organization of the market in milk products or through harmonization of relevant national legislation, the Member States may prescribe the standards which products intended for human consumption must satisfy in their own territories. However, the national provisions in question cannot be exempt from the application of Article 30 et seq. of the Treaty.

3. The prohibition in Article 30 of measures having equivalent effect applies to all trading rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade.

   National legislation prohibiting the marketing of goods lawfully produced and marketed in the exporting Member State on the ground that they do not satisfy the microbiological requirements laid down in the importing Member State constitutes a measure equivalent in effect to a quantitative restriction within the meaning of Article 30 of the EEC Treaty.

4. National legislation which

   (a) does not allow active coliform bacteria to be present in a pasteurized milk product — the presence of such bacteria constituting a direct indication that the product may be a source of real danger to human health — and

   (b) is intended to prevent such a product from containing at the time of its consumption non-pathogenic micro-organisms in a quantity which may present a risk to the health of the most sensitive consumers and to that end fixes the maximum number of such micro-organisms that may be present on the date of sale of the product on the basis of its deterioration in the time between its sale and consumption

   complies with the requirements of Article 36 of the EEC Treaty.

In Case 97/83

REFERENCE to the Court under Article 177 of the EEC Treaty by the Hoge Raad der Nederlanden [Supreme Court of the Netherlands] for a preliminary ruling in the criminal proceedings against

CMC MELKUNIE BV, now called Melkunie Holland BV, having its registered office at Woerden,

on Articles 30 and 36 of the EEC Treaty with regard to the provisions of the Melkbesluit [Milk Order] of 25 October 1974 adopted pursuant to the Warenwet [Law on Goods] of 28 December 1935, as amended, laying down requirements as to the quality and description of goods,

THE COURT (Fifth Chamber)

composed of: Lord Mackenzie Stuart, President, Y. Galmot, President of Chamber, O. Due, U. Everling and C. Kakouris, Judges,

Advocate General: P. VerLoren van Themaat

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

A — National legislation applicable

The Melkbesluit [Milk Order] of 25 October 1974, adopted "in the interests of public health and fair trading" pursuant to Articles 14 and 16 of the Warenwet [Law on Goods] of 28 December 1935 laying down requirements as to the quality and description of goods [Staatsblad 1935, No 793], as amended, covers "pasteurized" and "sterilized" products and lays down the conditions they must satisfy.

Article 34 (2) of the Melkbesluit provides that the description "pasteurized" may be used only if products:

"(a) have undergone anti-microbial heat treatment or other treatment having the same anti-microbial effect; and

(b) on the premises where they were prepared were packed in containers closed with a firm seal which cannot be opened otherwise than by breaking the seal."

Article 34 (3) of the Melkbesluit provides that "pasteurized" products must satisfy the following requirements:

"(a) active coliform bacteria must not be detectable in one millilitre;

(b) the number of active micro-organisms must not exceed 50 000 per millilitre save in the case of

whipping cream, in which case that number must not exceed 200 000;

(c) no phosphatase must be present unless the product has undergone, instead of anti-microbial heat treatment, other treatment having the same anti-microbial effect."

Pasteurized products must bear the description "pasteurized" on their packaging (Melkbesluit, Article 34 (6)) and must also be kept and carried by the vendors at a temperature not exceeding 10° C (Melkbesluit, Article 43 (1)).

Requirements regarding the durability of pasteurized products are contained in the Algemeen Aanduidingenbesluit [General Description of Goods Order] (Warenwet) of 10 September 1981 (Staatsblad No 621). Article 4 (3) (c) read together with Article 10 of that order provides that pre-packed foods and drinks must bear the words "Best before ..." followed by the relevant date. If that date depends on the goods' being kept in a particular way, this must be stated.

Offences against those provisions are punishable under the Wet op de Economische Delicten [Law on Commercial Offences] of 22 June 1950 (Staatsblad No 258).

B — Origin and course of the main proceedings

Melkunie imported from the Federal Republic of Germany, for marketing and consumption in the Netherlands, milk products described on their packaging as pasteurized skimmed vanilla or caramel custard with whipped cream.

The Netherlands supervisory authority took samples in a number of areas of the product which Melkunie was holding for sale. Analyses carried out on five consignments between February and July 1980 revealed that on or immediately before the latest date for sale stated on the packaging of the product in question 9 000 000 active micro-organisms per millilitre were present in the first two consignments, 18 000 000 in the third, 90 000 000 in the fourth and 82 000 in the fifth, and active coliform bacteria were present in the third and fourth consignments.

In view of the results of those analyses, Melkunie was prosecuted before the Economische Politierechter [magistrate dealing with commercial offences] for holding in stock goods unfit for human consumption in contravention of the provisions of the Melkbesluit 1974 (Staatsblad, 699).

