OPINION OF ADVOCATE GENERAL MISCHO

delivered on 12 December 2002 [1]

1. The Commission of the European Communities asks the Court to declare that, by applying an administrative practice whereby enriched foodstuffs which are lawfully produced or marketed in other Member States may be marketed in Denmark only if there is a documented need for enrichment of food substances in the Danish population, the Kingdom of Denmark has failed to fulfil its obligations under Article 28 EC.

I — Legal background

2. Article 14 of the lov n° 471 om fødevarer m.m. (the Danish Foodstuffs Law) of 1 July 1998, which replaced Law No 310 of 6 June 1973, leaving the law on additives unchanged, provides that:

'Within the meaning of this Law, a food additive is any substance which, without itself being a food or a usual ingredient of compound foods, is intended to be added to foods in order to modify their nutritional value, their shelf-life, consistency, colour, taste or flavour, or for technical or other purposes.'

3. Under Article 15(1) of that Law, only substances authorised by the Minister of Food may be used or sold as additives.

4. According to Article 15(2) of the Law, the Minister may draw up rules relating to the conditions of use of additives, *inter alia* the aim, the quantities and the products with which they are associated, as well as rules relating to the identity and purity of additives.

5. Under Article 16(1) of the same Law, the Minister may draw up rules providing for the possibility of certain groups of specified additives (bacterial cultures, moulds and yeasts, enzymes and nutrients) being used after expiry of a period, fixed by the Minister, which may be up to six months

1 — Original language: French.

after the declaration made to the Minister. The Minister may, before the expiry of this period, prohibit the use of the substance which is the subject of the declaration.

6. The bekendtgørelse n° 282 om tilsætningsstoffer til fødevarer (Danish Decree on Food Additives), of 19 April 2000, imposes the obligation to declare additives to the Food and Veterinary Office six months before their use.

7. The *practice* followed by the Danish authorities makes authorisation of the addition of vitamins and minerals, which alone are at issue in this case, subject to one or more of the criteria laid down in accordance with the General Principles for the Addition of Essential Nutrients to Foods, taken from the Codex Alimentarius, established in 1963 by an international committee under the aegis of the FAO (United Nations Food and Agriculture Organisation) and the WHO (World Health Organisation).

8. The practice of adding vitamins and minerals can be lawful only in the following cases:

— the addition of the additive is required to correct (or prevent) a situation where a large part of the population has an insufficient intake of the nutrient in question (for example, the addition of iodine to salt);

— the addition of the additive must have the purpose of restoring any loss of a product's nutritional value during industrial processing (for example, the addition of vitamin C to fruit juices);

— the addition relates to new foodstuffs, or similar products, which may be used in place of and in the same way as a traditional product (for example, the addition of vitamin A to margarine, which is a butter substitute);

— the addition relates to foodstuffs that constitute a meal in themselves or are intended as special-purpose foods (for example, breast milk substitutes, baby foods or slimming products).

II — Facts and pre-litigation procedure

9. In 1998, a complaint was made to the Commission about obstacles to marketing Ocean Spray Cranberry, a soft drink. The complainant had been refused marketing authorisation by the Danish Food and Veterinary Office. The product contained added vitamin C.

10. On 4 November 1999, the Commission addressed a letter of formal notice to the Danish authorities, in which it drew attention to the fact that the administrative practice followed by the Danish authorities in regard to food additives constituted an unjustified obstacle to trade for the purposes of Articles 28 EC to 30 EC.

11. This question was examined at a meeting with the Danish authorities on 5 March 1999. It became apparent from the discussion that the Food and Veterinary Office had in fact refused marketing authorisation for the drink Ocean Spray Cranberry because of inadequate labelling. In those specific circumstances, the Commission took the view that the position of the Danish authorities was in accordance with Community law.

12. Despite the absence of a specific instance of the Kingdom of Denmark refusing to allow marketing of a foodstuff lawfully marketed in another Member State, the Commission sent a letter of formal notice calling into question the general administrative practice followed by the Danish authorities with regard to the addition of nutrients to foods. According to the Commission, it is indisputable that the Food and Veterinary Office interprets these provisions as prohibiting the addition of nutrients, and *inter alia* vitamins and minerals, to foods, unless there is a nutritional need for these substances in Denmark.

13. In their answer of 22 December 1999 to the letter of formal notice, the Danish authorities stated that, according to case-law of the Court, in particular the judgment in *Sandoz*,[2] a distinctive feature of vitamins is that they have characteristics which make it impossible to foresee or monitor the quantities absorbed by the consumer with other foods and that their degree of harmfulness cannot be determined with sufficient certainty, which means that excessive or prolonged consumption of vitamins may entail risk to health or have undesirable side-effects. According to the Danish authorities, the Court has clearly indicated that Member States, when they apply a prohibition on addition of vitamins, are not required to establish a specific risk linked to each

2 — Case 174/82 *Sandoz* [1983] ECR 2445.

product, since this task is impossible in existing circumstances. They conclude from this that Member States, in order to observe the principle of proportionality, have only to show that the enrichment of foodstuffs does not meet a real need.

14. On 12 September 2000, the Commission sent a reasoned opinion to the Kingdom of Denmark, in which it found that, in applying an administrative practice whereby enriched foodstuffs which are lawfully produced and marketed in other Member States may be marketed in Denmark only if there is a documented need for enrichment of food substances in the Danish population, the Kingdom of Denmark has failed to fulfil its obligations under Article 28 EC. In the reasoned opinion, the Commission claimed, *inter alia*, that 'a prohibition on marketing a product is therefore justified only if it is compatible with the need to protect public health, and it is not enough merely to plead this objective as justification. The burden of proof falls on the Member State, which must show that there is a real health risk in each particular case, and, even though the objective of encouraging the consumption of products enriched with nutrients only if they have a nutritional value is a desirable one, this does not mean that public health is threatened if such nutrients are added to foods even in the absence of nutritional need. In other words, in order to observe the principle of proportionality, it is not enough for Member States to establish the absence of a real need for enrichment with nutrients in their population'.

