1. This case presents a fresh opportunity to resolve the conflict between the principle of the free movement of goods and the requirement of health protection, both of which are protected by the Community legal order. The Commission of the European Communities brought infringement proceedings against the Kingdom of the Netherlands, claiming that, as a result of enactment of the Netherlands law governing the authorisation to market some food additives and its application by the administrative and judicial authorities, it had failed to fulfil its obligations under Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC).  

I — Facts and pre-litigation procedure

2. The Commission has combined three initially separate sets of proceedings in this one action. The pre-litigation procedure was initiated in response to complaints made by two private traders and upon the transmission by the Kingdom of the Netherlands of legislation pursuant to Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, as amended by Directive 94/10/EC of the European Parliament and the Council of 23 March 1994.

3. Kellogg's notified the Commission that the Netherlands authorities had rejected its application for authorisation to market breakfast cereals containing vitamin D and folic acid. On 26 June 1996 the Commission sent to the Kingdom of the Netherlands a letter of formal notice in which it criticised its rejection of that application by failing to present evidence to show that the marketing
of the cereals in question might pose a
danger to health and because the require­
ment to establish a nutritional need in the
population was contrary to Community law.
As the Commission was not satisfied with
the reply of 6 May 1997 from the Kingdom of
the Netherlands, it sent a reasoned opinion
to that Member State on 23 September 1997.

4. At the same time, Inkosport Nederland
also complained to the Commission about
the Netherlands authorities’ rejection of its
application for authorisation to market
energy bars. In that context the Commission
sent a letter of formal notice to the Kingdom
of the Netherlands on 26 June 1996. As the
Commission was not satisfied with the
Netherlands’ reply, it proceeded to the next
stage of the procedure, sending a reasoned
opinion to the Member State on 23 Septem­
ber 1997.

5. Moreover, the Kingdom of the Nether­
lands notified to the Commission the Wa­
renwetbesluit Toevoeging micro-voedings­
stoffen aan levensmiddelen (Decree of 24
May 1996 implementing the Commodities
Law in relation to the addition of micro­
nutrients to foodstuffs). That decree lays
down a body of rules derogating from the
prohibition on marketing micronutrients,
provided that, first, the addition of micro­
nutrients is proved to be harmless and,
secondly, such addition meets an actual
nutritional need. The decree is part of
Netherlands law on the manufacture and
marketing of food products.

6. Any addition of vitamins, fluorine or
iodine compounds, or amino acids or their
salts to foodstuffs had previously been
prohibited. That prohibition was relaxed
by the Decree of 24 May 1996 which allowed
those vitamins listed in the annex to the
decree to be present in enriched foodstuffs,
which are defined as ‘foodstuffs to which one
or more micronutrients are added but whose
fundamental purpose is not to supply
micronutrients’. Micronutrients, for their
part, are defined as ‘nutrients essential to the
functioning of the human body which the
body itself cannot produce and which must
be consumed in small quantities’. However,
some micronutrients are subject to a special
body of rules: ‘Vitamin A in the form of
retinoids, vitamin D, folic acid, selenium,
copper and zinc exclusively shall be added to

5 — Stbl. 1996, p. 311; hereinafter: ‘Decree on the addition of
micronutrients to foodstuffs’.

6 — Article 10 of the Warenwetbesluit Bereiding en behandeling
van levensmiddelen (Decree implementing the Commodities
Law in relation to the preparation and processing of

7 — Article 10 of the Decree of 24 May 1996 amends Article 10 of
the Decree implementing the Commodities Law in relation to
the preparation and processing of foodstuffs. The latter decree,
as amended, is hereinafter referred to as the ‘Decree on the
preparation and processing of foodstuffs’.

8 — Article 1(1)(b) of the Decree on the addition of micronutrients
to foodstuffs.

9 — Article 1(1)(a) of the Decree on the addition of micronutrients
to foodstuffs.
enriched foodstuffs to make substitute products or reconstituted foodstuffs. 10 According to the Netherlands legislation, a substitute product is 'an enriched foodstuff designed to replace an existing foodstuff and resembling it as far as possible in its appearance, consistency, taste, colour, smell and intended use, to which one or more micronutrients have been added in quantities no greater than those in which the substances concerned naturally exist in the foodstuff to be replaced'. 11 A reconstituted foodstuff is an enriched foodstuff to which one or more micronutrients have been added to make up for their loss during or after its preparation. 12

7. Considering those rules to be incompatible with the principle of the free movement of goods, the Commission gave the Netherlands authorities formal notice, by letter of 22 December 1997, to provide it with explanations in that regard. The Commission set out its complaints in a reasoned opinion of 31 August 1998 and supplementary reasoned opinion of 21 December 1998. In their replies, the Netherlands authorities expressed their disagreement with the Commission's views.

8. Accordingly, the Commission brought the present infringement proceedings, the single complaint underlying which involves the non-conformity of the Netherlands rules on marketing enriched foodstuffs with the principle of the free movement of goods, which address both the practice adopted by the Netherlands authorities and the legislation itself.

