological disease in which affected animals show signs that include; changes in mental state, abnormalities of posture and movement and of sensation. The clinical disease usually lasts for several weeks and it is invariably progressive and fatal.[12]

Leading up to the BSE crisis, deregulation of animal feed had led to a situation in which cattle (which are not naturally carnivorous) were being fed with rendered animal protein and bone meal and this development seems to have encouraged the transmission of the disease. As increasing numbers of cases of BSE were noticed among cattle there also seemed to be an increase in cases of variant Creutzfeldt-Jakob disease, which affects humans. Defra said that "[b]y 6 January 2006, there were 159 cases of definite or probable vCJD in the UK of whom 153 had died."[13]

In 1996 the UK banned the feeding of rendered mammalian protein to farmed livestock. The UK also instituted a program of culling cattle and a system of tracking cattle. The EU Commission adopted a decision in 1998 recognizing the steps the UK had taken to control BSE and authorizing the UK to send certain meat products to other Member States.[14] The EU also introduced rules prohibiting the use of processed animal proteins in feeds for farm animals kept for food production.[15] An EU Animal By-Products Regulation regulates the safe collection, transport, storage, handling, processing, uses and disposal of animal by-products.[16] And, because of the risk of transmitting the disease through infected blood, a directive regulates the collection and distribution of

---

[12] http://www.defra.gov.uk/animalh/bse/index.html .There is a similar disease, called scrapie, which affects sheep. The EU now refers to Transmissible Spongiform Encephalopathies to include bovine, ovine, caprine and cervid varieties.

[13] Defra, Transmissible Spongiform Encephalopathies (TSEs) in Great Britain 2005 – A Progress Report, 56, *available at* http://www.defra.gov.uk/animalh/bse/pdf/tse-gb_progressreport12-05.pdf .

[14] Commission decision of 25 November 1998 amending Decision 98/256/EC as regards certain emergency measures to protect against bovine spongiform encephalopathy OJ No. L 328/28 (Dec. 4, 1998) http://eur-lex.europa.eu/LexUriServ/site/en/oj/1998/l_328/l_32819981204en00280035.pdf. And see Commission Decision of 20 August 2002 amending Council Decision 98/256/EC concerning emergency measures to protect against bovine spongiform encephalopathy, OJ No. L 228/22 (Aug. 24, 2002) http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/l_228/l_22820020824en00220024.pdf.

[15] *See, e.g.*, Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding, OJ No. L 173/6 (Jul. 11, 2003) http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_173/l_17320030711en00060013.pdf.

[16] Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption, OJ No. L. 273/1 (Oct. 10, 2002) as amended by Commission Regulation (EC) No 808/2003 OJ No. L117/1 (May 13, 2003).

human blood.[17]

The EU's collective action in response to the BSE threat should substitute for unilateral action by the individual Member States. So, when the Commission decided that the UK could begin importing meat into the other Member States the other Member States should not restrict those imports (restrictions would be violations of Art. 28 and not justified by Art. 30 once the Commission had decided on the basis of expert scientific opinion that there was no basis for stopping the export of meat from the UK). France, however, maintained its ban on UK beef after this decision. The Commission initiated enforcement proceedings against France under **Art. 226**, and the ECJ found that France was in breach of its obligations under the Treaty.[18] **Commission v France** illustrates enforcement proceedings in the EU before the ECJ. Subsequently France successfully sued before the ECJ under **Art. 230** to annul a Commission decision that Portugal would be able to begin to export bovine products. **France v Commission** is an example of a challenge to an act of an EU institution.

These judgments are only very lightly edited so that you can get a sense of how a judgment of the ECJ is constructed. This does make the decisions harder to read, and you need to spend more time figuring out what is going on than you might need to if the cases were edited differently. This way you get a sense of the mix of procedural and substantive issues the Court is addressing.

In some places I have removed citations to cases in order to make it easier to read the text. At times when the ECJ refers to its prior case law or decisions, the judgment includes citations to specific decisions, and you do not always see these in this text.

Questions

Read both judgments carefully. Think about what the cases tell us about the different procedures involved. Why did France win in the second case and not the first? Should France have won the first case? What about the second case?

---

[17] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending directive 2001/83/EC, OJ No. L 33/30 (Feb. 8, 2003) at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_033/l_03320030208en00300040.pdf. Implemented in the UK by the Blood Safety and Quality Regulations 2005 at http://www.opsi.gov.uk/si/si2005/20050050.htm . Note that there is a more detailed list of EU measures at http://ec.europa.eu/food/food/biosafety/bse/chronology_en.htm .

[18] France did not rectify the situation until after the Commission initiated proceedings to have France fined for the breach. *See, e.g.*, Commission withdraws beef fines against France (Nov. 14 2002) at http://www.euractiv.com/en/food/commission-withdraws-beef-fines-france/article-113996 . Meanwhile, France had its own BSE problem: http://news.bbc.co.uk/2/hi/europe/720393.stm; http://www.medicalnewstoday.com/medicalnews.php?newsid=10311 .

Commission v France, Case C-1/00[19]

1. By application lodged at the Court Registry on 4 January 2000, the Commission of the European Communities brought an action under Article 226 EC for a declaration 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 [BSE]... 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 .. in particular, by refusing to permit the marketing in its territory of products eligible under that scheme... the French Republic has failed to fulfil its obligations under those two decisions, in particular their provisions referred to above, and the EC Treaty, in particular Articles 28 EC and 10 EC.
2. By order of the President of the Court of 13 June 2000, the United Kingdom of Great Britain and Northern Ireland was granted leave to intervene...

Community legislation
3. Following the discovery of a probable link between a variant of Creutzfeldt-Jakob disease, a disease affecting human beings, and bovine spongiform encephalopathy (hereinafter BSE) which was widespread in the United Kingdom at the time, the Commission adopted Decision 96/239/EC of 27 March 1996 on emergency measures to protect against [BSE]..(the ban decision).. prohibiting the United Kingdom from exporting from its territory to the other Member States and third countries, in particular, live bovine animals, meat of bovine animals and products obtained from bovine animals...
5. The ban decision provided, in Article 3, that the United Kingdom was to send to the Commission every two weeks a report on the application of the protective measures taken against BSE, in accordance with Community and national provisions.
6. Under Article 4 of the ban decision, the United Kingdom was invited to present further proposals to control BSE in its territory.
7. The seventh recital in the preamble to the ban decision stated that the decision would have to be reviewed once all the elements mentioned in it had been examined.
8. On 16 March 1998 the Council adopted Decision 98/256, by which it lifted the ban for certain meat and meat products from bovine animals slaughtered in Northern Ireland, subject to the strict conditions of a scheme based on the certification of herds (the Export Certified Herds Scheme, hereinafter the ECHS).
9. The resumption of exports under that scheme was authorised by Commission Decision 98/351/EC of 29 May 1998 setting the date on which dispatch from Northern Ireland of bovine products under the Export Certified Herds Scheme may commence by virtue of Article 6(5) of Decision 98/256 (OJ 1998 L 157, p. 110).
10. Under Decision 98/692, the principle of authorising the dispatch of bovine products under a Date-Based Export Scheme (hereinafter the DBES) was adopted by amendment of Article 6 of Decision 98/256.
11. The DBES is set out in Annex III to Decision 98/256, which was inserted in that decision by Decision 98/692.
12. Point 3 of Annex III to Decision 98/256 as amended defines animals eligible under the

[19] http://www.bailii.org/eu/cases/EUECJ/2001/C100.html

DBES 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.
13. Point 4 of Annex III states:
If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Decision, the animal must be automatically rejected. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates, and cancel issued certificates. If dispatch has already taken place, the competent authority must notify the competent authority of the place of destination. The competent authority of the place of destination must take the appropriate measures.
14. Point 5 of Annex III requires the slaughter of eligible animals to be carried out in specialised slaughterhouses not handling ineligible animals, and point 7 provides that traceability must be absolutely guaranteed:
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.
15. The 13th recital in the preamble to Decision 98/692 states in this connection:
Animals presented for slaughter under the ECHS or the DBES must meet all of the relevant conditions laid down in this Decision; ... if it [is] discovered after slaughter of an animal under one of those schemes that it should have been considered ineligible, the competent authority must take the necessary measures to prevent the dispatch of products from that animal; ... if any product from an animal subsequently found to be ineligible has been dispatched, the measures laid down in Article 9 of Directive 89/662/EEC must be applied.
16. Article 6(5) of Decision 98/256 as amended states that the Commission, after having verified the application of all the provisions of that decision on the basis of Community inspections and after having informed the Member States, is to set the date on which dispatch of the products referred to in Annex III to the decision may commence.
17. Pursuant to that provision, Decision 1999/514 set that date as 1 August 1999.

Facts and procedure
18. In French law, the prohibition on the import of beef and veal from the United Kingdom results from the order of 28 October 1998 establishing specific measures applicable to certain products of bovine origin dispatched from the United Kingdom (... hereinafter the order of 28 October 1998). That order was amended by an order of 11 October 1999 ... in order to permit

the transit of beef and veal originating from the United Kingdom.
19. On 10 September 1999 the Commission wrote a letter to the French Republic in which it expressed its surprise at the referral to the Agence française de sécurité sanitaire des aliments (French Food Safety Agency, hereinafter the AFSSA) in connection with the implementation, in French law, of Decisions 98/256 as amended and 1999/514. The Commission urged the French Republic to comply rapidly with those decisions, so that the Commission would not be compelled to resort to the procedure laid down in Article 226 EC.
20. By letter of 1 October 1999, the French Republic forwarded to the Commission the opinion issued by the AFSSA on 30 September 1999 and requested that the opinion and the data on which it was based be examined by the Scientific Steering Committee (hereinafter the SSC), set up by Commission Decision 97/404/EC of 10 June 1997 (OJ 1997 L 169, p. 85).
21. According to that opinion, recent scientific advances and the factual context still raised questions with regard to the safety of products subject to the DBES. In the opinion, the experts claimed in particular that the risk of cattle being infected with BSE could come from a third route, and not only from the two routes already known about, namely feed and maternal transmission. Given the incubation period for the disease, there were no scientific data enabling the validity of the eligibility criteria for animals under the DBES to be established. Only diagnostic tools helped to control the risk. Furthermore, according to the experts, the reliability of the programme set up depended on the reliability of the system for identification and tracing of animals although, under the legislation in force, traceability of certain products was not guaranteed.
22. The Commission forwarded that opinion to the SSC, requesting answers to the following questions:
(1) Do the opinions and documentation provided by the French authorities contain scientific information, epidemiological data or other evidence which has not been taken into account by the SSC?
(2) If that documentation contained new information, data or evidence, or if the SSC had any such new information at its disposal, would that necessitate a re-examination of any of the four SSC opinions directly relating to the scientific justification for the DBES?
(3) In the light of the answers to the above question, does the SSC confirm or not its position that the conditions of the DBES, if appropriately complied with, are satisfactory with regard to the safety of meat or meat products?
23. Those questions were examined first by the group specialising in transmissible spongiform encephalopathies, the TSE/BSE ad hoc group. At its meetings of 14 and 25 October 1999, the group considered the AFSSA opinion and did not reach unanimous conclusions with regard to the questions put to it by the Commission.
24. At its meetings of 28 and 29 October 1999, the SSC also examined that opinion and the questions from the Commission. It pointed out that new data were continually becoming available and were examined by it and by the TSE/BSE ad hoc group at their monthly meetings. It noted that the value of rapid diagnostic tests was not new, but that the newly-developed tests had not yet been evaluated. That evaluation would be complex but should be accorded priority. Having examined the epidemiological data relating to BSE in the United Kingdom up to mid-October 1999, it found that the incidence of the disease was continuing to decline and that there was therefore no reason to suppose that there was a new route of infection. It concluded that there were no grounds for re-examining its conclusions relating to the justification for the DBES. It stressed that its risk assessment was dependent on the action taken by the Commission and the Member States to ensure that the proposed measures for preventing or limiting the risk were meticulously complied with. It pointed out that the assurance provided by

the United Kingdom DBES was very dependent on maintaining the prohibition of the use of feed made from meat-and-bone meal, on the 30-month rule and on clear evidence that the risk through maternal transmission was reduced to a minimum. In conclusion, it took the view that the measures adopted by the United Kingdom made the risk to human health from the United Kingdom DBES at least comparable to that in the other Member States.

25. Since the French Republic did not lift its ban, various meetings were held on 2, 5, 12 and 15 November 1999 between representatives of the French and United Kingdom authorities and of the Commission.

26. On 17 November 1999 the Commission sent the French Republic a letter of formal notice under Article 226 EC. In that letter the Commission stated in particular that, by refusing to allow United Kingdom beef conforming to Community requirements to be marketed in its territory after 1 August 1999, the French Republic had failed to fulfil its obligations under Community law. In the letter, the Commission requested the French Government to submit its observations to it within 15 days and reserved the right, after examining them, to deliver a reasoned opinion under Article 226 EC.

27. On 24 November 1999 the French and United Kingdom authorities and the Commission drew up a protocol of understanding (hereinafter the protocol of understanding). According to that protocol, the French authorities were satisfied with the clarifications provided by the United Kingdom authorities and the Commission with regard to traceability of products in the United Kingdom and on-the-spot controls in that Member State. The protocol of understanding envisages implementation of a disease surveillance project on cohort animals from cattle farms where an animal born after 1 January 1996 has contracted BSE and the carrying out of new post mortem diagnostic tests.

28. With regard to traceability of products outside the United Kingdom, point 5 of the protocol of understanding states:

DBES meat directly dispatched to France could be subject to a specific identification laid down in the framework of the French legislation, allowing for a transparent traceability in a way which, if necessary, would allow for a recall as quickly as possible.

The existing Community legislation already provides for traceability but not in a very transparent or rapid manner. An improvement of the system to cover, in particular, triangular trade is ensured through an interpretative declaration of the Commission and, if appropriate, through an agreement based on the mutual assistance between Member States.

29. Annex II to the protocol of understanding contains the Commission's interpretative declaration, worded as follows:

The Commission declares that, in accordance with its obligations as regards traceability and recall, and following Decision 98/256/EC as amended by Decision 98/692/EC, each Member State, in order to guarantee the effectiveness of this measure based on the precautionary principle, shall take binding measures with a view to maintaining maximum traceability by ensuring that all meat and all products dispatched from the United Kingdom in accordance with Annex II and III of that Decision:

- are marked or labelled upon their arrival on its territory with a distinct mark which cannot be confused with the Community health mark;
- remain marked or labelled as above where the meat or products are cut, transformed or rewrapped on its territory.

Each Member State is invited to notify to the Commission and the other Member States the model of the distinct mark which has been chosen. In the light of the experience gained, the Commission will endeavour to clarify and complete if needed the existing Community legislation, for instance based on the system of mutual assistance and/or by adopting a

decision...
Furthermore the Commission confirms that where traceability cannot be established, a Member State is in a position to refuse, in conformity with Community law and, in particular, with Article 7 of Directive 89/662/EEC, meat or products containing such meat which do not clearly comply with this obligation.
This declaration will be addressed to all the Member States.
30. By letter of 1 December 1999, the French Government requested a one-week extension for replying to the letter of formal notice, in order to enable it to submit the protocol of understanding to the AFSSA.
31. The AFSSA gave its opinion on 6 December 1999. Paragraph 2 of that opinion states:
Pending scientific or epidemiological evidence positively enabling the premisses upon which the DBES is based to be confirmed or invalidated, the additional clarifications and measures relating to checks, traceability and labelling may effectively contribute, should the French authorities decide to lift the ban, to better control of those of the risks that might be the result of imperfect implementation of the DBES, or to being better placed to be able to act upon new information, in particular any warning signs.
32. Paragraph 4 of the opinion is worded as follows:
Any decision must take into account:
- the elements of risk, which are plausible but not currently quantifiable, linked to the absence of certainty, first, as to the distribution of BSE infectivity in the body of bovine animals over time and, secondly, as to all the modes of transmission of the infectious agent in animals;
- the fact that steps to strengthen controls and monitor the machinery, such as to ensure that the measures adopted are actually complied with, do not, however, have any direct and immediate impact on those elements of risk;
- the need to provide that the measures taken may be reversed in order to stop immediately any exposure of consumers to a risk which is confirmed subsequently.
33. On 8 December 1999 the French Prime Minister's press office issued a press release announcing that France is not currently able to lift the ban on British beef and veal. After noting the AFSSA's conclusions, the press release states that French Republic is unable to lift the ban in the absence of adequate guarantees on the following points:
- the establishment and implementation of programmes of tests, which must be improved and widened. For this purpose, it appears necessary for the Commission to organise meetings between scientific experts, in particular United Kingdom and French experts;
- the adoption of Community legislation which would provide a basis for ensuring traceability and compulsory labelling in Europe of United Kingdom beef and veal and derived products.
34. By letter of 9 December 1999, the French Government replied to the Commission's letter of formal notice. Its letter essentially reproduces the text of the press release of 8 December 1999.
35. On 14 December 1999 the Commission sent a reasoned opinion to the French Republic referring to the press release of 8 December 1999 and calling on it to adopt, within five working days, the measures necessary in order for it to comply with its Community obligations.
36. That reasoned opinion was replaced by a second one, of 16 December 1999, which also set a time-limit for compliance of five working days. At the request of the French Republic that time-limit was extended to 30 December 1999.
37. By letter of 29 December 1999, the French Government replied to the reasoned opinion. It pointed out that, under French law, the AFSSA had to be consulted before any amendment of the order of 28 October 1998. According to the opinions given by the AFSSA, serious doubts remained as to the risks presented by products subject to the DBES.
38. The French Government also argued that the Commission had not taken account of

minority opinions within the TSE/BSE ad hoc group, thereby infringing the precautionary principle, or of the fact that the French Republic had contested the date set for the lifting of the ban, which it considered premature.
39. The French Government maintained that the guarantees provided by the protocol of understanding were ineffective since they presupposed that products of United Kingdom origin were traceable in the other Member States, whereas traceability had not been achieved. The discussions which took place in the course of the meetings of the Standing Veterinary Committee of 23 and 24 November and 6 December 1999 demonstrated that a majority of the Member States were not prepared of their own accord to fall in with the Commission's interpretation and thus to ensure product traceability. Faced with that situation, the Commission should have imposed application of its interpretation and, at the very least, proposed an amendment to Council Regulation (EC) No 820/97 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products ... On the contrary, it proposed deferring implementation of compulsory labelling of beef and veal until 31 December 2000.
40. In addition, the French Government reiterated the importance attached by it to rapid implementation of a programme of detection tests, a concern which had not been met at that stage.
41. In the light of those factors, the French Government contended that the scientific arguments contained in the AFSSA's opinion should have led the Commission to revise the decision on lifting the ban or, in any event, to suspend its application. By not doing so, the Commission infringed the precautionary principle.
42. The French Government also drew attention to the very short time-limits which it had been allowed for replying to the letter of formal notice and the reasoned opinion, time-limits which demonstrated the Commission's intent to require the French Republic to implement a decision not providing all the guarantees necessary in order to ensure that human health was protected.
43. Furthermore, the French Government announced its intention to bring before the Court an action relating to the refusal to amend Decision 1999/514.
44. On 29 December 1999 the French Republic brought an action before the Court for annulment of the decision by which the Commission was alleged to have refused to amend or repeal Decision 1999/514. According to the French Government, that decision was revealed by a statement made by Commissioner Byrne, and by the choice made by the Commission on 17 November 1999 to give the French Republic formal notice requiring it to comply with Decision 1999/514.
45. However, ruling on an objection of inadmissibility raised by the Commission, the Court declared that action manifestly inadmissible by order of 21 June 2000 in Case C-514/99 France v Commission [2000] ECR I-4705. At paragraph 47 of the order, the Court pointed out that the Commission had not received an express request for the amendment of Decision 1999/514, but merely some allegedly new evidence which might have altered the legal and factual context taken into consideration. It held at paragraph 48 of the order that, if the applicant considered that the information in question gave rise to an obligation for the Commission to adopt a fresh decision, it was for the applicant to have recourse to the procedure for failure to act for which provision is made by the Treaty.
46. In view of the French Republic's reply to the reasoned opinion, the Commission brought the present action.

Objection of inadmissibility
47. By separate document, the French Republic objected in accordance with Article 91(1) of the

Rules of Procedure that the action is inadmissible.
48. In accordance with Article 91(4) of the Rules of Procedure, the Court, by decision of 23 May 2000, reserved its decision on the objection for final judgment and new time-limits were prescribed for the further steps in the proceedings.
49. The objection is based on two pleas in law. The first plea alleges defects in the pre-litigation procedure and the second that the principle of collegiality was infringed.

