In Case 53/80

REFERENCE to the Court under Article 177 of the EEC Treaty by the Gerechtshof [Regional Court of Appeal], Amsterdam, for a preliminary ruling in the proceedings pending before that court between

OFFICIER VAN JUSTITIE [Public Prosecutor]

and

KONINKLIJKE KAASFABRIEK EYSSEN BV,

on the interpretation of the provisions of the EEC Treaty regarding the free movement of goods within the Community,

THE COURT (First Chamber),

composed of: T. Koopmans, President of Chamber, A. O'Keeffe and G. Bosco, Judges,

Advocate General: J.-P. Warner
Registrar: A. Van Houtte

gives the following

## JUDGMENT

## Facts and Issues

### I — Facts and written procedure

By a summons of 22 December 1977 Koninklijke Kaasfabriek Eyssen BV (hereinafter referred to as "Eyssen") was ordered to appear before the Economische Politierechter [Magistrate in Economic Matters], Alkmaar, on a charge of having held in stock certain quantities of cheese spread and rindless cheese intended for sale for human consumption, to which had been added nisin, a substance whose addition is not authorized by the Netherlands law applicable in the matter.

Nisin is an antibiotic formed by certain types of lactic bacteria and occurring naturally in varying quantities in most varieties of cheese which has the property of retarding the process of deterioration of cheese caused by the presence of butyric bacteria. The addition of nisin, it appears, may be of great importance in the preservation of cheese, particularly in the case of certain varieties such as processed cheese, which tend to deteriorate more rapidly than others.

The legal basis of the Netherlands law on additives is to be found in the "Warenwet" (Law on Goods) of 1935 which enables the Crown to adopt by decree "Algemene Maatregelen van Bestuur" [general administrative regulations] in the interest of public health or fair trading. In pursuance of that delegation of legislative power, the Crown made on 11 July 1949 an order called the "Algemeen Besluit" containing general rules applicable to all foodstuffs and drinks. Under Article 10 (1) of that order, antibiotics may be added to drinks and foodstuffs only where the minister has authorized their use. Such authorization has never been given in the case of nisin. In the absence of an authorization having general application, the use of an additive may be permitted by orders, themselves made on the basis of the Warenwet, which are concerned with specific foodstuffs or drinks. As far as processed cheese is concerned, two orders are applicable thereto: the "Kaasbesluit" [Cheese Order] and the "Smeltkaasbesluit" [Processed Cheese Order]. The "Smeltkaasbesluit" prohibits any additive to processed cheese other than substances whose addition is expressly authorized or substances whose addition is permitted by the "Kaasbesluit" for cheese in general. The addition of nisin is permitted neither by the "Smeltkaasbesluit" nor by the "Kaasbesluit".

New drafts of the "Kaasbesluit" and the "Smeltkaasbesluit" limiting the natural occurrence of nisin to a certain degree of concentration are under preparation, but they have not yet gone beyond the first stages of the legislative procedure.

Finally, the possibility exists of a general derogation from the rules mentioned above. Products intended for export are exempted by regulation from the prohibition of the addition of nisin. That derogation does not apply to products intended for the domestic market. The addition of nisin to those products is therefore prohibited and considered as an offence under the law on economic offences.

By decision of 30 January 1978, the Economische Politierechter referred the case to the Meervoudige Economische Kamer [Economic Chamber] of the Arrondissementsrechtbank [District Court] Alkmaar. That court decided to dismiss all proceedings against Eyssen on the grounds that the limited quantities of nisin used by the accused did not present any danger to public health and that the prohibition on the use of nisin in the Netherlands constituted a measure having an effect equivalent to a quantitative restriction within the meaning of Articles 30 and 34 of the EEC Treaty, the addition of that substance to cheese being authorized in other Member States.

