OPINION OF ADVOCATE GENERAL ALBER

delivered on 7 November 2000 [1]

I — Introduction

1. These proceedings are concerned with the permissibility of amalgamating the procedure for the provision of information under Directive 83/189/EEC and the Treaty infringement proceedings under Article 226 EC. This question arises from the examination of the compliance with Article 28 EC of a draft French order concerning rubber materials and rubber articles entering into contact with foodstuffs, food products and beverages.

II — The applicable rules

2. Article 226 EC provides:

'If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.

If the State concerned does not comply with the opinion within the period laid down by the Commission the latter may bring the matter before the Court of Justice.'

3. Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, amended by Council Directive 88/182/EEC of 22 March 1988 (hereinafter 'Directive 83/189') provides: [2]

'*Article 8*

1. Member States shall immediately communicate to the Commission any draft technical regulation, except where such technical regulation merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a brief statement of the grounds which make the enactment of such a technical regulation necessary, where these are not already made clear in the draft. Where

1 — Original language: German.

2 — OJ 1983 L 109, p. 8.

appropriate, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.

The Commission shall immediately notify the other Member States of any draft it has received; it may also refer this draft to the Committee referred to in Article 5 and, if appropriate, to the Committee responsible for the field in question for its opinion.

2. The Commission and the Member States may make comments to the Member State which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. At the express request of a Member State or the Commission, Member States shall communicate to them, without delay, the definitive text of a technical regulation.

4. ...

Article 9

1. Without prejudice to paragraphs 2 and 2(a), Member States shall postpone the adoption of a draft technical regulation for six months from the date of the notification referred to in Article 8(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged must be amended in order to eliminate or reduce any barriers which it might create to the free movement of goods. The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.

2. The period in paragraph 1 shall be 12 months if, within three months following the notification referred to in Article 8(1), the Commission gives notice of its intention of proposing or adopting a Directive on the subject.

2(a) If the Commission ascertains that a communication pursuant to Article 8(1) relates to a subject covered by a proposal for a directive or regulation submitted to the Council, it shall inform the Member State concerned of this fact within three months of receiving the communication.

Member States shall refrain from adopting technical regulations on a subject covered

by a proposal for a directive or regulation submitted by the Commission to the Council before the communication provided for in Article 8(1) for a period of 12 months from the date of its submission.

Recourse to paragraphs 1, 2 and 2(a) of this Article cannot be cumulative.

3. Paragraphs 1, 2 and 2(a) shall not apply in those cases where, for urgent reasons relating to the protection of public health or safety, the protection of health and life of animals or plants, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible. The Member State shall give, in the communication referred to in Article 8, the reasons which warrant the urgency of the measures taken. The Commission shall take appropriate action in cases where improper use is made of this procedure.'

4. Articles 1, 2, 4, 5 and 7 of the French order of 9 November 1994 concerning rubber materials and rubber articles entering into contact with foodstuffs, food products and beverages, provide:

'Article 1 — Rubber materials and rubber articles that are held for sale, offered for sale or sold for contact with foodstuffs, food products and beverages and rubber materials and rubber articles brought into contact with those foodstuffs, food products and beverages must meet the requirements of this Order.

Article 2 — "Polymers" shall mean

— dry natural latex and rubber;

— dry synthetic latex and rubber, consisting of organic homopolymers or copolymers. An indicative list of these polymers and of the abbreviations that can be used in referring to them is contained in Table A of Annex I.

The synthetic polymers used in manufacturing the materials and articles listed in Article 1 must be produced only from monomers, base materials and modifying agents listed in Table B of Annex I. For some of these monomers and base materials, a maximum permitted residue ("Qm"

expressed in milligrams per kilogram of the material or article) and/or a specific migration limit ("SML", expressed in milligrams per kilogram of foodstuffs or foodstuff simulants shall be set). Adherence to these two types of limit is to be verified in the ready-to-use material or article.

...

Article 4 — In the manufacture of the rubber materials and rubber articles referred to in Article 1, only the additives which are listed in Annex II may be added to the polymers designated in Article 2 of this Order.

The conditions for use and the restrictions laid down in Annex II for specific substances or groups of substances shall be adhered to. Where appropriate, the specific migration limits (SML) and/or the maximum permissible absorption quantities (Qmax) shall be specified.

