DETAILED STATEMENT OF GROUNDS

THE CLAIMANTS

1. The First Claimant is a Europe-wide association of manufacturers, wholesalers, distributors, retailers and consumers of food supplements.[1] It was founded with the specific purpose of safeguarding the free availability of the widest possible range of food supplements in the light of a number of initiatives at UK, European and international level to regulate the area. Details of its structure, membership and aims are contained in the Witness Statement of Dr Robert Verkerk, the First Claimant's Executive Director.

2. The Second Claimant is a small distributor and retailer of food supplements. The bulk of its turnover is accounted for by imports of advanced food supplements from the United States. Examples of its product range include GlucoBalance, a food supplement widely used to further the effective regulation of blood glucose and prevention of diabetes, and Matrixx, a formula designed to support connective tissue such as joints, tendons and ligaments. Details of its products and trading activities are contained in the Witness Statement of Michael Ash, the Second Claimant's Managing Director.

SUMMARY OF THE CLAIM

3. This claim is directed at the implementation by the Government 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 ("the Directive").[2] The Directive entered into force on 12 July 2002, the day of its publication in the Official Journal of the European Communities, in accordance with its Article 16.

4. The Directive is in the course of being transposed into English law by The Food Supplements (England) Regulations 2003 ("the Regulations").[3] These were made on 9 May 2003 and laid before Parliament on 2 June 2003. They will enter into force on 1 August 2005. Having been subject to the negative

[1] The term "food supplement" is defined in Directive 2002/46/EC 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."

[2] A copy of the Directive is at Annex 1 hereto.

[3] A copy of the Regulations is at Annex 2 hereto.

resolution procedure, the Regulations became a definite part of English law on 11 July 2003, when the Regulations had been laid for 40 days.[4]

5. The Claimants contend that certain provisions of the Directive contravene European Community law on a number of grounds. The unlawfulness of provisions of the Directive means that the Regulations are *ultra vires* to the extent that they purport to transpose those provisions into English law. The Regulations will have a considerable impact on the activities of the persons represented by the First Claimant and on the business of the Second Claimant in that they ban many of the food supplements currently lawfully manufactured, sold, distributed and consumed in the United Kingdom. The Claimants therefore have sufficient interest, within the meaning of section 31(3) of the Supreme Court Act 1981, in the matters to which this application relates.

6. It is recognised that only the Court of Justice of the European Communities ("the ECJ") has the jurisdiction to declare the Directive unlawful and therefore invalid. If permission to proceed is granted, therefore, a reference to the ECJ under Article 234 of the EC Treaty is inevitable and should be made as soon as possible.

BACKGROUND

The Directive

7. The central motivation for the Directive was the fact that the rules and regulations applicable to food supplements under the laws of the various Member States of the European Community varied widely. Problems concerning mutual recognition of food supplements (whereby products approved for sale by the authorities of one Member State can automatically be sold in all other Member States) arose in that Member States routinely sought to justify their own particular legislative requirements by reference to the need to protect health, and frequently sought to rely on Article 30 of the EC Treaty. To facilitate the free movement of food supplements, a degree of harmonisation was deemed desirable by some Member States and the Commission.

8. Consultations on a directive liberalising trade in the sector were started in June 1997 when the Commission issued a discussion paper entitled "Addition of Vitamins and Minerals to Foods and Food Supplements".[5] The Commission's

[4] As regards the timing of this Application, reference is made to a section under para. 33.
[5] Annex 4 hereto.

formal Proposal for the Directive was published on 8 May 2000[6] and received its first reading by the European Parliament on 14 February 2001.[7] Following the publication of an Amended Proposal by the Commission[8] and the adoption of a Common Position by the Council,[9] the Directive received its second reading by the European Parliament on 12 March 2002.[10] The Directive was approved by the Council on 30 May 2002 and finally adopted on 10 June 2002.[11]

9. The Directive contains a variety of provisions laying down Community-wide rules for food supplements. The bulk of these are enthusiastically welcomed by the whole food supplements industry, including the Claimants. In particular:

   (a) the Directive for the first time defines the term "food supplements" and clarifies that they are food rather than medicines (Article 2) and cannot therefore be subjected to pharmaceutical controls by Member States;

   (b) it adopts a mechanism for defining purity criteria for ingredients on a harmonised basis (Articles 4(2) to 4(4)); and

   (c) it lays down harmonised labelling requirements (Articles 6 to 9).

10. Where food supplements comply with the requirements of the Directive, Article 11(1) provides that "Member States shall not, for reasons related to their composition, manufacturing, specifications, presentation or labelling, prohibit or restrict" trade in them. In other words, food supplements which comply with the rules laid down in the Directive cannot be subjected to additional national regulation as to the same aspects. That is the normal approach taken by harmonising measures – indeed it can be said to be the essence of harmonisation itself.

11. The Directive, however, goes further than ensuring the free movement of food supplements which comply with its provisions. By its Article 3, it bans the marketing of food supplements which do not comply. By its Article 4(1), it

[6] Annex 5 hereto.
[7] Annex 7.
[8] Annex 8.
[9] Annex 9.
[10] Annex 12.
[11] For an overview of the legislative history, see Annex 28 which is a printout from the Commission's PreLex legislation service.

bans the use of vitamins and minerals not listed in its Annex I and in forms not listed in its Annex II in the manufacture of food supplements ("the Ban").