15. Applying these principles to Danish administrative practice, the Commission concludes that a refusal by the Food and Veterinary Office on the ground that the addition of vitamins or minerals does not meet any nutritional need constitutes an unjustified obstacle to trade as contemplated in Articles 28 EC, 29 EC and 30 EC. According to the Commission, the Danish authorities must demonstrate that the product would constitute a real threat to public health if it were sold and consumed on the Danish market. *This means, in the Commission's view, that the Danish authorities have to put forward the scientific data on which they based their refusal as well as the reasons for which the vitamin and mineral content of the relevant products represented a threat to public health.*

16. By letter of 6 November 2000, the Danish authorities replied to the reasoned opinion. They claimed that the Court had clearly indicated, in its judgment in *Sandoz*, that Member States, when they apply a prohibition on addition of vitamins, are not required to establish a real risk attached to

the relevant product, a task which is impossible under existing circumstances. In the Danish authorities' view, in order to ensure observance of the principle of proportionality, Member States have only to show that the addition of the nutrient in question does not meet a real need. According to the Danish authorities, the scientific uncertainties that existed at the time of the *Sandoz* judgment have been in no way dispelled since then. On the contrary, new knowledge and new proofs continue to come to light regarding the harmfulness of consuming vitamins and minerals in higher doses than those found in a normal diet. *It is these scientific uncertainties regarding the consequences of the addition of vitamins and minerals that form the basis of the Danish provisions, which, according to the Danish authorities, comply with the precautionary principle* laid down in the Commission Communication of 2 February 2000 (COM(2000) 1). Finally, the Danish authorities claimed that it is impossible to apply less radical measures, such as labelling, because there is insufficient knowledge of the actual composition of people's diets, and that, furthermore, labelling would be likely to have the negative effect of encouraging the consumer to buy the product.

III — Forms of order sought by the parties

17. The Commission's application was lodged at the Court Registry on 4 May 2001.

18. The Commission claims that the Court should:

'— declare, pursuant to Article 226 EC, that, by applying an administrative practice whereby enriched foodstuffs which are lawfully marketed and produced in other Member States may be marketed in Denmark only if there is a documented need for enrichment of food substances in the Danish population, the Kingdom of Denmark has failed to fulfil its obligations under Article 28 EC;

— order the Kingdom of Denmark to pay the costs of the proceedings'.

19. The Kingdom of Denmark contends the Court should:

— dismiss the application;

— order the Commission to pay the costs.

IV — Analysis

A — *The existence of an obstacle to freedom of movement*

20. The parties do not deny that the practice based on the Danish Foodstuffs Law constitutes an obstacle to freedom of movement.

21. The Commission has rightly pointed out that the prohibition on enrichment with vitamins relates to requirements affecting the product's 'composition' and, consequently, constitutes an obstacle to intra-Community trade. [3]

22. Similarly, the Danish Government, placing the significance of the effects of its practice on freedom of movement in context, recognises that this practice '... constitutes... an obstacle to the sale of products to which nutrients have been added which are not justified from a nutritional point of view'.

23. Therefore, the question that is at the heart of this case, and over which the parties are in dispute, is whether that obstacle is justified by the requirements laid down in Article 30 EC and, specifically, by the 'protection of health and life of humans'.

B — *Justification for the obstacle to freedom of movement*

1. Summary of the parties' submissions

24. During the proceedings before the Court, the parties gave further details of their positions as follows.

25. The *Commission* considers that the contested Danish practice uses as its sole criterion the nutritional need for an additive even though that criterion does not constitute a ground accepted under Article 30 EC.

26. Referring to the Court's judgment in *Van der Veldt* [4] and to the judgment of the Court of the European Free Trade Associ-

3 — See, *inter alia*, Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraph 15, and Case C-217/99 *Commission* v *Belgium* [2000] ECR I-10251, paragraph 16.

4 — Case C-17/93 *Van der Veldt* [1994] ECR I-3537, paragraphs 17 to 21.

ation (or 'the EFTA Court') in *EFTA Surveillance Authority* v *Kingdom of Norway*,[5] the Commission submits that the Member State must be able to demonstrate in every case that the restriction on trade is necessary for the protection of public health.

27. According to the Commission, the prohibition on enrichment with vitamins requires the Member State to carry out a full risk analysis of the health consequences of the addition of certain vitamins to specific foodstuffs. The fact that there is a risk linked to the intake of certain vitamins, such as vitamins A, B or B6, does not justify a general prohibition on enrichment of foodstuffs in cases other than those covered by the Codex Alimentarius.

28. According to *the Danish Government*, the Danish prohibition is justified specifically by the fact that there is a potential health risk, inasmuch as nutrients are added to foodstuffs when there is no corresponding 'nutritional need' in the population. Nutritional need is used as a criterion for determining whether the addition of vitamins and minerals is acceptable from a public-health point of view.

29. The Danish Government refers to a long series of scientific studies on the addition of vitamins and minerals to foodstuffs which, it claims, shows the harmful effect of vitamins and minerals not only in high doses but also as a result of combinations of vitamins and minerals in relatively low doses. It points out again that its contested practice is directly inspired by the Codex Alimentarius.

30. It again refers to paragraph 19 of the judgment in *Sandoz* from which it follows, it claims, that Member States are not required to establish the existence of a real danger relating to a given product.

31. Specifically, the Danish Government maintains that 'the Court, in paragraph 19 of its judgment in *Sandoz*, found that, where they maintain a prohibition on the addition of vitamins, Member States are not required to establish the existence of a real danger relating to a given product, since this is an impossible task in the current state of science'.

32. In addition, the Danish Government, referring to the case of *Commission* v *France*,[6] maintains that a national authority may refuse to authorise the use of an

5 — Case E-3/00 *EFTA Surveillance Authority* v *Kingdom of Norway* [2001], paragraphs 35 and 36.

6 — Case C-344/90 *Commission* v *France* [1992] ECR I-4719.

additive if there is no genuine technological or nutritional need speaking in favour of addition of the additive under consideration.

2. Assessment

(a) Introduction

33. This case thus raises the question of the extent to which a Member State may rely on the absence of nutritional need to justify an obstacle to freedom of movement.