By a judgment of 16 April 1981, Melkunie was acquitted of the charges.

On appeal by the Openbaar Ministerie [Public Prosecutor's Department], the Gerechtshof [Regional Court of Appeal], Amsterdam, ordered Melkunie, by judgment of 7 May 1982, to pay five HFL 4 000 fines for "five offences committed by a corporate body against a provision adopted pursuant to Article 16 of the Warenwet".

Melkunie appealed against that decision to the Hoge Raad which decided to submit the following two questions to the Court of Justice:

"1. Must the provisions of the Melkbesluit (Warenwet) 1974, in particular the requirements which Article

34 (3) of that order places on goods described as 'pasteurized', namely that

(a) active coliform bacteria must not be detectable in one millilitre; and

(b) the maximum number of active micro-organisms must not exceed 50 000 per millilitre save in the case of whipping cream, in which case that number must not exceed 200 000;

be regarded as measures having an effect equivalent to quantitative restrictions on imports within the meaning of Article 30 of the EEC Treaty if they are applied in conjunction with the provisions referred to in part 6 of this judgment to goods imported from another Member State of the European Communities?

2. If Question 1 is answered in the affirmative, is the adoption of the requirements referred to in that question and their application to goods imported from another Member State of the European Communities none the less justified under Article 36 of the EEC Treaty on one of the grounds mentioned in that article and in particular on grounds of the protection of the 'health of humans'?"

In part 6 of its judgment the Hoge Raad states that, although contravention of the requirements laid down by the Melkbesluit 1974 is an economic offence within the meaning of the Wet op de Economische Delicten of 22 June 1950, the prohibitions in question were made pursuant to the Keuringsverordening [Inspection Regulations] of the municipality of Veenendaal, adopted under Article 6 of the Warenwet.

The judgment making the reference was registered at the Court on 27 May 1983.

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice, written observations were submitted by Melkunie, represented by R.A.A. Duk of the Hague Bar; the Netherlands Government, represented by I. Verkade, Secretary General at the Ministry of Foreign Affairs, acting as Agent; the Danish Government, represented by Laurids Mikaelsen, Legal Adviser at the Ministry of Foreign Affairs, acting as Agent; and the Commission of the European Communities, represented by its Legal Adviser, R. Casper Fischer, acting as Agent.

Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided, in accordance with Article 21 of the Statute and Article 45 of the Rules of Procedure, to conduct measures of inquiry.

By letter dated 15 December 1983, the Registrar of the Court asked the Commission to communicate before 20 January 1984 the text of the German legislation applicable to the products in question.

On 19 January 1984 the Commission produced the text of that legislation. In the observations attached to the documents it produced, the Commission states that it cannot say with any certainty which requirements of the German legislation were applicable to the products in question. The reason for this is that there is insufficient evidence in the file concerning in particular the composition of the products in question

and the circumstances in which they were exported to the Netherlands, and secondly that various aspects of the Federal German food legislation have been made the responsibility of the regional governments.

Whereas the Hoge Raad confined itself to the finding that the products in question were imported into the Netherlands from another Member State, Melkunie maintains that they conformed to the requirements of the legislation of the country from which they were exported and that those requirements are equivalent to the relevant Netherlands requirements. The Commission considers that, although the document dated 9 February 1981 annexed by Melkunie to its written observations does not support Melkunie's argument in any way, it does provide some guidance in answering the question asked by the Court.

In the Commission's view it is difficult to distinguish between the qualitative requirements and the health requirements laid down by the German legislation. Considering, however, that, in view of the evidence on file and the judgment making the reference, the preliminary questions concern only the protection of public health, the Commission confines its commentary to the relevant requirements of the German legislation. The extracts given to the Court are taken from Part A of "Lebensmittelrecht" [Food Law], by Walter Zipfel.

In accordance with Article 54 of the Rules of Procedure the date for the opening of the oral procedure was fixed for the end of the period in which the questions asked by the Court were to be answered.

By order of 14 December 1983 made pursuant to Article 95 (1) and (2) of the Rules of Procedure, the Court assigned the case to the Fifth Chamber.

II — Summary of the written observations submitted to the Court

Melkunie points out that the Melkbesluit 1974, which, without making any distinction between domestic and imported products, lays down the conditions under which milk products may be marketed in the Netherlands, is meant to satisfy the two requirements of fair trading and the protection of public health.

