OPINION OF ADVOCATE GENERAL GULMANN
delivered on 8 April 1992 *

Mr President,
Members of the Court,

1. These three cases have been brought by the Commission under Article 169 of the EEC Treaty and concern the ban, in Italy, Greece and France, on the importation and marketing of cheeses to which nitrate has been added at the manufacturing stage.

In all three cases the Commission claims that, by prohibiting the importation of cheeses lawfully produced and marketed in other Member States to which nitrates have been added during the manufacturing process within limits recognized by international scientific opinion as acceptable (50 mg per kg), the Member States in question have failed to fulfil their obligations under Article 30 of the EEC Treaty.

The Kingdom of Spain intervened in the case against France in support of the Commission.

The three Member States have contended that the applications should be dismissed.

2. An account of the legislation in the three Member States is contained in the Reports for the Hearing. It can be summarized as follows:

— in all three Member States there is a prohibition against manufacturing foodstuffs with additives and marketing such foodstuffs unless the additives in question are expressly authorized;

— none of the three Member States has authorized the use of nitrate in the manufacture of cheese and accordingly the marketing of cheese to which nitrates have been added is prohibited in the three Member States;

— according to information from the Member States, that prohibition is only applied to imported cheeses if the nitrate content exceeds a certain tolerance threshold corresponding to what the Member States consider to be natural res-

* Original language: Danish.

idues of nitrate in cheese, which, in the case of Italy, is 2 mg per kg, in the case of Greece 10 mg per kg, [1] and in the case of France 15 mg per kg.

The harmonization directives on the subject

3. Nitrate is referred to in the annex to Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorised for use in foodstuffs intended for human consumption. [2] The Court has had occasion to interpret Directive 64/54/EEC many times and has decided that if an additive is included in the list in the annex to the directive that indicates that the Member States may authorize the use of the substance in question but is not obliged to do so. Most recently, in its judgment of 13 December 1990 in the *Bellon* [3] case, the Court stated:

'According to its preamble, the directive is merely the first stage in the approximation of national laws in that field. At this stage, therefore, Member States are not obliged to authorize the use of all the substances listed in the annex to the directive. However, their freedom to determine their own rules concerning the addition of preservatives to foodstuffs may be exercised only subject to the twofold condition that no preservative not listed in the annex to the directive may be authorized for use and that the use of a preservative which is listed there may not be totally prohibited except, in the case of foodstuffs produced and consumed within their own territory, in special cases where the use of such a preservative does not meet any technological need ...' (paragraph 9). [4]

Let me say right away that the condition to the effect that nitrate may not be completely prohibited does not give rise to difficulty in the present cases since the three Member States permit the addition of nitrate to meat products.

As is shown in the paragraph cited above, the Court attaches weight to the fact that Directive 64/54/EEC constitutes only the first stage in the approximation of the laws on preservatives. Complete harmonization in this area has not yet been accomplished. The Council has adopted Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member

1 — Greece maintains that the limit is in practice 15 mg. The Commission claims that Greece may not contend that a limit set by an express provision is departed from in practice. I see no reason to enter any further into that debate.
In particular in the Greek case there was discussion over how far a tolerance threshold applies only to the natural occurrence of nitrate in cheese or also to added nitrate. The Greek Government claimed that it applies regardless of the fact that the provisions in question expressly state that the tolerance threshold only applies to 'substances that are naturally present'. The Greek Government's argument is that it is not possible to determine the substance's origin by analysis. The Commission indicated that it is possible to check whether nitrate has been added to cheese by other methods and that the tolerance threshold must therefore be regarded as applying to natural residues of nitrate.
I do not think it necessary to enter any further into that debate. The question to be decided by the Court in these cases is whether the three Member States are entitled to refuse to allow the importation of cheeses to which up to 50 mg of nitrate have been added in the manufacturing process. In this connection it is only of secondary importance whether the Member States allow, in principle, the importation of cheese to which certain lower quantities of nitrate have been added or completely prohibit the import of cheese to which nitrate has been added.

2 — OJ, English Special Edition 1963-1964, p. 99.

3 — Case C-42/90 *Bellon* [1990] ECR I-4863.

4 — See also the judgments in Cases 88/79 *Grunert* [1980] ECR 1827 and 108/80 *Kugelmann* [1981] ECR 433.

States concerning food additives authorized for use in foodstuffs intended for human consumption, [5] but the directive is merely a framework directive which requires directives to be drawn up with lists of the authorized additives, the foodstuffs in which those additives may be used and the conditions for their use.

The position is that until that harmonization is achieved, the Member States are entitled to lay down their own rules as regards nitrate as an additive in foodstuffs.