9. A hearing took place on 14 July 2004 during which the parties were able to submit the conclusions appropriate to their case, drawn from the recent case-law of the Court of Justice and in particular from the judgment of 23 September 2003 in Case C-192/01, 13 which provided further information on the matter at issue.

II — The issues raised

10. These infringement proceedings against the Kingdom of the Netherlands have several issues in common with the proceedings that the Commission brought against the Kingdom of Denmark and that resulted in the Court's finding against that defendant in the abovementioned judgment in Commission v Denmark. However, whereas in that case the Danish legislation was applied systematically,
the Netherlands legislation at issue here is applied to six nutrients alone. Furthermore, the main issue raised in this case differs from that on which the Court of Justice had to adjudicate in the Danish case inasmuch as the definition of nutritional need applying in the Netherlands is not as strict as that prevailing in Denmark; none the less, the Kingdom of the Netherlands attempts to connect that concept with that of a risk to health. Indeed, the Kingdom of the Netherlands justifies the special rules applying to some nutrients by the fact that a fine line separates recommended quantity from a level of intake that can be harmful. Any such addition of nutrients to foodstuffs could thus — according to the Kingdom of the Netherlands — give rise to health risks.

11. Before embarking on a detailed analysis of the Netherlands rules, I would specify the assessment criteria that have been laid down in the case-law in this area. It is common ground between the parties that the requirement to obtain prior authorisation for marketing a product in one Member State when that product is already authorised in other Member States constitutes a measure having an effect equivalent to a quantitative restriction on the free movement of goods for the purposes of Article 30 of the Treaty.

12. Since the marketing of foodstuffs enriched with micronutrients has not been harmonised thus far at Community level, Member States retain the possibility of circumscribing it. Nutrients are defined in Article 4(2) of Directive 89/398 as 'substances with specific nutritional purposes such as vitamins, mineral salts, amino acids and other substances intended to be added to foodstuffs intended for particular nutritional uses'. The Netherlands law applies indiscriminately to all foodstuffs, irrespective of their origin. The system of prior authorisation for marketing foodstuffs containing nutrients which is in force in the Netherlands may thus be justified on grounds of the protection of health, which ranks foremost

14 — Namely, vitamin A in the form of retinoids, vitamin D, folic acid, selenium, copper and zinc, pursuant to Article 5 of the Decree on the addition of micronutrients to foodstuffs.

15 — Under Danish administrative practice, the addition of additives was authorised only in certain cases, namely, in order to meet a nutritional or processing-related need, or in the context of adding additives to substitute products or products intended as special-purpose foods (Commission v Denmark, cited above, at paragraph 11).

16 — Explanatory memorandum setting out the grounds for the Decree on the addition of micronutrients to foodstuffs, mentioned in paragraph 37 of the application.


18 — Hereinafter I shall use the term 'nutrient' to mean 'micronutrient'.
among the protected interests listed in Article 36 of the Treaty.\(^\text{19}\)

13. It is apparent from the case-law that the analysis to be carried out to establish whether a prior authorisation system qualifies for the exception under Article 36 of the Treaty comprises two stages, the first examining the conditions of validity of a prior authorisation procedure and the second considering the criterion used to justify a prohibition on marketing.

A — \textit{The conditions of validity of a prior authorisation procedure}

14. In the absence of Community harmonisation with regard to nutrients, Member States are at liberty, in principle, to choose their intended level of protection of health. They may, for instance, establish a procedure under which prior authorisation is required for the marketing of foodstuffs authorised in other Member States.\(^\text{20}\)

15. However, recourse to a system of prior authorisation is compatible with the requirements of the free movement of goods only if it is justified by the aim of protecting public health and proportionate to the objective envisaged.\(^\text{21}\)

16. Accordingly, such a procedure may continue to be applied only if it is shown to be necessary.\(^\text{22}\) The type of prior procedure to which recourse is had is also subject to review in order to ensure that the marketing of foodstuffs containing vitamins does not become more difficult as a result of their automatic classification as medicinal products.\(^\text{23}\) The scope of the prior authorisation procedure is to be limited as much as possible. If the same objective of protecting health can be achieved by having recourse to a system which imposes fewer restrictions on


21 — See, for example, Case 174/82 \textit{Sandoz} [1983] ECR 2445, paragraph 18, and, most recently, Case C-443/02 \textit{Schreiber} [2004] ECR I-7275.


23 — In that context, the adoption by the Federal Republic of Germany and the Republic of Austria of a general and systematic approach based exclusively on the recommended daily amount and not on the potential danger of each vitamin or group of vitamins and each mineral has been found to be contrary to Articles 30 and 36 of the Treaty: Case C-387/99 \textit{Commission v Germany} [2004] ECR I-3751, paragraphs 78 and 79, and Case C-150/00 \textit{Commission v Austria} [2004] ECR I-3887, paragraph 96.
trade, that system should be favoured over any other.  