The first question

In Melkunie's view, it is clear from both the Commission's official views, expressed in the Communication concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 *(Rewe-Zentral AG* v *Bundesmonopolverwaltung für Branntwein* [1979] ECR 649, Official Journal C 256, 3. 10. 1980), and from that decision itself, confirmed by the judgments of 26 June 1980 in Case 788/79 *(Gilli and Andres,* [1980] ECR 2071), of 16 December 1980 in Case 27/80 *(Fietje,* [1980] ECR 3839) and of 19 February 1981 in Case 130/80 *(Kelderman,* [1981] ECR 527), that, even if the national legislation under which the prosecution is brought is a reasonable measure not immediately caught by the prohibition contained in Article 30 of the Treaty, no criminal sanction should be imposed if the product in question satisfies the conditions laid down by the legislation of the country of its origin.

Even if the conditions laid down by the exporting Member State and the importing Member State are not the same, a general prohibition of marketing the product cannot be justified if appropriate labelling, indicating that the product "derogates" from the national legislation in question, is sufficient to achieve the purposes of the importing Member State.

Melkunie points out that, although the Court will readily investigate whether a national measure is reasonable or not, it leaves it to the national court to decide whether such a measure should be applied where the goods in question satisfy equivalent conditions laid down by the legislation of the exporting Member State.

Melkunie suggests that the first question should be answered as follows:

"Application of the provisions referred to in this question to products imported from another Member State amounts to a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 of the EEC Treaty if the products satisfy the conditions applying to them in that other Member State and if those conditions are equivalent to the provisions in question. If that is not the case, it must be established that it was not possible to take sufficient account of the interests protected by those provisions by other less stringent measures, such as a provision requiring products to bear labels showing the differences between them and products complying with those provisions."

The second question

Melkunie's first point is that whether the Netherlands legislation is compatible with Article 36 is irrelevant, as the criminal proceedings brought against it are based upon a local regulation whose purpose is solely to protect consumers.

Its second point is that, by confining itself to the finding that Article 34 (3) of the Melkbesluit was dictated by the interests of public health, the Gerechtshof made the wrong or at any rate an inadequate inquiry in so far as it did not verify whether the provision in question could reasonably protect public health.

After stating that the purpose of pasteurizing milk and milk products is to kill micro-organisms present in the untreated product, Melkunie goes on to distinguish between pathogenic micro-organisms, the very presence of which makes the use of the products harmful to health, and "ordinary" bacteria which do not make the product unfit for consumption unless their growth, which is dependent in particular on the temperature at which the product is kept, exceeds a specific limit fixed by Article 34 (3) of the Melkbesluit within a period indicated by the latest date for sale. In the second case, it is necessary therefore to distinguish between the inevitable, gradual change in the product, which has no effect on human health, and its permanent deterioration.

Melkunie maintains that the number of micro-organisms present in a product on the latest date for sale provides no indication of the risk to health or of the efficacy of the pasteurization process.

Accordingly, Melkunie observes that, although the Gerechtshof apparently based its decision on paragraph 13 of the judgment of 5 February 1981 in Case 53/80 *(Kaasfabriek Eyssen,* [1981] ECR 409), in the present state of scientific knowledge it is not possible, except in the case of additives such as nisine, to establish "the maximum quantity of micro-organisms that man may absorb daily without serious risk".

It also observed that the number of micro-organisms present in a product depends not on the effectiveness of the pasteurization process, which a considerable number of micro-organisms always survive so long as the product is not sterilized, but on the conditions in which it is kept. In Melkunie's view it follows from these points, first, that the efficacy of the pasteurization process itself offers no guarantee for human health, and, secondly, that, if on the latest date for sale the number of micro-organisms exceeds the maximum permitted by law, this will mainly be due to the fact that the period between the date of production and the date for sale was too long and did not take into account the conditions (especially temperature) in which the product was or must be kept.

Melkunie suggests that the answer to the Hoge Raad's second question should be as follows:

"The requirement that goods of the kind in question in this case imported from the Federal Republic of Germany must satisfy the conditions laid down in Article 34 (3) of the Melkbesluit on the latest date for sale marked on their packaging is not justified on any of the grounds referred to in Article 36 of the EEC Treaty and, in particular, on the grounds of human health."

The *Netherlands Government* first sets out the main provisions of the legislation in question and the reasons for its adoption and then examines the question whether it is compatible with Community law.

1. The national legislation

After setting out the terms of Article 34 (3) of the Melkbesluit, the Netherlands Government observes that the purpose of the local regulations adopted pursuant to Article 6 of the Warenwet, which are the same in every municipality, is to "exclude" from the market, and thus to prohibit the sale of, products which, if used as intended, are harmful to human health, of poor quality or not in accordance with the conditions laid down by law or regulation.