4. However, it is also clear from the settled case-law of the Court that application of Article 30 of the Treaty is not excluded even where harmonization directives have been adopted and that the basis for applying Article 36 will only be removed when Community directives prescribe complete harmonization of all the measures necessary to ensure the protection of health and establish Community procedures for supervising compliance with those measures. [6]

National legislation which lays down rules for the marketing of cheese manufactured with added nitrate is therefore only valid if it complies with Articles 30 and 36 of the Treaty.

Do the national rules constitute an obstacle to trade within the meaning of Article 30?

5. The Commission has stated that eight other Member States permit nitrate to be added in the manufacture of certain cheeses. [7] In most cases a maximum limit of 50 mg per kg of cheese is set, but in certain situations a nitrate content of up to 150 mg per kg cheese is permitted.

The prohibitions at issue in these cases is therefore said to be capable of hindering the importation of cheese lawfully produced in other Member States and thus constitute measures which 'are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade'. [8] The national rules are therefore covered by Article 30 of the Treaty prohibiting all quantitative restrictions and measures having equivalent effect in trade between Member States.

6. In this connection France and Greece have claimed that the existing tolerance thresholds make it possible for most cheeses to be imported. According to the consistent case-law of the Court such a circumstance is irrelevant when it can be established that rules in the importing State impede the importation of goods lawfully produced in

5 — OJ 1989 L 40, p. 27

6 — See the judgments in Case 247/84 *Motte* [1985] ECR 3887, at paragraph 16, in Case 304/84 *Muller* [1986] ECR 1511, at paragraph 14, and Case C-42/90 *Bellon*, at paragraph 10, see footnote 3 above.

7 — Luxembourg prohibits the use of nitrate in the manufacture of cheese in Luxembourg, but allows the marketing of cheese lawfully manufactured in other Member States using nitrate.

8 — See the judgment in Case 8/74 *Dassonville* [1974] ECR 837.

other Member States. France further pointed out that imports from the Netherlands to France increased even for cheeses which, under Netherlands manufacturing rules, may be manufactured with added nitrate, and claimed that that shows that the prohibition at issue does not constitute a barrier to trade. The Court's case-law shows clearly that that circumstance cannot be regarded as relevant. [9]

Are the national rules justified on public health grounds under Article 36?

7. The crucial question in these cases is therefore whether the prohibitions against the marketing of cheese with added nitrate is justified with regard to the protection of human health under Article 36.

In a whole series of cases the Court has laid down the basic principles for assessing whether a prohibition against marketing products manufactured with additives is in conformity with Article 36 of the Treaty. [10] The Court's most recent judgment in the *Bellon* case [11] summarizes the case-law as follows:

'It must be borne in mind that, as the Court has consistently held ... in so far as there are uncertainties in the present state of scientific research, it is for the Member States, in the absence of harmonization, to decide what degree of protection of the health and life of humans they intend to assure, having regard, however, for the requirements of the free movement of goods within the Community.

It is also clear from the Court's case-law ... that in those circumstances *Community law does not preclude* the adoption by the Member States of *legislation whereby the use of additives is subjected to prior authorization* granted by a measure of general application for specific additives, in respect of all products, for certain products only or for certain uses. Such legislation meets a *genuine need of health policy*, namely that of *restricting the uncontrolled consumption of food additives.*

However, the application to imported products of prohibitions on marketing products containing additives which are authorized in the Member State of production but prohibited in the Member State of importation is permissible only in so far as it complies with the requirements of Article 36 of the Treaty as it has been interpreted by the Court.

It must be borne in mind that in its judgments in Case 174/82 *Sandoz*, Case 247/84, *Motte*, Case 304/84, *Ministère Public* v

9 — See, for example, Case 12/74 *Commission* v *Germany* [1975] ECR 181, at paragraph 14.

10 — Judgments in Case 174/82 *Sandoz* [1983] ECR 2445, Case 247/84 *Motte* (see footnote 6), Case 304/84 *Muller* (see footnote 6); Case 178/84 *Commission* v *Germany* [1987] ECR 1227 (hereinafter 'Beer judgment', and Case C-42/90 *Bellon* (see footnote 3)).

11 — See footnote 3.

Muller, and Case 178/84, *Commission* v *Germany*, ... the Court inferred from the *principle of proportionality* underlying the last sentence of Article 36 of the Treaty that prohibitions on the marketing of products containing additives authorized in the Member State of production but prohibited in the Member State of importation must be restricted to what is *actually necessary* to secure the protection of public health. The Court also concluded that the *use of a specific additive which is authorized in another Member State must be authorized in the case of a product imported from that Member State* where, in view, on the one hand, of the findings of *international scientific research*, and in particular of the work of the Community's Scientific Committee for Food, the Codex Alimentarius Committee of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization, and, on the other hand, of the *eating habits prevailing in the importing Member State*, the additive in question does not present a *risk to public health* and meets a *real need*, especially a technological one.' (emphasis added) (Paragraphs 11-14).