17. In line with consistent case-law, the Court of Justice acknowledged that national procedures governing the prior authorisation of nutrients are lawful. After all, such nutrients, or at least some of them, may pose a danger to health. Furthermore, the relevant Community rules provide as follows: a framework directive on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption provides for the adoption of measures taken by the Council by qualified majority following consultation with the Standing Committee on Foodstuffs with regard to the exact designation of the food additives and their authorised uses. Member States are required to authorise additives which comply with the provisions of the framework directive. They are free to lay down the rules applying to additives which are not covered by implementing directives and, in particular, to set the danger threshold. In that context, it seems reasonable for Member States to be permitted to subject the addition of nutrients that may be dangerous to health if consumed in excess to a prior authorisation procedure. It may be observed in this regard that the Court adopts similar reasoning in acknowledging the compliance [with Community law] of prior authorisation procedures applying to pesticides or plant protection products.

18. Once the necessity of setting up a prior authorisation procedure to protect health has been established, the next step is to determine whether that procedure complies with the principle of proportionality.

19. Four procedural conditions have been identified in connection with that assessment of proportionality to justify a prior authorisation procedure: First, the Court of Justice ensures that the national procedure concerned does not involve any duplication of a procedure already undertaken in another Member State. Secondly, the relevant rules

24 — See inter alia Case C-24/00 Commission v France [2004] ECR 1-1277, paragraph 75.
25 — See, for example, Case 53/80 Eysen [1981] ECR 409; Sandoz, cited above, Case 247/84 Matte [1985] ECR 3887; and Case 304/84 Muller and Others [1986] ECR 1511. Under which Community law permits national rules prohibiting, without prior administrative authorisation, the marketing of foodstuffs to which vitamins have been added.
27 — Article 12(2) of Directive 89/107 provides: 'Member States may not prohibit, restrict or obstruct the marketing of food additives ..., if these comply with the provisions of this Directive ....

28 — Accordingly, at paragraph 13 of its judgment in Case 94/83 Hey [1984] ECR 3263, the Court of Justice points out that pesticides constitute a major risk to human and animal health and to the environment, that has moreover been recognised at Community level, in particular in the fifth recital in the preamble to the aforementioned Council Directive No 76/895, which states that "pesticides do not have only a favourable effect on plant production, since they are generally toxic substances or preparations with dangerous side effects". See, most recently, the abovementioned judgment in Schreiber, in which a national measure requiring authorisation for the placing on the market of blocks of red cedar wood having natural anti-moth properties is considered to comply with Community law. As regards plant protection products, see Case 272/80 Frans-Nederlands Maatschappij voor Biologische Producten [1981] ECR 3277.
must be set out clearly so that the procedure in question is readily accessible to traders. Furthermore, a procedure cannot comply with the principle of the free movement of goods if its duration and the costs to which it gives rise are so excessive as to deter traders from having recourse to it. Finally, any decision refusing authorisation must be open to challenge before the courts. However, those conditions are not specific to health protection.

**B — Authorisation to market foodstuffs subject to prior assessment**

20. The principle of proportionality does not merely call for the prior authorisation systems established by the Member States to be subject to the abovementioned formal procedural requirements; it also calls for checks to establish that the Member States have recourse to a criterion appropriate for determining whether to authorise or prohibit the marketing of a foodstuff. In fact, the process of ascertaining whether the decisions taken at the end of the national procedure meet the requirements of the principle of proportionality essentially involves examining the decisions to prohibit marketing, which are the most restrictive trade measures.

21. The Court has held that a decision to prohibit marketing, taken at the end of a prior authorisation procedure, is lawful only if it is based on the existence of a real risk to health. Such a risk must be established ‘on the basis of the latest scientific data available at the date of the adoption of such decision.’

22. The risk to health must be demonstrated by a ‘detailed assessment of the risk’, ‘in the light of national nutritional habits and in the light of the results of international scientific research’. Risk may be cited as the reason for prohibiting marketing only in the light of the results of such a risk analysis.

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30 — See the abovementioned judgments in Commission v Denmark, at paragraph 53, and Commission v France, at paragraphs 36 and 37.
31 — See, for example, Case C-95/01 Greenham and Abel [2004] ECR I-1333, paragraph 50.
32 — See, for example, Commission v France, cited above, at paragraph 26.
34 — Commission v Denmark, cited above, at paragraph 48.
35 — Commission v Denmark, cited above, at paragraph 48.
36 — Commission v Denmark, cited above, at paragraph 47; see also Case C-17/93 Van der Veldt [1994] ECR I-3537, paragraph 17: the risk invoked must be ‘measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research’.
37 — Commission v Denmark, cited above, at paragraph 46.
38 — The significance of risk analysis, which Member States are required to undertake, in defining a food policy is also established at Community level in Article 6(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1): ‘food law shall be based on risk analysis ...’
23. The requirement that a risk analysis be conducted to show the potential danger to health of the substance in question originates from the Court's previous decisions. In the judgments in Muller and Others 39 and Bellon 40 for example, the Court was already referring to the 'results of international research'.

24. The risk associated with a product is established in the light of two factors, namely appraisal of 'the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects.' 41 Demonstrating a mortal risk, even if the probability of its occurrence is only slim, can justify the adoption of protective health measures. Equally, a minor risk which is almost certain to occur can give rise to legislative measures.

