OPINION OF MR ADVOCATE GENERAL MANCINI
delivered on 22 October 1985 *

Mr President,
Members of the Court,

1. In connection with criminal proceedings brought against a Belgian national who is accused of having imported foodstuffs prepared with unauthorized colourants the Cour d'appel [Court of Appeal], Brussels, has asked the Court to interpret the rules of the EEC Treaty on the free movement of goods and in particular the principle contained in the first sentence of Article 36, according to which 'prohibitions or restrictions on imports ... justified on grounds of ... the protection of health and life of humans ...' are permissible. The Court is asked to establish whether that principle applies to national rules imposing a general prohibition (although the authorities may make exceptions in individual cases) on the marketing of foodstuffs to which colourants have been added and which have been imported from other Member States in which they may lawfully be marketed.

The facts may be summarized as follows. In 1978 Belgian food inspectors seized in a Brussels shop for analysis various pots of red and black coloured lumpfish roe. That product which was of the brand 'Popoff' was marketed by the company Wilhelm Erbst, Hamburg, and imported into Belgium by Léon Motte of Woluwé-Saint-Pierre. The analysis revealed the presence in the roe of two colourants (cochineal red and indigotin or indigo carmine) and a preservative (hexamethylene tetramine) which were not authorized under the Belgian legislation.

Charged with having introduced into Belgium foodstuffs containing prohibited additives, Mr Motte was acquitted by the Eighteenth Chamber of the Tribunal Correctionnel [Criminal Court], Brussels, by a judgment of 9 May 1984. The court of first instance made the following findings: (a) Although at the material time hexamethylene tetramine was prohibited, it was subsequently added to the list of permitted additives for non-smoked fish roe. Mr Motte was therefore entitled to rely on the second paragraph of Article 2 of the Penal Code according to which, 'if the penalty established at the time of the judgment differs from that which applied at the time of the offence, the less heavy of the penalties shall be applied'. b) The prohibition on the use in the preparation of lumpfish roe of the two colourants whose use was moreover authorized in other foodstuffs, was a measure liable to place a quantitative restriction on imports and thus contrary to Articles 30, 31 and 32 of the EEC Treaty.

The Ministère Public [Public Prosecutor] appealed against that decision and the Eighth Criminal Chamber of the Cour d'appel [Court of Appeal], Brussels, having upheld the judgment at first instance in respect of the charge concerning the use of hexamethylene tetramine, stayed the proceedings and requested the Court for a preliminary ruling pursuant to Article 177 of the EEC Treaty on the following question: 'Is the prohibition on the use of indigotin and cochineal A red colourant in the preparation of non-smoked fish roe, laid down by the Royal Decree of 27 July 1978,

* Translated from the Italian.

a measure equivalent in effect to a quantitative restriction on the free movement of goods' (judgment of 26 September 1984).

2. For a full understanding of the dispute it is necessary to supply certain details regarding the rules which govern the use of additives for foodstuffs in Belgium and the Community rules on colourants.

The Belgian rules are relatively simple. A colourant may be used in the preparation of a foodstuff if the combination of colourant and foodstuff appears on the list of permitted additives (Article 4 (1) of the Law of 24 January 1977 concerning consumer health protection in relation to foodstuffs and other products, Moniteur Belge 1977, p. 4501). The procedure for having a substance added to that list requires that an opinion be obtained from the Conseil Supérieur d'Hygiène [Public Health Board], which must assess the harmfulness of the additive, the degree of the human organism's tolerance for it and the necessity, usefulness and suitability of its use. Pursuant to the relevant provision (Article 4 (2)), the Royal Decree of 27 July 1978 established the list of additives authorized for foodstuffs (Moniteur Belge 1978, p. 12523). That list has however been amended on many occasions (17 April 1980, 15 October 1981, 22 June 1982 and 12 July 1984) by the procedure provided for in the Royal Decree of 1 December 1977.

In particular the colourants in question in the main proceedings are authorized for use in the preparation of numerous products (ice-cream, various confectioneries and alcoholic beverages), but not in the preparation of fish roe. However, other substances such as brilliant black BN, tartrazine, amaranth, erythrosine and orange yellow S may be used for the colouring of fish roe.