In those circumstances it may be concluded that authorization must be given for the marketing of cheese with added nitrate if the nitrate meets a real need and does not present a risk to public health.

8. It will be clear from what follows that there is a solid basis in the findings of international scientific research to support the view that nitrate does in fact meet a real need in the production of certain cheeses and that the addition of nitrate within specifically defined limits does not present a risk to health.

The three cases before the Court do not therefore appear to give rise to much difficulty at first sight. However, on closer examination it would appear that there are at least three issues in the cases which require consideration by the Court because its previous case-law contains no clear answers on these points.

Does nitrate meet a real need, especially a technological one?

9. The Commission has claimed that the addition of nitrate is necessary in the manufacture of certain cheeses in order to prevent the growth of anaerobic organisms of the '*clostridium tyrobutyricum*' type. Those bacteria disturb the maturing process and make the cheese 'blow', that is to say, there is a build-up of gas and a bad smell. The bacteria are to be found particularly in milk from cows which have been fed with silage. The problem arises in cheeses which take a medium to long time to mature, for example, Gouda, Edam, Tilsiter Samsø etc. There is therefore particular reason to use nitrate in Northern Europe where it is necessary to

use silage for a large part of the year and where cheeses of that type are manufactured. [12]

10. The defendant Member States have not contested the fact that there may be a technological need to kill the bacteria which cause 'late blowing' or that nitrate is an appropriate means of achieving that end. On the other hand, the Member States have claimed that the use of nitrate is not technologically necessary because there are other, less harmful, methods which can prevent 'late blowing'.

To that the Commission replies that, in determining whether an additive meets a technological need, it is not necessary to examine whether there are alternative and less harmful methods, because the sole issue is whether the additive is suitable to meet the technological need in question. In the alternative the Commission claims that the methods to which the Member States refer are not sufficiently effective.

11. The Court of Justice has not previously decided whether Member States can refuse to allow the marketing of a product by reference to the fact that the additive used is not *necessary* to meet a technological need *because the desired objective can be realized by other means.*

In my opinion the principles to be drawn from the case-law of the Court of Justice [13] may be summarized as follows:

— in laying down a requirement concerning technological need the Court wished to give the Member States an opportunity to prevent the importation of additives which may be regarded as *superfluous* in the sense that there is *no real need for them to meet*;

12 — In support of the need to add nitrate to certain cheeses the Commission referred to the fact that the Codex Alimentarius Committee of the FAO and WHO, which lays down standards for the manufacture of foodstuffs, recognizes the need for added nitrate in certain cheeses in quantities corresponding to 50 mg per kg of cheese. It appears from the documents that the addition of nitrate is required in the production of 15 out of a total of 34 cheeses for which standards have been laid down.
The Commission also relied on a report, 'Review of the Italian position with respect to the ban on importation of cheeses prepared with the addition of nitrate' drawn up at the request of the Commission by Professor R. Walker, Head of Division of Nutrition and Food Science, Department of Biochemistry, University of Surrey, England. In his report Professor Walker concludes that the use of nitrates is necessary from the technological point of view in order to prevent some cheeses being spoilt by anaerobic organisms.
Finally the Commission submitted a report on nitrate and nitrite dated 19 October 1990 prepared by the Scientific Committee for Food. Paragraph 3.1.2 of that report states as follows:
'The Committee was informed that even under hygienic conditions some microbial contamination of milk cannot be totally avoided. If the cows have been fed silage, which is a major feed in some areas, this contamination includes bacteria such as *Clostridium tyrobutyricum*. Although of no health concern, these bacteria prevent the manufacturing of certain cheeses and some kind of measure is necessary to control the growth during the maturing of these cheeses. The information available to the Committee indicated that the addition of 150 mg nitrate (expressed as sodium salt) per litre of cheese milk is sufficient for this use and it will result in a content in the final product not exceeding 50 mg nitrate/kg.'

13 — See in particular:
Case 174/82 *Sandoz*, paragraph 19, see footnote 10, and Advocate General Mancini's Opinion in the case, at paragraph 7;
Case 247/84 *Motte*, at paragraph 24, see footnote 6, and Advocate General Mancini's Opinion in the case, at paragraph 8;
Case 304/84 *Muller*, at paragraph 24, see footnote 6, and Advocate General Mancini's Opinion in the case, at paragraphs 4 and 5;
Case 178/84 *Commission* v *Germany*, the 'Beer judgment', at paragraph 52, see footnote 10, and Advocate General Sir Gordon Slynn's Opinion in the case, in particular at pp. 1254-1255.

— in its case-law the Court has therefore concentrated on whether there existed a real need which the additive in question would meet, and did not give its attention to whether it was possible to replace an additive by other methods;

— the Court is prepared to go a considerable way towards recognizing the desire to promote a certain quality in a given product as a 'real need'.