Article 5 — Where appropriate, the substances named in Annex II are to be accompanied by quantified data concerning adherence to specific purity criteria or to purity criteria recognised as being equivalent, and which have been set by the authorities of the Member States of the European Communities or of the Contracting Parties to the Agreement on the European Economic Area.

...

Article 7 — The rubber materials and rubber articles must meet the following criteria of inertness:

Volatile free organic substances ≤ 0.5 p 100;

Total migration

≤ 10 milligrams per square decimetre of the surface of the material or article coming into contact with it (mg/dm^2), or

≤ 60 milligrams of constituents transferred per kilogram of foodstuffs, food products and beverages (mg/kg), in the following cases:

(a) receptacles or articles comparable to receptacles with a filling capacity of between 500 ml and 10 litres;

(b) fillable articles where it is not possible to assess the surface area coming into contact with foodstuffs, food products and beverages;

(c) lids, seals, stoppers or other similar sealing devices.

Specific limits:

N-nitrosamines and N-nitrosable substances;

N-nitrosamines: SML ≤ 1 μg/dm^2

N-nitrosable substances: SML ≤ 10 μg/dm^2.

Those two specific limits shall not apply to materials used in the production of teats and dummies which shall fall under the specific provisions contained in Article 8 of this Order.

Primary and secondary aromatic amines: SML ≤ 1 mg/kg;

Formaldehyde: SML ≤ 3 mg/kg.

Peroxides: Finished, ready-to-use materials and articles must not give a positive reaction to peroxides, according to the method defined in the 10th Edition of the French Pharmacopoeia.'

III — Facts and proceedings

5. By letter of 18 November 1993, the French authorities submitted to the Commission, in accordance with Article 8 of Directive 83/189, a draft order concerning rubber materials and rubber articles entering into contact with foodstuffs, food products and beverages, in order for it to

be examined for compliance with Community law. On the basis of Article 9 of Directive 83/189, the Commission delivered a detailed opinion on 20 February 1994 regarding the draft order. In its introduction, reference was made to the procedure under Directive 83/189 and it expressly gave as its legal basis Article 9(1) and Article 8(2) of Directive 83/189. The Commission alleged that the draft order did not include clauses ensuring the application of the principle of mutual recognition. In order to make the draft conform to Community law, it required that specific provisions be inserted to ensure the recognition of technical regulations, standards and production procedures applied lawfully in other Member States or in a State party to the EEA Agreement. Furthermore, it stated that provision should be made for specific recognition of the results of checks and tests, as well as in this respect certificates of inspectorates and supervisory authorities of other Member States or contracting states of the EEA Agreement, or certificates issued by laboratories officially recognised in those countries, offering suitable, adequate guarantees, from the technical and specialist point of view and from the point of view of their independence. Expressly referring again to Article 9(1) of Directive 83/189, the Commission also pointed out that France was obliged, following delivery of the detailed opinion, to wait six months before adopting the order. A deadline of 19 May 1994 was set. Furthermore, France was reminded of its duty to inform the Commission how it intended to take account of the detailed opinion. The Commission concluded the opinion by stating that, if its objections were not taken into account, the opinion was to be regarded as a letter of formal notice, within the meaning of Article 226 EC, and that the response of the French Government would be regarded as observations within the meaning of Article 226 EC.

6. By letter of 9 August 1994, the French Government replied that the Commission had itself recognised the need to harmonise the rules on materials coming into contact with foodstuffs. Community legislation in this area which had already been adopted or which was under discussion was not characterised by mutual recognition, but by total harmonisation. Furthermore, the French Government claimed that the draft order submitted did contain a mutual recognition clause: its wording was identical to that used in the order on silicon elastomers which the Commission had accepted at the time. This letter did not address the legal qualification of the detailed opinion as a letter of formal notice or the question of any answer by the French Government being treated as observations within the meaning of Article 226 EC.

7. On 9 November 1994, the French order was adopted without the express recognition clauses requested by the Commission. On 5 January 1995, the French Government communicated the adopted text to the Commission.

8. Subsequently, discussions took place between Commission officials and the

French authorities without agreement being reached between the parties.

9. On 3 December 1997, the Commission sent to the French Republic a reasoned opinion pursuant to Article 226 EC. In this, it alleged, as in its letter of 20 February 1994, that Articles 2, 4, 5 and 7 of the French order were incompatible with Community law, in particular with the principle of free movement of goods (Article 28 EC). The order only permitted the use of the products listed in the specified provisions. There was no clause ensuring the mutual recognition of goods lawfully marketed in other Member States or in States parties to the EEA Agreement and of the checks and tests carried out in those other Member States or countries. Furthermore, the Commission considered that the prior approval procedures were a disproportionate restriction of the free movement of goods, in particular since the time of the entry into force of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs [3] and Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. [4] Referring to Article 226 EC, it set France a deadline of two months to align its legislation with Community law.