25. Different risks may exist in different Member States on account of 'national nutritional habits'. 42 Those different nutritional habits may be such that the total consumption of a particular nutrient varies from one Member State to another. By the same token, it may be justified to prohibit the marketing of an additive in one Member State whilst that additive is authorised in another.

26. At this stage it is established, however, that nutritional need cannot operate as an independent criterion in a State's assessment whether or not to authorise the marketing of a nutrient. 43 On that basis, in the absence of a risk to health, the argument that there is no nutritional need in the population for a

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41 — Commission v Denmark, cited above, at paragraph 48. See also Article 3(9) of Regulation No 178/2002 which defines risk as 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.' There is a parallel relationship between the conditions for derogating from internal market principles, on the one hand, where a harmonisation measure is adopted (in this case, under Article 95(5) EC or pursuant to safeguard clauses laid down in the relevant directive or regulation), and, on the other hand, where no such measure is adopted (on the basis of Article 30 EC). See in this regard Morelmans, K., 'The relationship between the Treaty rules and Community measures for the establishment and functioning of the internal market — Towards a concordance rule', 39 CMLRev 2002, p. 1303.
42 — Commission v Denmark, cited above, at paragraph 54: 'the criterion of the nutritional need of the population of a Member State can play a role in its detailed assessment of the risk which the addition of nutrients to foodstuffs may pose for public health.' At point 26 of his Opinion in Case C-95/89 Commission v Italy [1992] ECR I-4545, Advocate General Gulmann construes that statement as follows: 'an assessment must be made as to whether particular eating habits in respect of the product in question in the importing Member State can create special health problems in that Member State.' See also Joerges, C., 'Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalised Governance Structures', in Integrating Scientific Expertise into Regulatory Decision-Making, 1997, edited by Joerges, C., Ladeur, K.-H., and Vos, E., p. 295 (p. 320).
43 — See Commission v Denmark, cited above, at paragraph 54, in which it is stated that 'However,... the absence of such a need cannot, by itself, justify a total prohibition, on the basis of Article 30 EC, of the marketing of foodstuffs lawfully manufactured and/or marketed in other Member States,' and Greenham and Abel, cited above, at paragraph 46. Those judgments clarified the Court's previous decisions, which seemed at times to attribute an independent function to nutritional need and to suggest that the harmfulness of an additive was not the only criterion to be taken into account in order to decide as to its authorisation (see in particular the judgments in Motte and Muller and Others, cited above in footnote 25, at paragraphs 21 and 25 respectively). In their arguments, the parties rely mainly on paragraph 20 of the Sandoz judgment, cited above in footnote 21.

I - 11385
OPINION OF MR POIARES MADURO — CASE C-41/02

particular nutrient cannot justify a prohibition on marketing. On the other hand, if there is a need and no risk to health, the Member State is obliged to authorise the marketing of the nutrient concerned. 44

27. Provided that the available scientific data indicate a real and definite risk to health caused by ingesting the product in question, prohibiting the marketing of the product complies with Community law, given that health protection takes precedence in such circumstances over the principle of the free movement of goods.

28. By contrast, where there is uncertainty as to the existence or extent of a risk, the threshold of risk, which must be established by a Member State in order to justify a marketing prohibition, is not clearly defined. 45 Only a negative condition was laid down in the case-law: it is insufficient to rely on hypothetical considerations to establish scientific uncertainty. 46 That effectively signifies that scientific uncertainty can be shown only at the end of an assessment of risk.

29. The Kingdom of the Netherlands invokes the precautionary principle to justify the rejections of the manufacturers’ applications seeking to add to foodstuffs any of the six nutrients covered by the procedure at issue which does not meet a nutritional need in the population. Indeed, the fact that scientific uncertainty over the risk involved persists gives rise to recourse to the precautionary principle. In the specific context of balancing the requirements of the free movement of goods and health protection, that principle consists in the possibility of adopting a measure for the protection of health where uncertainties persist as to the existence or extent of the risks without having to wait until the reality and seriousness of those risks become fully apparent. 47

Health protection can in that case be cited as grounds for a marketing prohibition, which must be reviewed if the uncertainty relied on


45 — See the explanations concerning the scientific uncertainty over the risks involved in the consumption of nisin, at paragraph 13 of the judgment in Eyssen, cited above in footnote 25.


47 — Commission v Denmark, cited above, at paragraph 52: 'Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures'. See also the abovementioned judgments in Greenham and Abel, at paragraph 48, and Commission v France, at paragraph 56. That expression is set out in the Court's case-law on the adoption by the Member States of safeguard measures: see, for example, Monsanto Agricultura Italia and Others, cited above, at paragraph 111, Case C-157/96 National Farmers’ Union and Others [1998] ECR I-2211, at paragraph 63, and Case C-180/96 United Kingdom v Commission [1998] ECR I-2265, at paragraph 99.
no longer exists as a result of scientific development. 48 Thus, the precautionary principle can justify the adoption of restrictions on the free movement of goods only if the likelihood of real harm to health persists should the risk materialise. 49

30. Different consequences ensue from recourse to the precautionary principle depending on whether it is invoked by the Community institutions or by the Member States. If, for example, a State relies on the precautionary principle, its decision will lead to a partitioning of the single market. Furthermore, even if the measure adopted is not guided by protectionist considerations, the view of the other Member States cannot be taken into account, unlike in the case of a Community institution’s adoption of a decision under the precautionary principle. 50 In my view, that explains the case-law of the Court which set about imposing stringent restrictions on use of the precautionary principle where it is invoked by Member States.