The Netherlands Government points out first that, if the requirements laid down by those provisions are not met, the products are not immediately withdrawn from the market; the initial response of the authorities, especially where the product does not contain any

pathological micro-organisms and shows no organoleptic deviation from the norm, is merely to issue a warning or serve a cautionary summons so that production conditions or the treatment of the product are improved. In the case in point, sale of the product was never prohibited; summonses were served only after a warning had been given.

The second observation of the Netherlands Government is that, if the requirements laid down by Article 34 (3) of the Melkbesluit are not met, this does not make the sale or consumption of the product in question impossible, but it represents a potential danger to human health and indicates that hygiene was inadequate or not as good as it could be during the making of the product or thereafter. The purpose of Article 34 (3) of the Melkbesluit is to prevent the consumer from being offered products which may be either a threat to his health or not of the quality (as regards colour, smell, taste) which he is entitled to expect of a food product.

The decisive test in this regard is whether a product has been, or may very quickly become, contaminated by pathogenic bacteria, which will be indicated by the presence of coliform bacteria. The deterioration of the product depends on the number of micro-organisms it contains and is due to the effect of the substances they secrete.

The maximum number of micro-organisms permitted by the Melkbesluit for the purposes of establishing the general bacteriological state of a product is not only an objective but also a reasonable test. The number of micro-organisms specified in Article 34 (3) of the Melkbesluit was fixed on the basis of two criteria:

The first was the number of micro-organisms which may reasonably be expected to exist in a product which has been manufactured, carried and stored prudently and the threshold beyond which there is a risk that the product will become contaminated by pathogenic micro-organisms.

The second was that after the latest date for sale has passed the consumer should be allowed a reasonable period (about two days) to consume a product before its organoleptic qualities deteriorate. As the rate at which micro-organisms multiply when the product is kept in a refrigerator is known, the number of such organisms existing on the product's latest date for sale was fixed at 50 000, a figure which guarantees that the product will be in a reasonable state of conservation for the following two days.

By requiring the product's latest date for sale to be shown it is possible to determine not only the efficacy of the pasteurization process but also whether carriage and storage has affected the product in such a way as to make it unacceptable.

The Netherlands Government considers any other test based solely on a product's organoleptic qualities inadequate because it may give a satisfactory result despite

the existence of micro-organisms whose presence may be difficult to detect owing to the addition of substances to improve the product's taste, colour and aroma, and because such a test enables the state of the product to be determined only at the time of examination and does not indicate how it may develop in the future.

2. Whether the Netherlands legislation is compatible with Article 30 et seq. of the EEC Treaty

According to the Netherlands Government, the point at issue in both of the questions submitted by the Hoge Raad is simply whether the provisions in question, which apply to domestic and imported products alike, are compatible with Articles 30 and 36 of the EEC Treaty.

Referring to the judgment of 11 July 1974 in Case 8/74 *(Dassonville* [1974] ECR 837), the Netherlands Government states that, although the provisions in question may constitute obstacles to imports, such obstacles are permissible first under Article 36 of the Treaty if they are justified on grounds of, in particular, the protection of public health and secondly by virtue of the "reasonableness rule" implied in the Court's interpretation of Article 30 of the Treaty if the obstacles are justified by considerations of public interest including, for example, the protection of consumers.

Although in its written observations it concentrates mainly on the public health aspects, the Netherlands Government is not explicitly relying on one or the other possible grounds of justification afforded by Articles 30 and 36 of the Treaty. Nevertheless it reserved the right to return to this point at the oral stage of the procedure. Either way, it considers that the Melkbesluit, the provisions of which are necessary and justified, is compatible with the Treaty in so far as it ensures that products consumed are acceptable and harmless.

The *Danish Government* considers that national legislation governing the maximum bacteriological count in food products is justified by a number of considerations.

In the first place, the absence of Community harmonization leaves Member States a wide discretion and entitles them to lay down standards which products intended for human consumption must satisfy, subject to fines or a prohibition of sale for failure to comply. The freedom of action of the Member States is particularly justified where, as may be seen in this case, scientific investigation does not make it possible to determine with sufficient accuracy the bacteriological thresholds beyond which health may be endangered and consequently the strict rules of hygiene which must be observed throughout the production and marketing of a product.

The Danish Government observes, secondly, that, in view of Articles 30 and 36 of the Treaty and the decisions of the Court, the Netherlands legislation in question can be justified on a number of grounds.

As regards first Article 36 of the Treaty, the Danish Government states that the exception concerning the protection of

health and life of humans covers not only legislation designed to exclude direct, specific risks but also legislation adopted as a preventive measure whereby the sale of products presenting a potential risk may be prohibited. In the judgment given on 19 February 1981 in Case 130/80 (*Kelderman*, cited above) the Court accepted, moreover, that even in situations in which the life and health of persons are not directly affected some grounds may be legitimate.

