OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER

delivered on 25 April 1996 *

1. The Commission has brought this action before the Court of Justice for a declaration that the Italian Republic has failed to fulfil its obligations under Articles 8 and 9 of 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, [1] by adopting various internal decrees without notifying them to the Commission at the draft stage. In particular, the action concerns the following four decrees of the Ministry of Health: Decrees Nos 256 and 257 of 1 August 1990 concerning edible lamellibranch molluscs; [2] the Decree of 1 September 1990 concerning bivalve molluscs, [3] and the Decree of 7 June 1991 concerning proprietary medicinal products originating from cattle organs and tissues. [4]

2. To delimit the ambit of the dispute, I shall refer first to the prior notification procedure laid down by Directive 83/189 in relation to technical regulations. I shall then consider the problem of the admissibility of the application and, finally, I shall concentrate on examining the parties' substantive arguments.

Information procedure under Directive 83/189

3. Directive 83/189, as amended by Directives 88/182/EEC [5] and 94/10/EC, [6] established preventive machinery designed, in conjunction with the prohibition of measures having an equivalent effect to quantitative restrictions laid down by Articles 30 to 36 of the EC Treaty and the harmonization of national laws, to eliminate technical barriers to trade in the Community.

* Original language: Spanish.

1 — OJ 1983 L 109, p. 8.

2 — Ministerial Decree No 256 of 1 August 1990, amending the Ministerial Decree of 27 April 1978 concerning the microbiological, biological, chemical and physical characteristics of zones inhabited by natural deposits and beds of edible lamellibranch molluscs and of zones intended for the cultivation of molluscs, for the purpose of classifying them as approved, conditional and prohibited zones (*Gazzatta Ufficiale della Repubblica Italiana* No 211, 10 September 1990, p. 5).
Ministerial Decree No 257 of 1 August 1990 amending the Ministerial Decree of 5 October 1978 concerning the microbiological, chemical and biological characteristics of edible lamellibranch molluscs by reference to their intended use. Detailed rules for the sampling of edible molluscs which may be subject to analysis at different stages of production and marketing (GURI No 211, 10 September 1990, p. 7).

3 — Ministerial Decree of 1 September 1990 concerning the methods of analysis for determining the presence of biotoxic algae in bivalve molluscs and for the qualitative and quantitative determination of phytoplankton populations in sea waters intended for the cultivation of molluscs (GURI No 218, 18 September 1990, p. 8).

4 — Ministerial Decree of 7 June 1991 on measures concerning proprietary medicinal products made from cattle organs and tissues (GURI No 135, 11 June 1991, p. 13).

5 — Council Directive 88/182/EEC of 22 March 1988 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1988 L 81, p. 75).

6 — Directive 94/10/EC of the European Parliament and the Council of 23 March 1994 materially amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1994 L 100, p. 30).

4. The key element of this procedure is in Article 8 of Directive 83/189, which requires the Member States to notify the Commission of all draft technical regulations unless they merely transpose an international or European standard or unless they are adopted pursuant to Community provisions. [7] The Commission must notify the Member States of such draft immediately and must in addition, for the purpose of informing individuals, publish in the *Official Journal of the European Communities* a list of all drafts notified to it. [8]

5. Upon notification, Article 9 of Directive 83/189 gives the Commission and the other Member States the right to assess whether the draft technical regulation is compatible with Community law and, as the case may be, to deliver a detailed opinion within three months of the date of notification. If such opinion is not delivered, the Member State concerned may adopt the technical regulation after the expiry of the three-month standstill period. The period is extended to six months if a detailed opinion is delivered and 12 months if the Commission gives the Member State notice of its intention to propose or adopt Community rules on the subject. [9]

6. Under Article 9(3) of the abovementioned Directive, the standstill obligation does not arise in grave, unforeseeable situations requiring the urgent preparation of technical regulations by a Member State to safeguard fundamental interests such as the health of

7 — Article 8 of Directive 83/189, as amended by Directive 88/182, is worded as follows:
'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 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.'

8 — See Commission notice 89/C 67/03 of 17 March 1989 concerning the publication in the *Official Journal of the European Communities* of the titles of draft technical regulations notified by the Member States under Council Directive 83/189/EEC, as amended by Council Directive 88/182/EEC (OJ 1989 C 67, p. 3).