31. Critics of the precautionary principle lament the failure to set a risk threshold and the excessive emphasis placed on the decision-making procedure. 51 They are also concerned that such a principle promotes the illusion that it is possible to achieve ‘zero risk’. The precautionary principle could also be criticised for not taking account of the costs entailed by a protective measure and for merely taking account of the expected benefits to health.

32. Indeed, recourse to the precautionary principle cannot be based on scientific analysis alone. The policy dimension of determining acceptable risk would be disregarded if court appraisal was based solely on prior scientific risk analysis. In that connection, must the Community judicature’s review be restricted to addressing the various stages of the decision-making process, or should it assess the quality of the scientific analysis conducted or even review the latitude attributed to policy as opposed to science? It should be noted in that regard that Regulation No 178/2002 distinguishes

48 — The obligation incumbent on the Member States to review their laws in the light of scientific development was borne out in Heijn, cited above in footnote 28, at paragraph 18, and in Commission v Italy (Case C-420/01), cited above, at paragraph 32. A review of that kind is, for that matter, provided for in Article 7 of Regulation No 178/2002.

49 — Commission v Denmark, cited above, at paragraph 52. In assessing the lawfulness of recourse to the precautionary principle pursuant to Article 95(5) EC, the Court of Justice had required that ‘the risk assessment available to the national authorities [provide] specific evidence which, without precluding scientific uncertainty, makes it possible reasonably to conclude on the basis of the most reliable scientific evidence available and the most recent results of international research that the implementation of those measures is necessary in order to avoid novel foods which pose potential risks to human health being offered on the market’ (Monsanto Agricoltura Italia and Others, cited above in footnote 46, at paragraph 113).

50 — See, on this point, the article, cited above in footnote 42, by Joerges, C: ‘Member States are requested to design their legislation in a way that enables integration of scientific findings and they are bound to give credit to scientific analyses undertaken beyond their territories’ (p. 307). It is also stated in that article that ‘societies granting freedoms or imposing regulatory burdens must consider the adverse extraterritorial effects of their policies’ (p. 322).

between risk assessment and risk management, the former falling within the category of science and the latter within that of policy. Similarly, the national authorities enjoy discretion as regards decisions taken in the light of a scientific assessment of risk. It is indeed acknowledged in case-law that a decision taken at Community level in the context of risk management may depart from the findings of a scientific assessment.  

33. In this regard, three different lines of reasoning relating to the precautionary principle could be identified, each of them involving a different degree of policy appraisal. First of all, the uncertainty might derive from conflicting scientific results. Secondly, in order to achieve scientific certainty it might be necessary to collect data which are not yet available, since the novelty of the product means, for example, that all its effects on health cannot be known. Lastly, the impossibility of achieving scientific certainty may only be a material one inasmuch as the costs involved in conducting scientific research or in adopting legislative measures act as a deterrent. Proceeding from the first to the third argument envisaged for applying the precautionary principle, the involvement of policy considerations increases. Those considerations must be clear and distinct from scientific appraisal. At the same time, for the abovementioned reasons relating to the risk of partitioning the market and the failure to take account of the interests of all States potentially affected by a measure, the discretion that Member States are allowed as regards recourse to that principle is increasingly restricted the further they depart from scientific analysis and the more they rely on policy judgment. Therefore, it has not been established that they may act in the second or third situation described.

34. To facilitate a proper review of the decisions taken on the basis of the precautionary principle, those decisions must be subject to two conditions. First, in accordance with case-law, the findings of a scientific study — the quality of which is subject to special scrutiny — must be presented in the decision-making process prior to the adoption of a national measure.
intended to protect health. Secondly, the reasoning underlying the decisions must clearly indicate the policy choices adopted, setting them apart from the scientific results on which they are based, so that every citizen can identify them. As part of its review of the principle of proportionality, the Court is obliged to check that the Member States meet those two conditions.

III — Assessment

35. As explained above, Netherlands law in principle prohibits the addition of vitamin A in retinoid form, vitamin D, folic acid, selenium, copper and zinc to foodstuffs, unless such addition is made to reconstituted or substitute foods. However, the Minister for Well-being, Health and Culture is competent to issue a derogation effectively granting a marketing authorisation. Complaints may be lodged against decisions taken by the minister. At the end of that administrative procedure, the party concerned may bring legal proceedings before the College van Beroep voor het Bedrijfsleven (Administrative Court for Trade and Industry).

36. The Commission's complaint primarily concerns the Netherlands practice involving the competent authorities' refusal to grant a derogation for the marketing of foodstuffs containing any of the six nutrients concerned. I shall therefore begin by considering the merits of that complaint, following which it will be possible to determine whether the Netherlands rules themselves, under which those six nutrients are subject to a particular prior authorisation procedure, comply with the principle of the free movement of goods.