10. By letter of 18 February 1998, the French Government answered that the challenged order already contained provisions guaranteeing mutual recognition. It referred in particular to Article 5 of the order, which it said contained a recognition clause in relation to the purity criteria governed by Annex II of the order. The mutual recognition of checks and tests, as well as of certificates issued in relation to them, was guaranteed by the reference, in Annex III of the order, to the order of 14 September 1992. Finally, as to the mutual recognition of technical regulations, standards, etc., the French Government proposed to include in the order a new Article 4a, incorporating a clause used in another order and accepted by the Commission. The inclusion of a provision concerning the mutual recognition of standards and production procedures was, however, considered by the French Government to be neither justified nor opportune. It concluded its letter by expressing a desire for early harmonisation of the relevant regulations and by pointing out that the Member States were entitled, under Articles 7(2) and 11 of Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs, to continue to apply their national provisions. [5] The letter also did not comment on the legal qualification of the various documents exchanged.

11. Further correspondence took place between the Commission and the French Government, on 15 April and 9 June 1998, on the wording of the proposed new Article 4a without the parties reaching agreement.

3 — OJ 1989 L 186, p. 23.

4 — OJ 1993 L 175, p. 1.

5 — OJ 1989 L 40, p. 38.

12. By document of 8 June 1999, received on 15 June, the Commission brought an action against the French Republic.

IV — Arguments of the parties

13. The Commission takes the view that its action is admissible. It states that the pre-litigation procedure had been properly carried out before the action was brought. Article 226 EC merely provides that the Member State should be first of all afforded the opportunity to submit observations regarding the alleged infringement of its obligations under the Treaty, and that, at a second stage, it may comply with the terms of the reasoned opinion. Article 226 EC does not determine the form in which the Commission is to formulate its letters. The provision does not therefore preclude a detailed opinion from serving as a letter of formal notice. All that matters is that the Member State should be informed of the subject-matter of the infringement proceedings with sufficient precision to enable it to defend itself against the charge. There is no uncertainty for the French Republic. The Commission clearly expressed its view of the directive, and it was solely up to the French Government to decide whether or not the condition under which the detailed opinion would become a letter of formal notice would come about.

14. Substantively, the Commission alleges an infringement of the principle of the free movement of goods guaranteed by Article 28 EC. In the absence of Community law harmonisation in the field of elastomer and rubber products which may come into contact with foodstuffs, the Member States do have competence to adopt provisions concerning the production and marketing of those articles. However, the national provisions must adhere to Community law. The order in question infringes Community law in that it prohibits the marketing in France of rubber products lawfully produced in other Member States if they do not satisfy the provisions of the order. The requirement of prior approval provided for in the order is compatible with the principle of free movement of goods only if provision is made for a simple, fast procedure enabling market operators to have Annexes I and II of the order amended. For this reason, a mutual recognition clause is needed. A simple administrative practice under which recognition could be granted in individual cases, as proposed by the French Government, does not meet these requirements.

15. Whilst Article 5 of the order contains a certain flexibility as to the purity criteria for the materials named in Annex II, the list of monomers, base materials and modifying agents (agents modificateurs) contained in Table B of Annex I of the order is, however, presented in the order as exhaustive, and the list of additives contained in Annex II is also set out as an exhaustive list.

16. The Commission considers that inserting a mutual recognition clause would guarantee respect for the principle of proportionality within the framework of Article 30 EC. Whilst health protection is an element of the recognised considerations of general public interest, the contested order goes beyond what is necessary since it does not recognise equivalent rules made by other Member States. Even wording enabling national authorities and courts to decide in individual cases on approval of a product does not satisfy the requirements of legal security and transparency: these would not adequately inform operators of their rights.

17. As regards the mutual recognition clause quoted by the French Government, which has been included in a French order in another context, the Commission first of all states that the contentious order does not as yet contain such a clause, and that there is only a French proposal to amend the order. In any case, it is the wording of the order at the time of issue of the reasoned statement which is relevant in determining whether an infringement of Treaty obligations has been committed.

