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.

REPORT FOR THE HEARING
delivered in Case C-42/90 *

I — Facts and procedure

1. *Legal background*

Council Directive 65/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption (Official Journal, English Special Edition 1963-64, p. 99) lays down an exhaustive list of the preservatives whose use in foodstuffs intended for human consumption may be authorized by Member States.

The first item on that list is sorbic acid, EEC No E 200, for the use of which no conditions are prescribed.

Article 1 of the directive prohibits Member States from authorizing the use of any preservatives other than those listed in the annex thereto. Article 2(1) provides that, when the annex lays down conditions for the use of preservatives, Member States are to ensure that those conditions are complied with.

Article 2(2) provides that the directive 'shall not affect provisions of national laws specifying the foodstuffs to which the preservatives listed in the annex may be added and the conditions governing the addition of such preservatives'. The second sentence in that paragraph was modified by Council Directive 67/427/EEC of 27 June 1967 (Official Journal, English Special Edition 1967, p. 169). Under the new wording, a Member State may not totally prohibit the use, in foodstuffs produced and consumed in its own territory, of a preservative whose use is authorized by the directive unless there is no technological reason for such use.

* Language of the case: French.

The Council took a further step forward in the approximation of laws when it adopted Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (Official Journal 1989 L 40, p. 27), a framework directive which makes provision for complete harmonization of the laws concerning additives. Article 12(2) provides that Member States may not 'prohibit, restrict or obstruct the marketing of food additives, food or food ingredients on grounds relating to food additives, if these comply' with Directive 89/107, the existing specific directives and the comprehensive directive referred to in Article 3 of Directive 89/107.

Directive 89/107 was adopted after the events with which the main proceedings are concerned.

2. *Background to the dispute*

In the course of an inspection carried out on 5 October 1982 in a supermarket in Nice, officers of the Bureau for Consumer Affairs and the Prevention of Fraud found that light-pastry products manufactured in Italy under the name 'panettone' and containing sorbic acid were on sale. Sorbic acid is a preservative authorized under Italian legislation but prohibited in France.

Pursuant to an order made by an examining magistrate at Marseille on 27 August 1986, Jean-Claude Bellon, the manager of Bellon Import SARL, which was responsible for importing the goods into France, was sent for trial before the Tribunal correctionnel (Criminal Court) on a charge of having sold foodstuffs intended for human consumption which he knew to be adulterated or injurious to health (owing to the presence of a banned preservative) and having sold foodstuffs intended for human consumption containing chemical additives other than those whose use is lawful under French legislation.

The prosecution was based on the Law of 1 August 1905, which makes it an offence to commit frauds or falsifications in the sale of foodstuffs, and Article 1 of the Decree of 15 April 1912, which provides that it is 'prohibited to possess for the purpose of sale, to offer for sale or to sell any goods or foodstuffs intended for human consumption to which have been added chemicals other than those whose use is declared lawful by orders made jointly by the Minister for Agriculture and Rural Development, the Minister for Economic Affairs and Finance, the Minister for Industrial and Scientific Development and the Minister for Public Health on the advice of the High Council for Public Hygiene in France and the National Medical Academy'.

At the hearing before the Tribunal correctionnel, the defendant maintained that Council Directive 64/54 authorized the use of sorbic acid and that the prohibition on the importation into France of goods legally produced and marketed in another Member State constituted an infringement of Article 30 of the EEC Treaty.

3. *The national court's question*

By judgment delivered on 20 November 1987, the Tribunal de grande instance, Marseille, sought a preliminary ruling from the Court of Justice on the following question:

'Is it lawful under Community law to refuse entry into France to a foodstuff lawfully produced and marketed by a Member State on the ground that it contains sorbic acid, a preservative which is permitted under Directive 64/54/EEC of 5 November 1963, as supplemented and amended by Directive 67/427/EEC of 27 June 1967, by Directive 71/160/EEC of 30 March 1971 and by Directive 74/62/EEC of 17 December 1973, but which, under French law, may be used only in a limited number of stipulated foodstuffs, although no overriding reason is given?'

4. *Procedure before the Court of Justice*

The order for reference was received at the Court Registry on 15 February 1990.

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the European Communities, written observations were submitted:

on 7 May 1990 by the defendant in the main proceedings, represented by M. Grisoli, of the Marseille Bar, and

on 17 May 1990 by the Commission of the European Communities, represented by Blanca Rodríguez Galindo, a member of its Legal Department, assisted by Hervé Lehman, a French official placed at the disposal of the Commission's Legal Department, acting as Agents.