A — Consideration of the practice of the Netherlands authorities

37. These infringement proceedings are essentially concerned with the practice

54 — That procedural condition is analysed by Cruz Vilaça, J.L., in The Precautionary Principle in EC Law, European Public Law, June 2004, p. 369. The Court might find it necessary to determine the kind of study it considers relevant. In this regard a comparison can be made with the deferential attitude adopted by the US judiciary with regard to studies conducted by the regulatory authorities (see, for example, the judgments of the Supreme Court of the United States: Industrial Union Dept. v American Petrol. Inst., 448 U.S. 607 (1980) and Whitman, administrator of Environmental Protection Agency v American Trucking, decided February 27, 2001) and the detailed assessment carried out by the appellate body in the recent litigation in connection with the Agreement on the Application of Sanitary and Phytosanitary Measures (WTO Appellate Body Report in the cases of EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R, Japan — Measures Affecting Agricultural Products, WT/DS70/8/AB/R, and European Communities — Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/AB/R).

55 — In other words, science should not be used as an 'alibi' for policy decisions. See in that regard: Shapiro, M., The Frontiers of Science Doctrine: American Experience with the Judicial Control of Science-Based Decision-Making, in Integrating Scientific Expertise into Regulatory Decision-Making, cited above in footnote 42, at p. 325.

56 — Article 5 of the Decree on the addition of micronutrients to foodstuffs.

57 — Article 23 of the Commodities Law.
followed by the Netherlands authorities, which persistently refuse\(^\text{58}\) to authorise the marketing of foodstuffs containing the six nutrients at issue in these proceedings. At the hearing, the Commission submitted that that single complaint could be broken down into three limbs. First, the Kingdom of the Netherlands is criticised for subjecting the authorisation requests to two cumulative conditions: harmlessness for health and satisfaction of a nutritional need. Secondly, the competent Netherlands authorities do not base their decisions on a detailed analysis of the individual cases submitted to them. Lastly, the distribution of the burden of proof could equally be criticised, in that the burden would lie exclusively with the food manufacturer that requests a marketing authorisation whereas it would fall to the Member State that rejects the request to prove that the substance at issue is dangerous.

38. Initially I would point out that the Netherlands practice is a matter for the regulatory authorities (the Ministry of Health and its appeals committee) and the courts (the College van Beroep voor het Bedrijfsleven) which have essentially established on a number of occasions\(^\text{59}\) that, given that some nutrients do not meet a nutritional need in the population of the Netherlands, they were bound to pose a risk to health, as there was a very fine line between recommended quantity and the level of intake that may give rise to harmful effects.

39. The parties disagree on whether the condition relating to the nutritional need of the population in the Netherlands is independent from the condition relating to harmlessness. Whilst the Commission submits that it is apparent not only from the Explanatory memorandum setting out the grounds for the Decree on the addition of micronutrients to foodstuffs but also from the practice followed by the authorities that the conditions are independent and cumulative, the Kingdom of the Netherlands takes the view that nutritional need is only one factor in the general appraisal of harmlessness.

40. The fundamental argument put forward by the Kingdom of the Netherlands is that the potential danger of the nutrients concerned stems from the fine line separating the recommended quantity and the quantity in which it is dangerous to ingest those six nutrients. In its observations before the Court of Justice, the Kingdom of the Netherlands explains that it conducts its risk assessment 'by reference to the recommended daily allowance, the toxicological ceiling and normal (average) diet'.\(^\text{60}\) It also considers that the requirement to take

\(^{58}\) At the hearing, the representative of the Kingdom of the Netherlands stated that a marketing authorisation had been granted in 2000. She acknowledged that, up to that date, after expiry of the period prescribed in the most recent reasoned opinion, no authorisation had been issued.

\(^{59}\) In its application the Commission refers to several sets of proceedings which resulted in refusal by the Netherlands authorities to authorise marketing: Kellogg's cereals and Inkosport Netherlands energy bars are two such examples.

\(^{60}\) Rejoinder, paragraph 7.
account of consumers’ accumulated intake of nutrients explains the relationship that exists between the nutritional need of the population and the risk to health.

41. I would first of all emphasise that, even if it is correct in respect of the nutrients at issue, the truth of that statement is not demonstrated for each substance, as will become clear on consideration of the second limb of the complaint.

42. Secondly, the connection established between nutritional need, which is assessed by studying the nutritional habits of the population of the Netherlands, and the potential danger posed by the nutrients at issue is in itself problematic. Even though a reference to nutritional need assessed by reference to a recommended daily requirement of vitamins or other nutrients has the virtue of clarity and affords traders the benefit of legal certainty, it may not be used as a general and automatic criterion for assessing the potential danger of nutrients. The potential danger that they individually pose differs depending on their individual characteristics. In these proceedings, the fine line that separates the recommended level of intake and the level above which risks to health may arise certainly is not the same for each nutrient and, in any event, consumption in excess of that level will not give rise to the same health risks in the case of each nutrient concerned, whether in respect of their nature or their intensity.