12. The composition of the Annexes was based on reports of the EC Scientific Committee on Food ("SCF") which had been carried out in rather different contexts.

Annex I

13. Annex I was based on a Report dating from 1992 which dealt with "Nutrient and Energy Intakes for the European Community".[12] According to the Commission Proposal, the reason for compiling Annex I was that:

> "some doubts might arise as to whether some nutrients, in particular minerals like boron, vanadium or other, are essential. It would be therefore appropriate, for the sake of clarity, to include such a positive list of vitamins and minerals. This list comprises those nutrients which the Scientific Committee on Food (SCF) in its report on Nutrient and Energy Intakes for the European Community (31st series) considers essential."[13]

14. However, as is apparent from the introduction to the SCF Report, the SCF's mandate in drawing up that report was not to identify which nutrients were essential and which were not, but:

> "To advise on the establishment of European Recommended Dietary Allowances for a number of purposes, including nutrition labelling and Community programmes on research and nutrition, and to make recommendations."[14]

15. The SCF therefore at no stage set out to establish an exhaustive list of essential vitamins and minerals and neither did it assert that its Report was all-encompassing. The focus was on setting recommended daily allowances and reference intakes for the nutrients which were being considered, rather than to make any statements about the nutrients which were not being considered. Indeed, the SCF specifically commented:

> "The Committee is acutely aware that there are many gaps in the data it had to use to produce the variety of values presented in this report. Some are mentioned specifically in sections dealing with individual nutrients; others are implicit in that some decisions clearly have had to be made on the basis of inadequate evidence. In the Committee's view this unsatisfactory situation is in part a consequence of the limited amount of nutritional research that had been carried out in the Community and in the

[12] Annex 15.
[13] Commission Proposal (Annex 5), para 5.
[14] SCF Report (Annex 15), page 1.

> world at large. The nutritional needs of the normal healthy individual are commonly classified as a low priority for medical research."[15]

16. In the circumstances it soon became apparent that a number of minerals widely used in the food supplements industry were not contained in Annex I. The European Parliament at first reading adopted an amendment adding five minerals to Annex I, an amendment justified as follows by the responsible parliamentary committee:

> "Those minerals should be included where evidence can be provided of their usefulness in food supplements, which is clearly the case for boron, nickel, silicon, vanadium and tin. The range of minerals in food supplements should therefore in principle be extended to include these substances. In relation to the setting of maximum and minimum doses, the competent scientific committee should re-examine the justification for these minerals in food supplements."[16]

17. The Commission in its Amended Proposal did not seek to contradict the fact that the minerals in question play a useful role in food supplements. Its rejection of the amendment was merely consequential on its rejection of a connected amendment which would have added, among other substances, forms of the minerals in question to Annex II. In the absence of the addition of forms of the minerals, the Commission correctly reasoned that a mere addition of the minerals themselves to Annex I would have been meaningless:[17] if no *forms* of a nutrient are permitted to be used, it does not help a manufacturer that the nutrient itself is in principle permitted.

Annex II

18. The Commission explained its proposal for Annex II as follows:

> "There are different chemical forms of a nutrient that can be used in the manufacturing of foods. Their choice is naturally limited by technological considerations such as colour, odour and other physicochemical choices. Their safety and bioavailability should be subsequently the criteria of selecting such substances for use. For this reason a positive list comprising those substances would appear necessary. The SCF has over the years on the basis of the above criteria approved a number of chemical substances that may be used in the manufacture of foods for infants and young children and in other foods for particular nutritional uses. It would seem reasonable that these substances could also be used in the manufacture of food supplements. It would be necessary, of course, to update this list

[15] SCF Report (Annex 15), page 10.
[16] Amendment 26: Report for first reading (Annex 6), page 17/31; Legislative resolution OJ C 276 1.10.2001 (Annex 7), page 132.
[17] Explanatory Memorandum on the Amended Proposal (Annex 8), page 5.

> rapidly, through technical measures adopted by the Commission, in order to take into account technological and scientific developments." [18]

19. As is apparent, the SCF data in relation to suitable nutrients used as a basis for Annex II was obtained in the rather different context of substances permitted in the manufacture of foods for infants and young children and in other foods for particular nutritional uses.[19] While the conclusion that "[i]t would seem reasonable that these substances could also be used in the manufacture of food supplements" is clearly viable, there is no indication that this starting point could ever have yielded anything approaching a comprehensive list of nutrient forms either actually used or useful in food supplements.

20. Unsurprisingly, the European Parliament promptly adopted an amendment adding no fewer than 64 nutrient forms to Annex II. The justification provided by the responsible Committee made reference to the justification set out above in relation to Annex I as follows:

> "The additions arise from the comments on the previous amendment. It should be possible to use all appropriate chemical compounds of vitamins and minerals in food supplements."[20]

21. The addition of these nutrient forms to Annex II was rejected by the Commission in its explanatory memorandum to its Amended Proposal commenting that:

> "However this should not be taken as a judgment on their content of substances. Substances included therein are to be evaluated for their safety by the Scientific Committee for Food before prior to their eventual inclusion in Annex II."[21]

Objections to the Ban

22. The combined result of these provisions is that a wide range of food supplements which have for decades been lawfully manufactured and marketed in the United Kingdom will become unlawful once the Directive is transposed because they contain vitamins and/or minerals which are not listed and/or contain them in forms which are not listed in the Annexes to the Directive. Examples of the products affected are given in the **First Witness Statement of**

[18] Commission Proposal (Annex 5), para 6.
[19] The 'Parnuts' Opinion of the SCF (Annex 20), itself based on previous work in relation to foodstuffs intended for particular nutritional purposes, infant formulae and baby foods, is widely acknowledged to have provided the starting point for compiling Annex II.
[20] Amendment 27 Report for first reading (Annex 6), page 21/31; Amendments 39, 49 and 32 (revised): Legislative resolution OJ C 276 1.10.2001 (Annex 7), pages 133-134.
[21] Explanatory Memorandum on the Amended Proposal (Annex 8), page 5.