18. The French Republic takes the view that the action is inadmissible. So far as the Commission merges the procedure for the provision of information under Directive 83/189 with the procedure under Article 226 EC for establishing infringement of a Member State's obligations, it infringes the hierarchy of legal rules. The Commission's interpretation of Directive 83/189 is in violation of Article 226 EC, which provides for three steps in the procedure: the letter of formal notice, the reasoned statement and the application to the Court.

19. Furthermore, treating detailed opinions under Directive 83/189 as equivalent to a letter of formal notice goes against the distinction between preparatory acts and binding legal acts. The draft transmitted in the procedure for the provision of information under Directive 83/189 has not yet entered into force. There is therefore as yet no infringement of the Treaty which could give rise to a letter of formal notice.

20. Finally, the French Government claims a violation of the right to be heard. Making a detailed opinion equivalent to a letter of formal notice denies France an opportunity to submit observations in the context of the procedure to establish a breach of Treaty obligations.

21. On the substance, the French Government submits that Directive 89/109 makes provision for the harmonisation of rules relating to materials coming into contact with foodstuffs. On the basis of this framework directive, a directive on rubber should have been adopted, amongst other things. Since, however, this has not yet occurred, the French Government was prompted to issue regulations on this matter itself, for reasons of health protection. It was also in order to accelerate harmonisation in this

sphere that it notified the draft order in question.

22. The French Government considers the order to be proportionate. The Court has consistently held that, in the absence of harmonisation, a Member State may itself set the level at which it guarantees health protection. This could go as far as laying down a requirement for prior approval. Technical or chemical analyses or laboratory tests carried out in other Member States must simply be taken into consideration. The French Government never denied this in applying the contentious order. Under case-law, it is not necessary to include an express mutual recognition clause. All that is necessary is to ensure that recognition is possible in fact.

23. Furthermore, the Commission's view is untenable in so far as it has accepted in another context the legal validity of a mutual recognition clause similar to that used in the order now in question.

V — Opinion

1. *Admissibility of the action*

24. The first question to be considered is whether the action of the Commission is admissible. There are doubts in this regard in that the Commission communicated to France a detailed opinion within the meaning of Article 9(1) of Directive 83/189 but stipulated that the text would become a letter of formal notice within the meaning of Article 226 EC in the event of failure to abide by the terms of the opinion. It should be examined whether this procedure meets the requirements of Article 226 EC.

25. In its order of 13 September 2000 in Case C-341/97 *Commission* v *Netherlands* [2000] ECR I-6611, the Fifth Chamber of the Court answered this question in the negative. It reasoned that the dispatch of a letter of formal notice within the meaning of Article 226 EC presupposes an assertion of the existence of an infringement of a Member State's obligations under the Treaty. However, when a detailed opinion within the meaning of Directive 83/189 is sent, the Member State cannot yet have committed an infringement of its obligations under the Treaty since the legal act submitted in the procedure for the provision of information exists only in draft form. A conditional letter of formal notice, depending on the conduct of the Member State in question, does not satisfy the requirements of legal security. Adherence to this principle is, the Court held, indispensable in procedures which can lead to legal proceedings. [6]

26. That decision must be approved. Under Article 226 EC, the Treaty infringement procedure is divided into three stages. First of all, the Member State must be given an

6 — See paragraphs 18 to 20 of the order.

opportunity to submit its observations; this is done by a letter of formal notice; the Commission then draws up a reasoned opinion and only then may an action be brought.

27. The present case concerns the first stage — the opportunity to submit observations. It has been consistently held that the letter of formal notice fulfils two functions: first, the Member State is granted the right to be heard and, second, the letter of formal notice circumscribes the future subject-matter of the dispute.[7] The action taken by the Commission towards France may therefore be lawful only if in joining the detailed opinion with the letter of formal notice these two functions are maintained.

28. The question of guaranteeing the right to be heard does not appear to raise any difficulty in this case. It is true, as the French Government points out, that two procedures with quite different purposes are being amalgamated. The procedure under Directive 83/189 is meant to prevent future infringements of the Treaty. Before any infringement of the Treaty occurs, the legal situation is to be clarified beforehand and a solution which conforms with Community law worked out. In this respect, it is a preventive procedure. On the other hand, the procedure to establish an infringement of obligations under the Treaty, which starts with the letter of formal notice, is a repressive procedure. It is designed to restore observance of the Community legal order.