Next, as regards Article 30, the Danish Government observes that the Court has held that measures justified on general grounds of the protection of public health, fair trading and consumer protection do not constitute measures having an effect equivalent to quantitative restrictions if they are "reasonable", that is to say, not discriminatory and limited to what is absolutely necessary.

Accordingly, the Danish Government submits that in view of the general interests of consumers it is legitimate that Member States should be able by legislation to exclude from the market food products which do not merit that description. In its view, provisions of that nature should apply both to domestic and imported products in order to avoid a lowering of hygiene standards achieved after perhaps many years of effort by the authorities and the producers.

The Danish Government observes secondly that, in view of the requirements which the national legislation in question satisfies, rules requiring no more than appropriate labelling would be both insufficient and unsatisfactory in so far as they would be more burdensome for industry and commerce than simply having to comply with specific rules and would make the selling of products more difficult; they might also give rise to indirect discrimination between domestic and imported products.

The Danish Government suggests that the questions submitted by the Hoge Raad should be answered as follows:

"The laying down by a Member State, for the purposes of protecting human health, fair trading and the interests of consumers, of maximum bacteriological counts for milk products for which there are as yet no Community rules is compatible with Article 30 of the Treaty prohibiting quantitative restrictions on imports."

The *Commission* considers that, in order to ascertain whether the provisions in question are compatible with Articles 30 and 36 of the Treaty, it is necessary to determine whether their purpose is solely to ensure fair trading or whether they are partly or solely dictated by the interests of public health.

The fact that the Hoge Raad cites only Article 16 of the Warenwet as the legal basis of the Melkbesluit seems to indicate that, like the Gerechtshof and the Openbaar Ministerie, the Hoge Raad considers that the sole purpose of the Melkbesluit is to protect public health.

The first question

Having regard to the established case-law of the Court, the Commission states that, in view of the absence of harmonization in the Community and the differences between the laws of the Member States governing the marketing of food products, it is inevitable that all the provisions of the Melkbesluit constitute obstacles to trade. In the Commission's view, these are due not so much to the requirement of pasteurization itself, which in view of the nature of the products in question is probably to be found in the corresponding legislation of all the Member States, as to the microbiological and other standards that pasteurized products must meet from the time of their preparation to their consumption.

In the Commission's view the answer to the first question may be put as follows:

"The application by a Member State to goods lawfully produced and marketed in another Member State of legislation providing that certain milk products may not be marketed unless they are pasteurized and meet specific microbiological standards constitutes a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 of the EEC Treaty."

The second question

The Commission's first observation is that the microbiological aspects of the production and marketing of milk and milk products have not been regulated by the Community legislature either within the market organization for milk products or by the harmonization of national legislation in this sector. It is therefore open to the Member States to legislate on these questions in their own territory.

The Commission's second point is that in order to rely on Article 36 of the Treaty the importing Member State cannot simply state or demonstrate that its legislation is necessary to protect a public interest recognized by that provision; it must demonstrate that the legislation of the exporting Member State does not ensure, or adequately ensure, the protection of the public interest in question, in this case public health, and consequently that protection of that interest requires its own legislation to be extended to the imported products as well. The position of the Netherlands Government on this point is inadequately reasoned or at any rate not fully explained.

On the same point, the Commission notes that, in the judgment referred to the Hoge Raad, the Gerechtshof held that "the fact that other EEC countries may set lower requirements ... does not alter matters ... consumer habits, particularly as regards the quantity in which the product is consumed, are relevant to the requirements to be imposed as regards the number of micro-organisms present and those habits may vary from country to country".

Although this argument has quite rightly been accepted by the Court as regards the incorporation into food products of certain additives such as preservatives and vitamins (judgment of 5 February 1981 in Case 53/80 *Kaasfabriek Eyssen*, cited above, and of 14 July 1983 in Case 174/82 *Sandoz* [1983] ECR 2445), it is untenable in this case once it is accepted, as the Gerechtshof does, that the number

of micro-organisms present is no indication of the efficacy of the pasteurization process and also that the maximum of 50 000 active micro-organisms per millilitre is well below the critical level for public health, which is of the order of one to two million.

In this regard, the Commission contends that the two microbiological standards in question do not relate to public health in the same way and do not necessarily signify effective pasteurization.

As regards the first requirement imposed by the Melkbesluit, the Commission points out that, although the presence of active coliform bacteria in a pasteurized product is evidence of the presence of pathogenic micro-organisms and is therefore a direct indication that the product may endanger health, this danger may be due to poor pasteurization or external contamination after pasteurization.