34. For my part, I have already had occasion to examine this question in my Opinion of 16 May 2002 in the case of *Greenham and Abel.* [7]

35. There are two extreme positions, which are, firstly, the position that the absence of nutritional need can justify an obstacle to freedom of movement independently of any health-protection consideration — a position that might possibly be inferred from a literal reading of the judgment in *Commission* v *France*, cited above — and, secondly, the position that consists of excluding nutritional need from consideration while retaining as sole criterion the specific health risk to which consumption of the foodstuff in question would give rise. In my Opinion in *Greenham and Abel*, I have favoured an intermediate solution which, in my view, follows from the judgment in *Sandoz* and according to which nutritional need has a role to play in a context of scientific uncertainty as to the harmfulness of the nutrient in question.

36. Since the Danish Government has referred specifically to the *Sandoz* judgment to justify its practice, I propose, first of all, to examine the latter from the point of view of that judgment.

37. However, since the Commission has pointed out the importance of a risk analysis in allowing a Member State to rely on the plea of health protection, I shall, secondly, examine the implications for this case of such an approach.

(b) Analysis from the point of view of the *Sandoz* judgment

38. Having regard to the importance of *Sandoz* for this case, it seems to me

7 — Case C-95/01 *Ministère public* v *Greenham and Abel*, judgment of 5 February 2004, not published in the ECR.

appropriate to quote paragraphs 16 to 20 of that judgment in their entirety:

'16 As the Court found in its judgment in Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Producten* [1981] ECR 3277, in so far as there are uncertainties at the present state of scientific research it is for the Member States, in the absence of harmonisation, to decide what degree of protection of the health and life of humans they intend to assure, having regard however for the requirements of the free movement of goods within the Community.

17 Those principles also apply to substances such as vitamins which are not as a general rule harmful in themselves but may have special harmful effects solely if taken to excess as part of the general nutrition, the composition of which is unforeseeable and cannot be monitored. In view of the uncertainties inherent in the scientific assessment, national rules prohibiting, without prior authorisation, the marketing of foodstuffs to which vitamins have been added are justified on principle within the meaning of Article 36 of the Treaty on grounds of the protection of human health.

18 Nevertheless the principle of proportionality which underlies the last sentence of Article 36 of the Treaty requires that the power of the Member States to prohibit imports of the products in question from other Member States should be restricted to what is necessary to attain the legitimate aim of protecting health. Accordingly, national rules providing for such a prohibition are justified only if authorisations to market are granted when they are compatible with the need to protect health.

19 Such an assessment is, however, difficult to make in relation to additives such as vitamins the abovementioned characteristics of which exclude the possibility of foreseeing or monitoring the quantities consumed as part of the general nutrition and the degree of harmfulness of which cannot be determined with sufficient certainty. Nevertheless, although in view of the present stage of harmonisation of national laws at the Community level a wide discretion must be left to the Member States, they must, in order to observe the principle of proportionality, authorise marketing when the addition of vitamins to foodstuffs meets a real need, especially a technical or nutritional one.

20 The first question must therefore be answered to the effect that Community

law permits national rules prohibiting without prior authorisation the marketing of foodstuffs lawfully marketed in another Member State to which vitamins have been added, provided that the marketing is authorised when the addition of vitamins meets a real need, especially a technical or nutritional one.'

39. The parties interpret paragraph 20 of the *Sandoz* judgment in different ways.

40. According to the Danish Government, 'that judgment... contains a finding that, to observe the principle of proportionality, it is enough to authorise marketing only when the addition meets a real need to enrich the food'.

41. According to the Commission, on the other hand, '[the] interpretation that the Danish Government is putting on *Sandoz* rests on a mistaken converse inference from paragraph 20 of the grounds of the judgment.... [That judgment] establishes only that a prohibition on marketing foodstuffs to which vitamins have been added infringes the principle of proportionality where the addition meets a nutritional need'.

42. I cannot accept the interpretation that the Commission is thereby putting on the *Sandoz* judgment.

43. Firstly, it is true that nutritional need can never be, independently of any public-health consideration, a criterion justifying a prohibition on freedom of movement.

44. In pointing out, in paragraph 18 of *Sandoz*, that '... national rules providing for such a prohibition are justified only if authorisations to market are granted when they are compatible with the need to protect health', the Court has clearly shown that the context of its analysis is that of public-health protection. [8]

45. Secondly, having stated in paragraph 19 that there was scientific uncertainty as to the harmfulness of the additives in question and having specifically indicated that a health risk could not be excluded, [9] but that the degree of this risk could not be

8 — Advocate General Gulmann had the same reading of the *Sandoz* judgment in his Opinion of 8 April 1992 in *Commission* v *France*, cited above: 'It may, moreover, be noted that in no judgment [including *Sandoz*] has the Court accepted a prohibition on importation on the sole ground that there was no technological need and that, for obvious reasons, in its judgments most emphasis is placed on the question of risks to health' (paragraph 11).

9 — See, on this point, paragraph 12 of the *Sandoz* judgment: '... such a risk cannot be excluded in so far as the consumer absorbs with other foods further quantities of vitamins which it is impossible to monitor or foresee'.

determined with sufficient certainty, the Court, in paragraph 20, introduced nutritional need as an exception to Member States' right to prohibit the importation of enriched foodstuffs.

46. Thus, it is apparent from the relationship between paragraphs 19 and 20 that the nutritional-need criterion comes into play only in a context of scientific uncertainty with regard to the health risk posed by an additive.

47. Contrary to what the Commission maintains, I am of the view that, once that scientific uncertainty has been found to exist, the *Sandoz* judgment does allow Member States to prohibit foodstuffs to which the additive in question has been added, unless its addition meets a nutritional need.

48. It does not seems to me possible to read any differently paragraph 20 of the judgment in *Sandoz*, which is identical to point 1 of the operative part of that judgment, in which it was held that '... Community law *permits national rules prohibiting*... the marketing of foodstuffs... to which vitamins have been added, *provided that the marketing is authorised when the addition of vitamins meets a real need, especially a technical or nutritional one*'. [10]

49. In other words, if the additive meets a nutritional or technical need, the prohibition on freedom of movement is not justified. On the other hand, if it does not meet such a need, the Member State is entitled to take the safer route and to prohibit marketing of the foodstuff incorporating that additive, [11] in exercise of the broad discretion which the Court acknowledges the Member State as having in cases where there is scientific uncertainty.