The Community rules are contained in the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (Official Journal, English Special Edition 1959 to 1962, p. 279). That directive provides for a first stage in the harmonization of the rules of the Member States by the establishment of a single list of colouring matters which may be used in the preparation of foodstuffs. According to Article 1 the Member States may not authorize the use of colouring matters other than those which appear on the Community list and the use of substances which appear on that list may not be subject to any general prohibition. In addition, according to Article 5, the directive 'shall not affect national rules specifying which foodstuffs may be coloured by means of the colouring matters listed . . . or on what conditions they may be so treated'.

3. In the proceedings before the Court written observations were presented by Mr Motte, the Governments of Belgium and the Netherlands and the Commission of the European Communities. The Governments of the Federal Republic of Germany and of Denmark intervened only in the oral procedure.

All four of those governments took the view that the Belgian procedure, which is moreover similar to that provided for in the majority of the other Member States, was in conformity with Community law. Indeed, as may be inferred from Article 5 of the directive cited, that procedure was a consequence of the fact that the harmon-

ization in the sphere of colourants is as yet only embryonic. Moreover, in their view it is founded on the principle laid down in the first part of Article 36 of the EEC Treaty, which authorizes 'prohibitions or restrictions on imports . . . justified on grounds of ... the protection of public health and life of humans . . . '.

In the view of the Belgian Government, in particular, the disputed rules are in conformity with the 1962 directive. It considers that in the first place, cochineal red and indigotin are not the subject of a general prohibition since their use is permitted for the colouring of numerous products. Secondly, only substances which appear on the Community list are authorized for use in the preparation of non-smoked fish roe. It argues that in interpreting the similar directives on preservatives and anti-oxidants, the Court held that the Member States have a wide discretion to determine which additives may be used in foodstuffs, provided that the two conditions which I have cited above are satisfied (judgments of 12 June 1980 in Case 88/79 *Grunert* [1980] ECR 1827, and of 5 February 1981 in Case 108/80 *Kugelmann* [1981] ECR 433).

Furthermore the Belgian Government contends that the Law of 24 January 1977 and the Royal Decree of 27 July 1978 cannot be said to infringe Article 30 *et seq.* of the EEC Treaty. Trade between the Member States would be impeded only if the use of a colourant were prohibited for imported products but permitted for the same products of domestic manufacture. The procedure for having substances entered on the Belgian list of additives, on the other hand, applies to foodstuffs of both foreign and domestic manufacture.

The Governments of the Netherlands, Denmark and the Federal Republic of Germany do not accept that last argument. In their view, a national prohibition on the use of certain colourants in the preparation of foodstuffs is in principle liable to impede indirectly the importation of foodstuffs from another Member State in which use of the same colourants is permitted. Such a prohibition is, however, compatible with Community law both as a result of the extremely limited degree of harmonization which the directives on colourants, preservatives and anti-oxidants have achieved with regard to food additives, and on the basis of the Court's interpretation of those directives (judgments of 5 February 1981 in Case 53/80 *Kaasfabriek Eyssen* [1981] ECR 409, and 14 July 1983 in Case 174/82 *Sandoz* [1983] ECR 2445).

4. The Commission and, of course, the defendant in the main proceedings take the opposing view, namely that the contested provisions are unlawful.

The Commission's argument is well-constructed. Thus the Commission concedes that the Belgian legislation is in conformity with the Directive of 23 October 1962 (the two additives are not prohibited in every case and the use of substances contained in the list annexed to that directive is permitted for lumpfish roe). However, it maintains that the legislation is contrary to the scheme of Articles 30 to 36 of the EEC Treaty. In support of that proposition it refers in the first place to the letter which it drafted following the judgment of 20 February 1979 (Case 120/78 *Rewe* v *Bundesmonopolverwaltung für Branntwein ,Cassis de Dijon'* [1979] ECR 649), and subsequently sent to the Member States. It is stated in that communication that technical and commercial rules, in particular those covering the composition, designation, presentation and packaging of products must under no circumstances impede the marketing in a Member State of 'any product lawfully produced and marketed' in

another Member State. Clearly rules such as the Belgian provisions in question does not comply with that requirement. It follows that the prohibition laid down in Article 30 must apply unless such provisions are justified by one of the grounds set out in Article 36 or by one of the mandatory requirements defined in the judgment in the '*Cassis de Dijon*' case.