Although, in the Commission's view, the first requirement appears justified within the meaning of Article 36 of the Treaty, the question remains whether the Netherlands is entitled to apply this relatively strict requirement to products from a Member State which applies a somewhat less stringent test, such as the absence of coliform bacteria in 0.1 millilitre of the product. In this regard, the Netherlands authorities should either demonstrate that their requirements are indispensable for the protection of public health, which is a question of fact for the national court to decide, or, failing this, allow importation of the products in question.

As regards the second requirement laid down by the Melkbesluit, the Commission states that the maximum of 50 000 active micro-organisms per millilitre of product is too low to present a real risk to health. Although there are considerable differences in national legislation on this point (in France the maximum is 30 000 per millilitre on leaving the pasteurization plant, whilst in the Federal Republic of Germany the maximum for imported pasteurized milk on leaving the dairy is 100 000 per millilitre, with no maximum for other milk products), the Commission considers that there is a real risk to health only where the concentration of active micro-organisms reaches one to two million per millilitre, a level at which they secrete dangerous quantities of toxic substances.

As a test of effective pasteurization, the second requirement creates at most a presumption in so far as the aim of pasteurization is essentially to reduce the number of pathogenic organisms, that is to say coliform bacteria, to a level at which they no longer represent any significant danger to health. It therefore seems that, in the absence of coliform bacteria in a pasteurized product, a higher concentration may be due to the presence of a higher number of micro-organisms before pasteurization.

The Commission's final point is that the Netherlands authorities established the offences about 14 days before the latest date for sale of the product by simply applying the two tests in question,

without at the same time analysing the product so as to determine its microbiologial condition and the danger it presented to public health.

In the Commission's view, the testing method adopted shows, if not that the latest date for sale is inappropriate, at least that the method fails to take account of the fact that the microbiological condition of a pasteurized milk product, properly kept and carried, inevitably deteriorates with the passage of time and much more quickly than sterilized products in which, because they are heated to 100° C, all the microorganisms are killed. That is why legislation in some countries requires pasteurized products to meet the prescribed microbiological standards at the end of the pasteurization process.

The application of such a measure in its entirety to imported products cannot be removed from the ambit of Article 30 of the Treaty by invoking Article 36. The Commission therefore suggests that the second question should be answered as follows:

"The application by a Member State of the national legislation referred to in the first question to products lawfully produced and marketed in another Member State may be considered justified on grounds of the protection of public health within the meaning of Article 36 of the EEC Treaty in so far as it is shown:

(i) That it is necessary for the protection of that public interest, in particular because the legislation applicable to those products in the exporting Member State does not afford sufficient guarantees for the protection of public health in the importing Member State, and

(ii) That it was not possible to protect that interest sufficiently by other measures less restrictive to imports of the products in question, in particular by appropriate cooperation between the competent authorities of the Member States concerned.

Whether and the extent to which it has been shown that the microbiological standards applicable to the marketing of pasteurized milk products and referred to in the first question are justified on grounds of the protection of public health and that their application to imported products accords with the principles set out above is in this case for the national court to decide."

III — Oral procedure

At the sitting on 29 February 1984 Melkunie, represented by R. A. A. Duk of the Hague Bar, the Netherlands Government, represented by D. J. Keur, acting as Agent and the Commission of the European Communities, represented by R. C. Fischer, acting as Agent, presented oral argument.

The Advocate General delivered his opinion at the sitting on 11 April 1984.

Decision

1 By a judgment dated 10 May 1983, which was received at the Court on 27 May 1983, the Hoge Raad referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty two questions on the interpretation of provisions of the EEC Treaty concerning the free movement of goods within the Community.

2 The questions arose in the course of criminal proceedings brought against a Netherlands importer for holding in stock milk products unfit for human consumption, contrary to the Melkbesluit [Milk Order] of 25 October 1974. That order, which was adopted pursuant to Articles 14 and 16 of the Warenwet [Law on Goods] of 28 December 1935, laying down requirements as to the quality and description of goods (Staatsblad 1935, No 793), as amended, prescribes the conditions that pasteurized and sterilized products must satisfy in order to be marketed in the Netherlands.

3 Article 34 (3) of the Melkbesluit provides that on the latest date for sale pasteurized milk products must satisfy *inter alia* the following requirements:

"(a) active coliform bacteria must not be detectable in one millilitre;

(b) the number of active micro-organisms must not exceed 50 000 per millilitre save in the case of whipping cream, in which case that number must not exceed 200 000; . . .".

4 Analyses carried out by the Netherlands supervisory authority of five consignments imported from the Federal Republic of Germany for marketing in the Netherlands revealed that on or immediately before the latest date for sale stated on the packaging of the product in question 9 000 000 active micro-organisms per millilitre were present in the first two consignments,

18 000 000 in the third, 90 000 000 in the fourth and 82 000 in the fifth, and active coliform bacteria were present in the third and fourth consignments.