43. Consequently, a reference to the recommended daily value as the threshold beyond which a nutrient becomes potentially dangerous to health, if only for a limited number of nutrients, is not a relevant indicator because it is not directly related to the specific risks associated with each nutrient. Clearly, therefore, the infringement is established in that regard.

44. I shall now address the second limb of the Commission’s complaint, which deals with the requirement to conduct a scientific analysis on a case-by-case basis. It is clear from the Court’s case-law that any restriction imposed on the free movement of goods for the purpose of protecting health must be based on a precise scientific assessment of

61 — Point 56 of the Opinion delivered by Advocate General Geelhoed in Commission v Germany (Case C-387/99) and Commission v Austria (judgments cited above).

62 — See, by analogy, the abovementioned judgments in Commission v Germany (Case C-387/99), at paragraph 60, and Commission v Austria, at paragraph 95.

63 — Those differences are apparent from the information provided by the Kingdom of the Netherlands with regard to the risks entailed by excessive vitamin D or vitamin A consumption. Reference may also be had to the Reports of the Scientific Committee for Food (Thirty-first series). Opinion expressed on 11 December 1992 on nutrient and energy intakes for the European Community. It is clear from that opinion that the threshold beyond which there is a danger to health is approximately three times the population reference intake (PRI) for zinc, five times the PRI for vitamin D, ten times the PRI for vitamin A, copper and selenium, and almost 25 times the PRI for folate.
risk conducted on a case-by-case basis.\textsuperscript{64} The Kingdom of the Netherlands has an identical understanding of the case-law but maintains that it has met that condition and is justified in applying the precautionary principle. The documents in the case show that the Kingdom of the Netherlands relies on the health risks resulting from the intake of folic acid and vitamin D.

45. As regards folic acid, the Kingdom of the Netherlands refers to a report by the European Union Scientific Committee on Food of 28 November 2000.\textsuperscript{65} It also mentions an opinion issued by the Health Council of the Netherlands, upon a request from the Ministry of Health on 23 July 1998,\textsuperscript{66} which states that the enrichment of foodstuffs with folic acid may involve a number of risks. However, those risks are not described in any detail in terms of their nature or their intensity.\textsuperscript{67} In its conclusion to that opinion, the Health Council considers that, as a precautionary measure and pending proof that the nutrient in question is harmless, the population’s intake of folic acid should be limited.

46. As for vitamin D, the Kingdom of the Netherlands merely points out that excessive consumption can be harmful to health but does not have regard to any scientific study in support of that statement. It cites inter alia the risk ‘of hypercalciopexy and of more general symptoms of poisoning’.\textsuperscript{68}

47. Without there being any need for the Court of Justice to examine the quality of the scientific assessments carried out, it is clear in this regard that those assessments do not produce a clear analysis of the risks to health entailed in the excessive intake of the nutrients at issue. The studies mentioned do not indicate the likelihood of those risks materialising or the threshold beyond which they may materialise.\textsuperscript{69} In the absence of scientific uncertainty over the risks involved with the nutrients at issue, the Kingdom of the Netherlands therefore is not justified in invoking the precautionary principle to justify its policy.

48. As regards the assessment of the risks to health posed by the six nutrients which are the subject-matter of the proceedings, the Kingdom of the Netherlands cites another consumption study conducted in 1992.\textsuperscript{70} That study concerns the consumption of all...
vitamins and nutrients ingested by the population of the Netherlands, not just the six that are subject to specific rules under the Netherlands legislation.

49. Even though the study conducted by the Kingdom of the Netherlands would be useful as a supplement to the assessment of the specific risk to health posed by each of the six nutrients concerned, it cannot take the place of that assessment. It would merely serve to refine the results of a study of each nutrient by identifying the specific nutritional habits of the population of the Netherlands.

50. Since the scientific considerations that the Kingdom of the Netherlands relies on to establish the risks incurred through ingestion of the six nutrients at issue here do not involve a scientific assessment to identify the extent and seriousness of such risks to health, the Kingdom of the Netherlands is not justified in invoking the precautionary principle. Consequently, it must be established that the Kingdom of the Netherlands has failed to fulfil its obligations so far as the second limb of the allegation is concerned.

51. The Commission submits in the third limb of its complaint that the Netherlands practice is contrary to the principle of proportionality in that it imposes the burden of proving that a nutrient is harmless exclusively on the party requesting authorisation and not on the Member State.

52. The Kingdom of the Netherlands counters that complaint by reference to the nature of the prior authorisation procedure, in the course of which the party requesting authorisation is of course obliged to supply information on the products it is seeking to market, but, it argues, that does not constitute a reversal of the burden of proof.

53. Since it falls to the Kingdom of the Netherlands to justify a prohibition on the marketing of products by means of arguments relating to their potential danger which is scientifically established beforehand on the basis of a specific analysis of risk, there can be no reference here to a reversal of the burden of proof. Indeed, the Kingdom of the Netherlands may impose a prohibition only if it furnishes proof that the substance in question presents a risk to health. Therefore, the infringement does not seem to be established in this regard.

