In Case 174/82

REFERENCE to the Court under Article 177 of the EEC Treaty by the Arrondissementsrechtbank [District Court], s'Hertogenbosch, for a preliminary ruling in the criminal proceedings pending before that court against

SANDOZ BV, Uden,

for a preliminary ruling on the interpretation of the provisions of the EEC Treaty on the free movement of goods within the Community and in particular Article 36 of the Treaty,

THE COURT (Fifth Chamber)

composed of: J. Mertens de Wilmars, President, U. Everling (President of Chamber), Lord Mackenzie Stuart, O. Due and Y. Galmot, Judges,

Advocate General: G. F. Mancini
Registrar: H. A. Rühl, Principal Administrator

gives the following

## JUDGMENT

## Facts and Issues

The facts of the case, the course of the procedure and the observations submitted under Article 20 of the Protocol on the Statute of the Court of Justice of the EEC may be summarized as follows:

I — Facts and written procedure

1. By summons of 16 March 1982 Sandoz BV, Uden, was summoned to appear before the Economische Politierechter [Magistrate dealing with commercial offences] for the Arrondissementsrechtbank, 's-Hertogenbosch, charged with having sold and delivered in two places in the Netherlands for commercial purposes and human consumption and without an authorization from the responsible Minister, food and beverages to which vitamins had been added.

According to Article 10 (a) (1) of the Algemeen Besluit [General Decree] of 11 July 1949 adopted in implementation of Articles 14 and 15 of the Warenwet [Food and Drugs Law] of 1935, "no vitamins . . . " may be added to food and beverages without an authorization granted by the Minister responsible for implementing this decree. Such authorization may be subject to conditions".

In the present case Sandoz BV sold muesli bars, "Powerback" and analeptic beverages imported either from Switzerland or from the Federal Republic of Germany to which a number of vitamins and in particular Vitamins A and D had been added. All the products in question are lawfully marketed in the Federal Republic of Germany and Belgium.

It appears from the file on the case that before marketing the said products in the Netherlands the defendant had sought an authorization for that purpose pursuant to Article 10 (a) (1) of the aforesaid Algemeen Besluit. By letter dated 12 July 1979 the Inspecteur van de Volksgezondheid [Public Health Inspector] replied that an authorization "is granted only if it is shown that there is a demand for the products to which vitamins ... have been added". By decision dated 26 August 1981 the Minister van Volksgezondheid en Milieuhygiëne [Minister for Public Health and the Environment] rejected the application for an authorization on the ground that the Vitamins A and D in the products in question represented a danger to public health, particularly as the labelling did not display instructions as to usage which would make it possible to adapt the intake of vitamins to individual needs.

Sandoz BV contended in its defence before the Arrondissementsrechtbank that Article 10 (a) of the Algemeen Besluit was not binding since it was contrary to Article 30 *et seq.* of the Treaty. In order to decide upon the merits of that argument the national court stayed the proceedings and referred the following questions to the Court pursuant to Article 177 of the EEC Treaty:

"1. Where:

(a) food or beverages, or both, to which vitamins have been added, have been marketed in one or more Member States lawfully, that is to say in accordance with the legislation in force locally, and

(b) an importer of food or beverages, or both, established in another Member State imports lawfully marketed food or beverages, or both, to which vitamins have been added, from one of the Member States referred to under (a) above into the Member State in which he is established,

do the provisions derogating from the rules concerning the free movement of goods within the Community, in particular Article 36 of the EEC Treaty in so far as it relates to the protection of the health of humans, justify the government of the Member State of importation in prohibiting the marketing of such food or beverages, or both, in that State without ministerial authorization?

2. Must the previous question be answered differently if the general prohibition on the sale of food and beverages to which vitamins have been added, unless authorized by a ministerial decision, has the result

that the importer referred to under I (b) above bears the onus of proving that the food and beverages concerned are not a danger to public health and must therefore be authorized?

3. Must the question be answered differently if the application of the general prohibition of the sale of food and beverages to which vitamins have been added, unless authorized by a ministerial decision, has the result that the national authorities of a Member State prohibit the sale of such food and beverages which have been lawfully produced and marketed in another Member State, unless the producer or seller shows not only that such products are not a danger to health but also that it is desirable to market them and that there is a need for vitamins to be added?".