5 After being acquitted of the charges by a judgment of the Economische Politierechter [magistrate dealing with commercial offences] of 16 April 1981, Melkunie was ordered by a judgment of 7 May 1982 of the Gerechtshof [Regional Court of Appeal], Amsterdam, to pay five HFL 4 000 fines for "five offences committed by a corporate body against a provision adopted pursuant to Article 16 of the Warenwet".

6 Melkunie appealed against that decision to the Hoge Raad, which stayed the proceedings and submitted the following questions to the Court of Justice for a preliminary ruling:

"1. Must the provisions of the Melkbesluit (Warenwet) 1974, in particular the requirements which Article 34 (3) of that order places on goods described as "pasteurized", namely that:

(a) active coliform bacteria must not be detectable in one millilitre; and

(b) the maximum number of active micro-organisms must not exceed 50 000 per millilitre save in the case of whipping cream, in which case that number must not exceed 200 000;

be regarded as measures having an effect equivalent to quantitative restrictions on imports within the meaning of Article 30 of the EEC Treaty if they are applied in conjunction with the provisions referred to in part 6 of this judgment to goods imported from another Member State of the European Communities?

2. If Question 1 is answered in the affirmative, is the adoption of the requirements referred to in that question and their application to goods imported from another Member State of the European Communities none the less justified under Article 36 of the EEC Treaty on one of the grounds mentioned in that article and in particular on grounds of the protection of the 'health of humans'?"

7 Although the Court has no jurisdiction in proceedings under Article 177 of the EEC Treaty to rule on the question whether provisions of national

legislation are compatible with the Treaty, it may provide the national court with all such criteria for the interpretation of Community law which may enable it to answer that question.

8 Accordingly, it must be assumed that the Hoge Raad wishes to know:

whether national legislation prohibiting the marketing of pasteurized products lawfully produced and marketed in the exporting Member State on the ground that they do not satisfy the microbiological requirements of the importing Member State constitutes a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 and, if so,

in what circumstances does Article 36 of the Treaty allow such a restriction on imports on the grounds of the protection of health and life of humans.

The first question

9 It should be pointed out that the Community legislature has not laid down microbiological requirements affecting the production and marketing of milk and milk products either within the common organization of the market in milk products or through harmonization of relevant national legislation.

10 Although the Member States may therefore prescribe the standards which products intended for human consumption must satisfy in their own territories, the national provisions in question cannot be exempt from the application of Article 30 et seq. of the Treaty. According to a consistent line of decisions of the Court, the prohibition in Article 30 of measures having equivalent effect applies to all trading rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade.

11 Consequently, the answer to the first question must be that national legislation prohibiting the marketing of goods lawfully produced and

marketed in the exporting Member State on the ground that they do not satisfy the microbiological requirements laid down in the importing Member State constitutes a measure equivalent in effect to a quantitative restriction within the meaning of Article 30 of the EEC Treaty.

The second question

12 According to a consistent line of decisions of the Court, it follows from Article 36 that a national measure which has, or may have, a restrictive effect on trade is compatible with the Treaty only in so far as it is necessary for the purpose of effectively protecting human life and health. The proviso in Article 36 cannot therefore apply where human life and health can be protected just as effectively by measures less restrictive of intra-Community trade.

13 In this connection, Melkunie points out, first, that the product in question complied with the requirements of the legislation of the exporting Member State and that that legislation provides the same safeguards as the legislation of the importing Member States. Consequently, the requisite cooperation between Member State ought to induce the importing Member State to require no more than that the imported products should comply with the standards of the exporting Member State. Secondly, it contends that legislation of the Netherlands type cannot be justified under Article 36 since it goes beyond what is required by a strict concern to safeguard public health.

14 As far as Melkunie's first argument is concerned, it should be pointed out that, whilst it is true, as the Court has held many times, for example in its judgment of 8 February 1983 in Case 124/81, *Commission of the European Communities* v *United Kingdom,* [1983] ECR 203, that cooperation between the authorities of the Member States makes it possible to facilitate and simplify frontier checks whilst not precluding the authorities of the importing Member State from satisfying themselves that the goods imported comply with the requirements of that State's health legislation, none the less such cooperation cannot impair the right of each individual Member State to enact and apply its own legislation to protect public health. Such legislation

is compatible with the Treaty if the requirements of Article 36 are fulfilled. To this end, it must be shown that the standards are necessary for the effective protection of the health and life of persons residing in the importing Member State and do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

15 As regards the question whether the rules laid down by the Melkbesluit are justified in the light of Article 36 of the Treaty, it appears first of all from the documents before the Court that the presence of active coliform bacteria in a milk product means that there is a risk of pathogenic micro-organisms being present and is therefore a direct indication that the product may be a source of real danger to human health. A requirement which seeks to exclude the presence of any active coliform bacteria in such a product must therefore be regarded as justified within the meaning of Article 36 of the Treaty.