The plea alleging defects in the pre-litigation procedure
50. This plea subdivides into four complaints.
51. In the first complaint, the French Government submits that, by sending the letter of formal notice before the AFSSA issued its second opinion, the Commission infringed the principle that the subject-matter of the dispute must be clearly defined. In so acting, the Commission failed to have regard to the purpose of the pre-litigation procedure, which is to give the Member State concerned an opportunity to comply with its obligations under Community law or to avail itself of its right to defend itself.
52. The Commission replies that the complaint is unfounded on the ground that it was under no obligation to await that opinion. In any event, the sending of a letter of formal notice is intended to establish the complaints and does not in any way prevent discussions from continuing. Nor has the French Republic indicated any harm caused by the alleged prematurity in sending the letter of formal notice.
53. As to those submissions, it is to be observed that the function of the pre-litigation procedure laid down in Article 226 EC is to give the Member State concerned an opportunity to comply with its obligations under Community law or to avail itself of its right to defend itself against the complaints made by the Commission. The proper conduct of that procedure constitutes an essential guarantee required by the Treaty not only in order to protect the rights of the Member State concerned, but also so as to ensure that any contentious procedure will have a clearly defined dispute as its subject-matter....
54. It follows from that function that the purpose of the letter of formal notice is, first, to delimit the subject-matter of the dispute and to indicate to the Member State, which is invited to submit its observations, the factors enabling it to prepare its defence and, second, to enable the Member State to comply before proceedings are brought before the Court...
55. In the present case, the breach of obligations alleged was clearly defined in the letter of formal notice as being the refusal to adopt the measures necessary in order to comply with Decisions 98/256 as amended and 1999/514 from 1 August 1999.
56. The French Republic no doubt wished to persuade the Commission, by sending a copy of the AFSSA's second opinion, of the validity of the view which it had put forward in its letter of 1 October 1999 and at various meetings with the Commission. However, the Commission was entitled to retain unaltered its definition of the alleged failure by the French Republic to fulfil its obligations and to take the view that a supplementary opinion from the AFSSA would not affect that definition.
57. It follows that the complaint alleging that the letter of formal notice was flawed because of the time at which it was sent is unfounded.
58. In the second complaint, the French Government alleges that the Commission violated the fundamental rule which requires it to prove the infringement, by refusing to take account of the legal arguments put forward by the French Government to show that it was not possible to apply Decision 1999/514.
59. The Commission responds to this complaint that the French Republic had put forward a line

of argument which was not legal, but political, in nature and that, in any event, the complaint is clearly contradicted by the facts. It points out that it forwarded the AFSSA's opinion to the SSC and held numerous meetings with the French authorities.

60. It need only be stated in this regard that this complaint relates to an alleged failure to prove the infringement, that is to say to a substantive issue, and that, as such, it cannot affect the admissibility of the action.

61. In the third complaint, the French Government argues that the Commission required it to reply both to the letter of formal notice and to the reasoned opinion within urgent time-limits which it did not justify with regard to either traders' economic interests or protection of consumers' health. In so doing, the Commission infringed the audi alteram partem rule. It also committed an abuse of process by substituting a shortened pre-litigation procedure for proceedings for interim relief, in order to put pressure on the French Government, without observing the procedural and substantive conditions governing proceedings for interim relief.

62. The Commission responds to this complaint by stating that the period which a Member State is allowed for replying to a letter of formal notice must be reasonable and that, in order to determine whether it is, account must be taken of all the circumstances of the case... Here, the French authorities were well aware of the Commission's standpoint before the letter of formal notice was sent but had made clear their intention not to implement the decisions at issue and, moreover, announced that intention to the press before notifying the Commission. Furthermore, the present case did not involve a subtle and new interpretation of a provision of the Treaty or of secondary Community legislation, but a failure to implement Community measures benefiting from the presumption of legality against which no action for annulment had been brought within the time-limit laid down for that purpose. The Commission also points out that it granted the extension of time sought by the French Government.

63. In addition, the Commission denies the existence of an obligation to state reasons for the brevity of the periods in question and contests the argument that, to avoid committing an abuse of process, it should have applied for interim relief in parallel with the proceedings dealing with the merits of the case.

64. As to those arguments, it should be noted that the purpose of the pre-litigation procedure is to give the Member State concerned an opportunity to comply with its obligations under Community law or to avail itself of its right to defend itself against the complaints made by the Commission.

65. That dual purpose requires the Commission to allow Member States a reasonable period to reply to letters of formal notice and to comply with reasoned opinions, or, where appropriate, to prepare their defence. In order to determine whether the period allowed is reasonable, account must be taken of all the circumstances of the case. Thus, very short periods may be justified in particular circumstances, especially where there is an urgent need to remedy a breach or where the Member State concerned is fully aware of the Commission's views long before the procedure starts...

66. As stated in paragraph 19 of the present judgment, the French Republic had been informed as early as 10 September 1999 of the Commission's concern that it should implement Decisions 98/256 as amended and 1999/514 within a short time, failing which infringement proceedings would be brought.

67. Furthermore, the Commission had regard to certain requests and observations made by the French Republic, seeking a fresh opinion from the SSC and organising negotiations with the United Kingdom authorities in order to reach a friendly settlement of the dispute. However, the efforts which it expended to that end for three months remained fruitless.

68. Having regard to the binding nature of Decisions 98/256 as amended and 1999/514, the

period which had elapsed since the date on which imports of British beef and veal should have resumed, the economic interests involved, the warning given by the Commission on 10 September 1999 and the negotiations in progress at the time, the time-limits set by the Commission for replying to the letter of formal notice and the reasoned opinion were not unreasonable.

69. It should also be remembered that the Commission did not refuse to extend those time-limits for reply when asked.

70. As regards the part of the complaint alleging abuse of process, the Commission applied the Treaty rules correctly in bringing infringement proceedings under Article 226 EC. The Commission chose the proceedings specifically envisaged by the Treaty for cases where it considers that a Member State has failed to fulfil one of its obligations under the Treaty.

71. Nor did any provision of the Treaty compel the Commission to apply for interim relief. The Commission cannot be reproached for initiating the infringement proceedings rapidly, since there was no flaw in the pre-litigation procedure, as has been found above.

72. It follows that the complaint alleging that the pre-litigation procedure was flawed because of the brevity of the periods allowed for replying to the letter of formal notice and the reasoned opinion must be rejected.

73. In the fourth complaint, the French Government contests the action on the ground that the Federal Republic of Germany, which likewise did not implement Decisions 98/256 as amended and 1999/514, has not been subject to any proceedings before the Court.

74. The Commission responds by stating that it is also pursuing its efforts in relation to that Member State, which is, however, in a different position. It also points out that a Member State cannot justify its own failure to comply with Community law by reference to that of another Member State.

75. As to that, the absence of infringement proceedings against one Member State is irrelevant when assessing the admissibility of infringement proceedings brought against another Member State. The admissibility of the present proceedings cannot therefore be affected by the fact that analogous infringement proceedings have not been brought against another Member State.

76. Consequently, the first plea, alleging defects in the pre-litigation procedure, must be rejected.

The plea alleging that the principle of collegiality was infringed

77. The French Government states that the decision of the Commission acting as a college to authorise its President, Mr Prodi, and Commissioner Byrne to bring an action before the Court was adopted on 22 December 1999, that is to say at a time when the college of Commissioners was not yet acquainted with the French Government's reply to the reasoned opinion. Since, first, that reply made express reference to the precautionary principle and to the French Government's intention to challenge before the Court the Commission's refusal to amend Decisions 98/692 and 1999/514 and, second, the Commission was unable to examine that information as a college before making the application to the Court, the French Government concludes that the decision to make the application was not collegiate in the strict sense.

78. The Commission responds that the college of Commissioners was perfectly aware of the complaints relating to the French Republic, of factual developments such as meetings, memoranda and SSC opinions, of the legal bases for the action to be undertaken and of the AFSSA's argument upon which the French Government would rely when invoking the precautionary principle. The intention to bring an action before the Court was not mentioned but, in any event, at that time a mere procedural threat was involved. Since the college had all the information needed to adopt the decision, the requirement for collegiality was scrupulously

observed.
79. In this regard, it is to be remembered that, in accordance with settled case-law, the principle of collegiality is based on the equal participation of the Commissioners in the adoption of decisions, from which it follows in particular that decisions should be the subject of collective deliberation and that all the members of the college of Commissioners should bear collective responsibility at the political level for all decisions adopted...
80. The Court has stated that a decision by the Commission to bring infringement proceedings against a Member State must be the subject of collective deliberation by the college of Commissioners and that all the information on which that decision is based must be available to the members of the college ...
81. In the present case, the infringement sheet annexed to the decision of the college of Commissioners sets out the legal bases for the envisaged proceedings, the matter complained of and an account of the latest position summarising the opinion of the AFSSA, that of the SSC, the negotiations undertaken with the French and United Kingdom authorities and the terms of the French Government's press release of 8 December 1999.
82. In the light of those details, the members of the college of Commissioners had all the relevant information for adopting a decision to bring proceedings before the Court with full knowledge of the facts.
83. As regards the express reference to the **precautionary principle** which was not made until the reply to the reasoned opinion and was therefore unavailable to the college of Commissioners at the time of adoption of the decision to bring proceedings before the Court, it must be found that express reference to that principle did not alter the account of the latest position as submitted to the college. The French Government had for several months been putting forward arguments regarding the obligation to protect public health, scientific uncertainty in the matter and problems connected with risk management. The addition of the label **precautionary principle** to those arguments added nothing to their content.
84. The same is true of the French Government's intention to bring proceedings before the Court. This involved a mere threat to bring proceedings of an unspecified legal nature which would not in any event have undermined the presumption that Decisions 98/692 and 1999/514 were lawful and the binding nature of those decisions...
85. Furthermore, having regard to the position adopted by the French Government in the press release of 8 December 1999 and in the reply of 9 December 1999 to the letter of formal notice, the Commission was entitled to take the view that the pre-litigation procedure had achieved its objectives and that the file was ready to be submitted to the college of Commissioners for it to adopt a decision relating to the commencement of infringement proceedings, should the French Government keep to its position notwithstanding the sending to it of the reasoned opinion.
86. It follows that the second plea, alleging that the principle of collegiality was infringed, is unfounded.
87. In view of the foregoing considerations, the objection of inadmissibility must be dismissed.

Merits of the case
88. The Commission contends that, under Article 249 EC, decisions are binding upon those to whom they are addressed. Article 1 of Decision 1999/514, which set 1 August 1999 as the date on which dispatch of products subject to the DBES could commence, allowed the Member States no discretion as to that date and the conditions governing dispatch. A Member State cannot, by relying on the scientific opinion of a national body, substitute its own assessment of the risks for that carried out by the Commission in accordance with its powers, which in the present case are those conferred by Article 10(4) of Directive 90/425 and Article 9(4) of

Directive 89/662.
89. The Commission maintains that the **precautionary principle**, which guides its actions, does not have the effect of obliging it to follow every scientific opinion without any power to carry out its own assessment, be it an opinion issued by a Member State body or by minority members of a Community working party. It points out in this connection that Article 7 of Decision 97/404 states that minority views are always to be included in opinions of the SSC.
90. In the Commission's submission, a Member State cannot rely on internal legal reasons, possible problems of interpretation or alleged doubts concerning the validity of a Commission decision to justify unilaterally a failure to apply that decision. Similarly, it cannot make its implementation of decisions subject to the condition that certain amendments are made to them.
91. With regard to Decision 1999/514, the Commission explains that it was required to set the date on which the dispatch of products subject to the DBES was to commence inasmuch as the conditions laid down by Article 6 of Decision 98/256 as amended and Annex III thereto were materially fulfilled. The complaint that it failed to take account of considerations of expediency is therefore unjustified.
92. The Commission contends that, in addition to the breach of Decisions 98/256 as amended and 1999/514, the imposition of restrictions on the entry of goods from other Member States constitutes an infringement of Article 28 EC. Since the products concerned are covered by Community harmonisation constituting a coherent and exhaustive system intended to ensure that human and animal health are protected, the ban cannot be justified by the French Republic on the basis of Article 30 EC.
93. The Commission also submits that, by refusing to comply with Decisions 98/256 as amended and 1999/514 over several months, the French Republic failed to comply with its obligation under Article 10 EC to cooperate in the achievement of the Community's tasks.
94. The French Government essentially contends that the conditions for lifting the ban were not met because: (i) the DBES did not take account of new data such as the discovery of a suspected case of BSE; (ii) United Kingdom beef and veal did not comply with the conditions of the DBES; and (iii) there was no system for tracing products subject to the DBES and the Member States had refused to set up such a system, although this is a fundamental condition of the DBES. It maintains that the Commission is not entitled to bring proceedings against it for failure to fulfil an obligation to implement an unlawful decision when it is not ensuring that the other Member States comply with its fundamental elements. In those circumstances, the French Government was entitled to rely on Article 30 EC in order to prevent the import of United Kingdom beef and veal. Furthermore, the French Government denies that it has infringed its obligation to cooperate in good faith under Article 10 EC.

Challenge to the DBES on the basis of the discovery of a suspected case of BSE
95. The French Government relies on its concern as to the effectiveness of the DBES, a concern reinforced by events subsequent to the commencement of the present infringement proceedings.
96. In its submission, the discovery of a case of BSE in a United Kingdom cow born after 1 August 1996, the date on which the body of measures guaranteeing the application of the DBES was supposed to be fully effective, is a particularly significant fact. It presupposes the existence of a level of latent infectivity well before clinical signs of the disease appear, which means that animals slaughtered before 30 months could be infected while being eligible for export under the DBES. The fact that the United Kingdom authorities have been unable to explain that case and to state the cause of the death of the dam of the cow affected casts

serious doubt on the effectiveness of the whole of the United Kingdom monitoring system, which is the cornerstone of the DBES. Such circumstances call for appropriate means of control, such as tests.
97. The Commission contends that, by that argument, the French Government is challenging the validity of the decisions which the Commission is seeking to enforce in the present action. It is clear from the Court's case-law that a Member State cannot plead that the measure which the Commission is seeking to enforce is unlawful ...
99. As regards more specifically the case of a cow born after 1 August 1996 which contracted BSE, the Commission maintains that, in any event, the case does not call the DBES into question. First, as is apparent from the opinion of the SSC of 14 and 15 September 2000, scientists always considered that occasional cases of BSE in animals born after 1 August 1996 were possible, because of maternal transmission, and that has occurred only once to date. Second, there was no risk of that animal entering the DBES, because it did not meet two of the DBES eligibility conditions: it was over 30 months of age, and the dam did not survive for at least six months after its birth. Furthermore, as is apparent from the opinion of the SSC of 13 and 14 April 2000, the number of cases of infected cattle which may enter the food chain at an age below 30 months in their final year of incubation is extremely low. Finally, every animal eligible under the DBES is cut in an appropriate manner so as to remove certain parts and tissues, while the risk of infection from consuming meat comprising muscle is negligible.
100. As to those arguments, the French Government's questioning of the effectiveness of the DBES must be interpreted as a challenge, in the light of the **precautionary principle**, to the legality of the decision which established that scheme, namely Decision 98/692 which amended Decision 98/256 for that purpose.
101. However, the system of remedies set up by the Treaty distinguishes between actions under Articles 226 EC and 227 EC, which are directed to obtaining a declaration that a Member State has failed to fulfil its obligations, and those under Articles 230 EC and 232 EC, which are directed to obtaining judicial review of measures adopted by the Community institutions or of failure to act on their part. Those remedies have different objectives and are subject to different rules. In the absence of a provision of the Treaty expressly permitting it to do so, a Member State cannot, therefore, properly plead the unlawfulness of decisions addressed to it as a defence to infringement proceedings arising out of its failure to implement those decisions...

Challenge to the DBES on the basis of the alleged non-compliance of United Kingdom beef and veal with Community legislation

102. The French Government states that, according to point II.5.1 of the report of the inspection mission carried out in the United Kingdom from 20 to 24 March 2000 by the Food and Veterinary Office, more than 20% of the records/animals failed to meet the requirements of Article 3 of Regulation No 820/97. Furthermore, according to point III.2 of that report, Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Regulation No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals ... is not fully enforced in the United Kingdom. The report states: This means in practical terms that cattle for which no discrepancies were found but were kept in a holding with more than 20% discrepant cattle can enter the Date Based Export Scheme because a legal basis to restrict these animals is not existing.
103. The Commission replies that the failings noted by that report do not in any way alter the fact that, since the DBES is based on the individual status of each animal, only animals which comply with the identification and recording requirements can be eligible thereunder. The

failings simply mean that those animals may come from holdings in which 20% or more of the animals do not comply with those requirements. In any event, that issue did not come to light until after the decisions in question had been adopted and is not sufficiently serious to undermine the DBES.
104. As to those arguments, the essence of the French Government's complaint is that the DBES eligibility criteria take no account of a failure to comply with the Community legislation on traceability with regard to United Kingdom cattle, in particular animals reared in a holding where some cattle individually meet the conditions of the DBES and others do not.
105. In so doing, the French Government is again challenging the validity of the legislation which established the DBES, namely Decision 98/692. In contrast to the ECHS laid down by Decision 98/256, which is based on the certification of herds, the basis for the DBES is that each animal considered individually must comply with the conditions prescribed.
106. It should nevertheless be reiterated that, as stated in paragraph 101 of this judgment, in the absence of a provision of the Treaty expressly permitting it to do so, a Member State cannot properly plead the unlawfulness of decisions addressed to it as a defence to infringement proceedings arising out of its failure to implement those decisions.
107. It follows that the French Government cannot rely on failings relating to the identification of animals other than those eligible under the DBES to challenge that scheme and refuse to comply with Decisions 98/256 as amended and 1999/514.

Lack of traceability of products subject to the DBES
108. The French Government essentially argues that traceability of products subject to the DBES was one of the fundamental conditions of that scheme but that, when exports of British meat resumed, such traceability did not exist beyond United Kingdom cutting plants. At the meetings of the Standing Veterinary Committee of 23 and 24 November and 6 December 1999, the other Member States announced their decision not to implement the provisions of Decision 98/256 as amended and the Commission abandoned the idea of requiring them to do so. The French Government was not aware of those matters until after the time-limit had expired for bringing an action for annulment of Decision 1999/514 setting the date for the resumption of exports under the DBES, a fact justifying its challenge to the legality of that decision in the present action.
109. Given the lack of harmonisation regarding labelling and traceability, the French Government contends that it was entitled to rely on Article 30 EC in order to prevent the import of products subject to the DBES. Its reaction was consistent with the principle of proportionality because it did not prevent transit of those products through its territory. It submits that the Commission adopts too formalistic a position by requiring notification of a protective measure making express reference to the protective clauses in Directives 89/662 and 90/425. First, negotiations were in progress. Secondly, it is apparent from the account of the facts in the judgment in Case C-477/98 Eurostock [2000] ECR I-10695, at paragraph 24, that the Commission showed more concern for another Member State which had made a notification error. Pleading the circumstances of the case and in particular the fact that it was France that drew the Commission's attention to the problems posed by traceability, the French Government claims that it has complied with its obligation to cooperate in good faith under Article 10 EC.
110. The Commission acknowledges first of all that traceability was one of the fundamental conditions of the DBES. However, traceability was adequately provided for by the Community legislation in force at the material time. It was, moreover, improved by Regulation (EC) No 1760/2000 ... establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products...