It may, moreover, be noted that in no judgment has the Court accepted a prohibition on importation on the sole ground that there was no technological need and that, for obvious reasons, in its judgments most emphasis is placed on the question of risks to health.

12. The present cases raise the question whether the requirement that a technological need be met should be given a content different from and more extensive than that which can be inferred from the Court's case-law. Should the possibility offered in Article 36 for justifying a prohibition on importation on the ground of the risk to health presented by a product not merely cover the possibility of preventing the importation of additives that do not serve any purpose but also extend to the possibility of preventing the importation of additives which can be replaced by other substances which are presumed to be 'less harmful'?

13. Valid reasons may be adduced for an affirmative reply to that question.

Community law recognizes a general health policy objective that the use of additives in foodstuffs should be limited. as far as possible. That is evident *inter alia* from the fact that it is possible to introduce a general prohibition on additives and to refuse to allow the importation of superfluous additives, even though they cannot properly be described as a health risk. It is consonant with that objective to promote the use of alternative methods. Directive 89/107 thus expressly recognizes that in assessing the technological need for a particular additive regard must be had to possible alternative means. Annex II to the directive lays down the 'general criteria for the use of food additives' to be applied when including additives in a list, see Article 2(3) of the directive. Paragraph 1 in the annex provides that 'food additives can be approved provided that: — there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable'. [14]

14. The crucial question is, however, whether the *Member State of importation* should be able to ensure that the *Member State of production* only approves additives which cannot be replaced by other methods.

14 — It should, moreover, be noted that the directive appears to require the Member States to comply immediately with the directive's general criteria in their national approval system. Article 12(1) of the directive thus provides that 'Member States shall take all measures necessary to ensure that food additives ... may be marketed only if they conform to the definitions and rules laid down in this Directive and the Annexes thereto'.

Regardless of the fact that such a solution would undoubtedly constitute a step towards promoting the abovementioned general health policy objective, I believe that it would lead to a legal situation which, while not being sufficiently founded on considerations of health, could possibly jeopardize the effective application of the prohibition in Article 30 of the Treaty.

If the said broad construction of the requirement that a technological need be met is accepted, it is probable that in many cases the Member States will seek to justify import prohibitions by reference to the fact that in their view alternative means are available. It can hardly be doubted that an import prohibition on that basis will be met with protests from the Member State of production, which will contend that it has already carried out an examination of the adequacy of possible alternative methods when it approved the additive. The result will be a number of actions in which the Court will be faced with a choice between numerous possible methods of production. In this connection it is significant that the question of alternative methods is only significant where it has already been decided that the additive in question is capable of meeting a specified technological need and does not present a risk to health, and it is important that typically these will be cases concerning technically-involved questions where often no solutions are to be found in international scientific research as regards which methods should be considered, on the one hand, to present the least risk to health and, on the other, adequate in the light of the specific application.

The ultimate choice between many viable and in principle risk-free production methods is, in my view, a choice that must be made by establishing harmonization rules. At the present stage of harmonization public health must be regarded as adequately protected by the fact that the Member States are able to refuse to allow importation of additives which present a risk to health and of additives which do not serve to meet any real need, especially a technological one.

On this point, therefore, I would suggest that the Court uphold the Commission in its principal claims, namely that it is sufficient that it can be shown that in the production of certain cheeses there is a technological need which the addition of nitrate is a suitable means of meeting.

15. Since the defendant Member States, as mentioned above, have not disputed that the addition of nitrate could meet the technological need that has been found to exist, in my view it should be held that the Member States' prohibition cannot be justified on the basis that there is no technological need for the addition of nitrate to certain specified cheeses.

16. For the sake of completeness, I should, however, mention that from the information available in the cases, as far as I am able to assess it, there is no basis for considering that the technological need demonstrated can be wholly met by the use of other additives or other production methods.

17. The three defendant Member States have contended that 'late blowing' can be controlled by (1) the addition of lysozyme, which is an enzyme extracted from albumen; (2) bactofugation, that is to say the centrifugation of milk; (3) improvement of cattle nutrition, that is to say either by not using silage as fodder or the use of better quality silage; and (4) an improvement in milk hygiene.

The Commission has stated that:

— some of the bacteria to be killed are resistant to lysozyme and certain types of cheese do not tolerate any form of bacteria development;

— bactofugation can only be used with certain cheeses and in addition removes only a certain amount of bacteria;

— the use of better quality milk cannot be achieved in areas where cattle are fed with silage, that in the northern Member States it is necessary to use silage for a large part of the year and that it is difficult to lay down quality standards for silage; and

— better milk hygiene will never be able to prevent completely the presence of bacteria in milk.

The Member States do not dispute that some bacteria are resistant to lysozyme, or that bactofugation is not *per se* an adequate alternative or one that may be used in all cases. However, they claim that the use of better quality milk, possibly combined with the two methods mentioned, would be sufficient to bring the level of contamination to below the level which gives rise to 'late blowing'.