9 — Article 9 of Directive 83/189, as amended by Directive 88/182/EEC, is worded as follows:
'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.'

persons and animals, the protection of plants or public safety. [10]

7. Under Article 10 of Directive 83/189, this procedure for the prior notification of draft technical regulations is not applicable if such regulations are adopted as a consequence of obligations arising from a Community directive or regulation or an international agreement.

Admissibility of the action

8. The Commission became aware of the adoption by Italy of the four ministerial decrees which are the subject of this action and which, in its opinion, were technical regulations. As the Italian State had not complied with the information procedure laid down by Directive 83/189, the Commission decided to initiate the procedure under Article 169 of the EEC Treaty by sending the Italian Government two letters of formal notice. The first, dated 12 March 1991, referred to the three decrees concerning edible lamellibranch and bivalve molluscs, and the second, dated 12 February 1992, concerned the decree on proprietary medicinal products originating from cattle organs and tissues. In both letters the Commission informed the Italian authorities that the decrees were technical regulations and the fact that they had not been notified to the Commission at the draft stage was a contravention of Articles 8 and 9 of Directive 83/189. In view of this manifest failure to fulfil its obligations, the Commission invited the Italian Government to submit its observations on the matter and to suspend the application of the technical regulations in question which, in the Commission's opinion, could not be relied upon as against third parties.

9. The Italian Government submitted its observations with regard to the three decrees on edible molluscs on 18 April 1991, pointing out that they had been adopted because of the need to monitor the level of biotoxins in waters used for the cultivation of molluscs. The level had risen owing to a microalga in the Adriatic Sea. Such monitoring was essential to prevent the molluscs from affecting the health of consumers. With regard to the other Decree, the Italian Government stated in its observations of 31 March 1992 that it had been adopted as a matter of urgency to deal with the health problem arising from certain bovine viral diseases which had appeared in several European countries.

10. The Commission found the Italian Government's explanations unsatisfactory and

10 — Article 9(3) of Directive 83/189, as amended by Directive 88/182, is worded as follows:
'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 where improper use is made of this procedure.'

decided to continue the procedure prior to an action for failure to fulfil obligations. Accordingly, it sent the Italian Government a reasoned opinion on 2 December 1991 concerning the three decrees on molluscs, and a further reasoned opinion on 23 October 1992 concerning the decree on proprietary medicinal products of bovine origin. In both opinions the Commission reiterated its view that the Italian decrees were technical regulations. However, the first opinion gave no reasons for this assertion, while the second justified it by an analysis of the Decree which concluded that it was a technical regulation because it contained administrative provisions which were mandatory by law and it concerned the safety standards of proprietary medicinal products extracted from cattle organs and tissues.

11. In both opinions the Commission rejected the Italian Government's arguments of urgency, pointing out that Article 9(3) of Directive 83/189 permitted the immediate adoption of a technical regulation, but did not exempt the State from the obligation to notify the Commission of it and to specify the urgent grounds leading to its adoption. Secondly, the Commission repeated its argument that technical regulations which are not notified do not take legal effect as against third parties because of the direct effect of the Member States' obligations under Directive 83/189.

12. The Italian authorities did not reply to the two reasoned opinions and the Commission brought the present action before the Court of Justice for a declaration that Italy had failed to comply with Articles 8 and 9 of Directive 83/189 by adopting the four decrees in question without notifying them at the draft stage.

13. The Italian Republic contends that the action is inadmissible on the ground that the letters of formal notice are inadequate and in general terms because the Commission merely states its view that the Italian decrees are technical regulations, without explaining the reasons leading it to that conclusion, so that the Italian Government was not informed of the exact grounds of the action and was unable to formulate submissions in defence.

14. In my opinion, this submission must be dismissed. The Court has consistently held that, at the pre-litigation stage of proceedings for failure of a State to fulfil its obligations, the purpose of the letter of formal notice is to delimit the subject-matter of the dispute and to indicate to the Member State which is invited to submit its observations the factors enabling it to prepare its defence. [11] In the

11 — See, among others, Case 229/87 *Commission* v *Greece* [1988] ECR 6347, paragraph 12; Case 274/83 *Commission* v *Italy* [1985] ECR 1077 and Case 51/83 *Commission* v *Italy* [1984] ECR 2793.

present case, the two letters of formal notice from the Commission to the Italian Government identify perfectly Italy's alleged failure to fulfil its obligations, consisting in the adoption of four ministerial decrees containing technical regulations, without notifying them to the Commission at the draft stage, as required by Directive 83/189. It is true that the letters give only a brief statement of the grounds of such failure. However, as the Court has observed, [12] the initial letter will of necessity contain only an initial brief summary of the complaints while a fuller exposition with details and reasons will be given by the Commission in the reasoned opinion. This is what was done in the present case, where the two reasoned opinions sent by the Commission to the Italian authorities contain a clear statement of the complaint against Italy, accompanied by sufficient reasons.