111. The Commission then submits that the French Republic cannot put the legality of Decision 1999/514 in issue or plead as a defence the failure of the other Member States to fulfil their obligations. In any event, the failure of the other Member States to comply with their obligations regarding traceability affected only triangular trade, that is to say cases where products from the United Kingdom pass through another Member State before arriving in France. By contrast, where products were correctly labelled on leaving United Kingdom cutting plants, the French Government could not rely on the lack of traceability in its own territory to prevent direct imports of those products from the United Kingdom.
112. Finally, the Commission disputes that Article 30 EC may be relied on since the decisions at issue achieved full harmonisation and Directives 89/662 and 90/425 set out the procedure for applying the protective clauses.
113. As to those arguments, it should be noted at the outset that traceability of products subject to the DBES was a fundamental condition for the proper operation of that scheme, in order to protect public health.
114. As is clear from the 13th recital in the preamble to Decision 98/692 and point 7 of Annex III to Decision 98/256 as amended, it was essential for products subject to the DBES to be traceable up to the point of sale in order to enable a consignment to be recalled, in particular if it were to become apparent that an animal was ineligible under the DBES.
115. However, the evidence submitted to the Court shows that such traceability was not fully guaranteed by the Community legislation existing at the time of adoption of Decision 1999/514, in particular so far as concerns meat and products subject to the DBES which had been cut, processed or rewrapped.
116. The Commission acknowledged the existence of that legislative lacuna, since point 5 of the protocol of understanding stated that, at the time of signature of that document, traceability was not very transparent or rapid.
117 . In order to remedy that problem, point 5 of the protocol of understanding provided that consignments under the DBES directly dispatched to France could be subject to specific identification laid down under French legislation and allowing for transparent traceability in a way which, if necessary, would permit recall as quickly as possible.
118. As for triangular trade, the interpretative declaration of the Commission set out in Annex II to the protocol of understanding provided that each Member State was to take binding measures to ensure that all meat and meat-based products dispatched from the United Kingdom under the ECHS or DBES were marked or labelled with a distinct mark and remained so where the meat or meat-based products were cut, processed or rewrapped on its territory. Point 5 of the protocol of understanding stated, however, that, if appropriate, the system of traceability should be improved through an agreement based on mutual assistance between Member States.
119. It is apparent from the report of the meeting of the Standing Veterinary Committee of 6 December 1999 that, at that meeting, the representatives of most of the Member States stated that they did not intend to use a distinct mark for United Kingdom meat. They were nevertheless in favour of harmonisation of labelling at Community level.
120 . When the Commission reminded the veterinary authorities of the Member States, by letter of 16 October 2000, that, in accordance with the 13th recital in the preamble to Decision 98/692 and point 4 of Annex III to Decision 98/256 as amended, they could be required, if need be, to take measures at the place of destination and that the recall of meat or meat-based products would be facilitated if the Member States adopted specific marking which remained even when the meat or meat-based products were cut, processed or rewrapped, certain Member States expressed the view in reply that the Community legislation was sufficient or that additional

marking could not be introduced without amending the Community rules.
121. Regulation No 820/97 which, despite its title, merely contained provisions regulating the power of the Member States to impose a labelling system was to remain in force until 31 December 1999. It provided in Article 19(1) that a compulsory beef-labelling system shall be introduced which shall be obligatory in all Member States from 1 January 2000 onwards. As the Court has recorded in its judgment delivered today in Case C-93/00 Parliament v Council [2001] ECR I-10119, at paragraphs 8 and 10, it was, however, not until 13 October 1999 that the Commission presented to the European Parliament and the Council two proposals for regulations, the first designed to establish a compulsory labelling system with effect from 1 January 2003 and the second temporarily to prolong the validity of Regulation No 820/97.
122. On 21 December 1999 the Council adopted Regulation (EC) No 2772/1999 providing for the general rules for a compulsory beef labelling system ... Since it corresponded to the Commission's second proposal, its effect was, however, only to maintain in force the voluntary labelling system.
123. It was not until 17 July 2000 that the European Parliament and the Council, by Regulation No 1760/2000, established a complete compulsory tracing and labelling system. However that regulation, as stated in the second paragraph of Article 25, is applicable only to meat from cattle slaughtered on or after 1 September 2000.
124. Accordingly, at the time of adoption of Decision 1999/514, that is to say 23 July 1999, there was no binding legislation enabling the DBES to be implemented in compliance with the conditions imposed by it concerning traceability. It was thus for the Member States to adopt, on their own initiative, appropriate measures for organising a system of specific marking and tracing of products subject to the DBES.
125. It is in the light of those circumstances that the subject-matter of the failure to fulfil obligations and the defence put forward by the French Republic should be assessed.
126. The arguments relating to lack of traceability relied on by the French Government by way of defence are apposite in so far as they concern products subject to the DBES which have been cut, processed or rewrapped in another Member State and subsequently exported to France without the affixing of a distinct mark in order, in particular, to enable consignments to be recalled.
127. The Commission has not, however, established that the French Government would have prevented the import of all beef and veal or all meat-based products from other Member States not bearing the distinct mark of products subject to the DBES on the ground that certain consignments of meat or of cut, processed or rewrapped products could include beef, veal or products of United Kingdom origin which would not be identifiable as such.
128. It follows that the application for a finding of failure to fulfil obligations must be dismissed in so far as it concerns that category of products.
129. So far as concerns products subject to the DBES which are correctly marked or labelled, whether coming directly from the United Kingdom or from another Member State, the French Government has not put forward a ground of defence capable of justifying the failure to implement Decisions 98/256 as amended and 1999/514.
130. It is settled case-law that a Member State may not plead provisions, practices or circumstances existing in its internal legal system in order to justify a failure to comply with its obligations under Community law (Case C-217/88 Commission v Germany [1990] ECR I-2879, paragraph 26).
131. Furthermore, a Member State which encounters temporarily insuperable difficulties preventing it from complying with its obligations under Community law may plead force majeure only for the period necessary in order to resolve those difficulties (see, to that effect, Case

101/84 Commission v Italy [1985] ECR 2629, paragraph 16).
132. In the present case, the French Government has not referred to specific difficulties which would have prevented it from adopting, at the very least after expiry of the period allowed for complying with the reasoned opinion, the legislation necessary in order to ensure the traceability of any products subject to the DBES which are cut, processed or rewrapped on its own territory.
133. It should be noted that traceability requirements for meat and meat-based products originating from the United Kingdom were not established by Decision 1999/514, but had existed since 1 June 1998 under the ECHS, set up by Decision 98/256. Furthermore, Decision 98/692 made clear the importance of traceability for the proper operation of the DBES.
134. It is true that there were difficulties in interpreting and consequently in implementing Decision 98/256 as amended, since the requirements imposed on all the Member States were neither clear nor precise. Exports of products subject to the DBES were to commence at a time when there was no compulsory Community system providing a means of ensuring that those products could be traced. The protocol of understanding seems to permit the French Government to make arrangements for tracing products dispatched directly to France, whereas the Commission specifies, in the interpretative declaration annexed to that protocol, the obligations imposed on the Member States while retaining the possibility of improving if necessary the working of the system by an agreement negotiated between the Member States. It is also apparent from the documents relating to the positions adopted by the national veterinary authorities that certain Member States took the view that national legislation was not needed or that only Community harmonisation would enable the required traceability to be achieved.
135. However, the French Republic was fully informed by the protocol of understanding concluded on 24 November 1999 of the extent of its obligations under Decisions 98/256 as amended and 1999/514 as regards the traceability of meat and meat-based products from the United Kingdom dispatched directly to French territory. The same is true of correctly marked or labelled meat and meat-based products originating from the United Kingdom but coming from another Member State.
136. Since 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, it must be held that the infringement consisting of a failure to implement those decisions is proved only from expiry of the period allowed for complying with the reasoned opinion, that is to say after 30 December 1999.

Infringement of Article 28 EC
137. As regards the Commission's claim for a declaration that Article 28 EC has been infringed, it is to be observed that the Commission has not adduced in support of this claim evidence that is separate from the matters which constitute the infringement resulting from the failure to implement Decisions 98/256 as amended and 1999/514.
138. Nor does the Commission offer any justification for finding a separate infringement of Article 28 EC when it takes the view that the French Republic is not entitled to rely on Article 30 EC in support of its refusal to import products subject to the DBES on the ground that the applicable Community rules constitute exhaustive and coherent harmonisation in the field.
139. Given the lack of evidence adduced in support of this part of the application and the contradiction apparent in the application, the claim seeking a declaration that the French Republic has failed to fulfil its obligations under Article 28 EC must be held to be unfounded.

Infringement of Article 10 EC
140. As regards the Commission's claim for a declaration that the obligation to cooperate in good faith under Article 10 EC has been infringed, it is to be recalled that, as noted in paragraph 134 of this judgment, there were difficulties in interpreting and implementing Decision 98/256 as amended. It was specifically the French Government which drew the Commission's attention to the problems posed by the lack of clarity of that decision and of the Community rules applicable generally to the traceability of products subject to the DBES.
141. In the light of those factors, it has not been proved that the French Republic failed to comply with its obligation to cooperate in good faith under Article 10 EC.

Conclusion
142. It follows from all those considerations that the infringement is proved only in so far as, by refusing to adopt the measures necessary in order to comply with Decision 98/256 as amended, in particular Article 6 and Annex III, and Decision 1999/514, in particular Article 1, in particular by refusing to permit the marketing in its territory after 30 December 1999 of products subject to the DBES 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.
143, The remainder of the application must be dismissed....

On those grounds, THE COURT hereby:
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,
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;

France v Commission, Case C-393/01 [20]

1. By application received by fax at the Court Registry on 8 October 2001, and lodged and registered at the Registry on 10 October 2001, the French Republic brought an action under Article 230 EC for annulment of Commission Decision 2001/577/EC of 25 July 2001 setting the date on which dispatch from Portugal of bovine products under the Date-Based Export Scheme may commence by virtue of Article 22(2) of Decision 2001/376/EC ...

Legal background
2. Article 4 of Commission Decision 98/653/EC of 18 November 1998 concerning emergency measures made necessary by the occurrence of bovine spongiform encephalopathy in Portugal

[20] http://www.bailii.org/eu/cases/EUECJ/2003/C39301.html .

(OJ 1998 L 311, p. 23) provides:
'Portugal shall ensure that until 1 August 1999 the following are not dispatched from its territory to other Member States or to third countries, when derived from bovine animals slaughtered in Portugal:
(a) meat;
(b) products which are liable to enter the human food or animal feed chains;
(c) materials which are destined for use in cosmetic or medicinal products or medical devices.'
3. That decision is based on the EC Treaty, on Council Directive 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 ... and in particular Article 10(4) thereof, and on 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 ...
4. Article 2 of Decision 98/653 also prohibits the export to other Member States or third countries of live bovine animals and bovine embryos, meat meal, bone meal, and meat-and-bone meal of mammalian origin.
5. Article 13 of Decision 98/653 provides, in particular, that the Portuguese Republic is to implement a programme to demonstrate effective compliance with all relevant Community legislation on identification and registration of animals, the notification of animal diseases and epidemio-surveillance for transmissible spongiform encephalopathy ('TSE') and with all other Community legislation to protect against ...BSE... That Member State was also required to adopt a programme to demonstrate effective compliance with Decision 98/653 and with the relevant national measures to protect against BSE.
6. Article 14 of Decision 98/653 requires the Portuguese Republic to send the Commission every four weeks a report on the application of the protective measures taken against TSEs in accordance with Community and national provisions and on the results of the programmes referred to in Article 13 of that decision. Article 15 of the decision also provides that the Commission is to carry out Community inspections on-the-spot in Portugal.
7. The ban on bovine products originating in Portugal was extended until 1 February 2000 by Commission Decision 1999/517/EC... and then for an indefinite period by Commission Decision 2000/104/EC ....
8. The conditions for lifting that ban were laid down by Commission Decision 2001/376/EC... concerning measures made necessary by the occurrence of bovine spongiform encephalopathy in Portugal and implementing a date-based export scheme ... That decision repealed Decision 98/653, but did however reproduce some of its provisions.
9. The 7th, 8th, 9th, 10th and 11th recitals in the preamble to Decision 2001/376 are worded as follows:
'(7) A ban on the use of specified risk materials in human food or animal feed was introduced in Portugal on 4 December 1998. The ban has been extended in accordance with Commission Decision 2000/418/EC ... regulating the use of material presenting risks as regards transmissible spongiform encephalopathies ... as amended by Decision 2001/2/EC....
(8) According to the national BSE eradication plan in place in Portugal, birth cohorts and offspring of BSE cases shall be slaughtered and destroyed.
(9) A new centralised national system for identification and registration of bovine animals (SNIRB) was introduced in Portugal as of 1 July 1999.
(10) Portugal presented its first request for a date-based export scheme with a view to permitting, subject to certain conditions, the dispatch of products from animals born after a certain date, to the Commission on 3 December 1999. These technical proposals were

subsequently amended and supplemented on 18 February, 24 March, 27 July and 22 September. The amended and supplemented proposals provide a suitable framework for allowing the dispatch and export of products derived from bovine animals slaughtered in Portugal.
(11) The measures for implementation of the export scheme and the offspring cull will be examined by the Food and Veterinary Office of the Commission before the dispatch of meat and meat products may commence. If that examination is satisfactory the Commission will set the date on which dispatch may commence.'
10. Article 2 of Decision 2001/376 renews the ban on the export of, inter alia, meat-and-bone meal of mammalian origin. Article 5 of that decision provides, however, that Portugal may authorise the dispatch of such material for the purpose of incineration to other Member States which have given their authorisation. Member States of destination are to ensure that that material is incinerated in accordance with Annex II to the decision.
11. Article 6 of Decision 2001/376 maintains the ban on the export of meat, products which are liable to enter the human food or animal feed chains and materials which are destined for use in cosmetic or medicinal products or medical devices.
12. Article 7 of that decision provides, however, that the Portuguese Republic may authorise the dispatch from its territory to other Member States or to non-member countries of amino acids, peptides and tallow, produced in establishments under official veterinary supervision.
13. Article 11(1) of Decision 2001/376 states that by way of derogation from Article 6 of that decision the Portuguese Republic may authorise the dispatch of meat and products to other Member States or to non-member countries in accordance with the conditions laid down in various articles of the decision and in Annex IV thereto, headed 'Date-Based Export Scheme (DBES)'. Article 11(1) to (4) of the decision lays down specific conditions relating to slaughterhouses, cutting plants, storage and transport of meat.
14. Article 12 of that decision provides that meat and products exported under the DBES must be identified by an additional distinct mark.
15. Annex IV to Decision 2001/376 sets out the general conditions of the DBES and determines which animals are eligible for that scheme. It lays down various specific measures such as controls prior to slaughter, slaughter of eligible animals only in slaughterhouses which are not used for slaughter of ineligible animals, control of the cutting of meat, and conditions concerning the traceability and identification of eligible carcases.
16. Article 20 of Decision 2001/376 reproduces the wording of Article 14 of Decision 98/653 regarding the reports which the Portuguese authorities must submit to the Commission at regular intervals.
17. Article 21 of Decision 2001/376 states:
'The Commission shall carry out Community inspections on-the-spot:
(a) in Portugal to verify the implementation of official controls in respect of each of the products referred to in Articles 7 and 8 before the dispatch of these products may commence or recommence;
(b) in Portugal to verify the [application] of the provisions in Articles 11 and 12 and Annex IV before the dispatch of the products referred to in Article 11 may commence;
(c) in Portugal to verify the application of the provisions of this decision, in particular in relation to the implementation of official controls;
(d) in Portugal to examine the development of the incidence of the disease, the effective enforcement of the relevant national measures and to conduct a risk assessment demonstrating whether appropriate measures to manage any risk have been taken;
(e) in the Member State of destination to verify the application, as appropriate, of the provisions

in Article 5 and Annex II before the dispatch of the material referred to in Article 5 may commence.'
18. Article 22(2) of Decision 2001/376 is worded as follows:
'The dates on which the dispatch of material and products may commence or recommence pursuant to Articles 5, 7 and 11 shall be determined by the Commission taking account of the inspections referred to in Article 21 and after having informed the Member States.'

The contested decision
19. Pursuant to Article 22(2) of Decision 2001/376, by the contested decision the Commission set 1 August 2001 as the date for recommencement of the export of the bovine products referred to in Article 11 of Decision 2001/376.
20. The second and third recitals in the preamble to the contested decision state as follows:
'(2) Inspections carried out by the Commission services in Portugal from 14 to 18 May and 25 to 27 June 2001, in particular to assess the system of veterinary checks pursuant to Articles 11 and 12 and Annex IV to Decision 2001/376/EC, have shown that the conditions are complied with satisfactorily.
(3) The Commission has presented the results of the inspections and the consequences it draws from them to the Member States convened in the Standing Veterinary Committee. The Commission has received from Portugal guarantees on the full application and effective enforcement of Community legislation on surveillance for and eradication of TSEs, in addition to those guarantees requested by the report of the Food and Veterinary Office.'

Procedure before the Court
21. By orders of the President of the Court of 1 March and 8 March 2002, the Portuguese Republic and the United Kingdom of Great Britain and Northern Ireland respectively were granted leave to intervene in support of the form of order sought by the Commission.

The action
22. The French Government raises two pleas in law in support of its action. The first plea alleges infringement of Articles 21 and 22 of Decision 2001/376 and manifest error of assessment. The second alleges infringement of the precautionary principle as a result of poor risk management.

First plea
Arguments of the parties
23. The French Government submits that the Commission adopted the contested decision in breach of Article 21, in conjunction with Article 22, of Decision 2001/376 by not ensuring, before the date for lifting the ban was set, the effective implementation of the system for preventing BSE in Portugal, as required by that decision.
24. In addition, the Commission manifestly erred in its assessment by taking the view that the inspections carried out in Portugal had established that the conditions laid down in Decision 2001/376 for lifting the ban were met.
25. According to the French Government, the wording of Article 22(2) of Decision 2001/376, which provides that the dates on which the dispatch of material and products from Portugal may commence or recommence are to be determined by the Commission 'taking account of the inspections referred to in Article 21' of that decision, relates to all the inspections referred to in that article. According to that government, Article 21(c) and (d), which concern inspections of a

general nature, cannot be separated from Article 21(b), which is more specifically related to the DBES. In that connection, it makes reference to the statement of reasons on which Decision 2001/376 is based: first, the eighth recital of the decision, which recalls that the national BSE eradication plan is a prerequisite for the implementation of the DBES, then the ninth recital, which recalls in addition that the system for identification and registration of bovine animals is a prerequisite for the design and application of that scheme, and finally the eleventh recital of that decision, which requires the Food and Veterinary Office ('the FVO') to examine both the measures for implementation of the export scheme and the measures for theoffspring cull and states that only if that examination is satisfactory will the Commission set the date on which dispatch may commence.

26. The French Government submits that, prior to adopting the contested decision, the Commission did not in fact carry out the necessary checks required under Article 21 of Decision 2001/376. In that regard, it states that the last FVO inspection report to be submitted before the contested decision was adopted was the report of 19 July 2001 relating to the mission carried out in Portugal from 25 to 27 June 2001. That report found that it remained necessary for the competent authorities to adopt a draft decree and issue a circular containing the 'DBES manual' and recommended that no establishment other than slaughterhouses and cutting plants processing only DBES beef be approved before inspection by the FVO, which means that, contrary to the provisions of Article 21(c) of Decision 2001/376, 'the implementation of official controls' had not been verified and that, contrary to the requirements of Article 21(d), 'the effective enforcement of the relevant national measures' had not been ensured.

27. The legislative decree, which was not approved until 12 July 2001, and the DBES manual, which was submitted to the Portuguese Minister for Agriculture on 14 July 2001, were, in particular, intended to establish a procedure for the identification and traceability of bovine products in Portugal. The efficacy of that procedure could not therefore have been verified at the date on which the contested decision was adopted, nor indeed at the date set for the partial lifting of the ban.

28. More specifically, the French Government draws attention to the existence of a letter sent on 11 June 2001 by the Commission to the Portuguese authorities, which clearly shows that the DBES was not yet applied at that date and reveals numerous weaknesses in the system of traceability before and after slaughter and in the system for keeping separate the channels for eligible and ineligible products, and the absence of any alarm plan should an animal associated with risk be identified.

29. In that regard, it submits that the report of the mission carried out by the FVO from 25 to 27 June 2001 simply recalls the conditions of the DBES which had to be formalised in the draft legislative decree and the DBES manual, and does not contain anything to show that the points of non-compliance noted in the letter of 11 June 2001 resulted in specific corrective measures, in particular in respect of the rules on backwards and forwards traceability.

30. The Commission disputes the French Government's interpretation of Articles 21 and 22 of Decision 2001/376. Article 22(2) refers to three distinct schemes and cannot be interpreted as meaning that all the provisions of Article 21 apply to each of the three specific schemes. Only Article 21(b) has a direct link to the DBES. Article 21(a) and (e) concern matters which are expressly beyond the scope of that scheme. The provisions of Article 21(c) and (d) are taken verbatim from Article 15 of Decision 98/653, which instituted the ban on bovine products originating in Portugal, and do not have any direct link to the DBES.

31. The Commission therefore considers that the matters referred to in Article 21 of Decision 2001/376 had to be taken into account to varying degrees. It had to take account of all the inspections carried out since Decision 98/653 and to check rigorously whether the inspections

referred to in Article 21(b) of Decision 2001/376 had been carried out and supported the conclusion that the situation in Portugal provided all the necessary guarantees. It considers that those two requirements, which do not bind it to the same extent, were met when it decided to set a date for the recommencement of dispatches under the DBES.