18. In my view the Court's judgment in the 'Beer case' [15] can be used to support a rejection of the submission that cheese should be manufactured on the basis of a raw material other than that utilized, that is to say, from milk from cows that have either not been fed with silage or have been fed with better quality silage.

It seems to me reasonable to reject that submission in the actual cases before the Court, not least because it appears in these cases that both the need to use silage and the quality of that silage are linked to geographical situation.

As far as improvement of milk hygiene is concerned, it is stated in the Report of the

15 — See footnote 10. In paragraphs 51 and 52 the Court stated: 'It must be emphasized that mere reference to the fact that beer can be manufactured without additives if it is made from only the raw materials prescribed in the Federal Republic of Germany does not suffice to preclude the possibility that some additives may meet a technological need. Such an interpretation of the concept of technological need, which results in favouring national production methods, constitutes a disguised means of restricting trade between Member States.
The concept of technological need must be assessed in the light of the raw materials utilized and bearing in mind the assessment made by the authorities of the Member State where the product was lawfully manufactured and marketed ...'

Scientific Committee for Food that 'even under hygienic conditions some microbial contamination of milk cannot be totally avoided'. It seems doubtful whether an improvement in milk hygiene *per se* — that is to say, where no change in cattle feeding is specified — could bring the level of milk contamination down to a level where the addition of lysozyme would be sufficient to prevent 'late blowing'. It can probably be assumed (a) that lysozyme does not remove the last 10% approximately of bacteria and (b) that certain cheeses only tolerate a very low bacteria content.

It is therefore my view that the Member States have not produced evidence to show that the addition of nitrate can be avoided by the use of alternative means.

Does nitrate present a risk to public health?

19. Comprehensive material has been submitted to the Court containing research and evaluation of the possible harmful effects on health of nitrate, including various scientific reports, extracts from the literature on the subject etc. I do not believe it necessary to review all those documents. As is clear from the above-cited judgment in the *Bellon* case, in its case-law the Court has established that the question of health risks must be judged on the basis of *international* scientific research and in addition has specified that particular weight should be given to the conclusions drawn by the Community's Scientific Committee for Food [16] and the Codex Alimentarius Committee of the FAO and the WHO.

I consider that in the cases before the Court it is right to attach most weight to the Report on Nitrate and Nitrite drawn up by the Scientific Committee for Food. The Report was published on 19 October 1990 and takes as its starting point a large number of articles and monographs written in recent years. It further appears from the report that the Committee sought information concerning the use of nitrate and nitrite from both invited experts and the Member States. It should also be mentioned that the report is an expression of the unanimous opinion of the Committee. [17]

20. The findings of the report may be summarized as follows:

Nitrate does not present a direct risk to health of any appreciable significance. The possible risk to health linked to nitrate intake is due to its reduction to nitrite either before ingestion or *in vivo*. Nitrite in certain

16 — The Scientific Committee for Food was set up by the Commission's Decision of 16 April 1974, OJ 1974 L 136, p. 1.

17 — Under Article 9 of the Commission Decision relating to the institution of a Scientific Committee for Food (see footnote 16), where the members of the Committee are in unanimous agreement common conclusions are established. In the absence of unanimous agreement, however, the various positions are to be entered in a report drawn up under the responsibility of the representative of the Commission.

quantities does involve a direct risk to health. Further, there may be a possible connection between added nitrate quantities and the formation of volatile nitrosamines, which are cancer-forming.

The main scientific problem is to establish an 'acceptable daily intake' (hereinafter 'ADI'), that is to say the quantity that may be ingested daily without harm to the human organism.

The results of the latest experiments with rats have shown that no toxicological effect can be demonstrated after nitrate intake in quantities of 2 500 mg per kg bodyweight. For the sake of prudence the Committee considers it appropriate to employ a safety factor of 500 in calculating the ADI for nitrate, which may thus be set at 5 mg per kg bodyweight. [18] A person weighing 60 kg would thus be able to ingest 300 mg nitrate without running any risk to his/her health.

The Committee did not receive information concerning the nitrate intake for the whole of the Community, but regards it as clear that nitrate intake in all the areas investigated is 'generally well within the ADIs, except in areas where levels of nitrate in vegetables are high and levels in drinking water exceed Community standards'.

18 — The ADI for nitrate was thus, in earlier investigations, including the investigations carried out by the Codex Alimentarius Committee, set at 5 mg per kg bodyweight. Here, however, on the basis of earlier research, a so-called no-effect level of 500 mg per kg bodyweight was operated with a safety factor of 100.