2. The judgment making the reference was received at the Court Registry on 28 June 1982.

Written observations pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC were submitted by Sandoz BV, represented by Blackstone, Rueb and Van Boeschoten, Advocates at The Hague and Amsterdam, and by J. C. Schultsz and B. J. H. Grans, Advocates, Amsterdam, the Netherlands Government, represented by F. Italianer, acting for the Minister for Foreign Affairs, the Danish Government, represented by its Legal Adviser, Per Lachmann, the Italian Government, represented by Ivo M. Braguglia, Avvocato dello Stato, and the Commission of the European Communities, represented by its Legal Adviser, Rolf Wägenbaur and Thomas van Rijn, members of its Legal Department, acting as Agents.

Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General the Court decided, by order of 15 December 1982, to refer the present case to the Fifth Chamber pursuant to Article 95 of the Rules of Procedure and to open the oral procedure without any preparatory inquiry.

## II — Written observations

1. The company *Sandoz* emphasizes at the outset the part played by sports nutrition. Sportsmen have an increased energy need. Furthermore, physical and psychological effort tend to reduce the appetite and this may lead to an energy deficit.

The question raised in the present case is whether recourse to enriched sports nutrition constitutes a danger to health. Although it is generally recognized that excessive consumption of certain vitamins may have deleterious consequences and undesirable side-effects scientific research has enabled objective and internationally recognized criteria to be established as regards the level of toxicity for the various vitamins. If those criteria are applied to the Sandoz products it becomes apparent that it is in practice impossible to reach a toxic level by consuming them in view of the fact that the amounts which would have to be

consumed for this to occur would be beyond the process of digestion.

So far as the law is concerned, Sandoz emphasizes that there are no Community rules applicable in the matter. All that the Council Directive No 77/94 of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (Official Journal 1977, L 26, p. 55) contains are rules on the designation of such foodstuffs. That directive nevertheless deserves to be mentioned inasmuch as it recognizes in the recitals in the preamble thereto that it is necessary to adopt additional measures in relation to the composition and manufacture *inter alia* of foodstuffs intended for sports nutrition.

The case-law of the Court confirms that Article 30 of the Treaty must be understood as meaning that goods lawfully produced or marketed in a Member State must in principle be admitted to the market of any other Member State and that it is only exceptionally that a Member State may refuse or limit the access of such products to its market. A derogation from the principle of the free movement of goods is allowed only if the national rules are necessary, that is to say appropriate and not excessive, in order to satisfy mandatory requirements and if they pursue an aim which is in the general interest and are essential for the achievement of that aim, that is to say they constitute at once the means which is the most appropriate and the one which least impedes trade.

If those principles are applied to the present case it is apparent that the Netherlands rules are incompatible with Community law since, in the absence of ministerial authorization, they prohibit the addition of any vitamins to foodstuffs and beverages whatever their composition or purpose and there is no information available to the public concerning the criteria adopted in considering an application for authorization. Moreover it is contrary to the case-law of the Court to require an importer to supply evidence that the addition of vitamins is not only not harmful but also necessary and useful.

The Netherlands legislation is also incompatible with Community law inasmuch as the decision of the Minister rejecting the application for an authorization is subject only to a limited administrative appeal before the Raad van State [State Council] and in those proceedings the question whether the particular products do or do not represent a danger to public health cannot be considered.

Article 36 of the Treaty is not applicable in the present case since the addition of vitamins to the products in question does not reach a toxic level and does not therefore constitute a threat to health.

Furthermore, the Netherlands rules are not necessary. Since there are internationally recognized limits in relation to the absorption of vitamins it is sufficient from the point of view of public health to have recourse to rules which make it impossible for these thresholds to be exceeded by the consumption of products containing vitamins. That approach has moreover been adopted by other Member States such as the United Kingdom and Belgium (which have only

rules relating to designation and labelling), Germany and France (which have quantitative restrictions on the addition of certain vitamins), Denmark, Italy and Greece (which require only that foodstuffs to which vitamins have been added should be registered).

Finally there is an infringement of the principle of proportionality which requires that measures imposed in the interests of public health should be appropriate to their objective. In the present case it would be possible to ensure effective control by methods which restrict Community trade to a lesser degree, for example by subjecting the quantities and type of vitamins to be added to certain limits and imposing rules in relation to labelling. In that respect the present case may be distinguished from Case 53/80 *Eyssen* [1981] ECR 409 which was the subject of the judgment of 5 February 1981 where there was uncertainty as to the maximum dosage of an additive.