The Commission then considers the approach adopted by the Court in its judgments in *Grunert, Kugelmann, Eyssen* and *Sandoz*, to which I have already referred, and in its judgments of 30 November 1983 in Case 227/82 *van Bennekom* ([1983] ECR 3883, and of 19 September 1984 in Case 94/83 *Heijn* [1984] ECR 3263. As is well-known those cases all concerned national rules regarding additives for foodstuffs which could be regarded as measures having an effect equivalent to quantitative restrictions but which the various governments sought to justify by reference to the need to protect public health.

According to the Commission, those decisions lay down the following criteria: (a) The use of colourants has not yet been regulated by Community law. The Member States must therefore adopt national rules governing the use of such products in view of their harmfulness. (b) However, national rules may not conflict with the principles regarding the free movement of goods and in particular with the principle of proportionality (see last sentence of Article 36). The prohibition on the use of a particular substance cannot therefore be enforced where its use is compatible with the protection of public health and corresponds to a genuine technical or nutritional need. (c) It is for the national authorities which rely on Article 36 to justify measures restricting trade to prove in each case that such measures are necessary to protect effectively the interests referred to in that provision and in particular public health. (d) Because of the uncertainties which exist in the scientific field as to the degree of harmfulness of colourants, on the one hand, and the different eating habits existing within the Community, on the other, even measures which are different to those adopted for the same substances in another Member State may be lawful under Article 36.

The Commission assesses the contested provisions on the basis of those considerations. As I have stated it considers that, notwithstanding their conformity with the 1962 directive, the extension of the procedure for authorization to products lawfully manufactured and marketed in another Member State conflicts with the scheme of Articles 30 to 36. That may be inferred from the Court's decisions which prohibit a State from impeding the importation of a product to which a colourant has been added when: (a) the substance in question appears in the list annexed to the Directive of 23 October 1962; (b) the addition of the colourant has been authorized in the State of origin; and (c) the colouring of the product satisfies a technological or nutritional need.

Indeed, on importation, cochineal red and indigotin have already passed two inspections. In the first place, before they were included on the Community list, their harmfulness was assessed in the light of international scientific knowledge and, in particular, research carried out by the Scientific Committee for Food on the amounts of additives which may be ingested daily without endangering health. Secondly, the risks arising from the use of the two substances were assessed by the State of

origin in the course of the procedure of authorization for the use of the product. In addition, in the case of lumpfish roe, colouring undeniably corresponds to a technological need.

In the Commission's view it follows that rules such as those in force in Belgium constitute measures having an effect equivalent to quantitative restrictions and fall under the prohibition provided for in Article 30. It may be objected that, since, with regard to colourants only a small degree of harmonization has been achieved, Member States can restrict the freedom of movement of goods by relying on the derogation provided for in Article 36. However, the Commission denies that that is the case in this instance. In its view the contested provisions do not satisfy the criteria which the Court has extracted from that provision, since they have the effect of impeding the importation of products to which colourants have been added '*a priori*'; in other words no evidence of the danger that their importation represents for public health is provided. On the other hand, the governments' reference to the decisions in *Eyssen*, *Sandoz* and *van Bennekom* are not relevant. The additives in those cases (niacin and vitamins) were not included in the Community list, whilst the case before the Court concerns two substances which appear in the Annex to the 1962 directive.

In any event there is a breach of the principle of proportionality inasmuch as the extension of the authorization procedure to imported products seems excessive in relation to the objective pursued by the legislature. The same result could perfectly well be attained by requiring the importer who intends to market the product prepared with a colourant to inform the authorities of that fact. Indeed such a rule would permit those authorities to determine in the light of the eating habits and the presence on the market of foodstuffs containing the same additive, whether the importation of the product might lead consumers to ingest more than the acceptable daily intake. In any case such a procedure would be considerably less restrictive of trade.