50. Therefore, the nutritional-need criterion does not supplant the healthprotection criterion. What the Court has done in its judgment in *Sandoz* is to clarify, in paragraphs 19 and 20, the way in which the health-protection justification, as noted in paragraph 18, is to be understood where there is scientific uncertainty as to the health risk posed by an additive. In that sense, this judgment seems to me to constitute an application of the precautionary principle before the fact. [12]

10 — Emphasis added.

11 — See, also in support of this, Noiville, C., and de Sadeleer, N., 'La gestion des risques écologiques et sanitaires à l'épreuve des chiffres. Le droit entre enjeux scientifiques et politiques', *Revue du Droit de l'Union Européenne*, 2001, pp. 389, 436, footnote 171.

12 — See also Alemanno, A., 'Le principe de précaution en droit communautaire. Stratégie de gestion des risques ou risque d'atteinte au Marché intérieur', *Revue du Droit de l'Union Européenne*, 2001, pp. 917, 940: 'For the first time, the Court would seem to have recognised, although in an *obiter dictum* which does not explicitly mention the precautionary principle, the possibility of Member States adopting measures in a situation of scientific uncertainty'.

51. Is the contested Danish practice, which prohibits the addition of vitamins and minerals to foodstuffs except where a nutritional need for them has been established, a correct application of the Court's judgment in *Sandoz*?

52. I take the view that it is.

53. It is, of course, true that, in its judgment in *Sandoz*, the Court did not hold once and for all that there is scientific uncertainty as to the health risk posed by adding vitamins to foodstuffs.

54. However, the Danish Government refers to a long series of scientific studies on the addition of vitamins and minerals to foodstuffs; these, according to that government, highlight the harmful effect of vitamins and minerals not only in high doses but also where combinations of vitamins and minerals are present in relatively low doses.

55. It is clear from the Danish Government's detailed explanations that, although there have been developments over the last 20 years, these have not led from scientific uncertainty to certainty, but rather in the opposite direction: scientific investigations continue to bring to light the negative effects, previously unknown, both of high doses and of combinations of nutrients in relatively low doses.

56. The Commission, for its part, does not challenge the studies to which the Danish Government refers. It simply points out that it has no knowledge of any scientific data which enable it to take the view that excessive vitamin C consumption in itself entails a risk to public health. However, the Danish Government has replied, referring to scientific studies, that one of the effects of vitamin C, that of promoting the absorption of iron in the digestive tract, entails a risk to people who have large concentrations of iron, which, in their turn, are associated with a higher risk of cardiovascular diseases and of cancer.

57. It is true that, when questioned at the hearing as to whether the scientific uncertainty regarding the harmfulness of adding vitamins to foodstuffs, as found by the Court nearly 20 years ago, persists today, the Commission replied that developments in research since the early 1980s have made it easier for safety margins to be set for vitamins and minerals.

58. However, the Danish Government challenges that point of view, claiming that

'... it is not possible to maintain... that risk analysis enables the setting of "upper safety limits" for nutrients. The question of detrimental effects on health [of the addition] of vitamins and, in particular, the question of interaction [of vitamins and mineral salts] have not been... sufficiently clarified by scientific research. Therefore, it is not possible to base the determination of maximum limit values on sufficiently certain scientific data'.

59. In that regard, it must be noted that, in the course of the 19 years that have elapsed since the *Sandoz* judgment, the Community itself has not been able to establish maximum safety limits for vitamins and minerals.

60. This was confirmed by 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. [13] It was only then, in fact, that that directive, in Article 5(1), entrusted the Commission with the task of setting, in accordance with the regulatory-committee procedure, the maximum amounts of minerals and vitamins that can be incorporated into food supplements, taking the following into account:

'(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) intake of vitamins and minerals from other dietary sources.'

61. Indeed, Directive 2002/46 is interesting in two further respects.

62. Firstly, the Community legislature confirms the assessment that vitamins and minerals can produce harmful effects.

63. The 13th recital of Directive 2002/46 states as follows:

'Excessive intake of vitamins and minerals may result in adverse effects and therefore

13 — OJ 2002 L 183, p. 51.

[*this risk*] necessitate[s] the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer'. [14]

64. Secondly, the Community legislature itself introduces the concept of nutritional need into the debate about adding vitamins and minerals to foodstuffs, taking the view that the average consumer has no need for additional intake of vitamins and minerals and that this need exists only for certain population groups.

65. The third and fourth recitals of Directive 2002/46 state as follows:

'An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community.

Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through *food supplements*'. [15]

66. The Community legislature therefore seems to be starting from the principle that, if the general nutrition of the population or of a part of the population must be enriched, this must be done through food supplements identifiable as such and not through 'ordinary' foodstuffs.

67. Finally, it should be noted that the Danish practice is based on the 'General Principles for the Addition of Essential Nutrients to Foods' adopted by the Codex Alimentarius Committee in 1987 and amended in 1989 and 1991. [16]

68. On the one hand, the Court has always attached great importance to the 'findings... of the work of the Community's Scientific Committee for Food and of the

14 — Emphasis added.

15 — Emphasis added.

16 — CAC/GL 09-1987 (amended 1989, 1991).

Codex Alimentarius Committee of the Food and Agriculture Organisation of the United Nations (FAO)' [17] under Article 30 EC.

69. On the other hand, it is evident that the General Principles, which were adopted after the *Sandoz* judgment was delivered, approach the enrichment of foods, for health protection reasons, with great reticence, since they even go so far as to state that enrichment should be the responsibility of national authorities.