In conclusion Sandoz suggests the following answer to the questions referred to the Court for a preliminary ruling:

"1. A national rule of law which absolutely prohibits, irrespective of the specific purpose pursued, any addition of vitamins to foodstuffs and beverages without a ministerial authorization and which also has the effect of prohibiting the sale in that Member State of foodstuffs and beverages to which vitamins have been added and which originate in another Member State where they have been lawfully manufactured or marketed, is incompatible with Community law and finds no justification in the derogations from the rules on the free movement of goods unless the authorities of the Member States concerned show that the foodstuffs and beverages represent a danger to public health whatever the amount and type of vitamins added and also show that the measure in question is necessary in order to satisfy mandatory requirements, is appropriate and not excessive, pursues an aim which is in the general interest and the nature of which is so compelling that it justifies derogation from the fundamental rule of the free movement of goods and constitutes the most appropriate means and the one which least impedes trade.

2. A rule of national law which requires the importer to show that foodstuffs and beverages to which vitamins have been added and which originate in a Member State where they are lawfully manufactured or marketed constitute no risk to public health is incompatible with the principle of the free movement of goods. That is true *a fortiori* if the competent authority considers the evidence which has to be adduced in the light not of objective criteria but of criteria which relate not to public health but to the protection of national products and which are therefore subjective and discriminatory especially where the decision of the Minister cannot be challenged on its merits.

3. The application of a general prohibition of the sale, without ministerial authorization, of foodstuffs and beverages to which vitamins have

been added, which means that the competent authority of a Member State prohibits the sale of foodstuffs and beverages to which vitamins have been added and which are lawfully produced and marketed in another Member State unless the producer or importer or seller shows not only that the goods constitute no danger to public health but also that their marketing is useful and that the addition of vitamins meets a demand, is incompatible with Community law and finds no justification in the derogations from the rules governing the free movement of goods."

2. The *Netherlands Government* states that the Netherlands policy is restrictive regarding all kinds of food additives. Its aim is to ensure in a suitable manner that additives have no adverse effect upon public health. That precaution is made necessary by the very nature of the substances, such as additives used for their (bio-)chemical properties, which create the risk of undesirable side-effects. It is not possible to state categorically that a substance is or is not harmful in view on the one hand of scientific uncertainties and on the other of the fact that harmfulness depends on the quantity of the substance absorbed.

The policy of the Netherlands authorities is to subject food additives to the approval of the administration which takes into account both the daily intake which may be absorbed without risk by a person and the consumption per head of foodstuffs for which the addition is asked and the technological need for the additive. On that basis the administration may authorize the use of an additive and restrict it if necessary to certain foodstuffs and to a given maximum dosage.

The Warenwet provides both for general derogations from the criteria established and for systems of case-by-case approval. All the instruments of authorization are based on the rules that what has not been authorized may not be added. The system has been adopted in order to ensure in the best possible way the protection of public health in view of the rapid developments which are taking place in the sphere of additives.

The Netherlands Government states that the prohibition of adding nutrients to foodstuffs and beverages has its origin on the one hand in the protection of public health and on the other in the concern to prevent the consumer from being misled.

It has been scientifically proved that an excess of certain vitamins including Vitamins A and D is bad for the health of the consumer. The question whether other vitamins may be harmful is still being studied. Opinions of the Advisory Committee created by the Warenwet and the Voedingsraad [Food Council] show that the uncontrolled addition of vitamins creates an undesirable situation from the point of view of nutrition as a whole especially inasmuch as it renders nutritive deficiencies more likely and contributes in addition to confusing the consumer in his choice of foodstuffs.

Moreover Aricle 10 (a) (1) of the Algemeen Besluit does not prohibit the importation and marketing of vitamin preparations in every case. A certain number of these products are approved on the basis of the Wet op de Geneesmiddelenvoorziening [Law on the Supply of Medicinal Preparations] after a preliminary examination to ensure that the medicinal preparation is harmless.