Michael Ash, the Managing Director of the Second Claimant. The other Witness Statements of traders from other Member States and the United States demonstrate that the UK position is by no means an exception and the effects of the Ban would be felt throughout the European Community.

23. The **First Witness Statement of Robert Verkerk**, the Executive Director of the First Claimant gives details of the devastating effects on the food supplements industry. The consequence of the Ban will invariably be severe financial losses for many of the companies represented by the First Claimant as well as the Second Claimant. In many instances, the very economic survival of individual producers is threatened.

24. In the light of this it is unsurprising that the passage of the Directive through the legislative process was controversial right from the beginning. The debates of the European Parliament[22] give a good flavour of the controversy. Right at the beginning of the 1st reading, a Danish Member of the European Parliament (MEP) moved a motion of inadmissibility challenging the legal basis of the Directive and the competency of the Community to legislate in the area:

> "Mr President, I would ask permission to speak regarding the Rules of Procedure. The proposal for a directive which is being debated ought to be rejected pursuant to Rule 143 of the Rules of Procedure which specifies that, at the beginning of the debate on a specific item on the agenda, its inadmissibility may formally be moved. I am making such a proposal, and the reason why I think the proposal for a directive ought to be considered inadmissible is that it is, in my view, contrary to the Treaty. It is contrary to Article 152 of the Treaty, relating to public health, and there is no doubt that this proposal for a directive is entirely motivated by a concern to protect public health. Article 152 specifies that incentive measures may be taken, but excluding any harmonisation of the laws and regulations of the Member States. The proposal in question provides for a particularly intensive harmonisation of the laws and regulations of the Member States and is therefore contrary to Article 152. I searched the Commission's proposal and Mrs Müller's report in vain for a discussion of this question of where authority lies. I think the debate should be considered inadmissible until it has been clarified that the problem of authority is in order, and I would request that a vote be taken."[23]

25. This was countered by the following reply on the part of the rapporteur in charge of piloting the proposal through Parliament:

> "Mr President, Commissioner, ladies and gentlemen, when the Commission presents a proposal for a directive to us, I naturally assume

[22] Annexes 7 and 12.
[23] 13 February 2001 (Annex 7); Krarup, transcript p. 1.

> that it is legally in order. That is one of the reasons why I was appointed rapporteur. I believe that there can be no question of our not voting on this directive."[24]

26. The motion was defeated (and the Directive thus saved) by just one vote: 16 to 15. In addition to multiple criticisms of the legal basis and the composition of the Annexes, there was vitriolic criticism of the fact that the Community was seeking to legislate so widely at all. The following statement from the debate is illustrative of this:

> "Mr President, in the UK there are no specific laws controlling the sale of supplements sold as food. As a consequence, the UK consumers enjoy access to a relatively wide-range of products with minimal restrictions and competitive prices. No one is forced to buy these products and those that do buy them tend to be well informed about their purchases.
> Thus, for the Commission to suggest that we approximate our laws on food supplements is in fact to propose creating laws that do not exist at present in the UK. The reason the UK Government has not created them is that there has been no need for them."[25]

27. The general public controversy surrounding the proposal for the Directive was reflected in the fact that the Council had some difficulty in reaching a Common position on the Commission's Amended proposal, noting at the conclusion of its 2,351st meeting of 30-31 May 2001 that:

> "The Presidency concluded that its compromise proposals for a common position on the Directive relating to food supplements did not meet with a sufficient degree of agreement.
> The Council will therefore revert to this issue at one of its next sessions."

It in fact took until the 2,371st meeting of 27 September 2001 to reach agreement.

The Regulations

28. The Regulations are expressed to be made by the Secretary of State for Health:

> "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".

29. Section 17(1) of the Food Safety Act 1990 give the Secretary of State the power to:

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> "make such provision with respect to food, food sources or contact materials, including in particular provision for prohibiting or regulating

[24] 13 February 2001 (Annex 7); Müller, transcript p. 1.
[25] 13 February 2001 (Annex 7); Titford, transcript p. 6.

> the carrying out of commercial operations with respect to food, food sources or contact materials, as appears to him to be called for by any Community obligation."

The validity of such regulations inevitably depends upon the validity of the underlying Community obligation. In the event that a purported Community obligation is annulled or declared invalid by the ECJ (which, along with the Court of First Instance of the EC, is the only court competent to take such a step),[26] the regulations will therefore themselves be invalid, as lacking any or sufficient legal base in national law. Furthermore, since annulments and declarations of invalidity in the Community courts operate, as a rule, with retrospective effect,[27] the implementing regulations will normally prove to have been *ultra vires* from the moment of their adoption.