The Officier van Justitie [Public Prosecutor] for the District of Alkmaar lodged an appeal against that judgment with the Gerechtshof [Regional Court of Appeal] Amsterdam, which by judgment of 13 December 1979 decided to refer the following question to the Court of Justice of the European Communities for a preliminary ruling under Article 177 of the EEC Treaty:

"Having regard to the following facts:

A Netherlands producer of processed cheese produces such cheese both for his home market and for export to other EEC countries; and

Adds an antibiotic, nisin, to the processed cheese which he produces, in order to increase its keeping qualities; and

Nisin must be considered to be not absolutely but relatively (slightly) harmful to human health; and

The producer adds nisin to processed cheese in a quantity which remains below that regarded as permissible by the recommendation of September 1976 by the FAO/WHO committee of government experts;

However, such an additive is permitted in a number of EEC Member States, but not in several others, and furthermore the Directive of the Council of the 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, 1963-1964, p. 99) gives Member States the freedom to permit nisin as an additive or to prohibit it;

Must the requirements contained in the EEC Treaty regarding the freedom of movement of goods within the EEC, notwithstanding the provision in Article 36 of the Treaty regarding a prohibition which is justified on the grounds of the protection of health and the life of humans, be construed to the effect that a provision as contained in Article 8 (h) of the "Smeltkaasbesluit" containing a prohibition on the presence of additives, including nisin, in processed cheese other than those which the order permits or for which an exemption is granted, is incompatible with those requirements in its entirety or at least as regards the prohibition of adding nisin to processed cheese in respect of both home-produced cheese spread and cheese spread imported into the Netherlands; does it make any difference to the answer that as regards the addition of nisin to processed cheese such exemption is granted only for processed cheese which is clearly intended for export?"

The judgment making the reference was lodged at the Court Registry on 7 February 1980.

Pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were submitted by the Government of the Netherlands, represented by F. Italianer, Secretary-General at the Ministry for Foreign Affairs, acting as Agent, by the Government of the Federal Republic of Germany, represented by M. Seidel, Ministerial Adviser at the Federal Ministry for the Economy, and J. Sedemund, Rechtsanwalt, acting as Agents, and by the Commission of the European Communities, represented by P. Kuyper, acting as Agent and P. Oliver, acting as Assistant, both members of its Legal Department.

Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry.

By order of 2 July 1980 the Court decided to assign the case to the First Chamber under Article 95 (1) and (2) of the Rules of Procedure.

## II — Observations submitted pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC

The *Government of the Netherlands* first observes that although it is not possible to require an absolute guarantee of the innocuousness of a substance, which would in practice amount to the prohibition of any addition, it must nevertheless be reasonably certain that the additives to be used do not have adverse effects on public health.

Only rarely, if ever, is it possible to speak in absolute terms of the harmfulness or the innocuousness of a substance. On the one hand, there is scientific uncertainty regarding the harmful nature of this or that product, and, on the other hand, it must not be forgotten that substances which are relatively harmless by nature can have injurious consequences to health if taken in excess. Those reasons led the Netherlands authorities to pursue a restrictive policy so far as additions (of all kinds) to foodstuffs are concerned.

Having given a general outline of the laws through which that policy has been given expression, the Government of the Netherlands broaches the question which the Gerechtshof Amsterdam referred to the Court of Justice for a preliminary ruling in order to ascertain whether Article 8 (h) of the "Smeltkaasbesluit (Warenwet)" is compatible with Article 30 et seq. of the EEC Treaty.

Having regard to the specific case which gives rise to this question, it is necessary to consider both whether Article 8 cited above represents a measure having an effect equivalent to a quantitative restriction on exports and whether it constitutes a measure having an effect equivalent to a quantitative restriction on imports.

According to the Government of the Netherlands, the said provision does not have effects equivalent to those of a quantitative restriction on exports since products intended for export are exempted from the rules of the Smeltkaasbesluit by virtue of a decision of 19 August 1965, granting exemption, which was last amended by a decision of 14 May 1979. Furthermore, since none of the other Member States prescribes the addition to cheese of substances which are not authorized in the Netherlands, any impeding effect consisting in the possible need for a separate production line intended for export is also ruled out.

The contested provision may on the other hand represent a measure having an effect equivalent to a quantitative restriction on imports. Indeed, the possibility must not be ruled out that foreign producers' opportunities to import are directly or indirectly restricted because they require authorization in order to sell their products, to which a given substance has been added, on the Netherlands market.

Whether or not that is so, the provision in question may be justified, in the opinion of the Netherlands Government, on the basis of one of the interests mentioned in Article 36 of the EEC Treaty, in this case, "on grounds of the protection of health and life of humans, animals or plants".