According to established case-law of the Court the national legislature is free, in the absence of Community rules in the matter, to adopt national rules, especially as regards the production, marketing and consumption of the products in question, with due regard nevertheless to Article 30 *et seq.* of the Treaty. The prohibition of the addition of vitamins, qualified by a system of individual authorizations enabling needs to be met in a flexible manner, is justified by the requirements of the protection of public health referred to in Article 36 of the Treaty, since it cannot be established beyond all doubt that such additives are not harmful and since relative harmfulness depends on the food habits of the consumer.

In conclusion the Netherlands Government suggests the following answer to the questions referred to the Court for a preliminary ruling:

"The provisions of the EEC Treaty on the free movement of goods do not prevent a Member State from adopting on grounds of the protection of public health within the meaning of Article 36 of the EEC Treaty national measures prohibiting, in the absence of a preliminary examination, the addition of vitamins to foodstuffs and beverages produced in the country or imported."

3. The *Danish Government,* dealing only with the first question, states that the Danish legislation on the addition of vitamins to food products (Law No 310 of 6 June 1973 on food and other products; Decree No 65 of 20 February 1981 on additives to food products) is in certain respects comparable to that applicable in the Netherlands.

By virtue of that legislation the addition of nutrients, including vitamins, is allowed only subject to four conditions:

The addition must be presumed to make good or prevent an assumed lack of a certain nutrient in a large part of the population;

The addition must be intended to replace the loss of nutritive value resulting from industrial treatment of the food product;

The addition is confined to new kinds of similar food capable of replacing or duplicating a traditional food product, provided that the traditional product covers an appreciable part of the daily needs for the said nutritive substance;

The addition must relate to foodstuffs which constitute in themselves or are intended for a certain type of nutrition, provided that the amount of foodstuffs is adapted to the purpose and nature of the product and its energy content.

The system described above is based on the considerations that correct nutrition is of fundamental importance for human health and that a healthy diet depends on varied food. Danish policy is therefore aimed at avoiding "adorning" the natural qualities of a food product in order to prevent the addition of food substances to products with which they are not normally associated. In that respect it takes account of the fact that the addition of such substances, even if they are not harmful in themselves, constitutes a means of persuasion for the producer at the expense of the consumer.

It follows that it is not sufficient to contemplate labelling which shows the content of additives since such labelling is precisely the factor which leads the consumer to believe that the product in question is a healthy one.

Moreover certain substances, including Vitamins A and D taken in high doses, may in themselves cause poisoning or at least an imbalance in the general ingestion of nutrients.

The Danish Government adds that the rules and guidelines in the matter depend *inter alia* on the water, vegetation and soil and thus to a very large extent on specifically local conditions varying from State to State.

The Court has recognized that obstacles to intra-Community trade based on differences in national laws on the marketing of products must be accepted in so far as such provisions apply without distinction to domestic and imported products and are absolutely necessary for purposes *inter alia* of the protection of public health, the fairness of commercial transactions and the protection of the consumer. In that respect the judgment of 5 February 1981 in Case 53/80 *Eyssen* [1981] ECR 409 confirmed that "the issue of the addition of preservatives to foodstuffs is embraced by the more general issue of health protection which calls for the adoption of national measures designed to regulate the use of such additives in the interests of the protection of human health." Moreover the Court held in the judgment of 17 December 1981 in Case 272/80 *Biologische Producten* [1981] ECR 3277 that in the absence of harmonization it was for the Member States to decide what degree of protection of the health and life of humans they intended to ensure and in particular how strict the checks to be carried out were to be.

In conclusion the Danish Government proposes that the Court should answer the first question to the effect that national legislation on the addition of nutrients to foodstuffs of the kind referred to in the judgment making the reference is not incompatible (provided that it is not discriminatory and not more onerous than is necessary for the purposes of achieving the objective which it pursues) with the rules of the EEC Treaty on the free movement of goods within the Community even if the product is lawfully manufactured and marketed in another Member State.

4. The *Italian Government* points out that contrary to what the national court states dietary products have already been made the subject of preliminary harmonization by Council Directive No 77/94 of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses.

Article 2 of the directive provides that "the nature or composition of the products ... must be such that the products are appropriate for the particular nutritional use intended". Article 3 allows, in the absence of specific directives, national provisions to regulate changes made to products in order to make them appropriate for a particular nutritional use. Those provisions clearly show the need, for the purposes of protecting public health, of controls on the production and marketing of the products in question. A check on labelling does not suffice to prevent consumers from being misled as to the properties of the product. It is also necessary to check the composition of the product itself which must meet the requirements which it is intended to satisfy and must not be harmful.