The use of nitrate as a *food additive* contributes a relatively small amount to total intake because the predominant proportion originates from the *'natural nitrate content'* in vegetables and drinking water. Nitrate is used as an additive in meat products, cheese, milk and fish products. As far as the addition of nitrate to cheese is concerned the Committee concludes in Paragraph 3.1.2 of the Report that:

'... The information available to the Committee indicated that the addition of 150 mg nitrate (expressed as sodium salt) per litre of cheese milk is sufficient for this use [i. e. to control *clostridium tyrobutyricum*] and it will result in a content in the final product not exceeding 50 mg nitrate/kg. Nitrite is normally not found in amounts higher than 1 mg/kg. The Committee found this acceptable from a toxicological point of view and the *potential intake of nitrate from this source is considered insignificant compared with the ADI.*

Although a correlation between the addition of nitrate and the formation of volatile N-nitroso compounds in cheese has not been demonstrated, recent studies suggest a possible correlation between nitrate and the content of apparent total N-nitroso compounds. ... For this reason *the Committee recommends that the use of nitrate should be restricted to 150 mg in milk for cheese manufacture* until the toxicological significance of these results can be clarified. For control purposes it is also recommended that *a max-*

imum limit for residual nitrate is fixed at 50 mg per kg in the finished cheese.' (emphasis added)

21. The defendant Member States have disputed the proposition that in assessing the risk to health presented by nitrate the starting point to be taken should be a generally established ADI, because no account is thereby taken of specially sensitive groups of persons such as old people, pregnant women and children. Especially as far as infants are concerned, the Member States have claimed that as a result of the higher PH content of their stomachs nitrate is to a large extent reduced to nitrite.

In my opinion these submissions must be rejected, simply because it is clear from the Report of the Scientific Committee that in its conclusions it took account of the said particularly sensitive groups. In connection with its assessment of the risk to health linked to the addition of nitrite to foodstuffs, the Committee expressly mentions that certain subgroups of the population, for example babies, pregnant women, etc., may be exposed to a higher risk from nitrite in food. No corresponding general reservation is made in connection with its examination of the toxicological risks of nitrate. The Committee states in this connection however that:

'Since infants may be more likely to reduce exogenous nitrate to nitrite and are more sensitive to the acute effects of nitrite, nitrate should not be used as an additive in infant foods.' [19]

22. To summarize, the question whether nitrate, judged on the basis of international scientific research, presents a risk to public health can accordingly be answered as follows:

— a daily intake of up to 5 mg of nitrate per kg bodyweight does not present a risk to health; and

— a residual nitrate concentration in cheese of up to 50 mg nitrate can be regarded as acceptable from a toxicological point of view because the potential nitrate intake from that source is insignificant in relation to the established ADI.

19 — These conclusions are also supported by the Report drawn up by Professor Walker and submitted by the Commission, see footnote 12. It states *inter alia*:
'Nitrate is non-mutagenic in *in-vitro* assays and reproduction studies have not shown any specific adverse effects on reproductive function ... so it does not present a particular hazard during pregnancy. Levels of nitrate secreted into breast milk do not normally exceed maternal plasma levels so that the suckling infant is not exposed to significant levels by this route.' (p. 18)
'... the extent of conversion to nitrite may be higher in the neo-natal infant. ... It is for these reasons that the ADI for nitrate is not applicable to neo-natal infants. Since neonatal infants would not be consumers of the types of cheeses manufactured using nitrate and since maternal ingestion of such cheeses would not lead to detectable changes in nitrate levels in breast milk, there is no additional hazard to the neonatal infant from the use of nitrate in cheese ...' (p. 18-19).

23. As is clear from the above-cited judgment in the *Bellon* case, in assessing the risk to health of an additive account must also be taken of *eating habits prevailing in the importing Member State*.

24. The arguments put forward by the Member States in that respect concentrate mainly on showing that the established ADI is exceeded as a result of their respective population's *eating habits in respect of all foodstuffs, including water, containing nitrate*.

Italy has claimed (a) that it has a higher consumption of fruit and vegetables, in which there is a natural nitrate content, than the other Member States, and (b) that the average daily intake of nitrate in Italy is 312.75 mg and thus from the outset greater than the average ADI of 300 mg. Greece has claimed (a) that in Greece a greater amount of vegetables and more cheese are consumed than in the other Member States, and (b) that the average daily intake of nitrates in Greece is approximately 1720.23 mg. France has claimed (a) that France has the highest consumption of cheese in the world; (b) that in France there is a high nitrate content in drinking water and fresh vegetables; and (c) that there are particular problems in certain areas where the nitrate content in drinking water exceeds the Community norms.

25. The Commission contests the accuracy of much of that information but otherwise employs a different approach in its arguments on this point from that of the Member States. The Commission thus takes *cheese-eating habits* as its basis. In the Commission's view it is crucial that even where it is assumed that all cheese contains the maximum authorized quantities of nitrate, that is to say 50 mg per kg, cheese consumption can only result in an insignificant rise, namely of 2.1 mg, corresponding to less than 1%, in daily nitrate intake. Since by no means all cheese has added nitrate and the residual nitrate concentration in cheese to which nitrate is added is, as a rule, well under 50 mg per kg, the Commission states that to allow nitrate to be added to cheese will probably result in a rise of only 0.5 mg in daily intake.

