OPINION OF ADVOCATE GENERAL

GEELHOED

delivered on 5 April 2005 (1)

Joined Cases

C-154/04

The Queen

Alliance for Natural Health

Nutri-Link Ltd

v

Secretary of State for Health

and

C-155/04

The Queen

National Association of Health Stores

Health Food Manufacturers Ltd

v

Secretary of State for Health

and

National Assembly for Wales

(Reference for a preliminary ruling from the High Court of Justice of England and Wales)

(Approximation of laws – Food supplements – Directive 2002/46/EC – Ban on marketing of products which do not comply with the directive – Validity – Legal basis – Article 95 EC – Compliance with Articles 28 EC and 30 EC, and with Regulation No 3285/94 – Principles of subsidiarity, proportionality and equal treatment – Right to property – Freedom to carry on an economic activity – Duty to state reasons)

I – Introduction

1. These references by the High Court of Justice of England and Wales for a preliminary ruling concern the validity of 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 (hereinafter 'the Directive' or 'Directive 2002/46'). (2) More specifically they concern Articles 3, 4(1) and 15(b) of the Directive.

2. The main features of these provisions are that only food supplements in conformity with the Directive may be marketed in the Community, that is to say, inter alia, that only vitamins and minerals listed in the annexes to the Directive may be used and that from 1 August 2005 trade in non-compliant products is prohibited.

3. As I will explain later on, these provisions cannot be dealt with in isolation.

4. Furthermore, it is not the first time the Court has had to deal with questions of the appropriate legal basis, the principles of subsidiarity, proportionality, equal treatment and the fundamental rights protected by the European Convention of Human Rights, more specifically the right to property and/or the right to carry on an economic activity. The Court has dealt with similar questions in its *BAT* judgment (3) and in its judgments in *Swedish Match* and *Arnold André*. (4) The line of reasoning to be followed in the present cases can be deduced from those judgments.

I – Legal framework

5. Directive 2002/46, adopted on the basis of Article 95 EC, ‘concerns food supplements marketed as foodstuffs and presented as such’ (Article 1(1)).

6. For the purposes of the Directive, ‘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 (Article 2(a)); ‘nutrients’ means the following substances: (i) vitamins, (ii) minerals (Article 2(b)).

7. Under Article 3 of the Directive, 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.

8. Article 4 of the Directive contains the following provisions:

‘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.

…'

9. Article 11 of the Directive states:

'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.'

10. 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.

…'

11. Under Article 16, the Directive entered into force on 12 July 2002, the day of its publication in the *Official Journal of the European Communities*.

12. Annexes I and II to the Directive establish lists of,

respectively, '[v]itamins and minerals which may be used in the manufacture of food supplements' and 'vitamin and mineral substances which may be used in the manufacture of food supplements' (hereinafter 'the positive lists').

13. The Directive was transposed into law by the Food Supplements (England) Regulations 2003 (S.I. No 1387 of 9 May 2003) and the Food Supplements (England) Regulations 2003 (S.I. No 1719 (W.186) of 9 July 2003). Those two sets of regulations (hereinafter 'the Food Supplements Regulations') entered into force in July 2003.

II – Facts, procedure and preliminary questions

The parties and the national proceedings

14. The Alliance for Natural Health and Nutri-Link Limited, the claimants in the main proceedings in Case C-154/04, are, respectively, a European-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.

15. The National Association of Health Stores and Health Food Manufacturers Limited, the claimants in the main proceedings in Case C_155/04, are two trade associations representing around 580 small firms engaged in the supply of health foods in the United Kingdom.

16. On 10 October 2003, the National Association of Health Stores and Health Food Manufacturers Limited applied to the referring court for leave to commence proceedings for judicial

review of the Food Supplements Regulations. Separate proceedings were commenced by the Alliance for Natural Health and Nutri-Link Limited on 13 October 2003. In essence, all these parties claim that the combined provisions of Article 3 and 4(1), and subparagraph (b) of the second paragraph of Article 15 of the Directive (hereinafter the 'contested Community provisions'), which the Food Supplements Regulations transposed, and which, with effect from 1 August 2005, prohibit the marketing of food supplements which do not comply with the directive because of the use, in their manufacture, of substances not permitted by it, are incompatible with Community law and should therefore be annulled.

17. The Queen's Bench Division (Administrative Court) of the High Court of Justice of England & Wales granted the claimants in the main proceedings leave to apply for judicial review of the Food Supplements Regulations and, in those circumstances, decided, by two respective orders of 3 March 2004, to stay the proceedings and to refer a question – identical in both cases – to the Court for a preliminary ruling.