15. As a second ground of inadmissibility of the action, the Italian Government contends that, in the reasoned opinion of 2 December 1991 and in the application, the Commission takes no account of the adoption of Legislative Decree No 530 of 30 December 1992, which implements Directive 91/492/EEC. [13] This Italian measure replaced Decree No 257 of 1 August 1990 and the Decree of 1 September 1990 concerning edible molluscs and was duly notified to the Commission, which delivered a detailed opinion concerning it on 27 January 1993.

16. This ground of inadmissibility cannot be accepted either. As the Court has consistently held, 'the question whether there has been a failure to fulfil obligations must be examined on the basis of the position in which the Member State found itself at the end of the period laid down in the reasoned opinion and ... consequently the Court cannot take account of any subsequent changes'. [14] In the present case, the new Italian measure was adopted after the expiry of the period allowed in the reasoned opinion for Italy to remedy its alleged failure.

17. For the reasons stated, I consider that there are no grounds for declaring the Commission's action inadmissible.

12 — See, among others, Case 274/83, cited above, and Case 74/82 *Commission* v *Ireland* [1984] ECR 317.

13 — Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (OJ 1991 L 268, p. 1).

14 — Case C-105/91 *Commission* v *Greece* [1992] ECR I-5871, paragraph 21; Case C-80/92 *Commission* v *Belgium* [1994] ECR I-1019, and Case C-118/92 *Commission* v *Luxembourg* [1994] ECR I-1891.

Substance

18. To date the Court has had to examine several uncontested complaints [15] concerning failure to notify draft technical regulations, as required by Directive 83/189, and two contested cases, where complaints were made against Germany [16] and the Kingdom of the Netherlands. [17] In the present case the Italian Government disputes the Commission's allegation on the ground that two of the decrees in question are not technical regulations and therefore do not come within the ambit of Directive 83/189.

19. Article 1(5) of Directive 83/189 defines 'technical regulation' as follows:

'technical specifications, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing or use (of a product) in a Member State or a major part thereof ...'.

In turn, 'technical specification' is defined by Article 1(1) of Directive 83/189, as amended by Directive 88/182, as follows:

'a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions including the requirements applicable to the product as regards terminology, symbols, testing and test methods, packaging, marking or labelling and the production methods and procedures for agricultural products as defined in Article 38(1) of the Treaty and for products intended for human and animal consumption and for medicinal products as defined in Article 1 of Directive 65/65/EEC ..., as last amended by Directive 87/21/EEC ... .'

In accordance with these two provisions, I consider that all statutory, regulatory and administrative practices and provisions of the Member States which require conditions to be fulfilled for the production and marketing of goods are technical regulations. Consequently there are three requirements for a

15 — Case C-139/92 *Commission* v *Italy* [1993] ECR I-4707; Case C-52/93 *Commission* v *Netherlands* [1994] ECR I-3591, and Case C-61/93 *Commission* v *Netherlands* [1994] ECR I-3607.

16 — Case C-317/92 *Commission* v *Germany* [1994] ECR I-2039.

17 — See the judgment of 11 January 1996 in Case C-273/94 *Commission* v *Netherlands* [1996] ECR I-31.

measure to be a technical regulation: an act attributable to a Member State, a *de jure* or *de facto* obligation, and implications for the production or marketing of goods. [18]

20. In the present case the Italian Government denies that Ministerial Decree No 256 of 1 August 1990 is a technical regulation within the meaning of Directive 83/189. In its opinion, the Decree contains only provisions concerning the quality of waters intended for the cultivation of molluscs and does not lay down requirements for marketing them. Therefore the technical specifications in the Decree do not refer to a product, but to the waters in question.

21. That argument cannot be accepted. Decree No 256 is indeed a technical regulation because, as the Commission observes, it establishes a close connection between the quality of the water for the cultivation of molluscs intended for human consumption and the marketing of those molluscs. In other words, only molluscs cultivated in water which comply with the technical specification in Decree No 256 may be marketed. Therefore that Decree is a measure which affects the marketing of molluscs intended for human consumption, which was adopted by the Italian State and is *de jure* mandatory. It must therefore be deemed a technical regulation.