Accordingly national provisions which give the national authorities the right to check the composition of such products and to prohibit their marketing in the absence of authorization do not constitute unjustified obstacles to the free movement of goods for the purposes of Article 36 of the Treaty or the said directive in so far as such products have not already been subject to appropriate analysis in the exporting Member State (cf. the judgment of 17 December 1981 in Case 272/80 *Biologische Producten* [1981] ECR 3277).

The affirmative answer to be given to the first question deprives the other two questions of their purpose. The Italian Government nevertheless adds by way of a secondary observation that the terms of the procedure leading to an administrative authorization to produce or market such products lie, in the absence of harmonization, within the exclusive jurisdiction of the importing Member State provided that such terms are the same for domestic and imported products.

5. The *Commission of the European Communities* states that there is as yet no provision of Community law in force on the addition of vitamins to foodstuffs and maintains that the prohibition in Article 10 (a) of the Algemeen Besluit constitutes a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 of the Treaty since it is capable of constituting an obstacle to the marketing in the Netherlands of products from other Member States where the marketing of products with added vitamins is permitted. That prohibition is compatible with Community law only if it can be justified under Article 36 of the Treaty.

As to the *first question* it is necessary to determine whether the prohibition is required for the effective protection of the health of humans. That is not so if such protection can be ensured as effectively by measures which restrict

intra-Community trade to a lesser degree (judgment of 20 May 1976 in Case 104/75 *De Peijper* [1976] ECR 613).

In view of those criteria the Commission contends that vitamins are not harmful in themselves. According to scientific literature it is necessary to distinguish between vitamins soluble in water, such as Vitamin B2, which are harmless, and vitamins soluble in fat which may have harmful effects if absorbed in excessive quantities.

That conclusion is confirmed by the "International rules Recommended for Food for Babies and Young Children" adopted by the Commission of the Codex Alimentarius of the Food and Agriculture Organization and the World Health Organization and by the German legislation on the subject. The international rules do not lay down maximum quantities except for Vitamins A and D. Unless derogation is granted by the competent federal Minister, German legislation prohibits the addition of Vitamins A and D but allows the addition of other vitamins to foodstuffs provided that the product states the amount of vitamins it contains and the health authorities are informed.

The Commission is therefore of the view that a general prohibition of the marketing of imported products to which vitamins are added goes beyond what is required for the effective protection of the health of humans.

As to the *second question* the Commission refers to the judgment of the Court of 8 November 1979 in Case 251/78 *Denkavit* [1979] ECR 3369 to the effect that it is for the authority which relies on one of the grounds of justification set out in Article 36 to show that the measures it imposes are indispensable. It follows that it is for the national authorities to show that a specific product is harmful to public health although it is lawfully marketed in another Member State.

The *third question* asks whether the fact that there is or is not a demand for imported products to which vitamins have been added may be taken as a criterion for the grant of an authorization to market the product in question. The answer is in the negative since none of the grounds which are exhaustively stated in Article 36 and which justify a restriction on imports can be interpreted in such a way as to cover a requirement of a demand for a specific product.

In conclusion the Commission proposes that the questions referred to the Court for a preliminary ruling should be answered as follows:

"1. Article 36 of the EEC Treaty must be interpreted as meaning that a general prohibition of the marketing of products to which vitamins have been added and which are lawfully marketed in another Member State is not justified on grounds of the protection of public health.

2. It is for the national authorities to show that a product is harmful to public health.

3. The fact that there is no demand for products to which vitamins have been added cannot justify an obstacle to imports within the meaning of Article 30 of the EEC Treaty."

## III — Answers to questions put by the Court

In answer to a question put by the Court the company Sandoz, the Netherlands and Danish Governments and the Commission specified which vitamins in their opinion might represent a danger to human health and those which were harmless. Further, at the request of the Court, the Commission briefly set out the provisions laid down by law and regulation in relation to the addition of vitamins in force in the other Member States and specified in particular which vitamins are subject to such rules.