32. As regards the inspections and assessments carried out pursuant to Article 15 of Decision 98/653, the provisions of which are reproduced in Article 21(c) and (d) of Decision 2001/376, the Commission submits that the contested decision was the culmination of intense cooperation between its services and the Portuguese Government, in the course of which a large number of missions were carried out. The reports of those missions - to which the Commission makes reference - can be found on its internet site. The checks referred to in Article 21(c) and (d) were thus carried out throughout the entire duration of the ban and were accordingly taken into account in deciding on the date for the lifting of the ban.

33. The Commission draws attention, however, to the specific nature of the DBES, which is based on the individual status of the eligible animals and, in particular, on the traceability of each of those animals.

34. As regards the inspection required under Article 21(b) of Decision 2001/376, the Commission submits that the conclusions of the report of the mission carried out by the FVO from 25 to 27 June 2001 were generally favourable to the lifting of the ban, particularly as regards the effectiveness with which the procedures had been implemented. The only negative point raised in that report was the incomplete nature of the applicable legal provisions. The legislative decree published on 31 July 2001 was approved by the Portuguese Council of Ministers on 12 July 2001, countersigned by the Prime Minister on 23 July 2001 and promulgated by the President of the Republic on 29 July 2001. It came into force on 1 August 2001. The DBES manual was approved by the Secretary of State for Agriculture on 13 July 2001. The Portuguese system was thus in place, albeit not completely formalised, on the date when the contested decision was adopted, and the Commission considers that it met all the supervisory obligations imposed on it by Community law.

35. According to the Commission, the letter of 11 June 2001 referred to by the French Government merely pointed out certain residual problems. The FVO mission confirmed that on the basis of that letter the Portuguese authorities found solutions to each of the points it raised. In particular, the Portuguese Government responded to the problems of traceability raised by the Commission and that response was assessed by the FVO well before the date set for the recommencement of exports.

36. The Commission accepts that the FVO did not verify the actual operation of the DBES in the establishment visited, but it points out that such a verification was, in practice, impossible at a time when the authorisation to recommence exports had not yet been granted and the system could not be ready to function correctly.

37. In its statement in intervention, the Portuguese Government sets out the steps taken since 1999 to implement the DBES. All the eligibility procedures for farms and animals under that scheme were evaluated during a Community mission carried out in May 2001. Those procedures were found to be adequate and, in a number of cases, had been improved. The implementation of the DBES was evaluated during the mission which took place from 25 to 27 June 2001. That mission concluded that, with the mere exception of the adoption of the final version of the DBES manual and the publication of the applicable legislation, the requirements of Decision 2001/376 had been met.

38. The Portuguese Government submits that the conclusions of the report of that mission were presented to the Standing Veterinary Committee by the Commission and the FVO on 11 July 2001. The inspectors set out in detail the measures adopted by the Portuguese authorities,

without raising any reaction at all from the Member States. The committee was not informed of the specific date on which the contested decision was to take effect since the Commission had not yet come to the end of the internal procedure for adoption of that decision. However, after the committee's consent had been obtained, 1 August 2001 was the date initially given. The Portuguese Government submits that all the required guarantees had been provided, both by its permanent representative to the European Union and by the Portuguese Directorate-General for Veterinary Affairs, and that both the data and the content of the documents required was known to all the parties. The process which led to adoption of the contested decision took place in close collaboration with the competent bodies, the Commission and the sole establishment authorised to apply the DBES. The Portuguese Government is therefore surprised by the action brought by the French Republic and by the plea raised.
39. The United Kingdom Government did not lodge a statement in intervention.

Findings of the Court
40. As a preliminary point, it should be noted that Decisions 2001/376 and 2001/577 are based, inter alia, on Directive 89/662 which authorises the Commission to adopt interim protective measures on serious public-health or animal-health grounds.
41. In that regard, it should be recalled that the first paragraph of Article 152(1) EC provides that a high level of human health protection must be ensured in the definition and implementation of all Community policies and activities.
42. On several occasions the Court has drawn attention to the reality and the seriousness of the risks associated with BSE and the appropriateness of interim protective measures justified on the ground of protection of human health in the light of that disease, whether in respect of measures adopted by the Commission .... It is in the light of those factors that it is appropriate to examine the present action, which seeks to establish whether on the date of the contested decision the Commission was confident that adequate safety in the operation of the DBES had been achieved and that the conditions for lifting the ban on the export of bovine products originating in Portugal were accordingly met.
44. In order to do that, the Court must first identify the inspections which the Commission had to carry out before setting the date for recommencement of exports of the products referred to in Article 11 of Decision 2001/376, and the purpose of those inspections.
45. Article 22(2) of Decision 2001/376 states that the date is to be determined by the Commission 'taking account of the inspections referred to in Article 21' of that decision.
46. Article 21 of Decision 2001/376 provides for five types of Community inspections. The inspection referred to in Article 21(b) relates specifically to the products referred to in Article 11 of that decision and, indeed, it is undisputed that the Commission had to carry out that inspection. The inspections referred to in Article 21(a) and (e) concern different products from those referred to in Article 11 and it is clear that they need not be taken into consideration in respect of the recommencement of exports of the latter products.
47. The inspections referred to in Article 21(c) and (d) are more general in nature and were already provided for in Article 15 of Decision 98/653. It is in particular in the course of those more general inspections that compliance with the prohibition on meat meal, bone meal and meat-and-bone meal in animal feed and the proper operation of the systems for identification and traceability of bovine animals can be checked.
48. Even though the DBES is based on the individual status of eligible animals, compliance with the prohibition on meat meal, bone meal and meat-and-bone meal and the proper operation of the animal identification and traceability systems, in particular, remain essential to ensuring the safety required of that scheme. It is of no use for an animal to be individually identified as

eligible if meat meal, bone meal and meat-and-bone meal continue to be consumed in the Member State concerned or if the database which supplies the identity and the traceability of the animal contains a significant proportion of errors or is not regularly updated.
49. Consequently, even assuming that, as the Commission maintains, the matters referred to in Article 21(b), (c) and (d) of Decision 2001/376 could have been taken into account to varying degrees, the Commission was not permitted to confine itself to the inspection referred to in Article 21(b) before setting the date for recommencement of exports of the products referred to in Article 11 of that decision, but had also to carry out the inspections provided for in Article 21(c) and (d), at least in respect of the elements essential to the safety of the DBES.
50. As regards the purpose of those inspections, it should be noted, as the Advocate General pointed out in point 96 of his Opinion, that, as is made clear in Article 21 of Decision 2001/376, the purpose of those inspections is not merely to verify whether laws or regulations have been adopted or are adequate, but also to ensure the 'application' (Article 21(b) and (c)) or the 'effective enforcement' (Article 21(d)) of those and other applicable provisions.
51. In that regard, it should first be noted that the very wording of the third recital in the preamble to the contested decision shows that the Commission did not itself verify the full application and enforcement of Community legislation on surveillance for and eradication of TSEs, but merely relied on the guarantees provided by the Portuguese authorities.
52. Second, on the date when the contested decision was adopted, it was impossible for the Commission to verify whether any national legislation on the DBES, which met the requirements of that scheme, had been adopted, since the legislative decree was not promulgated by the President of the Republic or published until after the adoption of that decision.
53. Finally, as regards the DBES manual, whose effective implementation in the establishment applying for an approval for the treatment of products covered by the DBES was supposed to be verified by the mission carried out by the FVO from 25 to 27 June 2001, it need only be observed that the Commission has never verified its adoption by the Portuguese authorities and was not able to produce the manual at the hearing, with the result that the Court still does not know the date on which that manual was adopted, nor even whether it has in fact been adopted.
54. It was acknowledged at the hearing that the experts who, as part of the FVO's mission, went to the establishment applying for approval, visited a slaughterhouse without animals subject to the DBES and a cutting plant without meat covered by that scheme. As is clear from the manner in which the mission report was written, those experts could do nothing more than reiterate the DBES requirements at the various stages of the treatment of animals and meat.
55. It follows from the foregoing that the Commission evidently did not carry out the verifications required under Article 21(b) of Decision 2001/376.
56. As regards the more general inspections relating to BSE, referred to in Article 21(c) and (d), the purpose of the mission carried out by the FVO from 14 to 18 May 2001 was, in particular, to check compliance with the Community provisions relating to the ban on using meat meal, bone meal and meat-and-bone meal in animal feed. However, in point 6.2 of the report of that mission the experts stated, inter alia, that the relevant Community legislation had not been transposed into national law, the relevant national law still allowed the incorporation of processed animal proteins into non-ruminant feed, and the understaffing of the competent authority meant that it was not possible adequately to verify compliance with the Community rules.
57. As regards the identification and traceability of bovine animals, it must be observed that the last FVO mission concerned with those matters before adoption of the contested decision took place from 6 to 10 November 2000. That mission was a follow-up to a previous mission, which

took place from 13 to 17 March 2000 and which drew particularly negative conclusions in respect of the identification of bovine animals (unreliability of eartagging, significant proportion of errors in the computerised database SNIRB, delays in updating that database, inadequate cross checking between the various identification systems, and so on).
58. In the conclusions of the report of the mission carried out from 6 to 10 November 2000, the experts noted the remarkable efforts made by the Portuguese authorities to address the recommendations of the previous mission. They nevertheless concluded in point 6.3 of their report that the implementation of the controls in practice was still completely unsatisfactory. In addition, they considered that the situation as regards the number of errors in the SNIRB database had deteriorated (point 6.4 of the report). The traceability of an animal's offspring remained unsatisfactory (point 6.5 of the report).
59. It follows from the foregoing that, on the date the contested decision was adopted, the verifications carried out by the Commission in application of Article 21(c) and (d) of Decision 2001/376 were not sufficient to establish that the Portuguese Republic had correctly applied and effectively enforced the Community and national provisions designed to ensure compliance with the elements essential to the safety of the DBES.
60. Therefore in adopting the contested decision without first carrying out the verifications required so as to ensure adequate safety in the operation of the DBES applicable to the products referred to in Article 11 of Decision 2001/376, the Commission has infringed Article 21, in conjunction with Article 22, of that decision.
61. It follows that the contested decision must be annulled....

On those grounds, the Court (Fifth Chamber) hereby... Annuls Commission Decision 2001/577/EC of 25 July 2001 setting the date on which dispatch from Portugal of bovine products under the Date-Based Export Scheme may commence by virtue of Article 22(2) of Decision 2001/376/EC...

FOOD SAFETY: FOOD SUPPLEMENTS DIRECTIVE
A. LEGISLATION

Studying the Food Supplements Directive allows us to consider an example of EU legislation in some detail. In relation to the regulation of food supplements, as with the control of BSE, there is an underlying question about how legislators and regulators should deal with questions of risk, and of interpretation and application of scientific data.

Here is the text of the **Food Supplements Directive**:[21]

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

---

[21] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the Approximation of the Laws of the Member States Relating to Food Supplements OJ No. L 183/51 (Jul. 12, 2002): http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/l_183/l_18320020712en00510057.pdf . The Annexes are omitted. *See also, e.g.*, http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,
Having regard to the proposal from the Commission[22]
Having regard to the opinion of the Economic and Social Committee..
Acting in accordance with the procedure laid down in Article 251 of the Treaty

Whereas:
(1) There is an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented for supplementing the intake of those nutrients from the normal diet.
(2) Those products are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.
(3) An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community.
(4) Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements.
(5) In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling.
(6) There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.
(7) As a first stage, this Directive should lay down specific rules for vitamins and minerals used as ingredients of food supplements. Food supplements containing vitamins or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in this Directive.
(8) Specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage, provided that adequate and appropriate scientific data about them become available. Until such specific Community rules are adopted and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological effect used as ingredients of food supplements, for which no Community specific rules have been adopted, may be applicable.
(9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.
(10) There is a wide range of vitamin preparations and mineral substances used in the

[22] Citation omitted.

manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.
(11) The chemical substances used as sources of vitamins and minerals in the manufacture of food supplements should be safe and also be available to be used by the body. For this reason, a positive list of those substances should also be established. Such substances as have been approved by the Scientific Committee on Food, on the basis of the said criteria, for use in the manufacture of foods intended for infants and young children and other foods for particular nutritional uses can also be used in the manufacture of food supplements.
(12) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
(13) Excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer.
(14) When maximum levels are set, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels.
(15) Food supplements are purchased by consumers for supplementing intakes from the diet. In order to ensure that this aim is achieved, if vitamins and minerals are declared on the label of food supplements, they should be present in the product in a significant amount.
(16) The adoption of the specific values for maximum and minimum levels for vitamins and minerals present in food supplements, based on the criteria set out in this Directive and appropriate scientific advice, would be an implementing measure and should be entrusted to the Commission.
(17) General labelling provisions and definitions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs(4), and do not need to be repeated. This Directive should therefore be confined to the necessary additional provisions.
(18) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs(5) does not apply to food supplements. Information relating to nutrient content in food supplements is essential for allowing the consumer who purchases them to make an informed choice and use them properly and safely. That information should, in view of the nature of those products, be confined to the nutrients actually present and be compulsory.
(19) Given the particular nature of food supplements, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
(20) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission(6),

HAVE ADOPTED THIS DIRECTIVE:

Article 1
1. This Directive concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.
2. This Directive shall not apply to medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use(7).

Article 2
For the purposes of this Directive:
(a) "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;
(b) "nutrients" means the following substances:
(i) vitamins,
(ii) minerals.

Article 3
Member States shall ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in this Directive.

Article 4
1. Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements, subject to paragraph 6.
2. The purity criteria for substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 13(2), except where they apply pursuant to paragraph 3.
3. Purity criteria for substances listed in Annex II, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply.
4. For those substances listed in Annex II for which purity criteria are not specified by Community legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.
5. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).
6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:
(a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,
(b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.
7. Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements

containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II.
8. Not later than 12 July 2007, the Commission shall submit to the European Parliament and the Council a report on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of nutrients or of substances with a nutritional or physiological effect other than those referred to in paragraph 1, accompanied by any proposals for amendment to this Directive which the Commission deems necessary.

Article 5
1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:
(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;
(b) intake of vitamins and minerals from other dietary sources.
2. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.
3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.
4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the procedure referred to in Article 13(2).

Article 6
1. For the purposes of Article 5(1) of Directive 2000/13/EC, the name under which products covered by this Directive are sold shall be "food supplement".
2. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.
3. Without prejudice to Directive 2000/13/EC, the labelling shall bear the following particulars:
(a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;
(b) the portion of the product recommended for daily consumption;
(c) a warning not to exceed the stated recommended daily dose;
(d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
(e) a statement to the effect that the products should be stored out of the reach of young children.

Article 7
The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.
Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 13(2).

Article 8

1. The amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The units to be used for vitamins and minerals shall be those specified in Annex I.
Rules for implementing this paragraph may be specified in accordance with the procedure referred to in Article 13(2).
2. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.
3. Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Annex to Directive 90/496/EEC.

Article 9

1. The declared values mentioned in Article 8(1) and (2) shall be average values based on the manufacturer's analysis of the product.
Further rules for implementing this paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure referred to in Article 13(2).
2. The percentage of the reference values for vitamins and minerals mentioned in Article 8(3) may also be given in graphical form.
Rules for implementing this paragraph may be adopted in accordance with the procedure referred to in Article 13(2).

Article 10

To facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

Article 11

1. Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.
2. Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive.

Article 12

1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive or one of the implementing Community acts was adopted, has detailed grounds for establishing that a product referred to in Article 1 endangers human health though it complies with the said Directive or said acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.
2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee on the

Food Chain and Animal Health, and shall then deliver its opinion without delay and take appropriate measures.
3. If the Commission considers that amendments to this Directive or to the implementing Community acts are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure referred to in Article 13(2) with a view to adopting those amendments. The Member State that has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 13
1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002(8) (hereinafter referred to as "the Committee").
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.
3. The Committee shall adopt its rules of procedure.

Article 14
Provisions that may have an effect upon public health shall be adopted after consultation with the European Food Safety Authority.

Article 15
Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 July 2003. They shall forthwith inform the Commission thereof.
Those laws, regulations and administrative provisions shall be applied in such a way as to:

(a) permit trade in products complying with this Directive, from 1 August 2003 at the latest;
(b) prohibit trade in products which do not comply with the Directive, from 1 August 2005 at the latest.
When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be adopted by the Member States.

Article 16
This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 17
This Directive is addressed to the Member States.

Done at Luxembourg, 10 June 2002.
For the European Parliament The President P. Cox
For the Council The President J. Piqué I Camps

Question
How much discretion do the Member States have about how to go about implementing the Food Supplements Directive? Do the Member States just have

to include the directive's rules in their own legal systems?

The UK implemented the Food Supplements Directive in England by means of the **Food Supplements (England) Regulations 2003**:[23]

The Secretary of State, in exercise of the powers conferred by sections 16(1)(a) and (e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990 and now vested in him, having had regard... to relevant advice given by the Food Standards Agency and after consultation both as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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 and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

Title, commencement and extent
1. These Regulations may be cited as the Food Supplements (England) Regulations 2003; they come into force on 1st August 2005 and extend to England only.

Interpretation
2. - (1) In these Regulations -
"the Act" means the Food Safety Act 1990[24];
"catering establishment" means a restaurant, canteen, club, public house, school, hospital or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer and is ready for consumption without further preparation;
"Directive 2002/46" means Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements;
"dose form" means a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities;
"food supplement" means any food the purpose of which is to supplement the normal diet and which -
(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and
(b) is sold in dose form;
"preparation" includes manufacture and any form of processing or treatment, and "prepared" shall be construed accordingly;
"sell" includes possess for sale and offer, expose or advertise for sale;
"ultimate consumer" means any person who purchases otherwise than -
(a) for the purpose of resale;
(b) for the purposes of a catering establishment; or
(c) for the purposes of a manufacturing business.

---

[23] The Food Supplements (England) Regulations 2003, SI 2003 No. 1387, *available at* http://www.opsi.gov.uk/si/si2003/20031387.htm. The Schedules are omitted.

[24] http://www.opsi.gov.uk/acts/acts1990/plain/ukpga_19900016_en_1 .

(2) A food supplement shall be regarded as prepacked for the purposes of these Regulations if -
(a) it is ready for sale to the ultimate consumer or to a catering establishment, and
(b) it is put into packaging before being offered for sale in such a way that the food supplement cannot be altered without opening or changing the packaging.
(3) Other expressions used both in these Regulations and in Directive 2002/46 have the same meaning in these Regulations as they have in that Directive.

Scope of Regulations
3. - (1) These Regulations apply to food supplements sold as food and presented as such.
(2) These Regulations do not apply to medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

Restriction on form in which food supplements are sold to the ultimate consumer
4. No person shall sell any food supplement to the ultimate consumer unless it is prepacked.

Prohibitions on sale relating to composition of food supplements
5. - (1) Subject to paragraph (3), no person shall sell a food supplement in the manufacture of which a vitamin or mineral has been used unless that vitamin or mineral -
(a) is listed in column 1 of Schedule 1; and
(b) is in a form which -
(i) is listed in Schedule 2, and
(ii) meets the relevant purity criteria.
(2) The relevant purity criteria for the purposes of paragraph (1)(b)(ii) are -
(a) the purity criteria, if any, specified by Community legislation for the use of the substance in question in the manufacture of food for purposes other than those covered by Directive 2002/46; or
(b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.
(3) In the case of a vitamin or mineral which is not listed in column 1 of Schedule 1 or is not in a form listed in Schedule 2, the prohibitions in paragraph (1) shall not apply until 1st January 2010 if -
(a) the substance in question was used in the manufacture of a food supplement which was on sale in the European Community on 12th July 2002;
(b) a dossier supporting use of the substance in question was submitted to the Commission by the Food Standards Agency or a member State other than the United Kingdom by 12th July 2005; and
(c) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form in the manufacture of food supplements.