70. The Introduction to the General Principles informs us that they are intended, among other things, 'to prevent the indiscriminate addition of essential nutrients to foods thereby *decreasing the risk of health hazard* due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer'. [18]

71. The section relating to definitions then states, as follows:

'2.5 Fortification or enrichment means the addition of one or more essential nutrients to a food whether or not it is normally contained in the food for the purpose of preventing or correcting a *demonstrated deficiency* of one or more nutrients in the population or specific population groups'. [19]

72. According to Section 3, 'Basic principles':

'3.1 Essential nutrients *may be added* to foods for the purpose of:

3.1.1 restoration;

3.1.2 nutritional equivalence of substitute foods;

3.1.3 fortification;

3.1.4 ensuring the appropriate nutrient composition of special purpose food.

17 — Case 247/84 *Motte* [1985] ECR 3887, paragraph 24; Case 304/84 *Muller and Others* [1986] ECR 1511, paragraph 24; Case 178/84 *Commission* v *Germany* ('*Beer*') [1987] ECR 1227, paragraph 44; Case C-42/90 *Bellon* [1990] ECR I-4863, paragraph 14, and Joined Cases C-13/91 and C-113/91 *Debus* [1992] ECR I-3617, paragraph 17.

18 — Emphasis added.

19 — Emphasis added.

3.2 The essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient *considering amounts from other sources in the diet.*

...' [20]

73. Section 6, entitled 'Nutrient addition for purposes of fortification', is formulated as follows:

'6.1 *Fortification should be the responsibility of national authorities* since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.

6.2 The following conditions should be fulfilled for any fortification *programme*:

6.2.1 There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical *evidence of deficiency*, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.

6.2.2 The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.

6.2.3 The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.

...' [21]

74. Taking all the above into account, I am of the view that there is no reason to consider that adding vitamins to ordinary foodstuffs appears to be a more reliable

20 — Emphasis added.

21 — Emphasis added.

exercise from a scientific point of view than it was 20 years ago when the Court delivered its judgment in *Sandoz*.

75. The same applies to minerals. These were not the subject of that judgment, but the Commission neither alleges that they should be treated differently from vitamins nor challenges the scientific explanations concerning them provided by the Danish Government. Furthermore, the Community legislature itself also places minerals on the same footing as vitamins in Directive 2002/46. [22]

76. Faced with this situation, which the Danish Government has, in my view, satisfactorily shown to be not significantly different from that which formed the basis of the *Sandoz* judgment, the Danish government, in verifying whether the absorption of the quantity of vitamins or minerals contained in a particular food is intended to meet a nutritional need, seems to me to be acting perfectly in line with the case-law of the Court.

77. The above considerations could be sufficient to lead to the conclusion that the Commission's application should be dismissed.

(c) Examination of the issue from the point of view of risk analysis

78. However, the Commission has suggested that the approach taken by the Court in *Sandoz* is no longer up to date.

79. The Commission considers that 'the judgment of the [EFTA] Court must be viewed as an element in the development of the law. Since the judgment in *Sandoz*, practically 20 years ago, the methods used to determine health risks have undergone considerable changes. The fact that *risk analysis* has become a tool for determining specific health risks means that general health-related decisions, and *inter alia* possible prohibitions, may be taken on an objective, documented basis, taking account of the specific circumstances in each case. The judgment of the [EFTA] Court reflects this development'. [23]

80. The Danish Government, for its part, has stated, in its rejoinder, 'that it disagrees with [the EFTA Court judgment] and that [the latter] cannot be said to accord with the case-law of the European Court of Justice'.

22 — See, *inter alia*, the 13th recital.

23 — Emphasis added.

81. It therefore appears that each of the parties has chosen its approach in order to defend its view — the Danish Government taking the approach resulting from the *Sandoz* judgment and the Commission the approach resulting from the EFTA Court's judgment — and that in their eyes these two approaches are irreconcilable.

82. But are they really?

83. I have already indicated, referring for support to the legal literature, that, in my view, *Sandoz* is an application of the precautionary principle before the fact. [24] Other commentators, too, also place the *Sandoz* judgment in a risk analysis context. [25]

84. However, the issue is deserving of closer examination, which must begin with a precise understanding of the concept of risk analysis.

85. In that regard, I will take as my starting point the EFTA Court's judgment, from which it is apparent, according to the Commission, that '[the] prohibition on enrichment with vitamins requires the Member State to carry out a full *risk analysis* of the health consequences of the addition of certain vitamins to foodstuffs'. [26]

86. That judgment had its origin in a refusal by the Norwegian authorities to authorise the marketing of corn flakes enriched with certain vitamins and with iron. The reason for that refusal was the absence, within the Norwegian population, of a nutritional need for such enrichment.

87. The EFTA Court found that there was a failure to fulfil obligations laid down in Article 11 of the Agreement on the European Economic Area, for two reasons:

— the Kingdom of Norway's attitude was inconsistent because, while prohibiting the marketing of corn flakes fortified with iron, it allowed a certain type of cheese containing a high level of added iron to be freely sold in the country; [27]

— at the administrative stage, no 'comprehensive risk assessment' covering

24 — See paragraph 50 above.

25 — Noiville, C., and de Sadeleer, N., loc. cit., p. 435.

26 — Emphasis in the original.

27 — See paragraph 41 of the EFTA Court's judgment.

the addition of iron to foodstuffs had been carried out. [28]

88. The first of the two reasons above is not obviously relevant to the present case, since the factual situation is not the same. The second requires a better understanding of the concept of 'comprehensive risk assessment' and, in particular, the relationship of that concept to that of 'risk analysis'.

89. The risk-analysis approach is indeed nowadays ubiquitous. The Danish Government points out that it is made up of three stages: risk assessment, risk management and risk communication. It is defined by the Commission in its Communication of 30 April 1997 on consumer health and food safety [29] as being 'a systematic procedure comprising the scientific evaluation of hazards and the probability of their emergence in a given context (risk assessment), the assessment of all measures making it possible to achieve an appropriate level of protection (risk management), and the exchange of information with all the parties concerned: decision-makers, inspectors, consumers and producers in order to explain the reasons and to justify the management measures proposed (risk communication)'.

90. Explicit references to risk analysis can be found, for example, in the Commission's Communication of 2 February 2000 on the precautionary principle; [30] in Common Position (EC) No 2/2002 of 17 September 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 Regulation (EC) of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety; [31] at the international level, in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, [32] approved by the Council on behalf of the European Community, by Decision 2002/628/EC; [33] and, most recently judgments of the Court of First Instance in *Pfizer Animal Health* v *Council* [34] and *Alpharma* v *Council*. [35]

91. The two stages of risk analysis which are of interest to us in the context of this case are risk assessment and risk management.