54. In conclusion, for the reasons indicated above, the Netherlands practice must be considered to be contrary to Articles 30 and 36 of the Treaty inasmuch as it does not comply with the principle of proportionality, on the one hand because, within that practice, potential danger is determined exclusively in relation to nutritional need, and on the other hand because it is not based on a prior risk analysis specific to each nutrient.

71 — See, for example, Bellon, cited above in footnote 40, at paragraph 16.
B — Consideration of the Netherlands legislation

55. I would point out again that the scope of the infringement proceedings brought by the Commission is limited to the special rules applying to six nutrients: vitamin A in retinoid form, vitamin D, selenium, folic acid, zinc and copper.²²

56. The Commission's claim that the Kingdom of the Netherlands has failed to fulfil its obligations relates not only to the practice of the Netherlands authorities, that is to say, to their application of the legislation in force, but also to the legislation itself. At first sight it is difficult to dissociate a legal text from its interpretation by the authorities entrusted with its application. What is more, the Commission does not make its complaint very clearly. However, it appears in essence to criticise the Netherlands legislation for creating a presumption that the six nutrients at issue are dangerous. It would be impossible, it argues, to obtain authorisation to market a foodstuff containing any of those six nutrients, not only on account of the practice followed by the Netherlands authorities but also because the legislation in force does not allow scope for a different interpretation.

57. Challenging the very principle of a prior authorisation procedure for the six nutrients, the Commission takes the view that the use of labelling on foodstuffs to indicate, if necessary, whether they contain those nutrients would be sufficient to protect public health and inform consumers.

58. By contrast, the Kingdom of the Netherlands considers product labelling to be ineffective in terms of preventing the risk of the population or some groups within the population exceeding the acceptable safety limit in their consumption of some nutrients, because even very well-informed consumers are incapable of assessing the cumulative quantity of nutrients in their daily intake.

59. In this connection I consider that, subject to the Netherlands legislation's compliance with the principle of proportionality, it is permissible, as shown by consistent case-law, to subject the enrichment of foodstuffs with nutrients to prior authorisation, even though that measure constitutes a restriction on the free movement of goods.²³ The argument put forward by the Kingdom of

²² — Article 5 of the Decree on the addition of micronutrients to foodstuffs.

²³ — See, in particular, Sandos, cited above in footnote 21, at paragraph 17; Muller and Others, cited above in footnote 25, at paragraph 23; Case C-95/89 Commission v Italy [1992] ECR I-4545, paragraphs 8 to 10; Commission v Denmark, cited above, at paragraph 64, and Commission v Germany, cited above, at paragraph 70.
the Netherlands, that it is impossible for consumers to be aware of their accumulated intake of nutrients, is a persuasive one. Furthermore, labelling serves primarily to inform consumers, not to protect their health.

60. However, the documents in the case indicate that the Netherlands legislation at issue firstly does not provide that a specific analysis of risk must have been conducted in order to justify a refusal to authorise marketing and secondly confers a predominant role on the criterion of nutritional need in establishing whether a nutrient is dangerous.

61. I therefore propose to conclude that, by adopting and applying legislation such as that at issue here, under which six nutrients are subject to a particular system of prior authorisation, the Kingdom of the Netherlands has failed to fulfil its obligations under Articles 30 and 36 of the Treaty inasmuch as its legislation takes the criterion of the nutritional need of the Netherlands population as the basis for assessing whether nutrients are dangerous and does not provide for a prior assessment of the specific risk posed by each nutrient.

IV — Conclusion

62. In the light of the foregoing arguments, I propose that the Court should:

(1) declare that, by applying derogations in such a way that food products prepared and marketed lawfully in another Member State and enriched with vitamin A (in the form of retinoids), vitamin D, folic acid, selenium, copper or zinc, which are not substitute or reconstituted products, cannot be sold on the Netherlands market pursuant to the Warenwetbesluit Bereiding en behandeling van
levensmiddelen (Decree implementing the Commodities Law in relation to the preparation and processing of foodstuffs) of 10 December 1992 and the Warenwetbesluit Toevoeging micro-voedingsstoffen aan levensmiddelen (Decree implementing the Commodities Law in relation to the addition of micronutrients to foodstuffs) of 24 May 1996, the Kingdom of the Netherlands has failed to fulfil its obligations under Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC) in so far as in its practice the criterion of the nutritional need of the population is taken as the basis for assessing whether nutrients are dangerous and no provision is made for a prior assessment of the specific risk posed by each nutrient;

(2) declare that, by adopting a law on food additives (the Decree on the preparation and processing of foodstuffs of 10 December 1992 and the Decree on the addition of micronutrients to foodstuffs of 24 May 1996) so that food products prepared and marketed lawfully in another Member State and enriched with vitamin A (in the form of retinoids), vitamin D, folic acid, selenium, copper or zinc, which are not substitute or reconstituted products for the purposes of the abovementioned decrees, cannot be sold on the Netherlands market, the Kingdom of the Netherlands has failed to fulfil its obligations under Articles 30 and 36 of the Treaty in so far as its legislation takes the criterion of the nutritional need of the population as the basis for assessing whether nutrients are dangerous and does not provide for prior assessment of the specific risk posed by each nutrient.