30. It is well-established that the validity of a Directive may be the subject of collateral challenge in national proceedings brought against national implementing measures.[28]

31. It is clear that the Regulations do not go any further than the Directive and could thus have been implemented on the sole basis of section 17(1). It is evident from the legislative history of the Regulations that they were adopted with the sole purpose of transposing the Directive into English law. The Explanatory Memorandum to the Regulations clearly spells this out, stating:

> "1. These Regulations implement in England 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."

The Regulatory Impact Assessment contains a substantially identical statement under its first heading "Purpose and Intended Effect of Measure".

32. While it might also have been *possible* to adopt the Regulations under sections 16(1)(a) and (e), 26(1)(a) and (3) and/or 48(1) alone, it is clear that it was not intended to adopt a free-standing English regulatory framework for food supplements. Had that been intended, the Regulatory Impact Assessment and consultation would have been fundamentally different. In the circumstances it is submitted that the reference to those additional bases is strictly speaking otiose. It is not only that in the absence of the Directive, the Regulations would not have been adopted: the Secretary of State clearly took the Directive into

[26] Case 314/85 *Foto-Frost* [1987] ECR 4199.
[27] Case C-228/92 *Roquette* [1994] ECR I-1445, para 17.
[28] Case C-408/95 *Eurotunnel v SeaFrance* [1997] ECR I-6315.

consideration in making the Regulations and if the Directive proved to be invalid, the Secretary of State would accordingly have taken into account irrelevant considerations.

Timing

33. The Claimants take the view that although the Regulations do not come into force until 1 August 2005, it is clearly in the public interest that the validity of the Directive be verified well before then by way of a reference to the ECJ.

34. The Claimants take the view that time could formally not have begun to run for the purposes of CPR 54.5(1) before the Regulations became a definite part of English Law. The Regulations were subject to the negative resolution procedure and thus required to be laid before Parliament for 40 days under section 5(1) of the Statutory Instruments Act 1946. During that time, they could have been annulled by a simple vote of either House of Parliament. In fact, a resolution severely criticizing the Regulations which had been materially supported by the First Claimants was passed by the House of Lords on 30 June 2003 (by 132 votes to 79), although this stopped short of actually calling for an annulment.[29] This period of 40 days expired on 11 July.

35. Until it was clear that the Regulations would not be subject to an annulment, it must have been open to the parties to seek to resolve the issue by political lobbying and not to undertake the burden of commencing legal proceedings.[30] The initiation of legal proceedings presents a significant financial commitment in preparation for which funds had to be raised and voluminous documentation obtained. It had therefore been anticipated that a joint challenge would be brought together with the National Association of Health Food Stores ("NAHS"). Unfortunately, negotiations broke down irretrievably at an advanced stage on 6 October 2003, when it was decided to launch a separate challenge. In the Claimants' submission they clearly acted sensibly in initially seeking to join forces with other associations in the industry. Particularly in view of the fact that there is no *prejudice* to any other parties as a consequence of the challenge to the Ban, it is submitted that the Claimants acted with the requisite degree of promptness in all the circumstances.

[29] Annex 16.
[30] See for example Lord Steyn in *R (on the application of Burkett and another) v Hammersmith and Fulham London Borough Council* [2002] UKHL 23, [2002] 1 WLR 1593.

36. In the alternative, the Claimants respectfully request an extension of time under CPR 3.1(2)(a). They submit that the circumstances outlined above constitute good reason for any delay in instituting proceedings.

Pre-Action Protocol

37. The Claimants sent a letter before action on 8 October 2003.[31] A response to this letter was received on 10 October 2003 and is attached as Annex 24.

GROUNDS OF CHALLENGE

38. As already elaborated upon, Article 4(1) of the Directive, when read in combination with Article 3, purports to ban the manufacture and marketing of food supplements containing vitamins or minerals not listed in Annex I or in forms not listed in Annex II.

39. The Directive does lay down two procedures by which Member States can achieve derogations from the ban, but both are impracticable to be pursued in the majority of cases and therefore do little to lessen the draconian effects of the Ban. Firstly, Article 4(6) of the Directive makes provision for a machinery which may be invoked by Member States so as to derogate temporarily from the ban until, as an outside limit, 31 December 2009. Where a Member State avails itself of that machinery, it can continue to allow the manufacture and marketing in its territory of food supplements not containing unlisted vitamin or mineral ingredients. Article 4(7) makes clear that such food supplements do not benefit from the liberalisation brought about by the Directive for compliant food supplements. The second procedure for derogation is contained in Article 4(5) in combination with Article 13(2) of the Directive and allows for the addition of vitamins, minerals and forms of vitamins and minerals to the Annexes where their safety has been demonstrated. Both mechanisms require a time-consuming exercise of research to be carried out, set out in two sets of Guidelines.[32,33] The cost of this research will in all but very few cases surpass any profits which could be generated by a trader with a food supplement during its lifetime.[34] In

[31] Annex 23.
[32] EC Scientific Committee on Food: Guidance on submissions for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of foods, expressed on 11 July 2001; Annex 20.
[33] Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation, updated on 13 December 2001; Annex 22.
[34] The UK Full Regulatory Impact Assessment in respect of the Regulations (Annex 3) quotes an estimate of a cost of £80,000-£250,000 per ingredient: para 43.

addition, the first mechanism provides only a temporary derogation and must be initiated by Member States.

