OPINION OF MR ADVOCATE GENERAL MANCINI DELIVERED ON 4 MAY 1983 [1]

Mr President,
Members of the Court,

1. This reference to the Court for a preliminary ruling concerns the free movement of goods and in particular a principle contained in the first part of Article 36 of the EEC Treaty which authorizes "prohibitions or restrictions on imports ... on grounds of ... the protection of health and life of humans". The Court must establish whether that principle applies to national rules generally prohibiting (but enabling the administration to authorize in any particular case) the marketing of products containing added vitamins and imported from other Member States where their marketing is lawful.

Let me summarize the facts. Sandoz BV, the registered office of which is in Uden in the Netherlands, is a subsidiary of the Swiss company of the same name and is concerned with the sale in the Netherlands of food products containing added vitamins for sportsmen: muesli bars, Powerback and analeptic beverages, all imported from Switzerland and the Federal Republic of Germany. In 1979 the company sought an authorization from the Netherlands Minister for Public Health and Environment under Article 10 (a) of the Algemeen Besluit [General Decree] of 11 July 1949 to sell the said products. However, by a decision of 26 August 1981 the Minister rejected the application on the ground that the presence of Vitamins A and D in the food products in question represented a danger to public health, particularly as the labelling did not contain instructions for the adaption of the dosage to individual requirements.

Although it had no authorization Sandoz marketed the products I have mentioned by selling them in 1980 to retailers in various localities. For doing so it was summoned in March 1982 to appear before the Economische Politierechter [Magistrate dealing with commercial offences] of the Arrondissementsrechtbank [District Court] 's-Hertogenbosch to answer a charge of infringement of the aforesaid Article 10 (a). The proceedings were stayed, however, because the Netherlands court considered it necessary to submit the following questions to this Court for a preliminary ruling 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

1 — Translated from the Italian.

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?"

2. To understand the case fully it is necessary to supply certain information on the rules which in the Netherlands govern the marketing of food with added vitamins. That should not be necessary as a rule, but although the questions put by the court making the reference are framed in appropriate terms and refer to Article 36 of the EEC Treaty, they obviously seek to establish whether the particular national provisions which that court must apply are compatible with Community law. Let me spare the Court fresh complaint about this phenomenon caused, in my opinion, by the inadequate use the Commission makes of the procedure based on Article 169 of the Treaty. I shall confine myself to the observation that, as the present case shows, the practice is spreading and, as it does so, the risk of institutional imbalance to which I have several times drawn the attention of the Court increases (see my Opinion in Case 94/82 *Officier van Justitie* v *De Kikvorsch* and Case 59/82 *Schutzverband gegen Unwesen in der Wirtschaft* v *Weinvertriebs GmbH).*

I return now to the matter before us. Article 10 (a) (1) of the Algemeen Besluit provides that "no vitamins ... may be added to food and beverages without an authorization granted by the Minister responsible for implementing this decree" and then immediately states "such authorization may be subject to

conditions" ("conditions", as I interpret it, means "as a result of certain tests"). The Commission informs us that so far two measures of that kind have been adopted: one for the addition of Vitamin C (ascorbic acid) to buttermilk as an anti-oxidant and one for the addition of numerous vitamins to babyfood. The first decree, which goes back to 31 July 1974, determines the maximum amount of Vitamin C which may be added; the second, which is dated 29 September 1976, defines the maximum or minimum doses which may be added to the products (see point 5 of the observations of 11 August 1982).

3. I do not think there can be any doubt that rules such as those I have just described are likely to impede, be it only indirectly, international trade. The general prohibition (unless there is express authorization) on adding vitamins to food and drinks means that it is impossible to import and market such products. The court concerned with this case recognizes it in the wording of the questions, and in that respect neither the Commission, Sandoz B.V. nor the three intervening Member States (the Netherlands, Italy and Denmark) has expressed a different view. However, once we have established that premise and concluded that rules such as those in Article 10 (a) (1) of the Algemeen Besluit constitute "measures having an effect equivalent to a quantitative restriction" it is a question of establishing whether and how far the Member States may introduce or retain such rules in their legal systems.

The provisions to be considered from that point of view, which is really the main issue in the case, are Article 36 of the Treaty and, in certain respects, 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, L 26, p. 55 of 31 January 1977).

Let us start with Article 36. As is known, that article derogates from Article 30 (and from the following Articles 31 to 34) by authorizing prohibitions and restrictions on imports justified, *inter alia*, on grounds of "the protection of health and life of humans". According to the Netherlands Government Article 10 (a) (1) of the Algemeen Besluit complies with the Treaty because it answers the need to prevent the excessive consumption of certain vitamins, in particular Vitamins A and D, from harming the health of the consumer. In a general way at least, that argument is valid. Indeed, we all know, and the parties basically agree, that vitamins *may* be harmful to the health of the person who consumes an excessive quantity of them. At least vitamins soluble in fat are dangerous, whereas the risk is less or non-existent in the case of vitamins soluble in water because the human body eliminates them even if they are consumed in excessive quantities.