Restrictions on sale relating to labelling etc of food supplements
6. - (1) No person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is "food supplement".
(2) Without prejudice to the Food Labelling Regulations 1996, no person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless it is marked or labelled with the following particulars -

(a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;
(b) the portion of the product recommended for daily consumption;
(c) a warning not to exceed the stated recommended daily dose;
(d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
(e) a statement to the effect that the product should be stored out of the reach of young children; and
(f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.
(3) The information required by paragraph (2)(f) shall -
(a) be given in numerical form;
(b) in the case of a vitamin or mineral listed in column 1 of Schedule 1, be given using the relevant unit specified in column 2 of that Schedule;
(c) be the amount per portion of the product as recommended for daily consumption on the labelling of the product;
(d) be an average amount based on the manufacturer's analysis of the product; and
(e) in the case of a vitamin or mineral listed in the Annex to Council Directive 90/496/EEC on nutrition labelling for foodstuffs, be expressed also as a percentage (which may also be given in graphical form) of the relevant recommended daily allowance specified in that Annex.
(4) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the labelling, presentation or advertising of that food supplement includes any mention, express or implied, that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Manner of marking or labelling

7. - (1) No person shall sell any food supplement which -
(a) is ready for delivery to the ultimate consumer, or
(b) is ready for delivery to a catering establishment and is prepacked,
unless the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) appear -
(i) on the packaging;
(ii) on a label attached to the packaging; or
(iii) on a label which is clearly visible through the packaging,
save that where the sale is otherwise than to the ultimate consumer such particulars may, alternatively, appear only on the commercial documents relating to the food supplement where it can be guaranteed that such documents, containing all such particulars, either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement, and provided always that the particulars required by regulation 5(a), (c) and (e) of the Food Labelling Regulations 1996 are also marked or labelled on the outermost packaging in which that food supplement is sold.
(2) No person shall sell any food supplement which is ready for delivery to a catering establishment and is not prepacked, unless the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) appear -
(a) on a label attached to the food supplement;
(b) on a ticket or notice which is readily discernible by the intending purchaser at the place where he chooses the food supplement; or

(c) in commercial documents relating to the food supplement where it can be guaranteed that such documents either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement.
(3) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) are easy to understand, clearly legible and indelible and, when a food is sold to the ultimate consumer, those particulars are marked in a conspicuous place in such a way as to be easily visible.
(4) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) are in any way hidden, obscured or interrupted by any other written or pictorial matter.

Enforcement
8. - (1) Each food authority shall enforce and execute these Regulations in its area.
(2) In this regulation "food authority" does not include -
(a) the council of a district of a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change; or
(b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple).

Offences and penalties
9. If any person contravenes regulation 4, 5, 6 or 7 he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence in relation to exports
10. In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove -

(a) that the food in respect of which the offence is alleged to have been committed was intended for export to a country which has legislation analogous to these Regulations and that the food complies with that legislation; and
(b) in the case of export to a member State, that the legislation complies with the provisions of Directive 2002/46.

Application of various provisions of the Act
11. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations -
(a) section 2 (extended meaning of "sale" etc.);
(b) section 3 (presumptions that food is intended for human consumption);
(c) section 20 (offences due to fault of another person);
(d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;
(e) section 22 (defence of publication in the course of business);
(f) section 30(8) (which relates to documentary evidence);
(g) section 33(1) (obstruction etc. of officers);
(h) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such

requirement as is mentioned in that subsection as applied by paragraph (g) above;
(i) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (g) above;
(j) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (h) above;
(k) section 36 (offences by bodies corporate); and
(l) section 44 (protection of officers acting in good faith).

Signed by authority of the Secretary of State for Health
Hazel Blears
Parliamentary Under Secretary of State, Department of Health
9th May 2003

Questions

1. Note the ways in which the UK's implementing regulations diverge from the contents of the directive. Write out a list.
2. If the UK's regulations are different from the directive do you think that the difference(s) is/are within the powers of the UK under the directive or not? Which aspects of the directive look as though they reflect the idea of the UK choosing its "form and methods" of implementation under Art 249 (i.e. adjusting implementation to national conditions)?
3. As a directive, the Food Supplements Directive won't produce direct effects allowing a purchaser to enforce the directive against a manufacturer/seller of food supplements which don't conform to the requirements of the directive (because this would be horizontal direct effect which does not exist in relation to directives). However, it would be possible to enforce rights under the directive against a Member State (e.g. if a Member State omitted to ensure that conforming products could be sold in its territory).
Do your conclusions about the Member States' discretion affect whether you think this is the right answer in this case?
4. If the EU institutions had acted by regulation would that have made a difference?

Subsequent Developments

There are some issues relating to the classification of certain products as either food products or medicinal products. In 2006, the Commission published a Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs.[25] The Alliance for Natural Health responded critically to the document.

[25] There is a 2006 Regulation which regulates vitamins added to foods. Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, OJ No. L 404/26 (Dec. 30,.2006).

Meanwhile, there was a debate in the US about the regulation of conventional foods marketed as "functional foods".[26] The FDA regulates food labelling under the Nutrition Labeling and Education Act of 1990.[27]

In the EU, a 2006 Directive regulates nutrition and health claims.[28] A recent Report from the Commission[29] states :

This Regulation lays down the conditions for the use of nutrition and health claims on food packaging. While the Regulation has been in force since 1 July 2007, it necessarily includes a transitional period for the circulation of products which were on the market when it entered into force but do not comply with its provisions. Furthermore, several implementing measures are being prepared. This Regulation is very important for the food supplement sector, in which claims, and in particular health claims, are a favoured means of communication with consumers.
The decisive criterion for use of a health claim is that the health effect claimed in relation to a nutrient or substance must absolutely be based on scientific evidence. It can thus be expected that the legal framework applicable to health claims will ultimately constitute, directly or indirectly, an element of harmonisation of the substances enjoying mutual recognition by the Member States, for which these claims will be authorised at the Community level. Moreover ... health claims authorised pursuant to Regulation (EC) No 1924/2006 will constitute a presumption that the product to which they refer belongs in the category of foodstuffs, thereby reducing the risk of conflicts of classification. Indeed, function claims and reduction of disease risk claims clearly establish that the product to which they refer is not liable to fall within the definition of medicinal product by presentation. However, they will not make it possible to completely exclude the risk of conflict of classification in cases where it could be claimed that the product concerned is liable to fall within the definition of medicinal product by function.

---

[26] Food & Drug Administration, Conventional Foods Being Marketed as ''Functional Foods''; Public Hearing; Request for Comments, 71 Fed. Reg. 62400 (Oct. 25, 2006); Extension of Comment period at 72 Fed. Reg. 694 (Jan. 8, 2007).

[27] *See, e.g.*, New York State Restaurant Association v New York City (2d. Cir, Feb 17, 2009) at http://www.nyc.gov/html/doh/downloads/pdf/cdp/Calorie-Posting-final-ruling.pdf (holding that this statute did not pre-empt New York rules: "As we will explain, the federal statutory scheme regulating labeling and branding of food is a labyrinth and interpreting the statute are a series of agency regulations that sometimes appear to conflict and are difficult to harmonize. It is our view, however, that Congress intended to exempt restaurant food from the preemption sections that are necessary to allow food to be sold interstate. In requiring chain restaurants to post calorie information on their menus, New York City merely stepped into a sphere that Congress intentionally left open to state and local governments. Furthermore, although the restaurants are protected by the Constitution when they engage in commercial speech, the First Amendment is not violated, where as here, the law in question mandates a simple factual disclosure of caloric information and is reasonably related to New York City's goals of combating obesity.")

[28] Regulation (EC) No 1924/2006 on nutrition and health claims, OJ No. L 12/3 (Jan. 18, .2007)

[29] Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements, COM (2008) 824 (Dec. 5, 2008).

B. LITIGATION: R. ON THE APPLICATION OF ALLIANCE FOR NATURAL HEALTH V SECRETARY OF STATE FOR HEALTH[30]

Set out below are three stages in the litigation over the claim that the Food Supplements Directive was invalid: the English High Court's decision to make a preliminary reference to the ECJ, the Advocate General's opinion, and the ECJ's judgment. Consider the questions set out after these three decisions.

A. Decision of the English High Court to make a preliminary reference to the ECJ[31]

RICHARDS J:
1 I am grateful to all counsel for what have been very well focused and succinct written and oral submissions in these cases. Having heard those submissions, I take the view that I do not need to hear further from Mr Thompson or Mr Quigley, and I do not need to give a lengthy judgment in this matter and that is because I have decided that permission to apply for judicial review should be granted in both cases. Where permission is granted, as opposed to where it is refused, it is not the general practice of this court to give detailed reasons.
2 I should make clear that in deciding whether permission ought to be granted in a case of this kind the right course, in my view, must be to apply the normal principles that operate at this stage of the judicial review procedure, that is to say the question is, in broad terms, whether the case is arguable, though the court may sometimes be influenced by the general importance of the issues raised.
3 The court is concerned at this stage with the application of a filter, designed to weed out cases that are truly unarguable, that simply have no foundation to them. It would, I think, be wrong in principle to apply a higher test at the permission stage simply because the subject matter of the case is a challenge to the validity of a Community directive and only the European Court of Justice has jurisdiction to declare such a directive invalid.
4 Applying the normal test applicable at this stage of judicial review proceedings, I am satisfied that the challenge to the directive that is made by both sets of claimants is arguable. Some of the points raised might be considered more arguable than others, but it would be wholly inappropriate for me to limit, in a case of this kind, the grounds upon which permission is granted.
5 It follows from what I have said that I reject the submission that in deciding whether to grant permission I should apply a somewhat higher threshold than is usual, for example a test of serious doubt as to the validity of the directive. I think that would be a somewhat higher test, although there is a danger in this area of playing with words. But, in any event, for the reasons that I have given I see no reason to depart from the normal course.
6 The grant of permission does not mean that a reference will automatically be made to the European Court of Justice under art 234. I can envisage the possibility of cases that concern a challenge to a directive and that get over the threshold of arguability, but where this court could take the view, once it had all the evidence before it and had heard full argument, that it was

---

[30] Cases C154/04, 155/04. The Alliance for Natural Health has a web site at http://www.alliance-natural-health.org/ .

[31] [2004] EWHC 405 (Admin).

confident that the challenge should be rejected, and it could and should therefore deal with the matter itself. There is no jurisdictional bar to the national court finding a directive valid. Exclusive jurisdiction lies with the European Court of Justice only in relation to declaring a Community measure to be invalid. It is clear that the national court should always consider carefully whether a reference is really appropriate, bearing in mind, amongst other things, the undesirability of burdening the European Court of Justice unnecessarily.

7 In the circumstances of this case, however, I take the view that a reference is plainly appropriate and that it ought to be made as soon as possible. I say that for a number of reasons. The challenge raises issues in relation to a directive, the prohibitions in which potentially affect a large number of people. The resolution of some of those issues at least may depend not just on consideration of the substantial body of evidence already lodged by the claimants, and such additional evidence as the defendants in the national proceedings might lodge, but also on material that the Community institutions might wish to place before the court.

8 Notwithstanding what I have said about the possibility of a national court looking at the substance of a challenge to a directive, and dealing with the matter itself, if it found the directive to be valid, the fact is that the European Court of Justice is generally better placed than the national court to make a judgment on many of the issues raised in such a challenge and, of course, the fact that it has exclusive jurisdiction to declare a directive invalid adds a special dimension and must inevitably make the national court readier to make a reference.

9 Finally, it is in the interests of everyone to avoid delay, and although a reference is itself a lengthy procedure, to delay a reference at this stage might well achieve nothing at the end of day beyond undesirable additional delay.

10 For all these reasons, I accede to the application that there should be a reference at the earliest possible stage to the European Court of Justice in both cases. Given the conclusion I have reached about the grant of permission, and given the nature of the case, I do not understand that course in fact to be opposed by the defendants. But, in any event, for the reasons I have given, I think it is the appropriate course. In the circumstances, and bearing in mind that there is no application before me for interim relief, it is not necessary, and I think it is not appropriate, for me to express any view beyond what I have already said about the strength of the case advanced in the two claims.

11 Now that is what I say by way of judgment on principle, but I need to discuss with counsel the mechanics of a reference. What is needed, of course, is the preparation of a schedule to the formal order for reference that will set out all the relevant details, including the nature of the case and the reasons why a reference is considered appropriate. There are two courses available, one of them is for the court to draft such a schedule, effectively a judgment in the case, the other is for the court to invite the parties in the first instance to draft a schedule, and for the court to decide whether to approve it in the form put forward or in amended form.

12 When I was at the Bar, I always favoured the latter, on the basis that if one left it to the court there would always be something missing from the judgment that was given or the schedule that was prepared which was thought to be of central importance, although somehow it never really seemed to matter at the end of the day. I think that having regard to the amount of work that has been done by the parties already, and the representation before me, there is in fact merit in inviting counsel to see whether they can draft and agree the terms of a schedule. I stress the importance of making it as succinct as possible, bearing in mind the constant encouragement one gets from the court in Luxembourg to try to keep the orders for reference down to a manageable size. It has to be translated and sent to everybody, and it is not a vehicle for making out the full case, but for identifying for all who may be interested in the matter what the issues raised are. I will hear counsel as to whether that is regarded as an acceptable

course.
13 I want to consider with you what would go to the Court of Justice together with the order for reference, that is to say what material that is before this court ought to be lodged in the court at Luxembourg and whether the schedule to the order for reference ought to refer to the extensive body of evidence that the claimants have lodged, and whether that ought to be lodged with the court, albeit not set out in the schedule but there available to the Court of Justice, so that it does not have to be sent separately with the parties' written observations in due course. It can be there as an object to be referred to. That, again, is something else to be considered.

B. Opinion of Advocate General Geelhoed

20. As a preliminary remark I note that the referring court has limited the scope of its questions to Articles 3, 4(1) and 15(b) of the Directive. These provisions, read together, restrict the marketing of non-positive list (NPL) goods as from 1 August 2005 at the latest.
21. However, the Directive does not concern only the use of positive lists or the prohibition on the use of non-listed vitamins and minerals or substances thereof. The Directive provides not only that only food supplements in conformity with the Directive may be marketed in the Community (Article 3), but also that Member States cannot prohibit or restrict trade in those products (Article 11(1)). These provisions have a general character. They apply to all the requirements laid down in the Directive, including the requirement here at issue. It is true that the use of a positive list is the most characteristic feature of the Directive, the others, such as provisions on labelling, do not have the same impact on the activities of economic operators. None the less, the question is whether the contested provisions can be viewed in isolation from the remainder of the Directive.
22. In essence, the system is as follows:
– From 1 August 2003, Member States must permit trade in food supplements containing vitamins and minerals positive listed (Articles 3, 4 and 15(a) of the Directive).
– From 1 August 2005, Member States must prohibit the trade in products that do not comply with the requirements of the Directive (Articles 4(1) and 15(b) of the Directive).
– Article 4(6) contains a temporary derogation on the prohibition on trade in food supplements containing non-listed vitamins and minerals. Member States may allow on their territory the use of these non-listed substances in food supplements until 31 December 2009, provided certain requirements are met: they were already marketed in the Community on 12 July 2002, a dossier supporting the use of substances has been submitted to the Commission by 12 July 2005, and the European Food Safety Authority has not given an unfavourable opinion of the use of that substance. Other Member States do not have to allow imports of these products (see Article 4(7) of the Directive).
– Modifications to the positive lists may be made according to the procedure mentioned in Article 4(5) and 13(2) of the Directive.
23. The questions referred do not, for example, cover the transitional derogation provided for in Article 4(6) of the Directive, nor the amendment-clause contained in Article 4(5) of the Directive. These provisions might be relevant in the examination in order to decide whether the system chosen by the Community legislature is proportionate. The effect of the invalidity of the contested Community provisions would be that the positive lists would lose their validity. That would deprive many other Articles of their substance. For example, the abovementioned amendment-clause concerning the positive lists would become meaningless. The same applies to the temporary derogation clauses in Article 4(6) and 4(7) of the Directive. Meanwhile, the

Member States are still obliged, under the free movement clause contained in Article 11(1) of the Directive, to allow food supplements which are in conformity with the Directive, without having recourse to Article 11(2) of the Directive. In the event of partial invalidity certain amendments of the Directive (and political choices to replace the positive list system) would certainly be needed. Be that as it may, in my opinion, the contested Community provisions should be examined in the context of the Directive as a whole.

The legal basis (Article 95 EC)

24. The claimants in the main proceedings in Case C-154/04 claim that Article 95 EC cannot serve as the basis for the prohibition arising from the contested Community provisions, since that prohibition does not in the least further the objective of improving the conditions for the establishment and functioning of the internal market. They add that, on the assumption that that prohibition is intended to protect public health and consumers, reliance on Article 95 EC is not only inappropriate, but also constitutes a misuse of powers since, under Article 152(4)(c) EC, the Community has no power to harmonise legislation on public health. The claimants in the main proceedings in Case C-155/04 also claim that Article 95 EC is not the correct legal basis. They argue that the contested Community provisions are incompatible with the principles of the free movements of goods within the Community, with which the Community legislature is required to comply in exercising its powers under Article 95 EC. Furthermore, they allege that those provisions contain direct and immediate restrictions on trade with non-member countries and they should therefore have been adopted on the basis of Article 133 EC.

25. The United Kingdom, Greek and Portuguese Governments, as well as the Parliament, the Council and the Commission, maintain that Article 95 is in this case an appropriate and sufficient legal basis. The main arguments put forward in this context are:

– the Directive's purpose is to improve the conditions for the functioning of the internal market by eliminating differences in national legislation in the field of food supplements and attendant present or future obstacles to trade.

– the fact that the Directive also pursues a public health and consumer protection objective does not mean that it can be concluded that reliance on Article 95 EC is inappropriate.

– since the aim and content of the Directive relate mainly to the internal market, the Directive's effects on international trade cannot lead to the conclusion that it should have been based on Article 133 EC.

26. I have already mentioned in point 4 that this is not the first time that the Court has had to deal with the issue of the appropriate legal basis. Nor is it the first time that the protection of public health is at stake. In the BAT judgment the Court recalled its earlier case-law on Article 95(1) EC.

27. At paragraph 60 of that judgment the Court held that the measures referred to in Article 95 EC are intended to improve the conditions for the establishment and functioning of the internal market and must genuinely have that object, actually contributing to the elimination of obstacles to the free movement of goods or to the freedom to provide services, or to the removal of distortions of competition.

28. The Court went on, in paragraph 61, to hold that recourse to Article 95 EC as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade from multifarious development of national laws; it further held that the emergence of such obstacles must be likely and the measures in question must be designed to prevent them.

29. Finally, in paragraph 62, the Court held that, provided that the conditions for recourse to Article 95 EC as a legal basis are fulfilled, the Community legislature cannot be prevented from relying on that basis on the ground that public health protection is a decisive factor in the

choices to be made.
30. So it is clear that the following requirements apply: real or potential (future) obstacles to free movement must exist and the Community measure must contribute to the elimination of those obstacles. Furthermore, if these two requirements are met, the Community legislature cannot be barred from relying on Article 95 EC if health issues are at stake.
31. In light of the aforementioned principles, I will now turn to the question whether the conditions for recourse to Article 95 EC as a legal basis are satisfied.
32. In my view it is beyond doubt that the conditions are met.

33. First, it is a well-known fact that the market for food supplements is a fast-growing market (see also recital one). Secondly, as noted in recital 2, those products are regulated in Member States by diverse national rules that may impede their free movement, and create unequal conditions of competition, thus making it necessary to adopt Community rules on those products marketed as foodstuffs.
34. As the Court has indicated, it is clear that national rules laying down the requirements to be met by products … are in themselves liable, in the absence of harmonisation at Community level, to constitute obstacles to the free movements of goods.
35. That obstacles with regard to food supplements materialise is clear. The Parliament, the Council and the Commission have all indicated that the number of complaints is growing; the fact that Member States have disparate approaches, therefore creating justified or unjustified obstacles to free trade, is also known from past and more recent case-law of the Court .. With respect to cases still pending I refer to HLM Warenbetrieb and Orthica in which I recently delivered my Opinion. In those Joined Cases the importation of food supplements containing certain vitamins and/or minerals, and allowed as such in the of origin, was barred by the of importation. That treated the products concerned as medicines because of health risks.
36. In my view, it is obvious that the Directive has a clear internal market dimension.
37. In this context I would also point to Article 11(1) of the Directive, the so-called free movement clause, which guarantees the free movement of products which comply with the Directive and, where appropriate, with Community acts adopted in implementation of the Directive. If the products concerned comply with the requirements of the Directive, Member States are prevented from prohibiting or restricting trade in those products, or, as the Court said in its BAT judgement, 'by forbidding the Member States to prevent, on grounds relating to matters harmonised by the Directive, the import, sale or consumption of [food supplements] products which do comply, that provision gives the Directive its full effect in relation to its object of improving the conditions for the functioning of the internal market'.
38. This brings me to the third aspect, which is that the Directive is highly influenced by public health concerns and the protection of the consumer.
39. According to the claimants in Case C-154/04 the Community has no power to harmonise public health measures.
40. It is correct that public health aspects have a heavy emphasis in the Directive. Indeed, it is the rationale behind the Directive. Divergent views by the Member States of health risks with regard to the consumption of food supplements are, after all, a threat to the free movement of those products. Therefore, as is stated in the second recital, harmonising measures were deemed to be necessary. The public health aspects and consumer protection aspects are reflected in different recitals, in particular in the fifth recital, which states that, in order to ensure a high level of protection of consumers and facilitate their choice, the products put on the market must be safe and bear adequate and appropriate labelling.
41. As we learned from the BAT case and the reference made therein to the Tobacco

advertising judgment, if a Directive's objective is to improve the conditions for the functioning of the internal market, and therefore Article 95 EC can serve as a legal basis, it is no bar that the protection of public health is a decisive factor in the choices involved in the harmonising measures which it defines. Moreover, the first subparagraph of Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities, and Article 95(3) EC expressly requires that, in achieving harmonisation, a high level of human protection should be guaranteed.
42. Does the Directive also need Article 133 EC as a legal basis? The answer to that question can be short.