40. The Claimants take issue with the Ban for four distinct reasons:

(1) the Ban could not have been lawfully adopted under powers conferred on the Community under Article 95 of the EC Treaty as it does not contribute to the establishment and functioning of the internal market;

(2) it infringes the principle of subsidiarity in regulating the sale of food supplements within the UK to UK consumers when the UK authorities would be far better placed to make the regulatory choices involved;

(3) it infringes the principle of proportionality in limiting the free movement of goods;

(4) it infringes the Claimants' fundamental right to property and/or the right to carry on an economic activity; and

(5) in adopting the Ban, the Community legislator infringed Article 253 of the EC Treaty and/or the duty to give reasons.

41. The ECJ has sole jurisdiction to declare the Directive or any of its provisions invalid. However, before granting permission and a reference, this court will no doubt wish to be satisfied that there are potentially arguable grounds for suggesting that the Directive is invalid. The Claimants here explain in outline their legal objections to specific features of the Directive and to the Directive as a whole, objections that they will seek to advance before the ECJ.

Legal Basis – Article 95

42. The Directive was adopted on the sole basis of Article 95 of the EC Treaty. This is the equivalent of the old Article 100a, prior to the renumbering of the Articles of the EC Treaty brought about by the Amsterdam Treaty. Directives adopted pursuant to Article 95 must, as the text of that Article makes clear:

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> "have as their object the establishment and functioning of the internal market".

43. It is not enough that the preamble of a directive, or those promoting a directive, assert that it fulfils those conditions. Nor is it enough to point to some "remote and indirect" effect that a directive may have on competition. As the European Court made clear in the *Tobacco Case*:[35]

> "a measure adopted on the basis of Article 100a [now 95] of the EC Treaty *must genuinely have as its object* the improvement of the conditions for the establishment and functioning of the internal market" (emphasis added).

A directive will not have a "genuine" internal market object if it does not "in fact pursue […] the objectives stated by the Community legislature" (Judgment, para 85). It can be said to pursue those objectives only if, as a minimum:

> "it actually contributes to eliminating obstacles to the free movement of goods and to the freedom to provide services, and to removing [appreciable, not remote or indirect] distortions of competition"

(Judgment, para 95; see also paras 106-109). It was on this basis that in that case the tobacco advertising directive was annulled, notwithstanding the unsubstantiated protestations in its preamble that it met internal market concerns.

44. This factual test is to be applied not only to a directive as a whole, but to each identifiable separate element thereof. Otherwise, it would be possible for the Community legislature to circumvent the limits imposed by Article 95 by simply inserting unrelated provisions with different objectives into internal market legislation. That would be contrary to Article 5 of the EC Treaty which provides:

> "The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein."

45. Community institutions wishing to justify an internal market measure on the basis that it "actually contributes to eliminating obstacles to the free movement of goods" (*Tobacco Case*, judgment at para 95), must show:

(a) that the individual provision in question is "designed to prevent" such obstacles (para 86); and

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[35] Case C-376/98 *Germany v Parliament and Council*, Judgment of 5 October 2000, para 84. A copy of this Judgment, together with the Opinion of A.G. Fennelly, is at Annex 17 hereto.

(b) that the individual provision in question actually contributes to their elimination (para 95).

46. There is, in addition, room for anti-avoidance provisions to be incorporated in internal market legislation (para 100). As para 100 itself demonstrates, however, that concept is restrictively construed. Such provisions will be justified on internal market grounds only if they can be shown to be *necessary* to ensure *that rules validly adopted for internal market purposes* are not circumvented.

47. It is impossible to understand how the ban of food supplements containing unlisted vitamin or mineral substances could either directly contribute to eliminating obstacles to the free movement of compliant food supplements, or be necessary to ensure the non-circumvention of internal market rules.

48. Free movement of the compliant food supplements is mandated by Article 11(1) of the Directive. Any Member State seeking to limit the circulation of those food supplements would be acting in breach of its Community law obligations. There is no need in order to bring about the free movement of compliant products to add any other provisions. Normally, EC legislation concerning the harmonisation of products provides for a CE-mark to be attached to compliant goods, and for such goods then to be traded freely.

49. Conversely, the Ban *restricts* the trade in non-compliant food supplements by outlawing them. Where those products could hencetofore be traded between Member States which did not find it necessary to impose restrictions on them, that trade would under the Directive become outlawed. Far from facilitating the establishment and functioning the internal market in those products, the Directive *destroys* it.

50. In fact, the motivation for imposing the Article 4(1) ban is to protect the public health. This was acknowledged by the Community institutions during the development of proposals for the Directive, played a major role in the debates in Parliament and was a recurring theme in the press releases issued by the competent Commissioner. Following the *Tobacco Case* provisions of legislation which are intended primarily for public health purposes cannot claim to be grounded on Article 95. If follows that Article 4(1) is invalid as having no lawful legal basis.