29. But the right of the Member State concerned to be heard is not thereby infringed. Because of the amalgamation of the detailed opinion and the letter of formal notice, the Member State has, it is true, less opportunity of expressing its views. But the principle of granting a hearing only requires an actual opportunity to submit observations to be granted, not that this must be done several times. When the Commission communicates a detailed opinion in which it states that a draft law is not compatible with Community law and gives its reasons, the Member State must consider the Commission's arguments and respond to them just as in the case where it receives a letter of formal notice. This conclusion is confirmed by the conduct of the Commission and France in the present case. The detailed opinion of 20 February 1994 expressly calls upon the French Government, as provided for in Article 9(1) of Directive 83/189 as amended by Directive 88/182, to report to the Commission on the measures which the Member State intends to take as a result of the detailed opinion. And the French Government, by letter of 9 August 1994, replied that it considered the view of the Commission to be incorrect. In this respect, there is no element of surprise, as the French Government claimed at the hearing. The, conclusion must therefore be that the course taken by the Commission meets the requirement of ensuring the right to be heard and that it is compatible with Article 226 EC in this respect.

7 — Case 274/83 *Commission* v *Italy* [1985] ECR 1077, paragraph 19; Case C-135/94 *Commission* v *Italy* [1995] ECR I-1805, paragraph 5.

30. However, as far as the second function of the letter of formal notice is concerned, that of the subject-matter of the dispute, the Commission's course of action gives rise to legal reservations. Whilst it has been consistently held that no excessive requirements should be made of letters of formal notice, they must contain a first, brief summary of the Commission's allegations. [8] The reasoned opinion to be submitted at a second stage on the basis of the facts set out in the letter of formal notice must clearly define the subject-matter of potential future infringement proceedings. It must contain a detailed, coherent description of the reasons forming the basis of the Commission's conviction that the Member State in question has violated an obligation incumbent upon it under the Treaty. [9]

31. The Commission's course of action does not meet this requirement. In cases like this, in which the draft submitted was later adopted without any change, no legal uncertainty should arise in relation to the future subject-matter of the dispute. However, the Member State could, for instance, partly take account of the Commission's objections contained in the detailed opinion. Certainly, it may then be open to question whether and to what extent the Commission would then consider the legal text, amended in part to meet its objective, to be unlawful. In this situation, the question of legal certainty arises.

32. The situation is also unclear if a long period of time elapses between the detailed opinion and the adoption of the national legal text. During that time, Community law, or indeed national law, could change, so that the draft might then be judged differently by the Commission. In such cases, too, it may not be sufficiently certain whether or not an infringement of obligations under the Treaty has taken place.

33. The amalgamation by the Commission of the procedure for the provision of information with the Treaty infringement procedure may therefore lead to uncertainty in relation to the assessment of the legal situation by the Commission and thus to uncertainty as to the subject-matter of any legal proceedings.

34. It could be objected that this uncertainty is removed by the issue of the reasoned opinion. This, however, appears insufficient. On the one hand, a certain period of time elapses between the Member State's response and the issue of the reasoned opinion, during which it is unclear whether the Commission is going to pursue proceedings at all. On the other hand, the document which is treated as a letter of formal notice once the condition suspending this status materialises no longer contains an initial delimitation of the subject-matter of the dispute if the legal situation is altered through the adoption of a new national law or new Community law. In this respect, the Commission's course of action does not satisfy the requirements of Article 226 EC.

8 — Case 274/83 *Commission* v *Italy*, cited above at footnote 7, paragraph 21; Case C-135/94 cited above at footnote 7, paragraph 7.

9 — Case C-135/94, cited above at footnote 7, paragraph 7.

35. The solution proposed here should not be treated as pure formalism if, in addition to the detailed opinion, the sending of a letter of formal notice having broadly the same content as the detailed opinion were required. It is necessary to distinguish between these two documents, for the reasons of legal certainty mentioned above, and for the following substantive reason: when the information procedure is being conducted, there is still no Treaty infringement: there is only a potential infringement. When the letter of formal notice is sent, on the other hand, a Treaty infringement has already taken place, always assuming the Commission's analysis to be correct.

36. This difference in the legal situation affects the attitude of the Member States. The urgency with which the Member State must act is different. In the first case, the Member State acts in conformity with the Treaty as long as it does not adopt the legal act. But in the second case the Member State is obliged to act without delay and to restore a situation in conformity with the Treaty. Also, this difference between the two situations, grounded as it is in the substantive law situation, justifies, besides the requirement of legal certainty, the clear formal distinction between them.