1. *Sandoz* states that toxic levels have been found for vitamins soluble in water, namely B1, B6, C, niacin, calcium-pantothenate and folic acid and for Vitamins A, D3 and E, which are soluble in fat. On the other hand, no harmful side-effect has been recorded in the case of Vitamins B2, B12 and biotin which are soluble in water. No toxic level has been established for Vitamin K1 which is soluble in fat.

Sandoz adds that the addition of all vitamins may be calculated in such a way that their consumption can involve no risk for human health since it would be necessary to consume excessive quantities of products, which the organism would be incapable of assimilating, to reach the toxic level.

2. The *Netherlands Government* states that the absorption of any vitamins in high dosages or over a prolonged period may create health risks. Levels at which dosages may prove to be toxic are nevertheless not yet sufficiently known. Toxicity depends on the one hand on the kind of vitamin and the quantity absorbed and on the other on the characteristics of the consumer. In general, vitamins soluble in fat are more toxic than vitamins soluble in water because they are not easily eliminated.

In the absence of precise information vitamins ought not to be consumed in quantities substantially higher than the "Recommended Dietary Allowance" which represents the quantity of vitamins necessary for the proper maintenance of physical functions.

3. The *Danish Government* considers that the absorption of Vitamins A, B, C and D in abnormal quantities or over a prolonged period may give rise to symptoms of intoxication. On the other hand B1, B2, B6, B12, niacin, pantothenic acid, biotin and Vitamins E and K do not really provide any cause for concern in the matter of health even if consumed in abnormal quantities. The Danish Government nevertheless states that the greatest risk to health in relation to nutrition is not the danger of intoxication but on the contrary the lack of certain nutrients as the result of incorrect diet.

4. The *Commission of the European Communities* confirms that vitamins are not in themselves harmful substances or a danger to human health. Only vitamins soluble in fat and more particularly Vitamins A and D may have harmful effects if absorbed in excessive doses over a certain period. The position is different as regards vitamins soluble in water such as Vitamins B1, B2, B6, B12,

C and H, any excesses of which are eliminated.

IV — Oral procedure

Sandoz BV, represented by J. C. Schultsz and B. J. H. Crans, Advocates, Amsterdam, assisted by W. H. M. Saris, expert; the Netherlands Government, represented by A. Bos, acting as Agent, assisted by R. F. van der Heide, expert; the Italian Government, represented by I. Braguglia, Avvocato dello Stato; and the Commission of the European Communities, represented by R. Wägenbaur and J. F. Verstrynge, acting as Agents, assisted by P. Elias, expert, presented oral argument at the sitting on 9 March 1983.

The Advocate General delivered his opinion at the sitting on 4 May 1983.

## Decision

1 By judgment of 3 May 1982, received at the Court on 28 June 1982, the Economische Politierechter [Magistrate dealing with commercial offences] for the Arrondissementsrechtbank [District Court], 's-Hertogenbosch, referred to the Court under Article 177 of the EEC Treaty for a preliminary ruling three questions on the interpretation of provisions of the EEC Treaty in relation to free movement of goods within the Community and in particular Article 36 thereof.

2 The questions were raised in criminal proceedings brought against Sandoz BV, Uden, for having sold and delivered in the Netherlands for commercial purposes and for human consumption, without an authorization from the responsible minister, food and beverages to which vitamins had been added.

3 According to Article 10 (a) (1) of the Algemeen Besluit [General Decree] of 11 July 1949 adopted in implementation of Articles 14 and 15 of the Warenwet [Food and Drugs Law] of 1935 "no vitamins . . . may be added to food and beverages without an authorization granted by the Minister responsible for implementing this decree".

4 In the present case Sandoz BV (hereinafter referred to as "Sandoz") sold in the Netherlands muesli bars, "Powerback" and analeptic beverages to which certain vitamins, in particular Vitamins A and D, had been added. It appears

from the file that all the products in question are lawfully marketed in the Federal Republic of Germany or in Belgium. Before marketing them in the Netherlands Sandoz applied for authorization pursuant to the aforesaid legislation. The responsible Netherlands authority replied first that authorization would be granted only if there was a market demand for the products in question. The application for authorization was subsequently rejected on the ground that the Vitamins A and D in the products in question represented a danger to public health.