16 As regards the second requirement, laying down the maximum permissible number of active non-pathogenic micro-organisms, Melkunie and the Commission first point out that, in the present state of scientific knowledge, it is not possible to establish the maximum quantity of such micro-organisms that man may absorb every day without serious risk. They go on to state that it is only where the concentration of such micro-organisms reaches one or two million per millilitre of the product in question — much higher than the maximum level of 50 000 stipulated by the Melkbesluit — that there is possibly a risk to human health. Finally, they consider that to stipulate the maximum number of non-pathogenic micro-organisms that may be present on the latest date for sale of a pasteurized product is excessively strict and that it would be sufficient to apply a requirement of that kind at the end of the pasteurization process.

17 It must first be noted that, according to the documents before the Court, the Member States which lay down a maximum limit for non-pathogenic micro-organisms stipulate levels of the same order of magnitude as the figure of 50 000 laid down by the Melkbesluit, even though that requirement is applied at different marketing stages.

18 Secondly, the data available at the present stage of scientific research do not make it possible to determine with certainty the precise number of non-pathogenic micro-organisms above which a pasteurized milk product becomes a source of danger to human health. In the absence of harmonization in this field, it is for the Member States to determine, with due regard to the requirements of the free movement of goods, the level at which they wish to ensure that human life and health are protected. In those circumstances, national legislation seeking to ensure that at the time of consumption the milk product in question does not contain micro-organisms in a quantity which may constitute a risk merely to the health of some, particularly sensitive consumers, must be considered compatible with the requirements of Article 36.

19 Lastly, in assessing the validity of a rule laying down the maximum number of micro-organisms that may be present in milk products — not on the date of their consumption but on the latest date for their sale — it is also legitimate, as the Netherlands Government maintains, to take account of national consumption habits, such as keeping such products for a period of time in less suitable conditions than those in the distributor's plant before consuming them. When assessing the validity of the requirement at issue, it is proper therefore for the national court to take account of the rate at which the micro-organisms multiply during the time which generally elapses between the sale of such products and their consumption.

20 The second question must therefore be answered as follows. National legislation which:

(a) does not allow active coliform bacteria to be present in a pasteurized milk product, and

(b) is intended to prevent such a product from containing at the time of its consumption non-pathogenic micro-organisms in a quantity which may present a risk to the health of the most sensitive consumers and to that end fixes the maximum number of such micro-organisms that may be

present on the date of sale of the product on the basis of its deterioration in the time between its sale and consumption

complies with the requirements of Article 36 of the EEC Treaty.

Costs

21 The costs incurred by the Danish Government, the Netherlands Government 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 (Fifth Chamber),

in answer to the questions referred to it by the Hoge Raad by judgment of 10 May 1983, hereby rules:

1. **National legislation prohibiting the marketing of goods lawfully produced and marketed in the exporting Member State on the ground that they do not satisfy the microbiological requirements laid down in the importing Member State constitutes a measure equivalent in effect to a quantitative restriction within the meaning of Article 30 of the EEC Treaty;**

2. **National legislation which:**

   (a) **does not allow active coliform bacteria to be present in a pasteurized milk product, and**

   (b) **is intended to prevent such a product from containing at the time of its consumption non-pathogenic micro-organisms in a quantity which may present a risk to the health of the most sensitive**

consumers and to that end fixes the maximum number of such micro-organisms that may be present on the date of sale of the product on the basis of its deterioration in the time between its sale and consumption

complies with the requirements of Article 36 of the EEC Treaty.

Mackenzie Stuart Galmot

Due Everling Kakouris

Delivered in open court in Luxembourg on 6 June 1984.

For the Registrar

H. A. Rühl

Principal Administrator

Y. Galmot

President of the Fifth Chamber

OPINION OF MR ADVOCATE GENERAL VERLOREN VAN THEMAAT DELIVERED ON 11 APRIL 1984 [1]

Mr President,
Members of the Court,

With this reference for a preliminary ruling made by the Hoge Raad [Supreme Court] in the criminal proceedings brought against the firm to which I shall refer as Melkunie the Court is once again confronted with the question how far provisions of Netherlands food legislation may conflict with Articles 30 and 36 of the EEC Treaty. Before discussing the facts I shall first review the Netherlands legislation applicable to milk and milk products which is at issue in this case.

1. The relevant legislation on milk and milk products

Netherlands food legislation is mainly based on the Warenwet [Law on Goods] of 28 December 1935 laying down

1 — Translated from the Dutch.