43. It is well established that, in the context of arguments as to the powers of the Community, the choice of a legal basis for a measure must rest on objective factors which are amenable to judicial review. Those factors include in particular the aim and the content of the measure.
44. If examination of a Community act shows that it has a twofold purpose or a twofold component and if one of these is identifiable as the main or predominant component, whereas the other is merely incidental, the act must be founded on a sole legal basis, that is, the one required by the main predominant purpose or component.
45. As stated before, it is clear that the Directive has an internal market dimension. Its purpose is to facilitate free trade in food supplements by harmonising aspects of health protection. Only food supplements which fulfil the requirements set by the Directive may be brought on to the market and can have the benefit of free circulation in the internal market. I do not deny that these requirements can affect products imported from outside the Community. However, this is a side effect. It clearly cannot warrant the choice of Article 133 EC as a legal basis, since the purpose of the Directive is clearly related to the internal market, and not to the regulation of international trade. The argument that the mere fact that international trade might be affected by a piece of Community legislation would suffice for recourse to Article 133 EC has also been rejected by the Court. Besides, if those products from outside the Community meet the requirements they can also freely be traded in the Community....

Principle of proportionality
59. The claimants in the main proceedings claim that the contested Community provisions are disproportionate. They argue that:
– the prohibition arising from the contested Community provisions is not at all necessary, given the discretion of the Member States under Articles 4(7) and 11(2) of the Directive to restrict trade in goods which do not comply with the directive.
– the positive lists were compiled on the basis of lists established in a completely different context, and not in the light of the criteria of safety and availability to be used by the body mentioned in the recital 11 in the preamble to the Directive. The prohibition affects substances and minerals which no one has ever doubted are essential for the diet and/or which have not been shown to represent a danger to health. The positive lists betray a preference for the inorganic forms of vitamins and minerals, which results in the unjustifiable and disproportionate exclusion, of their natural forms, which are nevertheless common in the normal diet and generally better tolerated by the body.
– the Directive's objectives could have been achieved by less restrictive solutions than the approach taken in this case ('negative list' or 'approved list system': positive list system accompanied by harmonised requirements and/or a centralised approval procedure for products which do not comply with the directive: positive lists containing all the nutrients which have been proved to be safe and beneficial to health).

– the procedures laid down in Article 4(5) and (6) of the Directive impose excessive financial and administrative constraints and lack transparency. They are not based on the criteria laid down by the case-law, (21) but on the criteria defined, essentially, by the European Food Safety Authority (EFSA) of its own initiative. A history of safe use of the substance in question is not sufficient for its acceptance by that agency.

60. All the other intervening parties submit that the Directive does not infringe the principle of proportionality.

61. I recall that the referring court refers only to Articles 3, 4(1) and 15(1) of the Directive. I have already observed that an examination of these provisions cannot take place without taking into account the remainder of the Directive.

62. I also wish to state at this juncture that the choice of a system of positive lists is as such appropriate. (22) It has the advantage of being clear for all interested parties as well as for the competent national authorities. The substances included in the list are examined and considered safe. This is, in my view, an important aspect, because Member States, as stated, have to allow all food supplements containing substances which are positive listed. Member States can no longer invoke Article 30 to bar these products from their markets. With a view to attaining a genuine internal market for these products it is therefore substantively appropriate.

63. In its judgments in BAT and Swedish Match, to which I have frequently referred above, the Court considered that the Community legislature must be allowed a broad discretion in making political, economic and social choices in the field of the protection of public health, and that such choices are based on complex assessments. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue.

64. It should be added that, on the one hand, courts must be reticent in assessing the political decisions made by the institutions in the course of the legislative process and, on the other, that Article 95(3) EC requires a high level of protection where health is concerned. The mere fact that the legislature might, in theory, have been able to attain a comparable level protection of public heath by less restrictive measures than those at issue, does not therefore suffice to support the conclusion that it has infringed the principle of proportionality as a system of positive lists undoubtedly provides a high level of protection eliminating ex ante as many potential health risks as possible.

65. The selection of a legislative instrument using positive lists of allowed substances that, on the one hand, aims at securing a high level of protection of public health, and, on the other, imposes far-reaching restrictions on the freedom of market operators in certain Member States to produce and market foodstuffs enriched with minerals and/or vitamins, cannot as such be regarded as being contrary to the principle of proportionality.

66. However, as such a choice significantly affects the freedom of market operators by impeding the continuation of activities previously regarded as permissible and safe, and subjects the development and production of new products to prior assessment by the Commission before inclusion in the positive list, the legal instruments employed must be designed with prudence and precision.

67. Without calling in question the substantive assessment made by the Community legislature, I must conclude that it has seriously failed in its duty to design such a far-reaching measure with all due care.

68. In its present form, Directive 2002/46 is seriously deficient in three respects.

– There is no mention, in the text of the Directive itself, of the substantive norm which the Commission must follow as a guiding principle in exercising its powers under Articles 4(5) and 13 of the Directive. The Directive thus contains no standard for assessing whether the

Commission has, in taking decisions concerning modifications of the positive list, remained within the limits of its legal powers;
– It is not clear whether the Directive allows private parties to submit substances for evaluation with a view to having them included in the positive lists. Recital 10 in the preamble to the Directive refers unambiguously to this possibility, yet Article 4(6)(b) of the Directive would seem to suggest the contrary;
– On the supposition that private parties are indeed able to submit substances for an evaluation with a view to inclusion in the positive lists, there is no clear procedure for this purpose which provides minimum guarantees for protecting those parties' interests.

69. The first deficiency is a particularly serious shortcoming, because it relates to the substantive norm governing the exercise by the Commission of the most far-reaching power provided for in the Directive, namely the decision to add to the as yet incomplete positive lists. The way in which this power is exercised determines the scope for interested parties to exercise their existing economic activities, as well as the restrictions to which they will be subject in the future. Even if we take as a basis only the minimum requirements of the legal certainty necessary in economic relations, it is indispensable that the legislative instrument should itself lay down a substantive standard. Without such a standard there is no basis for effective legal protection.
70. This deficiency is even more striking in view of the fact that the Directive does contain clear norms in respect of less intrusive decisions to be taken by the Commission and which provide guidance for the exercise of its powers, as in the case of labelling (Article 7, first sentence) and quantities (Article 8(1), first sentence.
71. Although the preamble to the Directive, at recital 5, provides a certain substantive point of reference for the decisions on the composition of the positive lists, where it states that 'the products that will be put on the market must be safe', such a recital in the preamble does not constitute a substitute for a standard which should appear in the corpus of the Directive.
72. The legislative technique applied here, if it merits such a title, is furthermore in direct conflict with points 10 and 13 of the Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation.
73. The striking conflict between recital 10 in the preamble and Article 4(6) of the Directive led to some confusion at the hearing, particularly on the part of the representatives of the Council and the European Parliament.
74. It is clear that the text of Article 4(6)(b) of the Directive does not provide a solution for that confusion. This provision refers to 'an unfavourable opinion (of the European Food Safety Authority) … on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State (my italics) …'. It may be inferred from this that it is the Member State which is to take the initiative and submit the dossier to the Commission. In turn, the Commission must forward the file to the EFSA which subsequently carries out the evaluation resulting in its 'opinion'.
75. This plainly contradicts the terms of recital 10 in the preamble:
'There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.'
76. The recital refers to neither the nor the Commission. It does expressly mention 'the interested parties' who, it would appear, must compile and present the necessary dossiers, not,

as Article 4(6) of the Directive would seem to indicate, with a view to obtaining a derogation for the period up to 31 December 2009, but for the purpose of evaluating the substances concerned to be included in the positive list.
77. Some assistance in seeking a solution to this contradiction is provided by the 'Administrative Guidance on Submissions for Safety Evaluation of Substances added for Specific Nutritional Purposes in the Manufacture of Foods.' (27) These technical, administrative official guidelines expressly apply to Directive 2002/46. They contain instructions for 'petitioners' submitting an application, a description of the administrative acceptance process and of how the dossier is to be composed when submitting 'the full application'.

78. The following section of point 2.1. of the 'Administrative Guidance', entitled 'Application for the authorisation of a nutritional substance for inclusion in the appropriate EU legislation', is particularly noteworthy. It reads as follows:
'An application for the authorisation of a nutritional substance should consist of the following separate elements:
– a letter clearly specifying the request with regard to nutrient(s) categories and, if appropriate, the specific nutrient(s) that the nutritional substance is intended to be used as a source of. In addition the specific Community legislation that the petitioner would like the substance to be included in should be specified, namely:– …
– Directive of the European Parliament and of the Council on food supplements …'
79. This section seems to confirm what is expressed in recital 10 in the preamble to the Directive, namely that:
a. interested parties (petitioners) are private parties, who
b. may request the 'inclusion of a substance on a positive list', within the meaning of the Directive
c. the Member States play no role in that part of the procedure which precedes the evaluation by the EFSA.
80. It follows from the above that an administrative practice undeniably exists which conforms to the terms of recital 10 in the preamble to the Directive, but which deviates from the text of Article 4(6)(b) of the Directive, as to both procedure and substance, in that it goes further than merely obtaining a temporary derogation for a substance. It is also undeniable that private parties ('petitioners' and 'applicants') are considered to be 'interested parties' in the context of that administrative practice.
81. Such an obvious contradiction between the text of a provision in the Directive and the corresponding recital in the preamble which, in turn, accords with an administrative practice, clearly results in legal uncertainty for the interested parties who have an evident interest in the prudent and transparent application of the Directive.
82. As a passing comment, I would add that a legislative act leading to an administrative practice which is not based on the provisions of that act, but on its preamble, is incompatible with points 10, 14 and 15 of the Interinstitutional Agreement of 22 December 1998 referred to above. It is also at odds with the Court's case-law which requires the reasons given for an act of an institution to cover the substance of that act.
83. These observations are in themselves sufficient to cast doubt on the validity of the extra legem procedure available to 'interested parties', in view of the fact that it is also, at least in part, contra legem. However, even assuming that it is valid, it does not comply with the minimum standards which apply to such procedures under the principles of sound administration.
84. Indeed the 'Administrative Guidance' indicates with some precision which requirements

apply to ‘petitions’ and, subsequently, to ‘full applications’. However, an ‘interested party’ never gets beyond the EFSA’s front door. It must patiently await the ‘scientific opinion’ of this body, following which, under Article 13 of the Directive, a decision is taken by the Commission or the Council in accordance with the so-called regulatory procedure of the Comitology Decision. Once they have submitted their application with the accompanying dossier, interested parties have no right to be heard. Nor are they given the opportunity to express their views on the EFSA’s (draft) ‘scientific opinion’. According to the ‘Administrative Guidance’ an applicant must consult the EFSA’s website to learn of the EFSA’s final judgment. If this judgment is favourable, the Commission remains free to decide whether to follow it up by submitting a proposal to the Standing Committee on the Food Chain and Animal Health, which acts as the regulatory committee referred to in Article 5(1) of the Comitology Decision. Neither the Directive nor the Administrative Guidance obliges the Commission to inform the interested party of its decisions and the reasons on which they are based.

85. In short, this procedure, in so far as it may exist and in so far as it may deserve this title, has the transparency of a black box: no provision is made for parties to be heard, no time-limits apply in respect of decision-making; nor, indeed, is there any certainty that a final decision will be taken. The procedure therefore lacks essential guarantees for the protection of the interests of private applicants.

86. At the hearing, the representative of the Council, responding to a question, remarked that the decisions on the composition of the positive lists are of general application and that it was not necessary, therefore, to accord procedural rights to individual interested parties at the preparatory stage. That position, it would appear to me, is based on a misunderstanding. Even though decisions relating to the extension or the shortening of the positive lists have effect erga omnes, plainly they may also affect the vital interests of individual parties. In order to ensure that these interests are taken into account in the decision-making process in a manner which is open to judicial scrutiny, the basic legislative act ought for that purpose to provide for the minimal guarantee of an adequate procedure. The Community legislature recognised this requirement in, e.g., Regulation (EC) No 384/96 (30) which provides, in precise terms, for guarantees for balanced decision-making in the procedure leading to the adoption of protective anti-dumping measures. Those measures, too, are generally applicable.

87. The claimants in the main proceedings in this case observed, in both their written and their oral submissions, that preparing an ‘admissible’ application within the meaning of the ‘Administrative Guidance’ is a costly matter and that the final decision – or the lack of such a decision – may have the consequence that the company concerned will have to cease (part of) its economic activities. These observations were not contradicted. In this light, the Community legislature in drafting a legislative act may at least be expected to act with such care as to make express provision for minimum conditions of prudent decision-making in that legislative act. The fact that these conditions were not included in Directive 2002/46 is in itself sufficient to conclude that the Community legislature has failed in this respect. The Directive does not comply with essential requirements of legal protection, of legal certainty and of sound administration, which are basic principles of Community law. Thus, lacking appropriate and transparent procedures for its application, the Directive infringes the principle of proportionality. It is, therefore, invalid.

88. I would make one further observation on the Interinstitutional Agreement of 22 December 1998, to which I referred above. The mutual obligations which the institutions entered into in respect of the quality of drafting of Community legislation are not intended primarily to achieve the linguistic aestheticism dear to legislative draftsmen. In a Community of law, such as the European Union, which is governed by the principles of the Rechtsstaat, there are two aspects to a legislative act as an expression of the legislature’s will. On the one hand, it is an instrument

for pursuing and, if possible, achieving justified objectives of public interest. On the other hand, it constitutes a guarantee of citizens' rights in their dealings with public authority. Qualitatively adequate legislation is characterised by a balance between both aspects. The wording and the structure of the legislative act must strike an acceptable balance between the powers granted to the implementing authorities and the guarantees granted to citizens. Directive 2002/46 does not comply with this essential quality requirement of proper legislation.
89. It should also be noted that the consequences of declaring the Directive invalid on these grounds would remain limited. Such a declaration would not, after all, affect the substantive assessment made by the Community legislature which led to the selection of a restrictive system with positive lists for marketing nutrients enriched with minerals or vitamins. A declaration of invalidity would, however, compel the Community legislature to take better account in such a system of the interests of private parties and to provide for the necessary guarantees for their protection. As the Directive only requires the Member States to prohibit trade in products which do not appear on the positive lists as from 1 August 2005 at the latest, the practical consequences of a declaration of invalidity will be limited if the necessary improvements and amendments to the text of the Directive are adopted quickly.

The principle of subsidiarity
90. According to the claimants in the main proceedings, the contested Community provisions infringe the principle of subsidiarity because they interfere unjustifiably with the powers of the Member States in a sensitive area involving health, social and economic policy.
91. The , Greek and Portuguese Governments, as well as the Parliament, the Council and the Commission, take the opposite view.
92. I can be very short on this point. The principle of subsidiarity, as laid down in the second paragraph of Article 5 EC, requires that in areas not falling within its exclusive competence, the Community is to take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and therefore, by reason of the scale or effects of the proposed action, can be better achieved at Community level.
93. The question therefore is whether the objective of the Directive could be better achieved at Community level.
94. As has been discussed earlier, the Directive's objective is to eliminate barriers to intra-Community trade in food supplements raised by existing differences of national rules regarding the composition, manufacturing specifications, presentation or labelling of food, whilst ensuring a high level of health and consumer protection in accordance with Article 95(3) EC.
95. Such an objective cannot be sufficiently achieved by the Member States individually and calls for action at Community level, as is also demonstrated by the many complaints received by the Commission and by the case-law of the Court.

The principle of equal treatment
96. The claimants in the main proceedings contend that there is a breach of the principle of equal treatment, in that it is unfair to include substances on the positive lists, without their having to undergo any additional tests, but to impose burdensome requirements on suppliers of products containing other substances who wish these to be added to the list.
97. It is settled case-law that the principle of non-discrimination or equality of treatment requires that comparable situations should not be treated differently unless such different treatment can be objectively justified.
98. It is clear that every substance needs to be evaluated before it can be added to the list. The substances currently included in the list have undergone such a scientific evaluation. It is true

that some of these substances have been evaluated in the context of other directives using positive lists. It would be odd to start the evaluation procedure from zero again when it is clear that the products concerned have already undergone a test using the same criteria: safety and bioavailability. Therefore the Community legislature was entitled to use existing evaluations as a starting point. That in itself does not mean that submitting all other substances for an evaluation before they can be put on the list amounts to discrimination. It also seems that the Council and Commission have refused to accept an amendment by the Parliament in which it proposed the inclusion of certain substances to the list, on the ground that those substances had not yet been evaluated.

99. So, even though it is established that the Directive as such is not discriminatory, this does not mean that it may not be applied in a discriminatory manner. For this reason, too, it is of vital importance that the Directive should provide for adequate and transparent procedures, suitable for preventing discrimination in the assessment of supplements. As I already explained above, it is precisely in this respect that the Directive is deficient.
100. As an obiter remark I would mention that the claimants also argue that the lists contain certain substances which might be considered dangerous. If that is the case, such a substance should be de-listed as quickly as possible. However, this in itself does not mean that the principle of a positive list is unlawful, or that it infringes the principle of equal treatment. It does presuppose, however, that in such a case the competent authority acts promptly and adequately, otherwise it may well amount to discrimination.

The fundamental rights
101. The claimants in the main proceedings claim that the contested Community provisions infringe their fundamental rights, in particular Article 8 of the European Convention on Human Rights and Fundamental Freedoms and the right to property as laid down in Article 1 of the First Protocol thereto, as well as the right to carry on trade or business. They also claim an infringement of consumers' rights, because the Directive restricts their choice.
102. It is well-established that fundamental rights form an integral part of the general principles of Community law, whose observance the Court ensures. These fundamental rights, however, are not absolute rights, but must be considered in relation to their social function. Thus, restrictions may be imposed on the exercise of those rights, provided those restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of those rights.
103. The consequence of using positive lists as laid down in Article 4(1) of the Directive is that trade in non-listed products is de facto prohibited and thus is indeed capable of restricting the freedom of manufacturers or traders of such products to pursue their trade or profession. However, their right to property is not called in question by the introduction of such a measure. No economic operator can claim a right to property in a market share, even if he held it at the time before the introduction of a measure affecting that market, since such a market share constitutes only a momentary economic position exposed to the risks of changing circumstances. Nor can an economic operator claim an acquired right or even a legitimate expectation that an existing situation which is capable of being altered by decisions taken by the Community institutions within the limits of their discretionary power will be maintained.
104. From what has already been said, it follows that the Directive's aim is to guarantee free circulation of food supplements that comply with the Directive. The necessary restrictive measures in that regard correspond to an objective of general interest: health and consumer

protection. These objectives are expressly mentioned in Article 95(3) EC. (Likewise, Article 8(2) of the ECHR specifically refers to health protection as a justificatory ground.)
105. I already concluded that the use of positive lists of allowed substances aiming at securing a high level of protection of public health and thereby limiting the freedom of market operators to produce and market NPL substances cannot as such be regarded as contrary to the principle of proportionality. However, I have also concluded that the Directive, from a procedural point of view, infringes the principle of proportionality, because it does not take into account the essential requirements of legal protection, of legal certainty and of sound administration. Plainly these requirements also play a role in the context of the assessment of whether fundamental rights are infringed.

106. As a result, although it is clear that any substance not included in the positive lists cannot be used in the production and marketing of food supplements and therefore is in some way likely to affect the ability of certain producers and certain persons trading in food supplements to carry on their professional activity, I do not consider that the Directive constitutes a disproportionate and intolerable interference impairing the exercise of that freedom or other fundamental rights invoked, provided that the procedural guarantees are inserted in the Directive.