Article 6 of Council Directive 64/54/EEC expressly leaves Member States free to authorize or not to authorize the addition of nisin to foodstuffs. The "Conserveermiddelenbesluit (Warenwet)", that is to say, the Netherlands order on preservatives, does not mention nisin as an authorized preservative. The Netherlands authorities adopted that attitude on the basis of the

consideration that, according to experts, the human body cannot absorb daily without danger a quantity of nisin exceeding 33 000 international units [0.78 milligrams] per kilogram of body weight. It is therefore necessary to ensure that that quantity is not exceeded in all the food which a person consumes daily.

Furthermore, it should be recalled that the Netherlands legislature is not the only one to have taken such a decision, as is shown by the fact that, for example, such a prohibition also exists in the Federal Republic of Germany.

The provision was not laid down in order to hinder trade under the guise of the protection of public health, nor does it involve arbitrary discrimination against persons of other Member States or between or amongst producers or importers.

A less radical form of intervention would not be effective. Rules whereby anything which is not expressly prohibited or restricted is to be regarded as authorized would not be adequate owing to the continual development of new additives. Equally, rules confined to a requirement that the substances added must be indicated on the packaging would be totally insufficient.

Finally, the prohibition is not absolute but merely constitutes the basic rule of a system of general and specific authorizations which allows flexibility in taking account of the needs of producers and importers, at least to the extent to which public health permits. Furthermore, in view of this the contested provision is consequently no more restrictive than public health requires.

The *Government of the Federal Republic of Germany* is of the opinion that the answer which must be given to the first part of the question referred to the Court of Justice is that national rules such as those described in the judgment making the reference are reconcilable with the provisions of the Treaty on the free movement of goods owing to the very fact that they satisfy the requirements of the protection of health and public policy and that neither their aim nor their effect is to favour national production or that of the domestic market of the Member State in question and thereby prejudice the production or trade of other Member States.

Indeed, on the basis of general considerations of a policy on health and food, it takes the view, that the first sentence of Article 36 of the EEC Treaty must apply even where an additive constitutes only a potential danger to the health of consumers.

The product which is the subject of the main proceedings, that is to say, nisin, belongs to what are called "food additives". It has been observed that a large, simultaneous increase in the use of food additives brings with it serious risks to the health of consumers. It is indeed possible that even a substance which is clearyl not harmful when considered in isolation may become dangerous owing to cumulative or combined effects when it is mixed with other chemical substances and compounds. Moreover, it must not be forgotten that those risks are all the more serious because the "combined effect" does not result only from the additives and extraneous substances added to a single product taken in isolation but from all the compound and extraneous chemical substances contained in all foodstuffs.

Acknowledgement of the existence of such risks has led to the adoption at both national and international level of rules designed to curb the use of food additives in the interest of health protection. Those rules, in general, only permit the use of additives which are necessary for technological reasons and which do not present a hazard to health. In nearly all countries whose laws on food and health are highly developed that principle, which was also adopted by the United Nations organizations concerned with food (FAO) and health (WHO), has led to the establishment of a system based on a general prohibition of additives coupled with "positive lists" on which substances appear which are authorized owing to their technical necessity and innocuousness. Both the Netherlands rules in question and the Community directives on additives are based on that system. The Community directives confer on Member States the right to restrict more severely the use of listed additives.

At all events, the Directive of 5 November 1963 reserves the decision concerning the authorization of the use of nisin to the Member States.

It is true that a document produced jointly by the FAO and the WHO, which was mentioned by the Court making the reference, declares nisin to be acceptable up to certain maximum amounts. Nevertheless, that document is based on limited experiments and does not therefore provide proof that nisin is harmless. In addition, it must be remembered that the quantity of an additive which is acceptable in a product cannot be determined absolutely. It is clear that the greater the consumption of the product the lower the permissible quantity of an additive added to the product must be. Countries such as the Netherlands and the Federal Republic of Germany, where the consumption of cheese is very high, are therefore obliged to adopt standards relating to the use of nisin which are more stringent than those adopted by countries where that food is consumed only to a lesser extent. Finally, the use of nisin is not necessary for technical reasons because it is possible to produce perfectly good processed cheese by microbiological means without adding nisin.