28 — See paragraph 42 of the EFTA Court's judgment.

29 — COM(97) 183 final. See p. 20.

30 — COM(2000) 1 final. See, in particular, paragraph 5.

31 — OJ 2002 C 4, p. 18. See Article 6.

32 — See Articles 15 and 16.

33 — Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety (OJ 2002 L 201, p. 48).

34 — Case T-13/99 [2002] ECR II-3305.

35 — Case T-70/99 [2002] ECR II-3495.

92. Although the boundary between these two stages is not always easy to define, [36] they accurately reflect a dual requirement: on the one hand, the requirement to introduce science into policy making and, on the other hand, the requirement to retain the autonomy of policy making from science. [37]

93. The Court of First Instance has analysed these two stages in detail in its judgments in *Pfizer Animal Health* v *Council* and *Alpharma* v *Council*.

94. As regards the 'scientific' stage — risk assessment in the strict sense — the Court of First Instance held that 'scientific risk assessment is commonly defined, at both international level... and Community level..., as a scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk' [38] and that 'the competent public authority must, in compliance with the relevant provisions, entrust a scientific risk assessment to experts who, once the scientific process is completed, will provide it with scientific advice'. [39]

95. With regard to the 'political' stage — that is, establishing the level of risk deemed acceptable — the Court of First Instance pointed out that:

'... it is for the Community institutions to determine the level of protection which they deem appropriate for society. It is by reference to that level of protection that they must then... determine the level of risk — i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects — which in their judgment is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty (see, to that effect, Case C-473/98 *Toolex* [2000] ECR I-5681, paragraph 45). Therefore, determining the level of risk deemed unacceptable involves the Community institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty.

Although they may not take a purely hypothetical approach to risk and may not base their decisions on a "zero-risk"...,

36 — Thus, although determination of the level of risk deemed unacceptable is viewed by the Court of First Instance as forming part of the risk assessment stage (see *Pfizer Animal Health* v *Council*, paragraph 149, and *Alpharma* v *Council*, paragraph 162), commentators consider that it forms part of the risk management stage (see Noiville, C., and de Sadeleer, N., loc. cit., p. 400, and Alemanno, A., loc. cit., p. 936). See also de Sadeleer, N., 'Le statut juridique du principe de précaution en droit communautaire: du slogan à la règle', *Cahiers de droit européen*, 2001, p. 91, 105: '... the division advocated by the Commission between risk assessment and the policy making that follows — risk management — is blurred by the constant push and pull between facts and values, nature and culture, science and politics'.

37 — See also Alemanno, A., loc. cit., p. 937.

38 — *Pfizer Animal Health* v *Council*, paragraph 156, and *Alpharma* v *Council*, paragraph 169.

39 — *Pfizer Animal Health* v *Council*, paragraph 157, and *Alpharma* v *Council*, paragraph 170.

the Community institutions must nevertheless take account of their *obligation* under the first subparagraph of Article 129(1) of the Treaty *to ensure a high level of human health protection*, which, to be compatible with that provision, does not necessarily have to be the highest that is technically possible (Case C-284/95 *Safety Hi-Tech* [1998] ECR I-4301, paragraph 49)'. [40]

96. Even though, specifically, that judgment of the Court of First Instance is concerned with Community institutions, there is no doubt that it also applies to the Member States.

97. It is settled case-law that, in so far as uncertainties continue to exist in the current state of scientific research about the harmfulness of food additives, it is for the Member States, in the absence of harmonisation, to decide what degree of protection of the health and life of humans they intend to assure, having regard however for the requirements of the free movement of goods within the Community. [41]

98. Furthermore, this Court very recently held, in paragraph 47 of its judgment in *Hahn*, [42] that '... Articles 28 EC and 30 EC [do not] preclude the application of national legislation laying down zero tolerance for Listeria monocytogenes in fish products which have not been chemically preserved', thus confirming that the Member States do in fact have a broad discretion in determining the level of health protection.

99. It is at this 'political' stage of determining the acceptable level of risk that the precautionary principle essentially comes into effect. [43]

100. In regard to that principle, the Court of First Instance, having referred, [44] *inter alia*, to the judgments in *National Farmers' Union and Others* [45] and *United Kingdom* v *Commission*, [46] in which the Court of Justice held that '[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait

40 — *Pfizer Animal Health* v *Council*, paragraphs 151 and 152, and *Alpharma* v *Council*, paragraphs 164 and 165. Emphasis added.

41 — See, *inter alia*, *Sandoz*, paragraph 16; *Debus*, paragraph 13; Case C-293/94 *Brandsma* [1996] ECR I-3159, paragraph 11, and Case C-400/96 *Harpegnies* [1998] ECR I-5121, paragraph 33.

42 — Case C-121/00 *Hahn* [2002] ECR I-9193.

43 — According to the Commission's Communication on the precautionary principle, paragraph 3, 'when there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation, the precautionary principle has been politically accepted as a *risk management strategy* in several fields' (emphasis added).

44 — *Pfizer Animal Health* v *Council*, paragraph 139, and *Alpharma* v *Council*, paragraph 152.

45 — Case C-157/96 *The Queen* v *Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise, ex parte National Farmers' Union and Others* [1998] ECR I-2211.

46 — Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265.

until the reality and seriousness of those risks become fully apparent',[47] held as follows:

'[I]n a situation in which the precautionary principle is applied, which by definition coincides with a situation in which there is scientific uncertainty, a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality (see, in that context, *Mondiet*, cited at paragraph 115 above, paragraphs 29 to 31; and *Spain* v *Council*, cited at paragraph 115 above, paragraph 31).

Nevertheless, it is also clear from the case-law cited at paragraph 139 above that a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified (see also, to that effect, *EFTA Surveillance Authority* v *Norway*, cited at paragraph 115 above, in particular paragraphs 36 to 38).