The duty to provide a statement of reasons
107. The final argument advanced by the claimants in the main proceedings in Case C-154/04 relates to the allegation that no reasons are given for the prohibition arising from the contested Community provisions, contrary to Article 253 EC and Article 4 of the Protocol on the application of the principles of subsidiarity and proportionality annexed to the EC Treaty.
108. According to the case-law of the Court, the statement of reasons must show clearly and unequivocally the reasoning of the Community authority which adopted the contested measure so as to enable persons concerned to ascertain the reasons for it and to enable the Court to exercise judicial review. It is sufficient for the contested measure to disclose clearly the essential objective pursued, without its being necessary to require a specific statement of reasoning for each of the technical choices made. (33)
109. To me it is evident that the reasoning, in a substantive sense, satisfies the test. The recitals provide a sufficiently detailed statement of reasons for the objective being pursued and of the reasons why the Community thought it necessary to act. As far as the objective is concerned, I would repeat that it is clear that the Directive seeks to strike down existing barriers to intra-Community trade in food supplements by ensuring a high level of health and consumer protection (see recitals 2 and 5). The Community legislature had to take into account the fact that these barriers were the result of genuine concerns relating to the protection of public health. Second, it also had to take into account the instruction to the Community institutions contained in Articles 152(1) EC and 95(3) EC to take into account a high level of heath protection in their respective activities.
110. In order to avoid possible controversy the Community legislature has chosen as a method the use of positive lists (see recitals 9 and 11). It seems that the claimants essentially contest the use of positive lists. As explained before, this choice is within the discretion of the Community legislature and as such is not incorrect.

...Conclusion
111. On the basis of the foregoing considerations, I propose that the Court should reply as follows to the questions submitted by the High Court of Justice of England and Wales:

Examination of the provisions of Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements has disclosed that the Directive infringes the principle of proportionality, because basic principles of Community law, such as the requirements of legal protection, of legal certainty and of sound administration have not been properly taken into account. The Directive is, therefore, invalid.

C. Judgment of the ECJ of 12 July 2005[32]

3 Directive 2002/46, adopted on the basis of Article 95 EC, 'concerns food supplements marketed as foodstuffs and presented as such', as is clear from Article 1(1) of the directive.
4 According to the first recital of the preamble to the directive, '[t]here is an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented for supplementing the intake of those nutrients from the normal diet'.
5 The second recital of the preamble to the directive states:
'Those products are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.'
6 The 5th recital states that '[i]n order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling'.
7 It is clear from the 6th, 7th and 8th recitals to the directive that, given the wide range of nutrients and other ingredients which might be present in food supplements, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts, the Community legislature gave priority to laying down measures for vitamins and minerals used as ingredients in food supplements. It is stated that other Community rules for nutrients other than vitamins and minerals, and for other substances with a nutritional or physiological effect used as ingredients in food supplements, are to be adopted at a later stage once adequate and appropriate scientific data are available and that until those Community rules are adopted national rules concerning those nutrients and substances can continue to be applied in compliance with the provisions of the EC Treaty.
8 The 9th, 10th, 11th and 12th recitals to Directive 2002/46 are worded as follows:
'(9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.

(10) There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent

[32] Grand Chamber composed of V. Skouris, President, P. Jann, C.W.A. Timmermans, A. Rosas, K. Lenaerts (Rapporteur), Presidents of Chambers, C. Gulmann, A. La Pergola, J.-P. Puissochet, R. Schintgen, J. Kluc(ka, U. Lõhmus, E. Levits and A. Ó Caoimh, Judges.

evaluation, as soon as appropriate files are presented by the interested parties.
(11) The chemical substances used as sources of vitamins and minerals in the manufacture of food supplements should be safe and also be available to be used by the body. For this reason, a positive list of those substances should also be established. Such substances as have been approved by the Scientific Committee on Food, on the basis of the said criteria, for use in the manufacture of foods intended for infants and young children and other foods for particular nutritional uses can also be used in the manufacture of food supplements.
(12) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.'
9 For the purposes of Directive 2002/46 'food supplements' is defined by Article 2(a) of the directive as 'foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities'.
10 Article 2(b) of the directive defines 'nutrients' as vitamins and minerals.
11 Under Article 3 of Directive 2002/46, Member States are to ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in the directive.
12 Article 4 of Directive 2002/46 provides:

'1. Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements, subject to paragraph 6...

5. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).

6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

(a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,

(b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.

7. Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II.… '

13 Article 11 of Directive 2002/46 provides:
'1. Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.
2. Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive'.

14 Article 13 of the Directive is worded as follows:
‘1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 … (hereinafter referred to as “the Committee”).
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.
3. The Committee shall adopt its rules of procedure.’
15 Article 14 of Directive 2002/46 provides:
‘Provisions that may have an effect upon public health shall be adopted after consultation with the European Food Safety Authority.’
16 Article 15 of the directive provides:
‘Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 July 2003. They shall forthwith inform the Commission thereof.
Those laws, regulations and administrative provisions shall be applied in such a way as to:
(a) permit trade in products complying with this Directive, from 1 August 2003 at the latest;
(b) prohibit trade in products which do not comply with the Directive, from 1 August 2005 at the latest.…’
17 Pursuant to Article 16, Directive 2002/46 entered into force on 12 July 2002, the day of its publication in the Official Journal of the European Communities.
18 Directive 2002/46 contains two annexes drawing up lists concerning the ‘[v]itamins and minerals which may be used in the manufacture of food supplements’ and ‘[v]itamin and mineral substances which may be used in the manufacture of food supplements’ (‘the positive lists’).

The main actions and the question referred to the Court
19 The claimants in Case C-154/04 are a Europe-wide association of manufacturers, wholesalers, distributors, retailers and consumers of food supplements and a small specialist distributor and retailer of food supplements in the United Kingdom.
20 The claimants in Case C-155/04 are two trade associations representing around 580 companies, the majority of which are small firms which distribute dietary products in the United Kingdom.
21 All the claimants in the main actions maintain that the provisions of Article 3 in conjunction with those of Article 4(1) and Article 15(b) of Directive 2002/46 are incompatible with Community law and must consequently be declared invalid. Those provisions, which prohibit with effect from 1 August 2005 the marketing of foodstuffs which do not comply with the directive, were transposed into national law by the Food Supplements Regulations.
22 The High Court of Justice of England and Wales, Queen’s Bench Division (Administrative Court), granted permission to apply for judicial review and decided to stay the proceedings and to refer to the Court the following question, cast in identical terms in both these cases:
‘Are Articles 3, 4(1), and 15(b) of Directive 200[2]/46/EC invalid by reason of:
(a) the inadequacy of Article 95 EC as a legal basis;
(b) infringement of (i) Articles 28 EC and 30 EC and/or (ii) Articles 1(2) and 24(2)(a) of Council Regulation (EC) No 3285/94 (of 22 December 1994 on the common rules for imports and repealing Regulation (EC) No 518/94 (OJ 1994 L 349, p. 53));
(c) infringement of the principle of subsidiarity;
(d) infringement of the principle of proportionality;
(e) infringement of the principle of equal treatment;

(f) infringement of Article 6(2) [EU], read in the light of Article 8 and Article 1 of the First Protocol to the European Convention on Human Rights, and of the fundamental right to property and/or the right to carry on an economic activity;
(g) infringement of Article 253 EC and/or the duty to give reasons?'
23 By order of the President of the Court of 7 May 2004, the national court's applications to apply to the present cases the accelerated procedure provided for in Article 104a of the Rules of Procedure were dismissed. By the same order, Cases C-154/04 and C-155/04 were joined for the purposes of the written and oral procedure and judgment.

The question referred to the Court
Part (a) of the question
24 By part (a) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid on the ground that Article 95 EC does not afford them an appropriate legal basis.
25 The claimants in Case C-154/04 submit that the prohibition arising from those provisions of Directive 2002/46 does not contribute to improving the conditions for the establishment and functioning of the internal market. On the assumption that the reason for the prohibition lies in public-health considerations, reliance on Article 95 EC constitutes a misuse of powers since, under Article 152(4)(c) EC, the Community has no power to harmonise national legislation on human health.
26 The claimants in Case C-155/04 claim, first, that Articles 3, 4(1) and 15(b) of Directive 2002/46 are contrary to the principle of the free movement of goods within the Community, a principle with which the Community legislature must comply when exercising its powers under Article 95 EC ... Second, the provisions entail direct and immediate restrictions on trade with third countries and should thus have been adopted on the basis of Article 133 EC.
27 In that regard, it must be borne in mind that, as provided for by Article 95(1) EC, the Council of the European Union, acting in accordance with the procedure referred to in Article 251 EC and after consulting the European Economic and Social Committee, is to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.
28 By virtue of the Court's case-law, while a mere finding of disparities between national rules is not sufficient to justify having recourse to Article 95 EC ... it is, however, otherwise where there are differences between the laws, regulations or administrative provisions of the Member States which are such as to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market ...
29 It also follows from the Court's case-law that, although recourse to Article 95 EC as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them ...
30 The Court has also held that, provided that the conditions for recourse to Article 95 EC as a legal basis are fulfilled, the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made ...
31 It must be noted in that regard that the first subparagraph of Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities, and that Article 95(3) EC explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed...

32 It follows from the foregoing that when there are obstacles to trade, or it is likely that such obstacles will emerge in the future, because the Member States have taken, or are about to take, divergent measures with respect to a product or a class of products, which bring about different levels of protection and thereby prevent the product or products concerned from moving freely within the Community, Article 95 EC authorises the Community legislature to intervene by adopting appropriate measures, in compliance with Article 95(3) EC and with the legal principles mentioned in the Treaty or identified in the case-law, in particular the principle of proportionality...
33 Depending on the circumstances, those appropriate measures may consist in requiring all the Member States to authorise the marketing of the product or products concerned, subjecting such an obligation of authorisation to certain conditions, or even provisionally or definitively prohibiting the marketing of a product or products...
34 It is in the light of those principles that it is necessary to ascertain whether the conditions for recourse to Article 95 EC as legal basis were satisfied in the case of the provisions to which the national court's question refers.
35 According to the second recital to Directive 2002/46, food supplements were regulated, before the directive was adopted, by differing national rules liable to impede their free movement and thus have a direct impact on the functioning of the internal market.
36 As the European Parliament and the Council have noted in their written observations, those statements are borne out by the fact that prior to the adoption of Directive 2002/46 a number of cases were brought before the Court which related to situations in which traders had encountered obstacles when marketing in a Member State other than their State of establishment food supplements lawfully marketed in the latter State.
37 Furthermore, at point 1 of the Explanatory Memorandum to the proposal for a directive... on the approximation of the laws of the Member States relating to food supplements.... it is stated, as the Greek Government, the Council and the Commission have pointed out in their written observations, that before that proposal was presented the Commission services had received 'a substantial number of complaints from economic operators' on account of the differences between national rules which 'the application of the principle of mutual recognition did not succeed in overcoming'.
38 In those circumstances action on the part of the Community legislature on the basis of Article 95 EC was justified in relation to food supplements.
39 It follows from the foregoing that Articles 3, 4(1) and 15(b) of Directive 2002/46, which give rise to a prohibition, with effect from 1 August 2005 at the latest, on marketing food supplements which do not comply with the directive, could be adopted on the basis of Article 95 EC.
40 In view of the cases cited at paragraphs 30 and 31 of this judgment, the fact that human health considerations played a part in the formulation of the provisions concerned cannot invalidate the foregoing assessment.
41 As regards the argument of the claimants in Case C-155/04 that Articles 3, 4(1) and 15(b) of Directive 2002/46 should be based on Article 133 EC, it must be stated that the fact that those provisions may incidentally affect international trade in food supplements does not make it possible validly to challenge the fact that the primary objective of those provisions is to further the removal of differences between national rules which may affect the functioning of the internal market in that area...
42 Consequently, Article 95 EC constitutes the only appropriate legal basis for Articles 3, 4(1) and 15(b) of Directive 2002/46.
43 It follows that those provisions are not invalid by reason of lack of an appropriate legal basis.

Part (b) of the question

44 By part (b) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of infringement of Articles 28 EC and 30 EC and/or infringement of Articles 1(2) and 24(2)(a) of Regulation No 3285/94.

45 In both the present cases the claimants in the main actions submit that the prohibition arising from the provisions with which the question referred to the Court is concerned constitutes a restriction on intra-Community and international trade in food supplements hitherto lawfully put into circulation.

46 The claimants in Case C-155/04 add that neither Article 30 EC nor Article 24(2)(a) of Regulation No 3285/94 can justify the sudden introduction of a restriction on trade in products whose safety had never before been put in doubt.

Articles 28 EC and 30 EC

47 It must be observed that by virtue of settled case-law the prohibition of quantitative restrictions and of all measures having equivalent effect, laid down in Article 28 EC, applies not only to national measures but also to measures adopted by the Community institutions...

48 Nevertheless, as Article 30 EC provides, Article 28 EC does not preclude prohibitions or restrictions justified, inter alia, on grounds of protection of the health and life of humans...

49 The provisions of Article 3 in conjunction with those of Article 4(1) and 15(b) of Directive 2002/46 constitute a restriction covered by Article 28 EC. By prohibiting the marketing in the Community of food supplements containing vitamins and minerals, or vitamin and mineral substances, not included on the positive lists, those provisions are capable of restricting the free movement of food supplements within the Community.

50 As the Advocate General has stated at point 40 of his Opinion, it is clear from the preamble to Directive 2002/46, and in particular from the 5th, 9th, 10th and 11th recitals thereto, that the Community legislature gives, as the rationale for the prohibition, considerations related to the protection of human health.

51 It remains necessary to ascertain whether the measure is necessary and proportionate in relation to the objective of protecting human health.

52 With regard to judicial review of those conditions, the Community legislature must be 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. Consequently, the legality of a measure adopted in that area can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue

53 In the present cases, the claimants in the main actions submit that the prohibition at issue is neither necessary nor proportionate in relation to the objective put forward.

54 First, they deny that the prohibition is necessary. They maintain to that end that Articles 4(7) and 11(2) of Directive 2002/46 give the Member States the power to restrict trade in food supplements which do not comply with the directive. A Community prohibition is thus superfluous.

55 First of all, it must be stated that Article 4(7) of Directive 2002/46 – as is clear from its actual wording and from the legislative history of the directive – is intrinsically linked to Article 4(6) of the directive, as was confirmed at the hearing by the Parliament, the Council and the Commission.

56 It follows that the power of the Member States laid down in Article 4(7) of Directive 2002/46 to continue to apply, in compliance with the rules of the Treaty, existing national restrictions or bans on trade in food supplements containing vitamins and minerals or vitamin and mineral

substances not included on the positive lists is merely the corollary of a Member State's ability under Article 4(6) to allow in its territory until 31 December 2009 the use of such constituents on the conditions set out in that provision.
57 As the Advocate General has observed at point 22 of his Opinion, the purpose of Article 4(7) of Directive 2002/46 is solely to provide that Member States other than a State which allows on its territory, within the limits and in compliance with the conditions set out in Article 4(6), the use in the manufacture of food supplements of vitamins, minerals or vitamin or mineral substances not included on the positive lists, do not have to allow imports into their own territory of food supplements containing such ingredients.
58 The argument of the claimants in the main actions which is founded on Article 4(7) of Directive 2002/46 thus does not give grounds for concluding that the prohibition at issue is unnecessary.
59 Next, as regards Article 11(2) of Directive 2002/46, when that provision is read in conjunction with the 8th recital to the directive, it becomes clear that its purpose is to preserve, until specific Community rules are adopted, the application, in compliance with the Treaty, of national rules concerning nutrients other than vitamins and minerals or other substances with nutritional or physiological effect used as ingredients in food supplements.
60 Article 11(2) of Directive 2002/46 is thus directed solely at food supplements containing nutrients or substances not falling with the material scope of the directive. Consequently, it is of no relevance for the purpose of ascertaining whether the prohibition in Articles 3, 4(1) and 15(b) of the directive is necessary.
61 Second, the claimants in the main actions maintain that the prohibition is disproportionate.
62 They submit in that regard that the positive lists are inadequate. That is because the list of substances in Annex II to Directive 2002/46 was compiled on the basis not of the criteria pertaining to safety and bioavailability set out in the 11th recital in the preamble to the directive but of lists identifying ingredients authorised in the manufacture of food for particular nutritional purposes. It follows that the prohibition affects a large number of nutrients which are none the less suitable for a normal diet and are currently manufactured and marketed in certain Member States and which have hitherto not been shown to represent a risk to human health. The prohibition in Directive 2002/46 is also unjustified and disproportionate in the case of vitamins and minerals in natural forms, although they are usually found in the normal diet and are better tolerated by the body than vitamins and minerals from synthetic sources.
63 It must be stated, at the outset, that if the various recitals in the preamble to Directive 2002/46 are read together, it is apparent that the directive concerns food supplements containing vitamins and/or minerals derived from a manufacturing process using 'chemical substances' (11th recital), and not food supplements whose ingredients include 'amino acids, essential fatty acids, fibre and various plant and herbal extracts' (6th recital), whose conditions for use consequently remain 'until … specific Community rules are adopted' within the scope of 'national rules', 'without prejudice to the provisions of the Treaty' (8th recital).
64 Next, it must be noted that the positive lists correspond, as the claimants in Case C-155/04 have observed, to the list of substances included in the categories 'vitamins' and 'minerals' in the Annex to Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses ...

65 As is stated in the 4th recital in the preamble to Directive 2001/15, the selection of the substances identified in the annex to the directive took into account criteria of safety and availability for use by humans, criteria referred to in the 11th recital to Directive 2002/46.
66 As is clear when the 10th and 11th recitals to Directive 2002/46 are read together, the fact

that a certain number of chemical substances used as ingredients in food supplements marketed in some Member States are currently not authorised at European level is explained by the fact that the substances at issue in the main actions had not, at the time when the directive was adopted, received a favourable evaluation, from the point of view of the criteria of safety and bioavailability, from the competent European scientific authorities.

67 The information provided by the claimants in the main actions in their written observations about certain vitamin or mineral substances not included on the positive list in Annex II to Directive 2002/46 is not such as to cast doubt on the merits of that explanation. It is apparent from it that at the time when the directive was adopted those substances had not yet been evaluated by the Scientific Committee on Food or that, at the very least, the committee continued to entertain serious doubts, in the absence of adequate and appropriate scientific data, regarding their safety and/or their bioavailability.

68 In those circumstances and in view of the need for the Community legislature to take account of the precautionary principle when it adopts, in the context of the policy on the internal market, measures intended to protect human health... the authors of Directive 2002/46 could reasonably take the view that an appropriate way of reconciling the objective of the internal market, on the one hand, with that relating to the protection of human health, on the other, was for entitlement to free movement to be reserved for food supplements containing substances about which, at the time when the directive was adopted, the competent European scientific authorities had available adequate and appropriate scientific data capable of providing them with the basis for a favourable opinion, whilst giving scope, in Article 4(5) of the directive, for obtaining a modification of the positive lists by reference to scientific and technological developments.

69 It is also necessary to state in that regard that, by virtue of Article 7 of Regulation (EC) No 178/2002 ... 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... the Community legislature is entitled to adopt the provisional risk management measures necessary to ensure a high level of health protection and may do so whilst awaiting further scientific information for a more comprehensive risk assessment, as is stated in the 10th recital to Directive 2002/46.

70 Contrary to the contention of the claimants in Case C-154/04, a negative list system, which entails limiting the prohibition to only the substances included on that list, might not suffice to achieve the objective of protecting human health. Reliance in this instance on such a system would mean that, as long as a substance is not included on the list, it can be freely used in the manufacture of food supplements, even though, by reason of its novelty for example, it has not been subject to any scientific assessment apt to guarantee that it entails no risk to human health.

71 The claimants in the main action submit that the procedures referred to in Article 4(5) and (6) of Directive 2002/46 lack transparency because of the lack of precision in the criteria applied by the European Food Safety Authority in its examination of dossiers seeking authorisation to use a substance not included on the positive lists. The procedures thus represent a particularly heavy financial and administrative burden.

72 In that regard, a measure which, like that at issue in the main actions, includes a prohibition on marketing products containing substances not included on the positive lists laid down in the applicable legislation must be accompanied by a procedure designed to allow a given substance to be added to those lists and the procedure must comply with the general principles of Community law, in particular the principle of sound administration and legal certainty.

73 Such a procedure must be accessible in the sense that it must be expressly mentioned in a

measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorised substances may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts ...

74 In the case of Directive 2002/46, the procedure accompanying the measure at issue, by which a vitamin, a mineral or a vitamin or mineral substance may be added to the positive lists, is referred to in Article 4(5) of the directive, which deals with modification of the lists.

75 It follows that, for the purposes of assessing the validity of the prohibition stemming from Articles 3, 4(1) and 15(b) of Directive 2002/46, the Court's review must concern solely the legality of the procedure referred to in Article 4(5) of the directive. A review of the validity of the procedure laid down in Article 4(6), which is designed for obtaining a temporary national authorisation and which thus pursues a different purpose from that of the procedure laid down in Article 4(5), falls, however, outside the scope of the assessment in these cases.

76 Article 4(5) of Directive 2002/46 refers to Article 13(2) of the directive, which provides, in its first subparagraph, that '[w]here reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof'.