Since nisin is therefore unnecessary and may be harmful, the Federal Republic of Germany has continued to prohibit the use of the product.

In the opinion of the Federal Government there is no doubt that prohibitions of the use of additives, such as are laid down by national law and by Community law, are solely designed to ensure the protection of the health and life of consumers. Such measures do not pursue any economic objective; in particular, they are not intended to ensure that national production or the domestic market of the Member State concerned has a particular advantage, thereby prejudicing the production or trade of other Member States, and they therefore satisfy the negative requirements laid down by the second sentence of Article 36.

The "protection of health and life of humans" takes precedence over the free movement of goods. It is clear that the tests for judging that concept may differ somewhat from one country to another and from one period to another, depending on technological development, climate, dietary habits and the

degree of industrialization and ensuing pollution of the environment. In this respect, the concept cited above is similar to the concept of "public policy" which, as appears from the case-law of the Court of Justice, Member States may define very liberally according to their national needs.

The Federal Government's view that the determination of the limits within which a national legal system may ensure protection of health requires the allowance of a suitable area of discretion is in accordance with the case-law of the Court.

Indeed, the Court has confined itself to requiring that the national measures adopted in exercise of the powers provided for by Article 36 must be reasonable and intrinsically necessary and must not constitute discrimination.

The system on which the national rules are based conforms to the international development of the law and also to the principles of the Community legislation on food additives. It is therefore justified and necessary within the meaning of the case-law of the Court on Article 36.

Furthermore, that system is in accordance with the principle of proportionality since its objective of preventing the use of unnecessary additives in foodstuffs intended for human consumption cannot be achieved by measures which restrict intra-Community trade to a lesser extent.

Finally, the absence of any discrimination against products coming from other Member States and of any disguised restriction on trade between member States does not need to be proved since it is expressly acknowledged in the judgment making the reference.

For the sake of completeness, the Federal Government observes that, as has been shown, the restrictive effects of the Netherlands rules on the free movement of goods do not exceed "the effects intrinsic to trade rules" and in particular are not "out of proportion to their purpose". Those rules are not therefore to be counted amongst the measures hindering intra-Community trade such as are described by Commission Directive 70/50/EEC of 22 December 1969.

Finally, the Federal Government points out that the dispute which has given rise to the present case is comparable in essential respects with that which led to the reference for a preliminary ruling in Case 15/79, where the prohibition on the use of horse meat in the manufacture of sausages was also concerned, although in a wider sense, with the problem of the permissibility of certain ingredients of products intended for human consumption. If the grounds of the judgment in Case 15/79 are applied to the present case, it may be observed that the Netherlands rules limiting the use of food additives do not have as their object the specific restriction of the pattern of imports and exports, but apply objectively and without distinction and in particular are not directed towards conferring a special advantage on national production, thereby prejudicing the production or trade of other Member States.

On those grounds also it must be concluded that those rules are not contrary to the provisions of the Treaty.

With regard to the second part of the question, a reply is unnecessary. The Federal Government confines itself to the observation that the fact that exemption from the prohibition of use of nisin may be granted for exports in no way brings into question the compatibility of the prohibition with Community law. Furthermore, those exemptions are intended to permit exports to countries whose requirements with regard to health policy are less strict and are therefore capable only of furthering intra-Community trade.

The *Commission of the European Communities* first sets out the Netherlands legislation on additives and then examines the Community rules, in particular Article 6 of Council Directive 64/54/EEC on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption, which states that the Directive shall not affect provisions of national laws concerning nisin, and Article 22 of Regulation (EEC) No 804/68 on the common organization of the market in milk and milk products, which confirms the prohibition of any quantitative restriction or measure having equivalent effect between Member States.

Having thus described the legal position, the Commission considers the matter of the answer which should be given to the question raised by the court making the reference. It points out that since nisin is authorized in several Member States, the prohibition of the use of the product by a Member State involves a restriction of trade between Member States. Such restrictions are however not contrary to Community law where they prove necessary in order to satisfy imperative requirements, one of which is the protection of public health. In order to determine whether a prohibition of use is necessary for the protection of the public health it must first be established whether nisin is harmful. According to the Commission, that question must however be decided by the national courts themselves. In that event the burden of proof rests on the person who asserts that the restriction is justified on the ground of the protection of public health.