Subsidiarity

51. The Ban violates the principle of subsidiarity. The Community must take action in accordance with the principle of subsidiarity only:

> "… if and in so far 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." (Article 5 EC)

52. Rules concerning measurement methods, the approval of testing laboratories, and the dissemination of information to consumers are not only outwith the Community's competence under Article 95 due to their public health motivation, but are also measures which can be sufficiently achieved by national legislation if Member States so wish. As the ECJ stated in its Judgment in the *Tobacco Case*, Article 95 does not vest in the Community legislature a general power to regulate the internal market, since this:

> "would not only be contrary to the express wording of [Articles 3(1)(c) and 14 EC concerning the internal market] but would also be incompatible with the principle embodied in [Article 5 EC] that the powers of the Community are limited to those specifically conferred on it."[36]

53. Insofar as the products are sold within a Member State which does not regard those products as remotely harmful or as a threat to public health, it is principally a matter for the Member State itself to regulate the trade on public health grounds. Each Member State is better placed to determine the requirements of public health for its own nationals.

Proportionality

54. The principle of proportionality has long been recognised as one of the general principles of Community law by the case law of the ECJ,[37] and the principle now has express recognition in Article 5 EC, the final paragraph of which reads:

> "Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty."

55. A measure will not meet the requirements of the test for proportionality unless:

(a) it is an appropriate measure for the attainment of a legitimate objective; and

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[36] Para 84 of the Judgment.
[37] See, for example, the judgment in Joined Cases 279/84, 280/84, 285/84 and 286/84 *Walter Rau Lebensmittelwerke and Others v Commission* [1987] ECR 1069, para 34.

(b) the means employed are limited to what is necessary for the attainment of the legitimate objective; and

(c) the disadvantages caused or restrictions imposed are not unacceptable given the objective pursued.

56. Article 4(1) of the Directive fails each element of the test for proportionality. It is not an appropriate measure for the attainment of a legitimate objective, for the reasons summarised above.

57. By imposing a ban it is disproportionate in that it constitutes a far more draconian interference with the Claimants' rights than is necessary to pursue any legitimate objective which the provision might arguably have.

58. Finally, the disadvantages caused to the Claimants and the members of the First Claimant in in many cases being unable to continue running their businesses far outweigh the value of any conceivable objective pursued.

Interference in property rights and right to carry on an economic activity

59. Manufacturers of innovative food supplements and practitioners using them have invested considerable effort and resources in developing effective formulations for food supplements. In many instances their products are scientifically much more advanced and therefore much safer and more effective than products merely relying on the substances now listed in the Annexes to the Directive. They have built up reputations and associated goodwill for themselves and their individual products as well as obtaining registered and unregistered intellectual property rights associated with a wide variety of food supplements. To the extent that the Directive purports to ban those food supplements, it deprives the enumerated assets of any economic value and is therefore tantamount to an expropriation without compensation.

60. The Ban accordingly infringes the right to respect for property enshrined in Article 1 of Protocol No. 1 to the European Convention on Human Rights[38] and

[38] Plainly, an infringement of Convention rights protected by section 1 of the Human Rights Act 1998 not required by primary legislation is also contrary to section 6 of the 1998 Act. This claim is nevertheless not brought as a claim under the Human Rights Act in view of the EC law context as identical obligations are incumbent on the Defendant under the overriding and directly applicable rights of the Claimants under Community law, which must be given effect even if this were to mean disapplying inconsistent primary legislation.

now expressed in Article 17 of the Charter of Fundamental Rights of the European Union:[39]

> "Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest."

Although the EU Charter has not been incorporated into the Treaty on European Union, it is nonetheless being referred to by the ECJ as enunciating well-established rights which are fundamental principles of EC law.[40]

61. While interferences in property rights can in principle be justified by reference to the public interests, the interference with the Claimants' property rights which Article 4(1) of the Directive purports to bring about is disproportionate to any possible internal market objective which it may have.[41]

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62. The Ban further infringes the Claimants' right to carry on an economic activity, recognised and protected by the constant case law of the ECJ.[42]

Failure to give reasons

63. As elaborated upon above, it seems impossible that the Ban was adopted with the intention of furthering the internal market. No attempt is made in any of the proposals or explanatory memoranda to state the reasons on which the decision to resort to a ban of non-compliant products is based.

64. Matters are made worse by the fact that it is not even entirely clear whether the Commission in its original proposal intended to introduce any ban of non-compliant products. The original Proposal for the Directive would on a strict reading not actually have restricted the manufacture of substances not included in the Annexes as long as they were not being used together with substances listed in the Annexes:

(a) The prohibition in Article 4(1) of the original Proposal provided:

[39] Done at Nice, OJ C 364, 7.12.2000, p1.
[40] See, for example, the Opinion of A.G. Jacobs in Case C-377/98 *Netherlands v Parliament and Council* (14 June 2001), paras 197 and 210 and the Judgment of the Court of First Instance in Case T-112/98 *Mannesmannröhren-Werke v Commission* (20 February 2001).
[41] The Claimants would submit if necessary that the ban is disproportionate also to any public health objective that may be advanced for it, though since the legal base advanced is Article 95, the correct legal analysis is to concentrate on the internal market objective.
[42] Case 44/79 *Liselotte Hauer v Land Rheinland-Pfalz* [1979] ECR 3727.

"Only the vitamins and minerals listed in Annex I and the vitamin formulations and the permitted mineral substances listed in Annex II may be used for the manufacture of food supplements."