77 As is stated in the 12th recital to Directive 2002/46, the reference to the procedure laid down in Articles 5 and 7 of Council Decision 1999/468/EC .... laying down the procedures for the exercise of implementing powers conferred on the Commission ... meets the concern that it should be possible, when it is necessary to revise the positive lists to reflect scientific and technological developments, to use a simplified and accelerated procedure in the form of technical implementing measures for whose adoption the Commission is responsible.

78 As is shown by the 7th and 9th recitals in the preamble to Decision 1999/468, that procedure, known as 'comitology', is intended to reconcile, on the one hand, the requirement for effectiveness and flexibility arising from the need regularly to amend and update aspects of Community legislation in the light of developments in scientific understanding in the area of the protection of human health or safety and, on the other hand, the need to take account of the respective powers of the Community institutions.

79 Within the framework of the comitology procedure, provision is made, under Article 5 of Decision 1999/468, for the Commission to submit to the committee referred to in Article 13(1) of Directive 2002/46, a draft of the measures to be taken, on which the committee must deliver its opinion 'within a time-limit which [its] chairman may lay down according to the urgency of the matter' (Article 5(2)). When the committee has delivered its opinion, it is for the Commission to adopt the measures envisaged if they are in accordance with the opinion (Article 5(3)). If that is not the case or if the committee does not deliver an opinion, the Commission must, 'without delay', submit to the Council a proposal relating to the measures to be taken and must inform the European Parliament (Article 5(4)) and the Council may act within a period of three months (Article 5(6), first subparagraph, of Decision 1999/468; Article 13(2), second subparagraph, of Directive 2002/46). If within that period the Council opposes the Commission's proposal, the Commission must re-examine its proposal and may submit the same proposal or an amended proposal to the Council or present a legislative proposal on the basis of the Treaty (Article 5(6), second subparagraph). However, if on the expiry of that period the Council has neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, those measures are adopted by the Commission (Article 5(6), third subparagraph).

80 The provisions of Article 13(2), second subparagraph, of Directive 2002/46 in conjunction

with those of Article 5 of Decision 1999/468, to which Article 4(5) of Directive 2002/46 refers, ensure that once the matter has been brought before the committee by the Commission under Article 5(2) of the decision the procedure for amending the positive lists is completed within a reasonable time.

81 It would, no doubt, have been desirable, as regards the stage between the filing of a dossier seeking modification of the positive lists and the time when the matter is brought before the committee (a stage which includes, inter alia, consultation of the European Food Safety Authority as envisaged in both Article 14 of, and the 10th recital to, Directive 2002/46), for the directive to have included provisions which in themselves ensured that that stage be completed transparently and within a reasonable time.

82 The absence of any such provisions cannot, however, be regarded as such as to jeopardise the proper functioning of the procedure for modifying the positive lists within a reasonable time. It is none the less the responsibility of the Commission, by virtue of the implementing powers conferred on it by Directive 2002/46 concerning, inter alia, the way the procedure is operated, to adopt and make accessible to interested parties, in accordance with the principle of sound administration, the measures necessary to ensure generally that the consultation stage with the European Food Safety Authority is carried out transparently and within a reasonable time.

83 By providing for the procedure established in Article 5 of Decision 1999/468 to apply, Article 4(5) of Directive 2002/46 also ensures that an application for inclusion on the positive lists of a vitamin, a mineral or a vitamin or mineral substance can be rejected only by a binding legal act, which may be subject to judicial review.

84 It must be added in that regard that Directive 2002/46 contains nothing to compel or encourage the competent European authorities to take account, in the procedure referred to in Article 4(5) of the directive, of criteria which do not relate to the objective of protecting human health.

85 On the contrary, it is clear from the 9th recital to Directive 2002/46 that the criterion that the vitamin or mineral be normally found in, and consumed as part of, the diet is the only relevant criterion for the purposes of the list in Annex I to the directive. As the claimants in Case C-154/04 have observed, although the proposal for the directive mentioned at paragraph 37 of this judgment provided for a second criterion, namely that the vitamins and minerals in question should be ‘considered essential nutrients’, as is shown by the 7th recital in the preamble to the proposal, that criterion is no longer included in the 9th recital to Directive 2002/46. As regards the list in Annex II to the directive, it is apparent from the 11th recital that the only relevant criteria are those relating to the safety and bioavailability of the chemical substance in question.

86 Such statements show that the relevant criteria for the purposes of the positive lists and the application of the procedure for modification of those lists can, as conceived by the Community legislature, relate only to grounds of human-health protection, to the exclusion of considerations concerning nutritional needs.

87 It should also be stated that the criticisms made by the claimants in the main actions of the procedure for modifying the positive lists concern in essence the administrative and financial burdens involved in presenting files seeking such modifications and the way in which the criteria of safety and bioavailability set out in the 11th recital to Directive 2002/46 are applied by the European Food Safety Authority when considering individual files.

88 However, although such factors may, depending on the circumstances, be advanced in support of an action for annulment of a final decision refusing an application for modification of the positive lists or an action for damages against the European Food Safety Authority under Article 47(2) of Regulation No 178/2002, they cannot, in themselves, affect the legality of the

procedure for modifying the positive lists, as the Greek Government has pointed out in its written observations.
89 It must therefore be concluded that the analysis at paragraphs 76 to 88 of this judgment has not revealed any factor of such a kind as to affect the legality of the procedure laid down in Article 4(5) of Directive 2002/46 with regard to modification of the positive lists.
90 Finally, it should be noted that, when the Community legislature wishes to delegate its power to amend aspects of the legislative act at issue, it must ensure that that power is clearly defined and that the exercise of the power is subject to strict review in the light of objective criteria ... because otherwise it may confer on the delegate a discretion which, in the case of legislation concerning the functioning of the internal market in goods, would be capable of impeding, excessively and without transparency, the free movement of the goods in question.
91 In this instance, as has been stated at paragraphs 85 and 86 of this judgment, the 9th and 11th recitals to Directive 2002/46 state that the only relevant criteria concerning the positive lists relate, as regards vitamins and minerals, to the fact that the latter are normally found in and consumed as part of the diet and, as regards chemical substances used as sources of vitamins or minerals, to the safety and bioavailability of the substance concerned.
92 Those statements, which are closely related to the concrete expression of those criteria through the positive lists in the body of Directive 2002/46 and which should ideally have been included in the actual provisions of the directive (see, to that effect the Inter-Institutional Agreement of the European Parliament, of the Council and of the Commission of 22 December 1998 on common guidelines for the quality of drafting of Community legislation ... limit the Commission's power to modify the lists through their reference to objective criteria connected exclusively with public health. They show that in this instance the Community legislature laid down the essential criteria to be applied in the matter when the powers thus delegated are exercised...
93 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of Articles 28 EC and 30 EC....

Part (c) of the question
99 By part (c) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of an infringement of the principle of subsidiarity.
100 In both these cases, the claimants in the main actions submit that the provisions interfere unjustifiably with the powers of the Member States in a sensitive area involving health, social and economic policy. The claimants in Case C-154/04 add that the Member States are the best placed to determine, on their respective markets, the public health requirements which would justify a barrier to the free marketing of food supplements on their national territory.
101 In that regard, it is appropriate to recall that the principle of subsidiarity is set out in the second subparagraph of Article 5 EC, which provides that the Community, in areas which do not fall within its exclusive competence, is to take action only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.
102 Paragraph 3 of the Protocol on the application of the principles of subsidiarity and proportionality, annexed to the Treaty, states that the principle of subsidiarity does not call into question the powers conferred on the Community by the Treaty, as interpreted by the Court of Justice.
103 As the Court has already held, the principle of subsidiarity applies where the Community legislature makes use of Article 95 EC, inasmuch as that provision does not give it exclusive competence to regulate economic activity on the internal market, but only a certain competence

for the purpose of improving the conditions for its establishment and functioning by eliminating barriers to the free movement of goods and the freedom to provide services or by removing distortions of competition...
104 In deciding whether Articles 3, 4(1) and 15(b) of Directive 2002/46 comply with the principle of subsidiarity, it is necessary to consider whether the objective pursued by those provisions could be better achieved by the Community.
105 In that regard, it must be stated that the prohibition, under those provisions, on marketing food supplements which do not comply with Directive 2002/46, supplemented by the obligation of the Member States under Article 15(a) of the directive to permit trade in food supplements complying with the directive... has the objective of removing barriers resulting from differences between the national rules on vitamins, minerals and vitamin or mineral substances authorised or prohibited in the manufacture of food supplements, whilst ensuring, in accordance with Article 95(3) EC, a high level of human-health protection.
106 To leave Member States the task of regulating trade in food supplements which do not comply with Directive 2002/46 would perpetuate the uncoordinated development of national rules and, consequently, obstacles to trade between Member States and distortions of competition so far as those products are concerned.
107 It follows that the objective pursued by Articles 3, 4(1) and 15(b) of Directive 2002/46 cannot be satisfactorily achieved by action taken by the Member States alone and requires action to be taken by the Community. Consequently, that objective could be best achieved at Community level.
108 It follows from the foregoing that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the principle of subsidiarity.

Part (d) of the question
109 By part (d) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of an infringement of the principle of proportionality.
110 The claimants in the main actions maintain that those provisions constitute a disproportionate means of achieving the intended objective. The arguments put forward in support of that claim are those set out at paragraphs 54, 62, 70 and 71 of this judgment.
111 However, it is clear from the analysis set out at paragraphs 55 to 60, 63 to 70 and 72 to 92 of this judgment that Articles 3, 4(1) and 15(b) of Directive 2002/46 are measures appropriate for achieving the objective which they pursue and that, given the obligation of the Community legislature to ensure a high level of protection of human health, they do not go beyond what is necessary to attain that objective.
112 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the principle of proportionality.

Part (e) of the question
113 By part (e) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of an infringement of the principle of equal treatment.
114 The claimants in both actions submit that those provisions infringe that principle because certain substances which do not satisfy the criteria set out in the 11th recital to Directive 2002/46 were included on the positive lists without having been subject to additional tests, whereas burdensome requirements are imposed on manufacturers of food supplements containing non-authorised substances in order to prove that the abovementioned criteria have been met. They add that there is no objective justification for that difference in treatment, the lists not having been compiled on the basis of the criteria laid down by the Directive.

115 In that regard, it is appropriate to bear in mind that, by virtue of settled case-law, the principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified...
116 As the United Kingdom Government, the Parliament and the Commission have observed in their written observations, the vitamin and mineral substances which are not included on the positive list in Annex II to Directive 2002/46 are not in the same situation as those which are included on it. In fact, unlike the latter substances, those that are not included on the list, had not, at the time when the directive was adopted, been subject to a scientific evaluation by the competent European authorities so as to ensure their conformity with the criteria of safety and bioavailability referred to in the 11th recital to the directive.
117 Since each substance has, as is stated in those observations, its own characteristics, a substance which had not yet been evaluated in accordance with those criteria could not be treated in the same way as a substance included on the positive lists.
118 That difference in situations therefore permitted a difference in treatment, and an infringement of the principle of equal treatment cannot be successfully pleaded.
119 It follows from the foregoing that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the principle of equal treatment.

Part (f) of the question
120 By part (f) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of infringement of Article 6(2) EU, read in the light of Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 ('the ECHR') and Article 1 of the First Protocol to the Convention, and of the fundamental right to property and/or the right to carry on an economic activity.
121 In both cases the claimants in the main actions maintain that there is such an infringement. They submit that Directive 2002/46 is an unjustified and disproportionate impairment of the ability of manufacturers of food supplements to pursue their activities, which have hitherto been carried on entirely lawfully, and of the individual right to freedom of choice as regards food products.
122 In that regard, it must first be observed that Article 6(2) EU provides: 'The Union shall respect fundamental rights, as guaranteed by the [ECHR] and as they result from the constitutional traditions common to the Member States, as general principles of Community law'.
123 Article 8 of the ECHR entitled 'Right to respect for private and family life' provides, at paragraph (1), that '[e]veryone has the right to respect for his private and family life, his home and his correspondence' and, at paragraph (2), that '[t]here shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.
124 The fact that Articles 3, 4(1) and 15(b) of Directive 2002/46 may deprive people of the right to consume food supplements which do not comply with the directive cannot be regarded as amounting to a breach of respect for private and family life.
125 Article 1 of the First Protocol to the ECHR states, under the heading 'Protection of Property':
'Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one

shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.
The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties.'
126 It is clear from settled case-law that the right to property, with which the provisions reproduced in the preceding paragraph are concerned, and likewise the freedom to pursue an economic activity, form part of the general principles of Community law. However, those principles are not absolute but must be viewed in relation to their social function. Consequently, the exercise of the right to property and the freedom to pursue an economic activity may be restricted, provided that any restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed...
127 It is the case here that the prohibition on the marketing and placing on the Community market of food supplements which do not comply with Directive 2002/46 is capable of restricting the freedom of manufacturers of those products to carry on their business activities.
128 Nevertheless, their right to property is not called into question by the introduction of such a measure. No economic operator can claim a right to property in a market share, even if he held it at a time before the introduction of a measure affecting the market, since such a market share constitutes only a momentary economic position exposed to the risks of changing circumstances ... Nor can an economic operator claim an acquired right or even a legitimate expectation that an existing situation which is capable of being altered by measure taken by the Community institutions within the limits of their discretion will be maintained...
129 As has been stated above, the prohibition arising from Articles 3, 4(1) and 15(b) of Directive 2002/46 is intended to protect human health, which is an objective of general interest. It is not evident that the prohibition is inappropriate in relation to that objective. In those circumstances, the obstacle to the freedom to pursue an economic activity which a measure of that kind represents cannot be found, in the light of the aim pursued, to constitute a disproportionate impairment of the right to exercise that freedom or to the right to property.
130 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of infringement of Article 6(2) EU, read in the light of Article 8 of the ECHR and Article 1 of the First Protocol thereto, the fundamental right to property or the right to pursue an economic activity.

Part (g) of the question
131 By part (g) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of an infringement of the obligation to state reasons laid down in Article 253 EC.
132 The claimants in Case C-154/04 maintain that no reasons are given for the prohibition arising from those provisions, which, in their submission, amounts to an infringement of Article 253 EC.
133 In that regard, it should be observed that, although the reasoning required by Article 253 EC must show clearly and unequivocally the reasoning of the Community authority which adopted the contested measure so as to enable the persons concerned to ascertain the reasons for the measure and to enable the Court to exercise its power of review, it is not required to go into every relevant point of fact and law...
134 Furthermore, the question whether a statement of reasons satisfies the requirements must

be assessed with reference not only to the wording of the measure but also to its context and to the whole body of legal rules governing the matter in question. If the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for each of the technical choices made by the institution...
135 Here, the 9th recital to Directive 2002/46 explains that the vitamins and minerals affected by the prohibition are those which are not normally found in, or consumed as part of, the diet.
136 As regards existing vitamin and mineral substances covered by the prohibition, the 10th and 11th recitals to Directive 2002/46 clearly disclose that such a measure relates to the general concern, expressed in the 5th recital to the directive, to ensure a high level of protection for consumers by authorising the placing on the market only of products which are safe for human health and is explained by the fact that the substances concerned had not, at the time when the directive was adopted, been evaluated by the Scientific Committee on Food by reference to the criteria of safety and bioavailability on the basis of which the positive list in Annex II to the directive was drawn up.
137 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the obligation to state reasons laid down in Article 253 EC.
138 In view of all the foregoing considerations, the answer to the question referred to the Court must be that examination of the question has revealed no factor of such a kind as to affect the validity of Articles 3, 4(1) and 15(b) of Directive 2002/46.

Questions:
1. Do you agree with the judge's approach to the decision about whether the reference should be made?
2. Before the ECJ the claimants raised a number of different challenges to the validity of the Directive, based on various provisions of the Treaty and on general principles of Community law and fundamental rights. Assess these challenges and the Advocate General's responses. Do you agree with the opinion in all respects/some/none?
Note: Leendert A. Geelhoed. Born 1942; Research Assistant, University of Utrecht (1970-71); Legal Secretary at the Court of Justice of the European Communities (1971-74); Senior Adviser, Ministry of Justice (1975-82); Member of the Advisory Council on Government Policy (1983-90); Secretary-General, Ministry of Economic Affairs (1990-97); Secretary-General, Ministry of General Affairs (1997-2000); Advocate General at the Court of Justice October 2000-October 2006.
3. In what ways does the Advocate General's opinion read differently from the ECJ's decisions we have been studying?
4. How does the ECJ's judgment differ from the Advocate General's Opinion? Which approach do you find more persuasive? Why did the ECJ not follow the same approach as the Advocate General in the case?

After the ECJ's judgment in the ANH case, William Cash, a Conservative MP proposed a **Bill to Disapply the Food Supplements Directive** in the UK.[33] Clause 1 of

[33] http://www.publications.parliament.uk/pa/cm200506/cmbills/046/2006046.pdf . The Bill was a private member's bill - these are almost never enacted, and this Bill was not enacted.

the Bill provided that the 2002 Directive and any judgment of the ECJ relating to it shall have no effect in the UK. The Bill then stated in clause 3(3) (which would have amended the Food Safety Act 1990):

(1) The appropriate authority shall make regulations—
(a) prohibiting the sale of any food supplement in the manufacture of which a vitamin or mineral has been used unless that vitamin or mineral—
(i) is authorised for use in the manufacture of food supplements, and
(ii) is in a form which is so authorised and meets such purity criteria as shall be specified; and
(b) making such other provision relating to food supplements as it considers appropriate.
(2) Before making regulations under subsection (1) the appropriate authority shall consult—
(a) such persons or bodies as appear to it to be representative of the interests of complementary medicine, and
(b) such other persons or bodies as it considers appropriate.

The **European Communities Act 1972** is the statute which provides for European Community law to take effect within the UK. Section 2(1) of the Act provides that rights and obligations under Community law "shall be recognised and available in law, and be enforced, allowed and followed accordingly". Thus the doctrines of direct effect and indirect effect apply in English law. Section 3 provides that issues of Community law are to be treated as questions of law in courts in the UK and that judges are to take judicial notice of the Treaties, and of EU legislative measures and decisions of the ECJ.

The 1972 Act makes it clear that Community law is meant to take precedence over conflicting national law. However, the fundamental principle of English constitutional law is that Parliament is supreme and, as a corollary, no parliament can bind its successors. In a House of Lords case (about the statutory prohibition of fox hunting with hounds in the Hunting Act 2005) (the decision is not generally relevant for the purposes of our class),[34] Lord Bingham of Cornhill said: "The bedrock of the British constitution is.. the supremacy of the Crown in Parliament. It is… unnecessary for present purposes to touch on the difference, if any, made by our membership of the European Union. ..the Crown in Parliament [is] unconstrained by any entrenched or codified constitution. It could make or unmake any law it wished. Statutes, formally enacted as acts of parliament, properly interpreted, enjoyed the highest legal authority….

In another decision on the application of the European Convention on Human Rights in the UK (through the Human Rights Act 1998) Lord Scott of Foscote said in the House of Lords: "There are not, under English domestic law, any fundamental constitutional rights that are immune from legislative change."

Some English court decisions have suggested that there are some statutes (including the ECA 1972) that are to be regarded as "constitutional statutes" and therefore not to be impliedly repealed by subsequent statutes (e.g., Thoburn v

[34] *Jackson* v *AG* [2005] UKHL 56 http://www.bailii.org/uk/cases/UKHL/2005/56.html .

Sunderland City Council)[35] (although they could be repealed by "unambiguous words on the face of the later statute" (Laws LJ)). Lord Denning stated in 1979 (in Macarthys v Smith):

> Thus far I have assumed that our Parliament, whenever it passes legislation, intends to fulfil its obligations under the Treaty. If the time should come when our Parliament deliberately passes an Act-with the intention of repudiating the Treaty or any provision in it-or intentionally of acting inconsistently with it-and says so in express terms-then I should have thought that it would be the duty of our courts to follow the statute of our Parliament.

This sort of conflict between national constitutions and Community law does arise from time to time. The UK situation is different from that in other Member States because the UK Constitution is essentially unwritten (apart from "constitutional statutes") and therefore harder to amend than a written Constitution.

If the Food Supplements Bill had become law in the UK it would have been a breach of Community law which could give rise to enforcement action by the Commission (Art 226) or a Member State (art 227). In addition people could try to enforce their rights under the Directive before the national courts. Whereas an attempt to use direct effect would run up against the constitutional problem an action for damages against the UK might succeed in a case where a person could establish actual damage as a result of the UK's non-implementation of the directive.

INDEX

[35] http://www.bailii.org/ew/cases/EWHC/Admin/2002/195.html