However, even if it were shown that the national measures prohibiting the use of nisin where contrary to the EEC Treaty, Eyssen could nevertheless not rely on that incompatibility.

In fact, Eyssen is not affected by the restrictions on imports since it does not import (not is it affected by the restrictions on exports, since there is a general exemption for products intended for export).

Nor may Eyssen claim "reserve discrimination", if the prohibition of the addition of nisin were regarded as inapplicable, because it were contrary to the Treaty, to imported products alone. According to the case-law of the Court, such discrimination in fact arises from the differences between the laws of the Member States and can only be eliminated by means of the approximation of the laws within the meaning of Articles 100 and 101 of the Treaty.

Consequently, the Commission suggests that the following answer should be given to the question raised by the court making the reference:

"A national measure which prohibits the addition of nisin to processed cheese is contrary to Article 22 of Regulation (EEC) No 804/68 and to Article 30 of the EEC Treaty where it is established

that nisin does not endanger human health. It is for the national court to decide that matter. A prohibition such as that referred to above is, however, not contrary to Community law and in particular to Articles 30 and 34 of the EEC Treaty in so far as it is restricted to national production intended for national market".

III — Oral procedure

Eyssen, represented by R. A. A. Duk of the Bar of The Hague, the Government of the Netherlands, represented by A. Bos, acting as Agent, assisted by Mr Van Der Heyde, in his capacity as an expert, the Government of the Federal Republic of Germany, represented by J. Sedemund, acting as Agent, assisted by L. Gross, in his capacity as an expert, and the Commission of the European Communities, represented by P. J. Kuyper, acting as Agent, assisted by A. Kinch in his capacity as an expert, presented oral argument at the hearing on 16 October 1980.

On that occasion Eyssen stated that the prohibition of the addition of nisin to cheese is incompatible with Article 30 of the EEC Treaty. It added that the exception embodied in Article 36 was applicable only if the Netherlands Government showed that nisin, in the concentration established in the present case, constituted a danger to health. That exception, however, plays no part in this case owing to the fact that, even though it had been proved that the product was relatively harmless, the Netherlands Government is prepared to authorize the addition of nisin only in the case of technological necessity for its use. Consequently the prohibition in question is undeniably contrary to the Treaty.

The Advocate General delivered his opinion at the sitting on 27 November 1980.

## Decision

1 By judgment of 13 Decembe 1979, which was received at the Court on 7 February 1980, the Gerechtshof Amsterdam referred to the Court of Justice for a preliminary ruling under Article 177 of the EEC Treaty a question on the interpretation of the provisions of the Treaty on the free movement of goods within the Community, in particular Articles 30, 34 and 36.

2 That question is raised in the course of criminal proceedings instituted by the Netherlands authorities against a Netherlands manufacturer which produces processed cheese both for sale on the domestic market and for export to other Member States and which is charged with having held in stock for the purposes of sale in the District of Alkmaar certain quantities of processed

cheese intended for sale and for human consumption containing an additive, namely nisin, which is not one authorized by the Netherlands law applicable in this case.

3 It appears from the papers in the case and from information given during the oral procedure that nisin is an antibiotic formed by certain types of lactic bacteria and occurs naturally in varying quantities in most varieties of cheese. It has the property of preserving the product for a longer period by retarding the process of deterioration due to the presence of butyric bacteria.

4 The provisions of national law with whose breach the manufacturer is charged are in particular those adopted pursuant to the Law on Goods ("Warenwet") of 28 December 1935, which empowers the Government to adopt legislative measures for the purpose of prohibiting the marketing or importation of certain goods under conditions other than those prescribed.

5 Adopted in pursuance of that Law, the General Order ("Algemeen Besluit") of 11 July 1949 provides, in Article 10 bis (1) thereof, that antibiotics may be added to drinks and foodstuffs only where the competent minister has authorized their use. As far as processed cheese is concerned, the addition of nisin is not provided for in either the "Kaasbesluit" [Cheese Order] of 7 November 1959 or the "Smeltkaasbesluit" [Processed Cheese Order] of 5 November 1959. Under Article 8 (h) of the "Smeltkaasbesluit", the presence in processed cheese of substances other than those expressly mentioned in Article 1 thereof and those authorized by the "Kaasbesluit" is prohibited.