Mr Motte considers that the incompatibility of the Belgian provisions with Community law is clear from two further factors: (a) the conflict between the Royal Decree of 27 July 1978 and Article 32 of the EEC Treaty, which requires the Member States to refrain from making more restrictive measures existing at the date of the entry into force of the Treaty; and (b) the fact that it is impossible to regard the assessments carried out by the Belgian public health authorities concerning the necessity, value or suitability of the use of the additives as measures for the protection of public health justified under Article 36.

5. Expressed in terms which are more appropriate for proceedings under Article 177, the question submitted by the Cour d'Appel concerns the conformity with Community law of a national provision which prohibits the marketing, without prior administrative authorization, of foodstuffs prepared with the addition of colourants included in the Community list of permitted additives and marketed in the Member State of origin. It is therefore necessary to supply the Cour d'Appel with the criteria which will enable it to determine whether the preventive control which is the purpose of the authorization procedure may lawfully be imposed also in respect of products which are imported and which have already undergone similar checks in the State of origin, or whether it is incompatible with the provisions of the Treaty and with the secondary legislation regarding the free movement of goods.

Expressed in those terms, the problem is not new. The Court has dealt with it in a number of judgments (*Grunert, Eyssen, Sandoz, Kugelmann, van Bennekom* and *Heijn*, to which I have already referred, and in the judgment of 17 December 1981 in Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Produkten* [1981] ECR 3277). Those decisions, if the particular features of each individual case are disregarded, represent a sound basis on which to construct the reply to the questions submitted by the Cour d'appel. I must say at once that in my view the arguments with which the four governments have put forward to establish the lawfulness of the disputed provision find considerable support in the decisions of the Court. *A contrario* the principles which the Court has laid down make it impossible to accept the arguments put forward by the Commission and Mr Motte.

6. In the first place all the interveners, with the exception of the Belgian Government, consider that the provisions in question are contrary to Article 30 of the Treaty. On that point, moreover, there can be no doubt. It is clear that a general prohibition on the addition (without an *ad hoc* authorization) of certain colorants to a foodstuff make it impossible to import and to market a product prepared in that way (see the judgment in *Sandoz*, p. 12, paragraph 8 of the decision). Moreover, when that has been established and it has been concluded therefrom that rules such as those laid down in the Royal Decree of 27 July 1978 impede intra-Community trade, it is necessary to determine whether and within what limits Member States may introduce or retain such rules in their legal order. As has been seen the provisions which must be taken into consideration for that purpose are contained in the Council Directive of 23 October 1962 and Article 36 of the EEC Treaty.

Bearing that premise in mind I shall now analyse the arguments of the Commission and Mr Motte in the order in which I have referred to them. The first of those arguments, it may be recalled, is based on the fact that cochineal red and indigotin are included in the list annexed to the directive. In substance the Commission maintains that the inclusion of an additive in that list compels the Member State to authorize it in every case and, based as it is on the research conducted by the Scientific Committee for Food, confers on it what is in fact an official endorsement of its harmlessness. The first proposition is certainly erroneous. The list is in no way intended to compel Member States to allow the use of the substances included in it, but, on the contrary, to prevent the States from authorizing the use of substances which are excluded from it. In other words the list imposes a *negative* obligation or, if it is preferred, a prohibition.

That interpretation is confirmed by Articles 1 and 5 of the directive. In Article 1 the Member States *may* (rather than must) authorize the use of a substance in a specific product. Under Article 5 the directive *does not affect* national rules which specify the products which may be coloured by the substances referred to in the list. Moreover, and more significantly, the aim of the directive provides further support for that interpretation. According to its preamble, it constitutes only the first stage in the process intended to harmonize national laws in the sector in question and that stage is to be achieved by the establishment of an exhaustive list of the substances whose use may be permitted. Thus, as I have already stated, the harmonization is only at the embryonic stage. It is not sufficiently advanced to impinge upon the Member States' fundamental power to draw up in their turn a list of products which may be prepared with the colourants listed in the directive and to define the conditions for their use.