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

II — Written observations submitted to the Court

5. *Jean-Claude Bellon*, the defendant in the main proceedings, draws attention to the wording of Articles 30 and 36 of the EEC Treaty and then analyses the development of the Court's case-law relating to those articles.

He states that, in its judgment in Case 8/74 *Procureur du Roi* v *Dassonville* [1974] ECR 837, the Court gave a broad interpretation to the concept of measures having equivalent effect when it held that all trading rules enacted by Member States capable of hindering, directly or indirectly, actually or potentially, intra-Community trade were to be regarded as measures having an effect equivalent to quantitative restrictions.

In Mr Bellon's view, the Court clarified that definition in its judgment in Case 120/78 *REWE* v *Bundesmonopolverwaltung für Branntwein* (the 'Cassis de Dijon' case) [1979] ECR 649, to the effect that each Member State must allow goods from another Member State into its territory

where those goods are lawfully produced and marketed in that other Member State.

Mr Bellon considers that the Commission, in its Communication of 3 October 1980 (Official Journal 1980 C 256, p. 2) concerning the abovementioned judgment, confirmed the Court's case-law by stating that any product imported from another Member State must in principle be admitted to the territory of the importing Member State if it has been lawfully produced, that is, conforms to rules and processes of manufacture that are customarily and traditionally accepted in the exporting country, and is marketed in the territory of the latter. Barriers to free movement are tolerated only when they are necessary to satisfy mandatory requirements and to serve a purpose which is in the general interest and for which they are an essential guarantee.

Mr Bellon also points out that the Court has already declared, in its judgment in Case 13/68 *Salgoil* v *Italy* [1968] ECR 453, that the exceptions provided for in Article 36 of the EEC Treaty may not be given a wide interpretation.

Mr Bellon points out that although the Court, in its judgment in Case 108/80 *Ministère public* v *Kugelmann* [1981] ECR 433, appears to have adopted a more flexible position as regards the powers of each Member State to lay down certain standards in the regulation of products, the limited scope of that judgment is clear not only from the Court's subsequent case-law (especially in its judgment in Case 130/80 *Kelderman* [1981] ECR 527, in which the Court stated that disparities between national laws relating to the manufacture and marketing of a product may be applied only if they are recognized as being necessary in order to satisfy imperative requirements) but also from Council Directive 83/189/EEC of 28 March 1983 (Official Journal 1983 L 109, p. 8). That directive lays down a procedure for the provision of information in the field of technical standards and regulations, and reasserts both that the prohibition of quantitative restrictions on the movement of goods and of measures having an equivalent effect is one of the basic principles of the Community and that barriers to trade resulting from technical regulations relating to products may be allowed only where they are necessary in order to meet essential requirements and have an objective in the public interest of which they constitute the main guarantee.

On the specific question of preservatives, Mr Bellon considers that the second sentence of Article 2(2) of Council Directive 64/54, which allows a Member State to prohibit totally the use in foodstuffs of a preservative authorized by the directive where there is no technological reason for its use, concerns only foodstuffs produced and consumed in that Member State's own territory.

From that, Mr Bellon infers that the French prohibition on the use of a preservative such as sorbic acid may not be enforced in the present case against a product lawfully manufactured and marketed in Italy. The Italian legislature has, by a Ministerial Decree of 31 March 1965, authorized the use of sorbic acid as a preservative in foodstuffs, including pastry products up to a proportion of 2 000 mg/kg. The analyses carried out on the occasion of the inspection demonstrate that the prescribed proportion was complied with.

In Mr Bellon's view, the attitude of the French administration in attempting to prevent the marketing of the relevant products by referring to the application of the aforementioned provision of Directive 64/54, which, it claims, allows it to prohibit the use of sorbic acid, must be regarded as discriminatory inasmuch as it benefits a typical national product through unfavourable treatment of products from other Member States.

Mr Bellon also claims that the existence of a harmonizing directive, such as that cited above, in the relevant field deprives the restrictive measures taken by the French administration of any justification.

In Mr Bellon's opinion, the principle of proportionality, to the effect that the measures implemented must be appropriate and must impede trade as little as possible, must also be applied. According to the Court's judgment in Case 304/84 *Ministère public* v *Muller* [1986] ECR 1511, where public health is involved Member States must establish the existence of a serious risk in the light of eating habits and the results of international scientific research. In the present case, however, the French authorities have not demonstrated that the use of sorbic acid presents a risk to the health of consumers.