6 However, by virtue of a government decision ("Vrijstellingsbeschikking") of 19 August 1965, last amended by decision of 14 May 1969, products intended for export are exempt form the prohibition resulting from those rules, including those laid down by the "Smeltkaasbesluit" of 5 November 1959.

7 When prosecuted under the Law on Economic Offences ("Wet op de Economische Delicten") of 22 June 1950 for a contravention of Article 8 (h) of the "Smeltkaasbesluit", the accused pleaded in particular that the quantities of nisin used in the present case did not present any danger to public health and that the addition of that substance to cheese was authorized in other Member States. From that the accused thus deduced that the

prohibition of the addition of nisin to processed cheese intended for the domestic market, which resulted from the provisions cited above, constituted a breach of the rules of the Treaty regarding the free movement of goods in the Community inasmuch as it amounted to a measure having an effect equivalent to a quantitative restriction within the meaning of Articles 30 to 36 of the Treaty.

8 In order to determine whether that submission was well-founded and thereby to decide the case, the Gerechtshof Amsterdam referred the following question to the Court of Justice:

"Must the requirements contained in the EEC Treaty regarding the free movement of goods within the EEC, notwithstanding the provision in Article 36 of the Treaty regarding a prohibition which is justified on the grounds of the protection of health and the life of humans, be construed to the effect that a provision as contained in Article 8 (h) of the "Smeltkaasbesluit" containing a prohibition on the presence of additives, including nisin, in processed cheese other than those which the order permits or for which an exemption is granted, is incompatible with those requirements in its entirety or at least as regards the prohibition of adding nisin to processed cheese in respect of both home-produced cheese spread and cheese spread imported into the Netherlands; does it make any difference to the answer that as regards the addition of nisin to processed cheese such exemption is granted only for processed cheese which is clearly intended for export?"

9 By that question, the national court is asking essentially whether the provisions of the Treaty relating to the free movement of goods within the Community must, having regard to Article 36 of the Treaty, be construed as meaning that they preclude national rules prohibiting the addition of nisin to products such as processed cheese and whether such a prohibition is compatible with the Treaty owing, in particular, to the fact that it applies only to products intended for sale on the domestic market and does not cover products intended for export to other Member States.

10 Consideration of the papers in the case and the information provided during the oral procedure show that the addition of nisin to processed cheese is not the subject of uniform rules in all the Member States. Whereas it is totally prohibited in domestic trade by certain Member States, such as the

Netherlands, it is permitted in other Member States without restriction or subject to prescribed maximum levels.

11 In view of this disparity of rules it cannot be disputed that the prohibition by certain Member States of the marketing on their territory of processed cheese containing added nisin is of such a nature as to affect imports of that product from other Member States where, conversely, the addition of nisin is wholly or partially permitted and that it for that reason constitutes a measure having an effect equivalent to a quantitative restriction.

12 However, although Articles 30 and 34 of the Treaty prohibit any quantitative restriction or measure having equivalent effect in trade between Member States, obstacles to intra-Community trade resulting from the disparity of national laws relating to the marketing of products are nevertheless permitted by Article 36 of the Treaty in so far as the provisions underlying those obstacles are justified on grounds of *inter alia* "the protection of health . . . of humans". However, the exemption on the aforementioned grounds from the application of Articles 30 and 34 of the Treaty which is provided for by Article 36 is permitted only on the express proviso, set out in the second sentence of Article 36, that the prohibitions or restrictions concerned shall not constitute "a means of arbitrary discrimination or a disguised restriction on trade between Member States".