However that may be, I do not think the Court need go further into those problems of the pathology of metabolism. Once it is established that there is uncertainty with regard to the quantity of vitamins which may be consumed without harm it is not possible not to allow the States the right to

introduce restrictions on their marketing at least so long as the national legal systems have not been harmonized in relation to food additives (see on that issue the judgment of 5 February 1981 in Case 53/80 *Officier van Justitie* v *Koninklijke Kaasfabriek Eyssen BV* [1981] ECR 409). Naturally that power must be exercised within the limits established by Title I of the Treaty. However, since the aims which those limits leave untouched include the protection of health and life, the Member States may assume responsibility therefor and, in particular, "decide . . . how strict the checks to be carried out [are] to be" for that purpose (see the judgments of 20 May 1976 in Case 104/75 *De Peijper* [1976] ECR 613 at p. 635 and 17 December 1981 in Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Produkten* [1981] ECR 3277, paragraph 12 at p. 3290). As regards the present case, I would say therefore that the preventive checks provided for by national law to ascertain the addition of vitamins to food fall within the terms of Article 36 inasmuch as they satisfy a condition specified therein. Moreover, Sandoz itself admits their expediency.

4. The lawfulness, however, of these checks may also be based on Directive No 77/94/EEC to which I have already referred. As we know, its aim is to approximate the national laws relating to "foodstuffs for particular nutritional uses" and to abolish, if only gradually, the differences between laws which "impede their free movement, may create unequal conditions of competition and thus have a direct impact on the establishment and functioning of the common market" (see the first recital). In the preamble it is explained that the said approximation requires, in the initial stage, "the determination of measures enabling the consumer to be protected" and in a subsequent stage the definition of "the particular characteristics applicable to certain groups of these products" (see the third and fourth recitals).

The foodstuffs to which this case relates are certainly intended for people, mainly sportsmen, who need special food: that they fall within the scope of the directive appears to me therefore to be obvious. Furthermore, the directive assumes that "the composition and preparation" of the products "must be specially designed to meet the particular nutritional requirements" of the persons for whom they are intended (see the sixth recital); it is precisely for that reason that Article 8 (1) provides that "the Council . . . shall lay down, as far as is necessary, the purity criteria for the substances for particular nutritional uses and *additives the use of which is authorized for each group of products*" (the italics are mine). It seems to me that that provision is highly relevant for our purposes. It recognizes the need for uniform rules on the use of additives and thereby postulates that in the meantime the States remain free to intervene even to the extent of introducing controls.

That is not all. Article 7 (2) is concerned with national provisions which for the protection of "public health" impede in some respect trade in the products in question, and regards them as lawful. It may therefore be said that it applies, at least as regards the food sector concerned with special requirements, the general principle contained in Article 36 in derogation of Article 30. That fact is also important and shows that at any rate the directive has a clear general bias against the use of additives. Moreover, in the opinion expressed on the proposal which led to the directive the Parliament stressed "the need in future to restrict as far as possible the use of additives in dietary foodstuffs in the light of scientific and technical research" (Resolution of 10 October 1969 in Journal Officiel, C 139/39 of 28 October 1969, point 11).

5. The first question from the Netherlands court does not only raise the question of whether a national rule prohibiting, unless authorized by the administration, the marketing of products to which vitamins have been added complies with Community law. It is in fact more specific: it concerns the case where the products have already circulated in one or more Member States in accordance with their respective laws. In brief, the Netherlands court wishes to know whether preventive inspection, such as that on which the said authorization depends, may be imposed even when similar checking has been carried out by the authorities of the State of origin.

That question was settled by the Court in the judgment in the *Frans-Nederlandse Maatschappij* case. The subject-matter of the case was official approval of disinfectants imported from another Member State. The Court held that "a Member State is not prohibited from requiring ... prior approval" for such products even if they have already been approved in another Member State (see paragraph 16 of the decision). Nevertheless it was stated that the authorities of the first State are required "to assist in bringing about a relaxation of the controls existing in intra-Community trade". That means that they "are not entitled unnecessarily to require technical or chemical analyses or laboratory tests" where such analyses and tests have already been carried out in the other Member State and their results are available to those authorities, or may at their request be placed at their disposal (see paragraph 14). Since the facts of the two cases are similar it seems to me that those words perfectly fit the present case.

There is one reservation, however. The judgment in *Frans-Nederlandse Maatschappij* tempered the State's power to intervene by applying the principle of proportionality. That principle may affect the authorization procedure; on the other hand it is not possible to rely on it in respect of the decision to allow or not to allow the product to be marketed. The decision depends on a basic assessment as to the protection of health; in that respect since there are still doubts about the harmfulness of

additives and the sector does not have uniform rules there is full power to intervene. Moreover, the said judgment of 5 February 1981 in Case 53/80 is to the same effect.