In contrast, it follows from the Community Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been "fully" demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken'.[48]

101. That passage from the judgments of the Court of First Instance fully expresses all the tension inherent in applying the precautionary principle: on the one hand, a measure cannot be based on a purely hypothetical risk, yet, on the other hand, one cannot wait until the risk has been established with certainty.[49] Indeed, in some cases, absolute certainty can be reached only when the risk has already materialised and by then it may be too late to correct it.

102. It therefore seems to me that a *plausible* public-health risk is enough, according to the precautionary principle, to allow a

47 — *National Farmers' Union and Others*, paragraph 63, and *United Kingdom* v *Commission*, paragraph 99.

48 — *Pfizer Animal Health* v *Council*, paragraphs 142 to 144, and *Alpharma* v *Council*, paragraphs 155 to 157.

49 — See also Salmon, N., 'A European perspective on the precautionary principle, food safety and the free trade imperative of the WTO', *European Law Review*, 2002, p. 138, which contains the following: 'Risk is measured not only by positive knowledge of a quantifiable likelihood, but also by the degree of uncertainty or lack of knowledge about a possible hazard.... On the continuum between a merely speculative risk and a conclusively demonstrated one lies a vast stretch of undemonstrated, unquantified but scientifically plausible risks. Within that zone, the risk of harm is real so long as safety is unproven'.

Member State to adopt measures on the basis of Article 30 EC. Moreover, the greater the scientific uncertainty, the broader the discretion of the Member States, which are responsible for protecting public health.

103. In the light of these considerations concerning the concept of 'risk analysis', has the *Sandoz* judgment become obsolete?

104. I take the view that it has not.

105. As far as the risk-assessment aspect is concerned, it must be noted that this Court was guided by parties' arguments on the risk posed by excessive consumption of vitamins.

106. The Court held, in paragraph 12 of *Sandoz*, that:

'It is not disputed by the parties who have submitted observations that the concentration of vitamins contained in the foodstuffs of the kind in issue is far from attaining the critical threshold of harmfulness so that even excessive consumption thereof cannot in itself involve a risk to public health. *Nevertheless such a risk cannot be excluded in so far as the consumer absorbs with other foods further quantities of vitamins which it is impossible to monitor or foresee*'. [50]

107. Therefore, there was a plausible risk, linked to excessive consumption of vitamins. However, according to paragraph 19 of the *Sandoz* judgment, the degree of that risk was not certain. Nevertheless, the Court upheld, in paragraph 20, the prohibition on marketing of foodstuffs, lawfully marketed in another Member State, to which the vitamin was added, while making that prohibition dependent on absence of nutritional need.

108. That nutritional-need criterion is perfectly comprehensible and justified in a risk-analysis context and, in particular, in a risk-management context.

109. Once the plausibility of the risk has been established, nutritional need comes into play as a criterion used by Member States in exercising their power to determine the level of acceptable risk.

50 — Emphasis added.

110. That criterion is also particularly appropriate here, since the two parties in the present case agree in saying that the existence of a *nutritional need* for the addition of vitamins may constitute a *presumption* that the product presents *no public-health risk*.

111. Furthermore, that characterisation of nutritional need as a risk-management criterion seems to me to be strengthened by Common Position No 2/2002, Article 6(3) of which states, as follows:

'Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, *other factors legitimate to the matter under consideration* and the precautionary principle when the conditions laid down in Article 7(1) are relevant'. [51]

112. Even though the nutritional-need criterion might not already have been taken into consideration under the precautionary principle, it should at least be able to be taken into account as 'a factor legitimate to the matter under consideration'.

113. I therefore take the view that it is perfectly possible to reconcile the approach taken by this Court in *Sandoz* with the approach which results from an application of risk analysis.

114. The Commission has again replied, however, that 'assessment by Member States of the risk to public health must rely on concrete scientific evidence of the risk presented by the addition of *each type of vitamin in particular*'. [52] The Commission referred, at the hearing, to the Opinion of Advocate General Geelhoed of 16 May 2002 in the cases of *Commission* v *Germany* and *Commission* v *Austria*. [53]

115. That Opinion concerns a different issue, namely whether all preparations with added vitamins containing three times the recommended daily dose could *automatically* be viewed as *medicinal products*.

116. I share the view expressed by Advocate General Geelhoed, that, in principle, there should be a case-by-case examination, but that one can also 'imagine situations in which general regulations could be acceptable in relation to certain groups or categories of products. This is particularly so

51 — Emphasis added.

52 — Emphasis added.

53 — Cases C-387/99 *Commission* v *Germany* and C-150/00 *Commission* v *Austria*, judgment of 29 April 2004, not published in the ECR.

when products belonging to a given category or to a given group present the same or strongly comparable health risks. In that case, assessment by groups or by categories is acceptable and has the advantages of greater transparency, fewer difficulties of implementation and use, and progressively reduced effects on the free movement of goods'. [54]

117. In the present case, none of the documents before the Court gives reason to believe that the Kingdom of Denmark does not proceed case by case. The competent authorities certainly appear to be examining each foodstuff for which marketing authorisation is requested, to ascertain which vitamins it contains and at what dose.

118. The Commission maintains, however, that, quite apart from the dose which meets the average consumer's nutritional need, the Member State must set upper safety limits for each vitamin or mineral.

119. However, the Commission does not give any fuller explanation on this subject, but simply refers 'by way of example of such an approach' to Directive 2002/46, adopted by the Council last June.

120. Yet, as we have seen above, that directive merely requires the Commission to set such limits for products referred to as 'food supplements'.

121. Therefore, it will fall to the Commission to demonstrate that the finding by the Court in paragraph 36 of its judgment in *Van Bennekom*, [55] according to which 'scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects' of vitamins and minerals, is no longer valid.

122. However, I take the view that, while waiting, Member States are not obliged to make that determination, each on their own account (and, therefore, to end scientific uncertainty by decree, so to speak), either in relation to food supplements, which alone are covered by Directive 2002/46, or in relation to 'normal' foodstuffs, which are at issue in the present case.

54 — Paragraph 63 of the Opinion.

55 — Case 227/82 *Van Bennekom* [1983] ECR 3883.