Mr Bellon considers, moreover, that sorbic acid falls within the additives authorized for use in foodstuffs intended for human consumption in accordance with recent Council Directive 89/107. He points out that the French legislature has embodied that directive in a decree of 18 September 1989 which lays down new rules governing authorized additives.

For all those reasons, the defendant in the main proceedings proposes that the Court should rule as follows on the question raised by the national court:

'As a result of the way in which directives of the Council of the European Communities have developed, France's refusal to authorize the use of a foodstuff lawfully produced and marketed by a Member State on the ground that it contains the preservative sorbic acid is not in conformity with Community law.'

6. The *Commission* points out, first of all, that the Court has already, on several occasions, had to interpret the terms of Directive 64/54/EEC (in its judgment in Case 88/79 *Ministère public* v *Grunert* [1980] ECR 1827, and in *Kugelmann*, cited above). The Court has specified that Directive 64/54 'is merely the first stage in the approximation of national laws relating to preservatives, involving the establishment of a single list of preservatives the use of which is authorized'.

With regard to Council Directive 89/107, the Commission considers that a measure adopted in 1988 cannot be taken into consideration for the purpose of resolving the dispute before the national court, which arises out of events which took place in 1982.

The Commission observes that, as the Court stated in its judgment in *Ministère public* v *Kugelmann*, at the stage which had been reached in 1982 in the approximation of

national laws in the field of the regulation of additives Member States were not bound to authorize for use in all foodstuffs all the preservatives referred to in the list in the annex to Council Directive 64/54. In the Commission's view, that would have also been the answer to the question raised here if the goods which the defendant is charged with having marketed had been produced in France.

But the goods were imported from Italy, and Member States must naturally exercise their powers to regulate food additives, in the absence of complete Community harmonization, in compliance with the provisions of Article 30 of the EEC Treaty.

In the Commission's view, a prohibition on the marketing of a foodstuff obviously hinders, and in fact prevents, the importation thereof. Such a prohibition could only be justified, on the basis of Article 36 of the EEC Treaty, on grounds of the protection of human health. The Commission points out that on a number of occasions (see the judgments in Case 174/82 *Sandoz* [1983] ECR 2445, in Case 247/84 *Motte* [1985] ECR 3887, in Case 304/84 *Ministère public* v *Muller*, cited above, and in particular in Case 178/84 *Commission* v *Germany* [1987] ECR 1227) the Court has pointed out that it follows from the principle of proportionality underlying the last sentence of Article 36 of the EEC 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 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.

The Commission adds that the Court also stated in those judgments that a Member State may set up an authorization procedure in order to determine whether the imported products meet those criteria. Such a procedure must be easily accessible to traders, capable of conclusion within a reasonable time and embodied in a measure of general application, and a refusal to grant authorization must be open to judicial review.

The Commission observes, finally, that the Court has pointed out that in such a case involving an exception to the principle of the free movement of goods, it is for the competent national authorities to demonstrate in each case that the prohibition of an additive is necessary to give effective protection to public health.

The Commission considers, as it stated in its communication of 24 October 1989 on the free movement of foodstuffs within the Community (Official Journal 1989 C 271, p. 3), that, in the case of a foodstuff containing an additive which is not auth-

orized in that foodstuff, but appears on a Community approved list and meets an established technological need, prohibition of that foodstuff can be justified only on the grounds of the risk of the acceptable daily intake being exceeded, since the general harmlessness of the additive has already been assessed.

In the Commission's opinion, the use of sorbic acid in 'panettone' in the present case does meet a real technological need. 'Panettone' is not a pastry product intended for immediate consumption. It is a product which may be kept for some time by the seller and again by the consumer. The use of sorbic acid is necessary in order to prevent the development of bacteria during such storage both before and, even more importantly if the purchaser does not consume the whole loaf the same day, after the packaging is opened.

As far as danger to public health is concerned, the Commission points out that sorbic acid is included in the list of preservatives laid down in Council Directive 64/54, without any specific conditions as to its use. That is because it is a substance which does not present a serious danger to human health. The Joint FAO and World Health Organization Expert Committee on Food Additives estimates the acceptable daily intake of sorbic acid at 25 mg/kg body weight for humans (see *Food Additives Series* No 5 of 1974).

According to the Commission, that means that an average consumer, with a body weight of 60 kg, could have a daily intake of 1 500 mg of sorbic acid with no risk to health. Thus, if the 'panettone' marketed in France contains the maximum level of sorbic acid permitted in pastry products in Italy, of 2 000 mg/kg, an average consumer could eat 750 g of 'panettone' every day with no risk to health.