(b) The term "food supplements" was defined in Article 2(a) of the Proposal as:

"foodstuffs that are concentrated sources of nutrients as specified in (b), alone or in combination, …"

(c) Article 2(b) in turn defined "nutrients" as:

"(i) vitamins listed in point 1 of Annex I,
(ii) minerals listed in point 2 of Annex I;"

In other words, the Article 4(1) prohibition of the original Proposal would have had the effect of mandating the use of substances listed in Annexes I and II only in the manufacture of foodstuffs which are concentrated sources of substances listed in Annex I. It would not have had any effect on the manufacture of foodstuffs which are concentrated sources of substances not listed in Annex I. The same applies to the general obligation imposed on Member States by Article 3 of the Proposal. It is not clear whether this was intentional or the result of shoddy drafting.

65. It certainly appears as if the Parliament's Committee on Industry, External Trade, Research and Energy may have read the Proposal as not affecting products including ingredients other than those listed in the Annexes.[43]

66. No real light is shed on the situation by the Explanatory Memorandum to the Commission's Proposal, which contains only very laconic statements concerning "positive lists":

(1) As regards Annex I, the Commission Proposal (wrongly) states that there was "no real controversy as to the vitamins and minerals that are considered essential for the human organism." It was purportedly for the sake of clarity only that a positive list was included in the Proposal.[44]

[43] Opinion of the Parliament's Committee on Industry, External Trade, Research and Energy for the Committee on the Environment, Public Health and Consumer Policy of 20 November 2000; Short Justification, para. 4(C).
[44] Explanatory Memorandum § 5.

(2) As regards Annex II, the Explanatory Memorandum merely states that the forms of a nutrient for use in the manufacturing of foods should be selected on the basis of their safety and bioavailability and that therefore "a positive list comprising those substances would appear necessary."[45]

67. None of the subsequent statements accompanying the progress of the Proposal through the legislative process shed any light on whether the Ban was intended or merely slipped into the Directive as an unforeseen consequence of an amendment introduced without further justification by Parliament at first reading.[46]

68. This instance provides a classic illustration of why a duty to state reasons exists in Community law as well as the public law systems of Member States: without reasons being given for legislative measures, the courts cannot begin to discharge their duty of controlling the limits of the competencies conferred on the legislator. A failure to give reasons for the imposition of the Ban is in itself a sufficient ground of invalidity.

69. The fact of the matter is of course that there is no conceivable purpose of the Ban other than the protection of health, referred to on a number of occasions during the legislative process. However, the EC Treaty expressly limits the public health initiatives which may lawfully be undertaken by the Community institutions. Article 152(1) provides:

> "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."

70. Article 152 goes on to specify particular actions which the Community may undertake in the public health field, in cooperation with and complementing the Member States' own actions. However, Article 152(4) expressly limits the relevant legislative measures which the Community may take to:

> "(c) incentive measures designed to protect and improve human health, *excluding any harmonisation of the laws and regulations of the Member States*." (emphasis added)

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[45] Explanatory Memorandum § 6.

[46] The Commission's Amended Proposal after the 1st Reading by Parliament was unambiguous in that it redefined "food supplements" in Article 2(1)(a) as "foodstuffs that are concentrated sources of nutrients or other substances with a nutritional or physiological function" and removed the link to the Article 2(1)(b) definition of "nutrients".

In the circumstances a resort to Article 95 to adopt what are in effect harmonisation measures aimed at health would constitute a blatant abuse of power.

Remaining provisions of the Directive

71. It is possible that the failings enumerated above affect not only the individual Article 4(1) in the Directive but also the Directive as a whole. The ECJ stated in the *Tobacco Case* when annulling the Tobacco Advertising Directive:

> "… partial annulment of the Directive would entail amendment by the Court of provisions of the Directive. Such amendments are a matter for the Community legislature. It is not therefore possible for the Court to annul the Directive partially."[47]

72. In the present case, it is however hoped that annulment of the Directive as a whole can be avoided. This is because contrary to the Tobacco Advertising Directive, the Article 4(1) ban in the present Directive is a provision which stands functionally apart from the other provisions of the Directive and can as such be excised without requiring amendments going beyond mere changes in cross-referencing. There is no question of a new balance between competing provisions having to be struck, which would have been the prerogative of the legislature.

REFERENCE TO THE ECJ

73. As already touched upon, only the ECJ (or in a direct action, the Court of First Instance of the European Community) has power to declare a directive invalid.[48] In the event that permission is granted, a reference to the ECJ on the question of validity pursuant to Article 234 EC is therefore inevitable.

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74. The mechanics of a reference to the ECJ are set out in CPR Part 68. It is for the referring court to decide on the questions, normally after receipt of drafts from the parties. The questions are accompanied on their journey to the ECJ by the statements of case and evidence, and by a brief judgment or an agreed statement of facts (which in this case could be very short), drafted by the parties and scheduled to the order for reference. Details are set out in the Practice Direction to CPR Part 68.

75. The Claimants propose the following questions for the ECJ. The aim has been to keep the questions as clear and simple as possible:

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47 Para 117 of the Judgment.
48 Case 314/95 *Foto-Frost* [1987] ECR 4199.

Is Article 4(1) of Directive 2002/46/EC invalid by reason of:

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

(b) infringement of the principle of subsidiarity;

(c) infringement of the principle of proportionality;

(d) the fundamental right to property and/or the right to carry on an economic activity; and/or

(e) infringement of Article 253 EC and/or the duty to give reasons?