123. Nor are Member States obliged to allow marketing of an enriched foodstuff solely because another Member State has taken the view that it was already in a position to make that determination. [56] In the absence of harmonisation, each Member State is entitled to decide the level at which it wishes to protect human health.

124. It is impossible to see, therefore, why a Member State could not, where there is a plausible risk, the degree of which cannot be established with certainty, decide to adopt as the safety limit, the level of nutritional need of its population, which it will have determined on the basis of the population's food habits or which corresponds to the level at which absence of danger is presumed.

125. It is true that the Commission takes the view that '[the] prohibition on marketing foodstuffs to which vitamins have been added is contrary to the *principle of proportionality* as established in the case-law of the Court'. [57] Here, the Commission is referring to paragraph 28 of the EFTA Court's judgment.

126. In paragraph 28 of its judgment, the EFTA Court held that '... [t]he mere finding by a national authority of the absence of a nutritional need will not justify an import ban, a most restrictive measure, on a product which is freely traded in other EEA States'.

127. However, the EFTA Court had also previously pointed out that:

'The need to safeguard public health has been recognised as, and remains, a primary concern, and the level of protection chosen by the Contracting Parties should not be placed in question. However, the principle of proportionality must be respected.

In that process, *the question of nutritional need* with regard to additives to foodstuffs in any given population *may have a proper place*....'. [58]

128. I understand these passages from the EFTA Court's judgment as meaning that the absence of nutritional need may be taken into account but that it cannot of itself alone justify an import ban, indepen-

56 — See *Van Bennekom*, paragraph 38.

57 — Emphasis in the original.

58 — Paragraphs 27 and 28 of the EFTA Court judgment. Emphasis added.

dently of any consideration relating to health risk.

129. In that sense, I do not see any contradiction with the approach adopted by this Court in its judgment in *Sandoz*.

130. In that case, the Court first found that there was a health risk, of which the severity could not be determined with certainty. It concluded from this that a prohibition on marketing was therefore justified, unless the existence of a nutritional need could be demonstrated. Therefore, nutritional need is a criterion for managing the risk found, but not an independent criterion for prohibiting marketing.

131. On this same issue of proportionality, the Commission again takes the view that appropriate labelling of foodstuffs offers a replacement solution that is more proportionate to the objective envisaged than that of preventing the free movement of the products concerned.

132. In that regard, I would first point out that, in its judgment in *Sandoz*, the Court did not adopt that solution since it did not consider a prohibition on freedom of movement to be a disproportionate measure. In this context, moreover, it should be borne in mind '... that it is also settled law that the health and life of humans rank foremost among the property or interests protected by Article 36 of the Treaty...'. [59]

133. Next, it would certainly not be sufficient simply to make a brief mention of the vitamin content of a foodstuff. As the Danish Government has noted, such information would rather be understood, by the average consumer, as an incentive to purchase, since, currently, the majority of consumers still think that the addition of vitamins to a foodstuff is beneficial to health.

134. For its part, the Commission seems to be conceding that the mention of vitamin content on the packaging could be accompanied by a warning.

135. In my view, such a warning should be of the following type: 'Attention, consumption of this foodstuff can harm your health if your regular diet already includes all the vitamins and minerals your body needs. This risk is greater still if you consume other foodstuffs enriched with vitamins and minerals'.

59 — Case C-320/93 *Ortscheit* [1994] ECR I-5243, paragraph 16.

136. However, it is immediately apparent that such a warning would be more a source of confusion than anything else. Furthermore, the average, even reasonably well-informed, consumer would have a great deal of difficulty in assessing the total vitamins and minerals he is already absorbing.

137. The Commission has also drawn attention to the fact that vitamin tablets containing vitamins in concentrated quantities, and particularly various B vitamins, are freely on sale in Denmark in hypermarkets and other sales outlets.

138. However, the Danish Government has, rightly in my view, replied that the sale of vitamins in supermarkets is an entirely different situation, which must not be confused or muddled with the sale of basic foodstuffs.

139. The fact is that food supplements and vitamin preparations are not viewed by consumers as foods and they are not consumed as such. They are products which are the subject of an active approach on the part of the consumer, in view of their supposed effect. They are a useful instrument for reaching population groups with specific nutritional needs, those who eat little or who have difficulty eating, and who therefore do not receive their quota of nutrients through their daily diet.

140. It seems to me, therefore, that the possible prohibition on marketing to which the contested Danish practice could lead would not be disproportionate to the objective of health protection which that practice seeks to attain.

141. In any case, the Commission has not alleged that the Kingdom of Denmark has rejected a request for authorisation to market a specific product, where that rejection was not justified by health protection. [60]

142. For all these reasons, I have reached the conclusion that the Danish Government's practice of granting marketing authorisation to an ordinary foodstuff enriched with vitamins or minerals only if the foodstuff falls into one of the categories in respect of which the Codex Alimentarius provides for such enrichment and only if its level of enrichment is justified by the nutritional needs of Denmark's population, is justified by the need to protect public health as provided for in Article 30 EC and that the practice is proportionate to that aim.

60 — The Commission has not, of course, at any time maintained that the Kingdom of Denmark is seeking to protect enriched foodstuffs produced in its territory from the competition of foodstuffs originating in or coming from other Member States.

143. That practice meets the conditions laid down by the *Sandoz* judgment, conditions which are, in my view, compatible with those that arise from applying risk-analysis theory.

144. The Danish Government has satisfactorily proved that the situation which lay at the basis of that judgment — that of scientific uncertainty as to the risk posed to health by the addition of vitamins to foodstuffs — persists today. For its part, the Commission has not demonstrated that the reasoning followed by the Court in that judgment was mistaken or is no longer valid today.

145. Finally, the fact that other Member States apply a less rigorous policy does not call into question the validity of this reasoning. The rules governing the free movement of goods must not lead to health protection standards in the Community being levelled down.

146. I therefore propose that the Court dismiss the infringement proceedings brought by the Commission against the Kingdom of Denmark.

V — Conclusion

147. Having regard to the above considerations, I propose that the Court should:

— dismiss the application;

— order the Commission to pay the costs.