26. In my opinion the Commission is right in that view. Where international scientific research has established that the use of a specific additive in a specific product in a specified quantity cannot be regarded as a risk to health, the condition that the eating habits in the importing Member State must be taken into consideration means that an assessment must be made as to whether particular eating habits in respect of the product in question in the importing Member State can create special health problems in that Member State. That must in any event apply where international scientific research (see above) has laid down that the potential nitrate intake from that source is insignificant in relation to the established ADI.

The significance of other sources of nitrate intake must primarily be taken into account when the acceptable maximum quantities for individual products are being laid down. That the Scientific Committee for Food in fact made its evaluation bearing that in mind is clear from the above-cited remarks in the report to the effect that a nitrate content of up to 50 mg per kg of cheese is regarded as acceptable from a toxicological point of view because 'potential nitrate intake from that source *is regarded as insignificant* in relation to the established ADI' (emphasis added).

I therefore consider that in the present cases the Court should confine itself to assessing whether the addition of nitrate to cheese constitutes a risk to health in the three Member States as a result of the cheese-eating habits in those countries and thus not assess how far nitrate as such constitutes a risk to health in the Member States as a result of their eating habits in general.

27. The Member States have not produced any information casting doubt on the fact that, on the basis of the cheese-eating habits in the three Member States, it can be concluded that the daily quantity of nitrate originating from that source is insignificant. It must therefore be assumed that the addition of nitrate to cheese does not present a risk to health in the three Member States.

28. In view of the foregoing I believe that to refuse to authorize the importation of cheeses in respect of which there is a technological need for the addition of nitrate and which contain a residual nitrate concentration not exceeding that which international scientific research has declared to be acceptable from a health point of view is not justified on health grounds and such refusal is thus contrary to Article 30 of the Treaty.

Is the obligation of the Member States to give authorization conditional on submission of an application by a trader?

29. It is clear from the case-law of the Court [20] that legislation which prohibits generally the use of additives unless positive authorization is given complies with Articles 30 and 36 of the Treaty. However, the Court has laid down a condition that the Member State should establish a procedure whereby the trader may request authorization to use additives. Authorization must be given if the material conditions described above are fulfilled. It is for the Member State to show that the conditions are not fulfilled and that a possible refusal on that ground is justified. [21] In its judgment in the *Bellon* case [22] the Court held:

20 — See the paragraphs of the *Bellon* case cited in point 7.

21 — The Commission has explained its interpretation of the requirements laid down by the Court for authorization procedures in the 'Communication on the free movement of foodstuffs within the Community', paragraphs 36-40 (OJ 1989 C 271, p. 3).

22 — See footnote 3.

'On a correct interpretation, Articles 30 and 36 of the EEC Treaty do not preclude a Member State from prohibiting the marketing of a foodstuff which has been imported from another Member State where it is lawfully produced and marketed and to which one of the substances listed in the annex to Council Directive 64/54/EEC of 5 November 1963 ... has been added. However, in the Member State of importation, *the marketing of that foodstuff must be authorized under a procedure which is readily accessible to manufacturers and traders and which can be completed within a reasonable period,* where the addition of the substance in question meets a genuine need — in particular a technological need — and represents no danger to public health. It is for the competent national authorities to show in each case, in the light of national eating habits and with due regard to the results of international scientific research, that their rules are necessary in order to give effective protection to the interests referred to in Article 36 of the Treaty.' (emphasis added)

30. France has claimed that a procedure exists in France whereby a trader may request authorization to import products manufactured with additives, but that the French authorities have never received any request for authorization to add nitrate to cheese. Since the general prohibition against the addition of nitrate to cheese does not *per se* constitute an infringement of Article 30, France claims that the action should be dismissed, on the basis that the Commission has not shown an infringement of the Treaty provisions in the form of an actual rejection of an application.

31. In my view France is undoubtedly right in the basic premise of its claim.

The case-law of the Court can only be understood as meaning that a Member State is not bound automatically to put an additive on its approved list simply because it fulfils a technological need and is not a risk to health. [23] Any infringement of Article 30 of the Treaty will only occur in connection with an actual decision on an application submitted for authorization to use an additive.