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INTERIM RELIEF

76. The Claim Form at this stage does not include a request for interim relief. That is because the Regulations specify that they will enter into force on 1 August 2005 only and if a timely reference is made, there is a good chance that a definitive ruling of the ECJ will have been obtained before that date.

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77. The Claimants however reserve the right to apply with reasonable expedition for interim relief in respect of the implementation of all or any part of the Directive, should that become necessary or appropriate.

SUGGESTED PROCEDURE ON THIS APPLICATION

78. The Government has indicated in its reply to the Claimants' letter before action (enclosing an earlier separate reply sent to solicitors acting for the National Association of Health Food Stores) that it intends to oppose the grant of permission and a reference to the ECJ. The Government, however, indicated in the final paragraph of the enclosed letter to the solicitors for the NAHS that it considered the outcome of a "similar application albeit in a different context" which was listed to be heard on 3 and 6 October 2003 of some importance for the present challenge. It is believed that that "similar application" was the case of *R (on the application of ABNA Ltd and others) v Secretary of State for Health and another*. Although the full judgment of that case has not yet been published, a digest which has been obtained.[49] It is possible that the Government may have changed its stance in relation to the present challenge in the light of the outcome of that case. In that event, the Claimants ask for permission to be granted on the papers and for a hearing to be fixed as early as possible for directions as to the making of the reference to the ECJ. Half a day should be sufficient for such a hearing.

[49] Annex 25 [2003] All ER (D) 93 (Oct); Administrative Court, Davis J, 6 October 2003.

79. If the Government were to continue to oppose the Claimants' application and the Court feels unable to resolve the issue in favour of permission on the papers, the Claimants ask for an oral hearing so that any issues on both permission and the proposed reference to the ECJ can be fully canvassed by the parties. Such a hearing might, depending on the nature of any objections taken by the Government, last up to one day and a half.

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CONOR QUIGLEY Q.C.

CARSTEN ZATSCHLER

10 October 2003

Brick Court Chambers
7-8 Essex Street
London WC2R 3LD

The Claimants believe that the facts stated in this Detailed Statement of Grounds are true.

SIGNED _____

DATED 10 October 2003

TABLE OF ANNEXES

1. 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 L 183, 12.7.2002, p. 51.
2. The Food Supplements (England) Regulations 2003; SI 2003/1387.
3. Full Regulatory Impact Assessment in respect of the Regulations.
4. Commission Discussion Paper on "Addition of Vitamins and Minerals to Foods and Food Supplements", III/5934/97.
5. Proposal for a directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements, OJ C 311 E 31.10.2000 p.207-212.
6. Report of the Parliament's Committee on the Environment, Public Health and Consumer Policy for 1st reading, A5/2001/25/.
7. European Parliament legislative resolution on the proposal for a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements (1st reading), OJ C 276 1.10.2001 p.126-134; including transcript of debates.
8. Amended proposal for a Directive of the European Parliament and of the Council on the approximation of the laws of the member states relating to food supplements, OJ C 180 E 26.6.2001 p.248-259.
9. Common Position (EC) No 18/2002 of 3 December 2001 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements, OJ C 90 E 16.04.2002 p.1-11.
10. Communication from the Commission to the European Parliament pursuant to the second subparagraph of Article 251 (2) of the EC Treaty concerning the common position of the Council on the adoption of a proposal for a European Parliament and Council Directive on the approximation of the laws of the Member States relating to food supplements, SEC/2001/1975 final.
11. Report of the Parliament's Committee on the Environment, Public Health and Consumer Policy for 2nd reading, A5/2002/44/.
12. European Parliament legislative resolution on the proposal for a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements (2nd reading), OJ C 47 E 27.2.2003 p.29-30, OJ C 47 E 27.2.2003 p.88 and OJ C 47 E 27.2.2003 p.101; including transcript of debate.
13. Opinion of the Commission pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty, on the European Parliament's amendment to the Council's common position regarding the proposal for a Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements amending the proposal of the Commission pursuant to Article 250 (2) of the EC Treaty, COM(2002)177.
14. PreLex overview of the legislative history of the Directive.

15. Scientific Committee on Food Report on "Nutrient and Energy Intakes for the European Community" (31st series), 1992.

16. Hansard extract of 30 June 2003: House of Lords debate of a motion on the Regulations.

17. Case C-376/98 *Germany v Parliament and Council*, "*the Tobacco Case*" opinion of AG Fennelly of 15 June 2000 [2000] ECR I-8419.

18. Case C-376/98 *Germany v Parliament and Council*, "*the Tobacco Case*" judgment of 5 October 2000 [2000] ECR I-8419.

19. Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission; OJ L 184, 17.7.1999, p. 23.

20. Opinion of the Scientific Committee on Food on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional purposes ('PARNUTS') expressed on 12 May 1999.

21. Scientific Committee on Food: Guidance on submissions for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of foods, expressed on 11 July 2001.

22. Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation, updated on 13 December 2001.

23. Letter before action dated 8 October 2003.

24. Reply to letter before action dated 10 October 2003.

25. *R (on the application of ABNA Ltd and others) v Secretary of State for Health and another*, Davis J (Administrative Court), 6 October 2003 (not reported yet - abstract only).