13 There can be no dispute 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 interest of the protection of human health. In the particular case of the addition of nisin to products intended for human consumption, such as processed cheese, it is indeed accepted that the increasingly widespread use of that substance, not only in milk but also in numerous preserved products, has revealed the need, both at national level in certain countries and at international level, to study the problem of the risk which the consumption of products containing the substance presents, or may present, to human health and has led certain international organizations, such as the Food and Agriculture Organization of the United Nations and the World Health Organization, to undertake research into the

critical threshold for the intake of that additive. Although those studies have not as yet enabled absolutely certain conclusions to be drawn regarding the maximum quantity of nisin which a person may consume daily without serious risk to his health, this is essentially due to the fact that the assessment of the risk connected with the consumption of the additive depends upon several factors of a variable nature, including, in particular, the dietary habits of each country, and to the fact that the determination of the maximum quantity of nisin to be prescribed for each product must take account not only of the quantities of nisin added to a particular product, such as processed cheese, but also those quantities added to each of the other preserved products which are intended to satisfy those habits and in which the nisin content may vary in the case of similar products depending on their place of origin, the method of manufacture or the particular need in the market in question for a longer or shorter period of preservation.

14 The difficulties and uncertainties inherent in such an assessment may explain the lack of uniformity in the national laws of the Member States regarding the use of this preservative and at the same time justify the limited scope which the prohibition of the use of the additive in a given product, such as processed cheese, has in certain Member States, including the Netherlands, which prohibit its use in products intended for sale on the domestic market while permitting it in products intended for export to other Member States where the requirements for the protection of human health are assessed differently according to dietary habits of their own population.

15 Whilst it is true that the obstacles to which the disparity of the national laws on the subject give rise in intra-Community trade in the products concerned may be eliminated only by a uniform set of rules adopted at Community level, such rules do not exist at the present stage of Community law. Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for foodstuffs intended for human consumption (Official Journal, English Special Edition 1963-1964, p. 99) in fact merely provides in Article 6 thereof that the directive "shall not affect the provisions of national laws concerning: ... (b) nisin" and thus by implication allows the Member States to retain in relation to the matter in issue a discretionary power within the limits laid down by the general provisions of Article 36 of the Treaty.

16 From those considerations it follows that whilst it has the effect of hindering trade between Member States in the product concerned, national legislation, such as that referred to by the national court, prohibiting the use of nisin as a preservative in processed cheese intended for the domestic market is included amongst the measures which Article 36 of the Treaty permits Member States to adopt on grounds of the protection of health of humans and for that reason it escapes the prohibitions resulting from Articles 30 and 34 of the Treaty. In view of the uncertainties prevailing in the various Member States regarding the maximum level of nisin which must be prescribed in respect of each preserved product intended to satisfy the various dietary habits it does not appear that the prohibition laid down by such legislation in the case of processed cheese sold on the domestic market and excluding that intended for export to other Member States, constitutes a "means of arbitrary discrimination or a disguised restriction on trade between Member States" within the meaning of Article 36 cited above.

17 For those reasons the answer which must be given to the question raised is that the provisions of the EEC Treaty regarding the free movement of goods do not, at the present stage of Community rules on preservatives in foodstuffs intended for human consumption, preclude national measures by a Member State which, on the ground of the protection of health and in accordance with Article 36 of the Treaty, prohibit the addition of nisin to home-produced or imported processed cheese, even if they limit such a prohibition only to products intended for sale on the domestic market of that State.

## Costs

The costs incurred by the Government of the Netherlands, the Government of the Federal Republic of Germany and 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 pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (First Chamber),

in answer to the questions submitted to it by the Gerechtshof Amsterdam, hereby rules:

**The provisions of the EEC Treaty regarding the free movement of goods do not, at the present stage of Community rules on preservatives in foodstuffs intended for human consumption, preclude national measures by a Member State, which, on the ground of the protection of health and in accordance with Article 36 of the Treaty, prohibit the addition of nisin to home-produced or imported processed cheese, even if they limit such a prohibition only to products intended for sale on the domestic market of the said State.**

Koopmans O'Keeffe Bosco

Delivered in open court in Luxembourg on 5 February 1981.

A. Van Houtte
Registrar

T. Koopmans
President of the First Chamber

## OPINION OF MR ADVOCATE GENERAL WARNER DELIVERED ON 27 NOVEMBER 1980

*My Lords,*

This case comes before the Court by way of a reference for a preliminary ruling by the Gerechtshof of Amsterdam. It arises from the prosecution of a Dutch cheese manufacturer, the Koninklijke Kaasfabriek Eyssen BV (which I shall call "Eyssen"), for offences against Dutch