5 The Economische Politierechter took the view that his decision on the matter depended on whether the aforesaid Netherlands legislation was compatible with Article 30 *et seq.* of the Treaty and therefore an interpretation of those provisions was necessary for him to give judgment; the proceedings were thereupon stayed and the following questions referred to the Court for a preliminary ruling:

"1. Where:

(a) food or beverages, or both, to which vitamins have been added, have been marketed in one or more Member States lawfully, that is to say in accordance with the legislation in force locally, and

(b) an importer of food or beverages, or both, established in another Member State imports lawfully marketed food or beverages, or both, to which vitamins have been added, from one of the Member States referred to under (a) above into the Member State in which he is established,

do the provisions derogating from the rules concerning the free movement of goods within the Community, in particular Article 36 of the EEC Treaty in so far as it relates to the protection of the health of humans, justify the government of the Member State of importation in prohibiting the marketing of such food or beverages, or both, in that State without ministerial authorization?

2. Must the previous question be answered differently if the general prohibition on the sale of food and beverages to which vitamins have been added, unless authorized by a ministerial decision, has the result that the importer referred to under 1 (b) above bears the onus of proving that the food and beverages concerned are not a danger to public health and must therefore be authorized?

3. Must the question be answered differently if the application of the general prohibition of the sale of food and beverages to which vitamins have been added, unless authorized by a ministerial decision, has the result that the national authorities of a Member State prohibit the sale of such food and beverages which have been lawfully produced and marketed in another Member State, unless the producer or seller shows not only that such products are not a danger to health but also that it is desirable to market them and that there is a need for vitamins to be added?".

## First question

6 In the first question the national court seeks in essence to know whether, and if so in what circumstances, the provisions of the Treaty on free movement of goods preclude national rules prohibiting without prior administrative authorization the marketing of food to which vitamins have been added and which are lawfully marketed in another Member State.

7 Article 30 of the Treaty prohibits in trade between Member States quantitative restrictions on imports and all measures having equivalent effect. According to established case-law of the Court all commercial rules of the Member States likely to impede directly or indirectly, actually or potentially intra-Community trade are to be regarded as measures having an effect equivalent to quantitative restrictions. Nevertheless, according to Article 36 of the Treaty the provision in Article 30 does not preclude prohibitions or restrictions on imports justified on grounds *inter alia* of the protection of human health provided that such prohibitions or restrictions do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

8 It is apparent that national rules of the kind referred to by the national court prohibiting without prior administrative authorization the marketing of food to which vitamins have been added are likely to impede trade between Member States and must therefore be regarded as a measure having an effect equivalent to quantitative restrictions within the meaning of Article 30 of the

Treaty. The answer to the question therefore depends on the applicability of Article 36 to such rules.

9 In that respect and in the opinion of Sandoz and the Commission, it is only in the event of excessive consumption, which is excluded however in the case of products of the kind in question, that vitamins and in particular vitamins soluble in fat, such as Vitamins A and D, may have harmful effects. A general prohibition on the marketing of food to which vitamins of any kind have been added is therefore not justified within the meaning of Article 36 of the Treaty on grounds of the protection of health and is in any event excessive within the meaning of the last sentence of that article.

10 On the other hand the Netherlands and Danish Governments contend that such rules are necessary owing to the very nature of the substances added since the absorption of any vitamins in high doses or for a prolonged period may entail risks to health or at least undesirable side-effects such as malnutrition. In view on the one hand of scientific uncertainties and on the other of the fact that the harmfulness of vitamins depends on the quantity absorbed with the whole nutrition of a person it is not possible to say with certainty whether any food to which vitamins have been added is harmful or not.

11 It appears from the file that vitamins are not in themselves harmful substances but on the contrary are recognized by modern science as necessary for the human organism. Nevertheless excessive consumption of them over a prolonged period may have harmful effects, the extent of which varies according to the type of vitamin: there is generally a greater risk with vitamins soluble in fat than with those soluble in water. According to the observations submitted to the Court, however, scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects.

12 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.

13 The addition of vitamins is thus subject to the general policy in relation to food additives, which are already to a limited extent the subject of Community harmonization. Thus in particular the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (Official Journal, English Special Edition 1959-62, p. 279) and Council Directive No 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption (Official Journal, English Special Edition 1963-64, p. 99), as amended, require the Member States to authorize only the colouring matters and preservatives set out in the list annexed but leave the Member States free to restrict, in certain circumstances, the use even of the substances listed.