Preliminary question

18. That question is:

'Are Articles 3, 4(1) and 15(b) of Directive 2002/46/EC invalid by reason of:

(a) the inadequacy of Article 95 as a legal basis;

(b) infringement of (i) Articles 28 and 30 of the EC Treaty

and/or (ii) Articles 1(2) and 24(2)(a) of Regulation (EC) No 3285/94;

(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) of the Treaty on European Union, read in the light of Article 8 of, 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?

Procedure before the Court

19. The orders of the High Court of Justice were received at the Court on 26 March 2004. By order of the President of the Court of 7 May 2004 the cases were joined for the purpose of the procedure and judgment. Written observations were submitted by the claimants in both cases, by the United Kingdom, Greek and Portuguese Governments and by the Parliament, the Council and the Commission. On 25 January 2005 a hearing was held.

III – Assessment

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, (5) without having recourse to

Article 11(2) of the Directive. (6) 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. (7)

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, (8) 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; (9) 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, such as *Commission* v *Denmark*, (10) *Commission* v *France* (11) and *Greenham and Abel.* (12) With respect to cases still pending I refer to *HLM Warenbetrieb and Orthica* (13) 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, (14) '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, (15) 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 (16) 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. (17) Besides, if those products from outside the Community meet the requirements they can also freely be traded in the Community.

Articles 28 EC and 30 EC and the Import Regulation

46. The claimants also argue that the contested provisions are incompatible with the EC Treaty (Articles 28 EC and 30 EC) and with the common commercial policy (Article 133 EC) as implemented by the Import Regulation (Article 1(2) and 24(2)(a)).

47. I will deal first with the question whether there is an incompatibility with Article 28 EC and the margin of discretion of the Community legislature.

48. Articles 28 EC and 30 EC apply primarily to unilateral measures adopted by the Member States. However, it is well established that the prohibition of quantitative restrictions on imports and all measures having equivalent effect applies not

only to national measures but also to measures adopted by the Community institutions. (18)

49. Thus, the Community institutions themselves must also have due regard to freedom of trade within the Community.

50. Article 30 EC can be invoked by the Member States to justify their unilateral measures. It is obvious that such unilateral measures by the Member States, in themselves justified, may nevertheless disturb intra_Community trade, thus triggering action by the Community legislature. The legal basis in the present case, as discussed earlier, is to be found in Article 95 EC.

51. In the exercise of this power the Community legislature has a wide margin of discretion as long as basic principles of Community law are taken into account.

52. In light of the fact that the Community legislature is also bound to observe the principle of freedom of trade, the question is whether the Directive as such can be regarded as introducing restrictions on the free movement of goods by introducing a positive list system.

53. To my mind the answer should be in the negative. It is clear that the Directive seeks to improve the conditions for the functioning of the internal market for food supplements, thereby limiting the possibilities for Member States to invoke Article 30 EC. Second and at the same time, the Directive seeks to strengthen in the general interest of the Community the protection of public health and consumers. These general interests are expressly mentioned in Article 95(3) EC and in

Article 152(1) EC.

54. Whether the Community legislature has complied with the principle of proportionality, and other fundamental principles of Community law, such as equal treatment and fundamental rights, will be dealt with in the next sections.

55. The claimants also claim that the contested Community provisions are in breach of Regulation (EC) No 3285/94 (19) (hereinafter the 'Import Regulation'), in particular Articles 1(2) and 24(2)(a) of the Import Regulation. Their arguments are basically the same as those used in the context of the alleged infringement of Articles 28 EC and 30 EC.

56. As the Commission pointed out, the claimants appear to equate these provisions with Articles 28 EC and 30 EC, but as applying to imports from third countries. The claimants also refer to the fact that many of the NPL goods are manufactured outside the Community and imported into individual Member States for sale on their individual territories.

57. I agree that the Import Regulation applies to the question of importation. However – and I refer to my Opinion in *Silvano Carbone* (20) and the judgment of the Court in that case – a distinction should be made between the time when goods are imported from third countries and the time when they are subsequently placed on the market. The Import Regulation applies to the former situation, the question of the import of goods into the Community, while the latter situation, the placing on the market of products within the Community, is governed by the relevant Treaty provision. It also means that, just as a product lawfully manufactured within the

Community may not be placed on the market on that ground alone, the lawful importation of a product does not imply that it will automatically be allowed onto the market. Furthermore, the reservation contained in Article 24(2)(a) of the Import Regulation relates to the importation and not to the placing on the market of the products referred to.