6. The second and third questions from the national court consider the hypothetical (but which obviously has reference to the practice of the Netherlands authorities) case of national rules which specify (a) the conditions which the product in question must meet before it may be marketed and (b) the onus of proof regarding those conditions. The two questions appear to me proper and important. Accepting that the control of the products in question is lawful for the protection of health the crux of the case lies in the aim of the controls and the means employed: that means precisely the conditions required for marketing the products and the formalities for authorization.

The second question relates to evidence. The Netherlands court wishes to know whether in Community law a rule which requires the importer to show that a product to which vitamins have been added is *harmless* is lawful. In my opinion that question must be answered in the negative. There is a precedent here, namely the judgment of 8 November 1979 in Case 251/78, *Denkavit Futtermittel* v *Minister für Ernährung, Landwirtschaft und Forsten* [1979] ECR 3369. The case was concerned with establishing whether health inspections of certain imported products (animal feedstuffs) may be carried out by requiring importers to produce the necessary documents; the Court held that when a State relies on Article 36 it is for that State to show that the measures it takes are necessary for the protection of health (see paragraph 24 of the decision). Applying that principle to the present case, if the national authorities intend lawfully to prohibit the sale of food they must show that the addition of vitamins has made the food harmful.

7. The third question has a double aspect: on the one hand it considers other conditions laid down for the marketing of food to which vitamins have been added and on the other hand it refers once again to the burden of proof. Under the first aspect the Netherlands court presupposes that a national law makes it a condition for the marketing of such food that it is "useful" and meets a demand. Consequently it must not only not be harmful but must be useful and meet actual needs: briefly, it must satisfy positive conditions.

That question requires a closer study of the scope of Article 36 in so far as it attaches importance to the protection of health. I have already said that according to that article it is possible to prohibit the marketing of a harmful food substance. But what is the position of a substance which is neither harmful nor useful? I do not think that a case of that kind falls within its scope. To prevent people from

consuming products which are not useful is certainly a socially valuable objective; however rules seeking to achieve it by prohibiting their consumption exceed the bounds of the permissible. None of the Member States challenges the lawfulness of rules allowing the marketing of substances such as tobacco and alcohol, the harmful effects of which are clear. If one reflects upon that fact it will be understood how absurd it would be to make a ban on the marketing of harmless food lawful under Article 36.

That said, I should add that the positive conditions taken into account in the third question relate rather *sub specie* to protection of the consumer: therefore although still within the ambit of Article 36 they relate to an interest different from those which justify intervention by the State under that provision. On that view, however, there seems to be no doubt that the intervention is contrary to the principle of proportionality if it goes so far as to ban the marketing of food which is neither harmful nor useful. Since campaigns to educate people in correct nutrition are clearly lawful the State should confine itself to guaranteeing the consumer all the necessary information about the products offered to him, especially as regards their nutritive properties. There would be a guarantee of that kind for example if their marketing were subject to the condition that the label and instructions for use must provide information about their properties.

Finally, I come to the second part of the last question. The national court asks whether the importer may be required to prove that the consumption of products to which vitamins have been added is desirable and meets the needs of consumers. Since I have said that it is not open to the Member States to require such conditions I can answer that only in the negative. In any event that answer is supported by the judgment I have cited in the *Denkavit Futtermittel* case to the effect that the burden of showing that goods are dangerous to public health is on the authorities who intend to prohibit or limit their sale on the basis of Article 36.

8. For all the reasons put forward above I propose that the questions put by the Economische Politierechter of the Arrondissementsrechtbank 's-Hertogenbosch by order of 3 May 1982 in the criminal proceedings against Sandoz BV, the registered office of which is at Uden in the Netherlands, should be answered as follows:

(a) *First question:* In the present state of Community law on foodstuffs to which vitamins have been added the provisions of the EEC Treaty and secondary law in relation to the free movement of goods must be interpreted as meaning that they do not prevent a Member State from adopting measures which on grounds of protection of health as referred

to in Article 36 of the Treaty prohibit the addition of vitamins to foodstuffs produced in that Member State or imported unless there is prior official authorization. That authorization may be required even if the manufacture and marketing of the said products have already been authorized in another Member State. Nevertheless the authorities of the importing State may not unnecessarily require technical or chemical analyses or laboratory tests when such examination has already been carried out in another Member State and the results are, or may upon request be made, available to the said authorities.

(b) *Second question:* In the present state of Community law on foodstuffs to which vitamins have been added the provisions referred to in (a) above must be interpreted as meaning that they prohibit a Member State from requiring the importer to show that products are harmless to public health in order to obtain authorization for their marketing.

(c) *Third question:* In the present state of Community law on foodstuffs to which vitamins have been added the provisions specified in (a) above must be interpreted as meaning that they prohibit a Member State from requiring that the producer or seller must show that the consumption of those products is desirable and that the addition of vitamins meets a need in order to obtain authorization for their marketing.