Furthermore, the stages for the harmonization of the sector (first the list, followed by further measures specifying the products and the additives permitted for each of them) are identical to those which the Community legislature has employed for the other directives concerning additives for food (Directives 64/54 on preservatives and 70/357 on anti-oxidants). It is therefore permissible to apply to this case the observations which the Court made in the judgments in *Grunert* and *Kugelmann* in interpreting those directives. It stated that 'the Member States have retained a certain discretion to determine their own rules concerning the addition (of additives) . . . , subject to the twofold condition that (no substance) may be authorized unless it appears in one of the lists annexed to the directives and that the use of (a substance) which is listed there may not be totally prohibited' (*Grunert*, paragraph 8 of the decision). That is so, clearly, only if the addition corresponds to a 'technological necessity' (*Kugelmann*, paragraph 7 of the decision).

Secondly, I consider the view that the inclusion of an additive in the Community list is equivalent to a certificate of harmlessness somewhat tenuous. For one thing I would think it improbable that a directive dated 23 October 1962 could take account of all the most recent scientific discoveries. Then again it is doubtful that the results of the research undertaken by the Committee for Food are as completely reliable as the Commission's arguments would suggest. In the first place the acceptable daily intake of a substance (0.5 milligrams per kilogram of bodyweight in case of the colourants in question) is determined by extrapolating results obtained from animal experiments. In the same opinion of the Committee for Food, which the Commission annexed to its observations, it is stated that: 'The extrapolation would be even more definite if the species used for the experiment were closer to man. Unfortunately, such an ideal situation is encountered infrequently and it is necessary to take into account the variability of reactions and sensitivities of different animal species and breeds selected for laboratory research' (Report of 22 February 1980, p. 22).

Moreover it transpires from other reports of the Committee that research into the effects of cochineal red A was carried out *in vitro* and no experiments were conducted on living organisms. In addition it appears that indigotin is at least 'poorly absorbed from the gut' (1984 Report, doc. EUR 8752, pp. 59 and 61, annexed to the Commission's observations). In those circumstances I consider that this case must come within the scope of the principle laid down by the Court in *Frans-Nederlandse Maatschappij* and confirmed in *Sandoz* and *van Bennekom*. The Court stated that 'in so far as there are uncertainties at 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 free movement of goods . . . '. Nor is it possible to object, as the Commission does, that in those cases the substances at issue (niacin and vitamins) were not included in the Community lists. In fact niacin is expressly mentioned in Article 6 of Directive 64/54 and vitamins do not appear in the lists because they are nearly always harmless.

7. The Commission's second argument is even more tenuous. It maintains that since the addition of colourants to lumpfish roe is authorized in the State of origin it cannot be made subject to a new authorization in the importing State. On the contrary the Court stated in *Frans-Nederlandse Maatschappij* — where the subject of the prohibition was a disinfectant to which toxic substances had been added — that a State 'is not prohibited from requiring (the product in question) to be subject to prior approval, even if (those products) have already been approved in another Member State' (paragraph 16 of the decision). Equally important for the purposes of this case in my view is the rule which the Court laid down in *Heijn* that Member States may introduce rules in respect of foodstuffs containing additives in a way which may 'vary from one country to another according to climactic conditions, the normal diet of population and their state of health ... . They may permit different levels (of the same product) in respect of different foodstuffs' (paragraph 16 of the decision).

Of course limits have been placed on those principles in the same and in other judgments. Thus the importing States cannot unnecessarily require analyses or tests if such analyses and tests have already taken place in another State and if their results are made available to it (see *Frans-Nederlandse Maatschappij*, paragraph 14 of the decision). However, those principles remain valid and the Court must continue to affirm them energetically if it wishes to avoid a situation in which the exercise of the power conferred by Article 36 on each Member State may bind all the other States of the Community. Indeed, if the Commission's argument were accepted, those other Member States could be forced to model their legislation on that of the State which had adopted the most permissive approach to public health. Article 36 would thus be used in a way which is completely foreign to its spirit as a direct instrument for harmonizing national provisions on the basis of the lowest level of awareness of the problems of public health.