58. It therefore follows that the Import Regulation is of no relevance in the present case and cannot be relied upon to question the legality of the Directive. The Regulation does not exclude Community rules that apply generally to the placing on the market of food supplements. As a passing comment, I would add that, once the import formalities have been complied with, these products are regarded as being in free circulation, which means that foodstuffs imported from third countries which comply with the Directive can also benefit from free movement within 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. (23)

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. (24)

– 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. (25)

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*.’ (26)

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. (28)

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. (29) 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 United Kingdom, 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. (31)

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. (32)

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.

IV – 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.

1 – Original language: English.

2 – OJ 2002 L 183, p. 51.

3 – Case C_491/01 *British American Tobacco (Investment) and Imperial Tobacco* [2002] ECR I_11453.

4 – Case C_210/03 *Swedish Match* [2004] ECR I_0000 and Case C_434/02 *ArnoldAndré* [2004] ECR I_0000.

5 – Basically requirements relating to specifications, presentation and labelling of food supplements.

6 – They might have recourse to Article 14 of Regulation No 178/2002.

7 – Cited in footnote 3.

8 – See the*BAT* judgment, cited in footnote 3, paragraph 64.

9 – In its written observations the Commission stated that it had received

complaints from operators about restrictions that they faced in marketing their products in several Member States and that this situation arose from the disparate approaches employed in regulating food supplements.

10 – Case C_192/01 *Commission* v *Denmark* [2003] ECR I_9693.

11 – Case C_24/00 *Commission* v *France* [2004] ECR I_0000.

12 – Case C_95/01 *Greenham and Abel* [2004] ECR I_0000.

13 – Joined Cases C_211/03, C_299/03, C_316/03, C_317/03 and C_318/03 *HLM and Orthica*, Opinion of 3 February 2005.

14 – Cited in footnote 3, see paragraph 74.

15 – Case C_376/98 *Germany* v *Parliament and Council* ('Tobacco advertising') [2002] ECR I_8419 (paragraph 88).

16 – *BAT* judgment, cited in footnote 3, paragraphs 93 and 94 and the case-law referred to therein.

17 – See Opinion 1/78 International Agreement on natural rubber [1979] ECR 2871.

18 – See Case C_210/03 *Swedish Match* [2004] ECR I_0000, paragraph 59 and the case-law therein referred.

19 – 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).

20 – Case C_296/00 *Silvano Carbone* [2002] ECR I_4657.

21 – The claimants refer in this context to *Commission* v *France*, cited at footnote 11, paragraphs 25 to 27 and *Greenham and Abel*, cited at footnote 12, paragraphs 35 and 36.

22 – The use of positive lists is not unusual in Community food legislation. See for example: Commission Directive 91/321/EEC on infant and follow-on formula, OJ 1991 L 175, p. 35, Commission Directive 96/5/EC, Euratom on processed cereal-based foods and other baby foods for infants and young children, OJ 1996

L 49, p. 17 and Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, OJ 2001 L 52, p. 19.

23 – See the *BAT* judgment, cited in footnote 3, paragraphs 122 and 123 and *Swedish Match*, cited in footnote 4, paragraphs 47 and 48 and the case-law referred to therein.

24 – There are further inaccuracies from the point of view of legislative technique in the Directive, such as the absence of a date marking the end of the competence of the Member States set out in Article 4(7), which was intended to be temporary and which corresponds to the final date mentioned in Article 4(6) for the derogation provided for in that article.

25 – OJ 1999 C 73, p. 1. These points read as follows: '10) The purpose of the recitals is to set out concise reasons for the chief provisions of the enacting terms, without reproducing or paraphrasing them. They shall not contain normative provisions or political exhortations.' … '13) Where appropriate, an article shall be included at the beginning of the enacting terms to define its subject-matter and scope.'

26 – My italics.

27 – http://www.europa.eu.int/comm/food/food/labellingnutrition/supplements/

28 – Inter alia Case C_84/94 *United Kingdom* v *Council* [1996] ECR I_5755 at paragraph 74.

29 – Council Decision 1999/468 of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ 1999 L 184, p. 23.

30 – Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community, OJ 1995 L 56, p. 1.

31 – See *Swedish Match*, cited in footnote 4, point 72, and the case-law referred to therein; see also Joined Cases C_20/00 and C_64/00 *Booker Aquaculture* [2003] ECR I_7411, paragraph 68, referred to by the Parliament, the Council and the Commission.

32 – See *Swedish Match*, cited in footnote 4, point 73, and the case-law referred to therein.

33 – See paragraphs 165 and 166 of the *BAT* judgement, cited in footnote 3.

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