14 As regards foodstuffs intended for particular nutritional uses there has been some degree of harmonization in Council Directive No 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (Official Journal 1977, L 26, p. 55). Article 7 thereof requires the Member States to adopt all the measures necessary to ensure that trade in the said products cannot be impeded by the application of non-harmonized national provisions governing the composition, manufacturing specifications, packaging or labelling of foodstuffs, subject nevertheless to provisions justified on grounds, *inter alia*, of protection of public health.

15 The abovementioned Community measures clearly show that the Community legislature accepts the principle that it is necessary to restrict the use of food additives to the substances specified, whilst leaving the Member States a certain discretion to adopt stricter rules. The measures thus testify to great prudence regarding the potential harmfulness of additives, the extent of

which is still uncertain in respect of each of the various substances, and leave a wide discretion to the Member States in relation to such additives.

16 As the Court found in its judgment of 17 December 1981 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 harmonization, 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 authorization, 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 authorizations 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 harmonization 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, authorize 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 authorization the marketing of foodstuffs lawfully marketed in another Member State to which vitamins have been added, provided that the marketing is authorized when the addition of vitamins meets a real need, especially a technical or nutritional one.

## Second question

21 In the second question the national court asks in essence whether Community law precludes national rules such as those referred to by the national court where the authorization to market is subject to proof by the importer that the product in question is not harmful to health.

22 Inasmuch as the question arises as to where the onus of proof lies when there is a request for authorization, in view of the answer to the first question, it must be remembered that Article 36 of the Treaty creates an exception, which must be strictly interpreted, to the rule of free movement of goods within the Community which is one of the fundamental principles of the common market. It is therefore for the national authorities who rely on that provision in order to adopt a measure restricting intra-Community trade to check in each instance that the measure contemplated satisfies the criteria of that provision.

23 Accordingly, although the national authorities may, in so far as they do not have it themselves, ask the importer to produce the information in his possession relating to the composition of the product and the technical or nutritional reasons for adding vitamins, they must themselves assess, in the light of all the relevant information, whether authorization must be granted pursuant to Community law.

24 The second question must therefore be answered to the effect that Community law does not permit national rules which subject authorization to market to proof by the importer that the product in question is not harmful to health, without prejudice to the right of the national authorities to ask the importer to submit all the information in his possession needed to assess the facts.

## Third question

25 In the third question the national court asks in essence whether Community law precludes national rules of the kind referred to by the national Court where authorization to market is subject to proof by the importer that the marketing of the product in question meets a market demand.

26 As regards the requirement of a market demand it must be emphasized that the sole fact of imposing such a condition constitutes in itself a measure having an equivalent effect to a quantitative restriction prohibited by Article 30 which cannot be covered by the exception in Article 36. The objective pursued by the principle of free movement of goods is precisely to ensure for products from the various Member States access to markets on which they were not previously represented.

27 The third question must therefore be answered to the effect that Community law does not permit national rules which subject authorization to market to proof by the importer that the marketing of the product in question meets a market demand.

## Costs

28 The costs incurred by the Netherlands, Danish and Italian Governments and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. As these proceedings are, in so far as the parties to the main proceedings are concerned, in the nature of a step in the proceedings before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber)

in answer to the questions submitted to it by the Economische Politierechter for the Arrondissementsrechtbank, 's-Hertogenbosch, by judgment of 3 May 1982, hereby rules:

1. **Community law permits national rules prohibiting without prior authorization the marketing of foodstuffs lawfully marketed in another Member State to which vitamins have been added, provided that the marketing is authorized where the addition of vitamins meets a real need, especially a technical or nutritional one.**

2. **Community law does not permit national rules which subject authorization to market to proof by the importer that the product in question is not harmful to health, without prejudice to the right of the national authorities to ask the importer to submit all the information in his possession needed to assess the facts.**

3. **Community law does not permit national rules which subject authorization to market to proof by the importer that the marketing of the product in question meets a market demand.**

Mertens de Wilmars Everling

Mackenzie Stuart Due Galmot

Delivered in open court in Luxembourg on 14 July 1983.

For the Registrar

H. A. Rühl

Principal Administrator

J. Mertens de Wilmars

President