8. The third argument advanced by the Commission refers to the assertion that the colouring of lumpfish roe corresponds to a technological or nutritional need. In the Commission's view, a State which disregards that need by prohibiting the substances which can meet it is adopting a position contrary to the principles laid down by the Court. Once again I do not agree. A technological need for food additives exists only when their addition is indispensable during the different stages of the production process of the product (for example preservatives, emulsifiers and gelatin). The reasons for the colouring of the foodstuff in question here are substantially different. They are of an organoleptic nature or, if it is preferred, psychological, as is proved by the fact that fish roe free of colouring is available on the Community market for those consumers who take the most uncompromising attitude towards disguising the natural appearance of their food and who are most concerned with its purity. I therefore consider it excessive to define as technological or nutritional a need such as that of rendering lumpfish roe more appetizing by making them similar in appearance — although certainly not in taste — to more exalted delicacies such as caviar, salmon roe and carp roe.

9. Fourthly the Commission maintains that the provisions in question prohibit *a priori* the importation of products to which

colourants have been added and that *'a priori'* means by releasing the importing Member State from its duty to state the reasons for which the introduction of such products constitutes a public health risk. It is easy to refute that proposition. In the provisions in question the prohibition is not absolute but constitutes the central rule in a flexible system under which applications from the producers and the importers may be accepted, at least when they are consistent with the requirements of the protection of public health. If they are found not to be consistent with those requirements, then clearly the authorities must provide proof.

It appears from the papers in the case, in addition, that the authorization to market coloured lumpfish roe was not granted because neither Mr Motte nor the other importers initiated the prescribed procedure.

10. Finally the Commission argues that the Belgian measure is not appropriate because it exceeds the aim pursued by the legislature and therefore infringes the principle of proportionality laid down by the Court with regard to public health in the judgments of *Sandoz* and *van Bennekom* (paragraphs 18 and 39 of the decisions respectively). Equally effective and less restrictive results could be obtained by requiring the importer to inform the appropriate authorities of his intention to release onto the market a product containing colourant, where the product in question has been lawfully manufactured and released for consumption in the State of origin.

Here, too, I disagree, and not only because to exempt the imported products from the authorization procedure would place them in an advantageous position capable of disturbing the balance of the market and not justifiable under the Treaty. The decisive consideration is that under the system proposed by the Commission there is a risk that things will be left as they stand or made considerably worse. Such a system would either consist of a control genuinely intended to establish whether the product was harmful and thus ultimately no less restrictive than the procedure which it was supposed to replace or become a bureaucratic formality and therefore clearly unsuitable to achieve the aims of the control of foodstuffs. *Tertium non datur.*

11. None of the arguments advanced by the Commission stand up to even cursory inspection. The same may be said of the propositions put forward by Mr Motte. The reference which he makes to the 'standstill' obligation (Article 32 of the Treaty) is without foundation because the exception provided for in Article 36 refers expressly to all 'the provisions of Articles 30 to 34'. His second argument is no less inconsistent. The analyses which the Belgian public health authorities carry out to determine whether the use of the additives is necessary, useful or suitable, in Motte's view, bear no relation to the protection of public health. Even if that is the case Motte forgets that the body in question is also required to assess the harmfulness of the additive and the degree of tolerance of humans for it.

12. On the basis of all the foregoing considerations I propose that the Court should reply to the question submitted by the Eighth Criminal Chamber of the Cour d'appel, Brussels, by judgment of 26 September 1984 in the criminal proceedings against Léon Motte of Woluwé-Saint-Pierre as follows:

In the present state of Community law on foodstuffs prepared with the addition of colourants, the provisions of the Treaty and secondary legislation on the free movement of goods must be interpreted as not precluding a Member State from adopting measures by which, on the grounds of the protection of public health referred to in Article 36 of the Treaty, the addition of such substances is prohibited without prior administrative authorization, provided that the rules are the same for domestic products and imported products and that they do not impose restrictions which are unnecessarily heavy on such imported products.

The authorization for marketing may be required even if the production and release for consumption of the products in question has already been authorized in another Member State. The authorities of the importing State are however not entitled unnecessarily to require technical or chemical analyses or laboratory tests where the same analyses or tests have already been carried out in another Member State and their results are available to those authorities or may at their request be placed at their disposal.