The Commission states that it has no information as to the amount of sorbic acid actually contained in the 'panettone' marketed by the defendant in France, nor does it possess any data suggesting that the consumption of pastry products in France is such that if the addition of sorbic acid to those products were permitted consumers would be likely to exceed the acceptable daily intake. It considers that, since this is a request for a preliminary ruling, it is for the national court to determine such factual matters and to assess them in the light of Articles 30 and 36 of the Treaty as interpreted by the Court.

The Commission therefore proposes that the Court should answer the question raised in the following terms:

'Articles 30 and 36 of the EEC Treaty are to be interpreted as meaning that, following an easily accessible procedure if that is considered necessary, a Member State must authorize the sale of a foodstuff lawfully produced and marketed in another Member State, containing an additive which is included in an approved Community list and which meets a real technical need, unless the competent national authorities can show that the quantity of the additive contained

in the foodstuff is such that, having regard to the eating habits of consumers in the State, the admissible daily intake is likely to be exceeded.'

III — Oral procedure

7. The *French Government*, which had not submitted any written observations, pointed out at the hearing that the French authorities had never refused Mr Bellon permission to market the 'panettone' in question, because Mr Bellon had never applied for such permission. The principle of granting permission by ministerial order issued after consulting two scientific bodies, the National Medical Academy and the High Council for Public Hygiene in France was nevertheless established in a decree of 15 April 1912, amended in 1973. Such orders specify the permissible levels of additives and conditions governing their use, and lay down rules concerning labelling, characteristics and purity.

The French Government explained that authorization to use an additive in foodstuffs is granted only if a toxicological report showing that the substance is harmless at recommended levels of use is submitted.

Such toxicological reports are governed by a circular of 8 August 1980, published in the *Journal officiel de la République française* on 25.9.1980. The authorization procedure was further modified, after the events with which this case is concerned took place, by a decree of 18 September 1989.

The Agent of the French Government explained at the hearing that under that procedure, in France, an importer or manufacturer wishing to market a foodstuff containing an additive not authorized for use in that product must submit an application to the Directorate-General for Competition, Consumer Affairs and the Prevention of Fraud in the Ministry of Finance and the Economy, which is responsible for referring it to the approved scientific bodies mentioned above. Within the framework of that procedure, the national authorities must, within a reasonable time, either grant or refuse authorization to use the additive. Any refusal must be justified for reasons of public health and, where appropriate, on grounds relating to a real technical need, in the words used in the Court's case-law.

The procedure must be easily accessible to traders and judicial review must be available.

The French Government considers that the Court has clearly confirmed that procedures of such a type are compatible with Community law as it stands (see in particular *Ministère public* v *Muller*, cited above).

The French Government adds that the use of sorbic acid is authorized in France in a certain number of foodstuffs. New applications for authorization are regularly dealt with by the competent scientific bodies. The scientific experts responsible for examining the applications take into

consideration not only the risk of exceeding the acceptable daily intake but also, where preservatives are concerned, the effect on the microbiological quality of the product to which they are added.

According to the French Government, the foodstuffs containing sorbic acid marketed in the different Member States are not always the same. Permitted doses may also vary. If uncontrolled free movement throughout the Community were introduced today for all such foodstuffs, there would probably be a considerable increase in the general level of intake of the additive, and it is quite likely that there would be a risk of the various national permitted daily intakes being exceeded to a dangerous extent.

In the French Government's view, the Commission's figure of 750 g of 'panettone' which an average consumer could eat every day with no risk to health is not decisive, since French consumers also eat other foodstuffs containing sorbic acid.

For all those reasons, the French Government proposes that the answer to the question raised by the Tribunal de grande instance, Marseille, should be that Articles 30 and 36 are to be interpreted as meaning that a Member State must, following an easily accessible procedure if it considers such a procedure necessary, authorize the sale of a foodstuff, containing an additive which is included in a Community list and meets a real technological need, lawfully produced and marketed in another Member State, unless the competent national authorities demonstrate that the quantity of additives contained in such foodstuffs is such that, in the light of the eating habits of consumers in that State, the acceptable daily intake is likely to be exceeded. Finally, the French Government adds that, in view of the facts in the case which gave rise to the national court's question, it would be useful to specify that a person who has not complied with the authorization procedure set up by a Member State, where that procedure is consistent with the Court's case-law, may not rely on Articles 30 and 36 of the Treaty.

G. C. Rodríguez Iglesias
Judge-Rapporteur