32. There are valid reasons for that legal position. Quite apart from the fact that it is in accordance with the basic principle of Community law concerning additives — a general prohibition qualified by specific authorization (the approved list system) — the authorities of the Member States must be in the best position to assess whether the material conditions for approval are satisfied where there is an application from a trader accompanied by the available information on the technological need for the additive in

23 — This view is indirectly supported by the Court's judgment in the *Bellon* case, which involved an importer who had been prosecuted for having imported pastry products containing an additive without previously applying for authorization. Advocate General Mischo stated in his Opinion *inter alia* as follows:
'It is therefore clear that, if there is no authorization to use sorbic acid in "panettoni", the French courts are entitled to apply the general prohibition laid down in French legislation and convict a defendant who has infringed that prohibition.' (paragraph 24)
The operative part of the Court's judgment does not contain an express formulation of the problem, but the above-cited conclusion in the judgment can, in my view, be interpreted as supporting this view.

question and the possible linked risks to health. On the one hand the trader is most familiar with the product in question, on the other he has a specific interest in being able to market it.

33. The question is, however, whether the obligation to approve an additive should arise solely when there is an application from a trader, or whether that obligation, as the Commission maintains, can also arise if the Commission approaches the Member State in question with a view to prevailing upon the Member State to authorize an additive in the manufacture of a specific product.

34. There would be advantages in accepting the Commission's view of the law. That would give the Commission the opportunity, if it was thought necessary, to ensure that there were no obstacles to trade in products lawfully produced in some Member States where the material conditions for the legality of such obstacles to trade were not satisfied. The effectiveness of the Treaty rules, which aim to ensure free movement of goods, would thereby be reinforced. It may be thought that there is particular reason to accept that view of the law in a situation such as the present involving an everyday foodstuff and an additive which has been known and used for many years.

That a Member State, in a case where an approach comes from the Commission and not from a trader, would presumably have to expend a good deal of effort in order to procure the necessary basis for its assessment would seem to be a difficulty that can be overcome.

35. There is however a question as to whether it would be proper at this point to alter the principles that can be derived from the case-law of the Court. It should not be possible for the Commission, in any event, simply on the basis of a finding that a specific additive is authorized in a product in one Member State to approach a Member State which does not allow such use in order to force that State, in reliance on Article 30 of the Treaty, to prove that the material conditions for the validity of the prohibition have been shown to exist. Such a course would tend towards the achievement of 'harmonization' of the rules of the Member States which it is the Commission's task to implement by issuing general legal measures at Community level.

Nor is there ground for thinking that the effectiveness of the rules in the Treaty on free movement of goods cannot be sufficiently ensured by the trader's being able to apply for authorization and by the possibilities which, under the case-law of the Court, must be available for judicial review of refusal of a request. It is clear that in this connection the Commission will have important responsibilities, within the framework of its usual powers under Article 169 of the Treaty, to ensure that the Member States administer the authorization system in accordance with the requirements which follow from the case-law of the Court.

There is therefore an undeniable advantage in following the view of the law put forward by France, because it is thereby ensured that the authorization procedures are only put into operation when a trader has shown that there is an actual need for them.

Accordingly I consider that the Court should adhere to its view that a general prohibition is compatible with Community law, whereas a rejection of a specific application by a trader would be in breach thereof if the material conditions for the legality of a rejection were not fulfilled.

36. It might perhaps seem less reasonable on the facts to dismiss the case against France. Both in the prior administrative procedure and in the procedure before the Court France has expressed the view that a prohibition of the use of nitrate is in accordance with the material conditions which result from the case-law of the Court. It might be wondered whether France might not be said to have made the possibility of applying for authorization illusory by clearly and categorically expressing its negative attitude to cheese manufactured with added nitrate. In my opinion that circumstance is not, however, by itself sufficient for a finding against France, not least because France has already, in connection with its defence to the application and again at the hearing, declared itself willing to make a specific assessment of a given application in the light of existing scientific opinion.

I therefore take the view that the necessary and logical consequence of the legal principles applicable in practice laid down by the Court is that the case against France must be dismissed, and I shall therefore suggest to the Court that it should find against the Commission.

37. It should be mentioned that no evidence has been submitted in the case against Italy or Greece to show that the authorities in those Member States have refused specific applications for authorization. The Greek Government has not claimed that the Greek authorities have never received any application for authorization. Such a submission was made by the Italian Government, but only at the hearing. I therefore take the view that it should be dismissed as being put forward too late. It should, furthermore, be pointed out that according to the information produced in the cases the Commission brought proceedings for infringement of the Treaty against Italy and Greece after it had received complaints from traders.

I shall therefore suggest to the Court that it should find against Italy and Greece in accordance with the Commission's claims.

On that basis I suggest that the Court hold that:

— by prohibiting the importation of cheeses lawfully produced and marketed in other Member States to which nitrates have been added at the manufacturing stage within limits recognized by international scientific opinion as acceptable, the Italian and Hellenic Republics have failed to fulfil their obligations under Article 30 of the EEC Treaty;

— the Italian and Hellenic Republics must pay the costs of their respective cases;

— the case against the French Republic is dismissed and the Commission must pay the costs of that case.