37. For these reasons, the distinction between the detailed opinion provided for by Article 9 of the Directive and the letter of formal notice provided for by Article 226 EC must be observed. Amalgamating them by inserting a suspensive condition is incompatible with Article 226 EC.

38. It must therefore be found that the Commission did not conduct the pre-litigation procedure in accordance with Article 226 EC, so that its action must be dismissed as inadmissible.

2. *In the alternative: the merits of the Commission's application*

39. Only in the alternative, in the event of the Court not accepting the argument set forth above but considering the action to be admissible, are its merits now considered.

40. The provisions of the contested order constitute a measure having an effect equivalent to a quantitative restriction in so far as it permits only the marketing of the substances and compounds listed in Article 2 in conjunction with Annex I, and in Article 4 in conjunction with Annex II. France justifies this measure on the ground that it is required in order to protect health effectively and the Commission in principle recognises this ground of justification. The only issue is whether the basic prohibition, subject to authorisation, introduced by the order is proportionate. The observations below will be confined to this aspect.

41. In areas not subject to Community law harmonisation, the Member States are basically permitted to provide for approval

procedures for goods that are to be marketed on their territory. [10] The authorities of the Member States are, however, obliged to contribute towards alleviating checks in intra-Community trade and to take into consideration any technical or chemical analyses as well as laboratory tests already carried out in another Member State. [11] The checks carried out by the Member States must not go beyond what is necessary. It is for the Member State concerned to provide evidence that the measures selected are necessary to protect human health. [12]

42. A basic prohibition of substances other than those listed in the French order, coupled with the possibility for a product with a different substance to be permitted in an individual case on the basis of official authorisation, is apt for safeguarding health protection. However, the question is whether it is also a necessary means to achieve health protection. This may be a matter of doubt in that a mutual recognition clause, as required by the Commission, would render approval unnecessary in individual cases, and in this respect a less constraining means is available to achieve the desired objective.

43. The effect of the order in question is that each rubber product that may come into contact with foodstuffs, irrespective of whether or not it has already been subject to inspection in another Member State, must be subjected to an approval procedure. If it emerges that the product contains a basic material within the meaning of Article 2 that is not listed in Annex I, approval must be refused under Article 1 of the order. Only for additives within the meaning of Article 4 does the order also provide in Article 5 for the recognition of other substances if they have already been tested in other Member States.

44. The French Government has neither explained why the exhaustive listing in Annexes I and II is necessary in order to ensure comprehensive health protection nor shown that there is no alternative within the Community to the level of protection and checking and testing procedures applied in France in order to achieve the desired aim of health protection. In its letter of 9 August 1994, it merely stated that the provisions of the order were based on an opinion of the Conseil Supérieur d'Hygiène Publique de France. However, that body cannot be the sole agency to lay down adequate health protection standards in relation to the use of rubber products coming into contact with foodstuffs. The solution indicated by the Commission, namely the recognition of other checks and tests and of reports on them, is a measure which constitutes less of a restriction for the free movement of goods and which is apt to afford just as sufficient a safeguard for health protection.

10 — Case 272/80 *Franse-Nederlandse Maatschappij voor biologische Producten* [1981] ECR 3277, paragraph 14; Case C-400/96 *Harpegnies* [1998] ECR I-5121, paragraph 33.

11 — *Harpegnies*, cited above at footnote 10, paragraph 35.

12 — Case C-228/91 *Commission* v *Italy* [1993] ECR I-2701, paragraph 27.

45. France's willingness to take into consideration the results of tests in individual cases cannot shake that conclusion. Firstly, the wording of the order provides no guarantee that the French authorities will carry out an examination in an individual case. Operators cannot therefore see immediately whether authorisation will be granted in an individual case. Furthermore, the result of an individual examination would also lead to an amendment of the lists contained in Annexes I and II of the order. This way of gaining approval in individual cases would be likely to inhibit interstate trade unnecessarily and is therefore disproportionate.

46. For these reasons, the French order would constitute a disproportionate restriction of the free movement of goods. It would therefore be in breach of Article 28 EC.

VI — Costs

47. In accordance with Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs of the proceedings if they have been applied for. France has not asked for the Commission to be ordered to pay the costs. Both parties must therefore bear their own costs.

VII — Conclusion

48. On the basis of the foregoing, I therefore propose that the Court should rule as follows:

(1) The action is dismissed as inadmissible.

(2) Each party is to bear its own costs.