22. According to the Italian Government, the Decree of 7 June 1991 concerning proprietary medicinal products originating from cattle organs and tissues is not a technical regulation either because it relates to proprietary medicinal products which require prior authorization for marketing in every Member State and because it relates to the controls and inspections which the national authority may order in the course of the registration procedure for such products. In the Italian Government's opinion, the Ministerial Decree is not a new technical regulation, but an exercise of its power or obligation to suspend the marketing authorization and of the power to require further information to supplement the report supporting the application for such authorization. In reply to a written question from the Court, Italy stated that it considered that the information procedure laid down by Directive 83/189 applies only to the rules relating to the methods and processes for the production of proprietary medicinal products, and does not affect the national authorities' powers of control and inspection under the special system for the registration of such products introduced by Directive 65/65/EEC. [19]

23. In my opinion, this argument must be dismissed. The Decree of 7 June 1991 is a technical regulation within the meaning of Directive 83/189 because it is a measure adopted by the Italian State, it is *de jure* mandatory and it sets out the safety requirements for authorizing the marketing of proprietary medicinal products made from cattle

18 — For a detailed analysis of this concept of a technical regulation, see my Opinion of 12 October 1995 in Case C-273/94 cited in footnote 17, paragraphs 22, 23 and 24.

19 — Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20).

organs and tissues. The fact that it relates to proprietary medicinal products does not mean that Directive 83/189 does not apply because under Article 1(1), as amended by Directive 88/182, the production methods and procedures for medicinal products as defined in Article 1 of Directive 65/65 are deemed to be technical specifications. Furthermore, Directive 88/182 also amended Article 1(7) of Directive 83/189 by extending it to cover 'any industrially manufactured product and any agricultural product', so that the proprietary medicinal products defined by Directive 65/65 remain subject to the information procedure after being expressly excluded by the original wording of Article 1(7) of Directive 83/189. In addition, the Court [20] has ruled that Directive 83/189 was applicable to a German provision which extended to disposable sterile medical materials the labelling requirements of Directive 65/65 concerning medicinal products.

24. In any case, the Italian Decree does not regulate the authorization procedure for medicinal products of this kind pursuant to Directive 65/65 and the later directives amending it, but lays down certain conditions to which their marketing is subject, with the object of preventing the health risks arising from the spread of infectious cattle diseases (particularly the dangerous bovine spongiform encephalopathy, commonly known as 'mad cow disease'). The Italian measure lays down strict conditions for the production and marketing of medicinal products made from cattle tissues and organs with the object of preventing the potential harmful consequences of 'mad cow disease'. It is therefore a technical regulation which had to be notified to the Commission under Article 8 of Directive 83/189. As the Italian measure was not adopted in implementation of the Community legislation concerning the registration of proprietary medicinal products, the exception in Article 10 of the Directive was not applicable.

25. The urgent reasons relating to a risk to public health relied upon by Italy to justify the failure to notify the four ministerial decrees cannot be accepted either. As I have already said, Article 9(3) of the Directive provides for an exception to the standstill obligation laid down in the two preceding paragraphs by permitting the adoption of technical regulations for urgent reasons without notification to the Commission at the draft stage. However, the Member States are under an obligation to notify the Commission of the technical regulations which they adopt and to state the grounds justifying urgent adoption. In sum, Article 9(3) contains an exception to the standstill obligation, but it does not release the Member State from the duty to notify the Commis-

20 — Case C-317/92, cited in footnote 16.

sion of technical regulations under Article 8. However, the Italian Republic did not subsequently notify the Commission of the ministerial decrees which it had adopted.

26. Finally, the Italian Government contests certain points of the Commission's complaint on the ground that under Article 10 of Directive 83/189 it is unnecessary to notify the Commission of technical regulations adopted in implementation of Community directives or regulations.

27. Italy considers that Decree No 256 relating to the characteristics of waters intended for the cultivation of molluscs serves to transpose Directive 79/923/EEC. [21] In reply to a written question from the Court, the Italian authorities asserted that the only technical specification in that Decree, namely the suspension of the collection of molluscs in waters polluted by biotoxins, laid down by Article 4, paragraph 5, is linked with Article 7(3) of Directive 79/923, which the permits the competent authority of the Member States to adopt appropriate measures where waters do not conform with the quality requirements of the Directive. In their opinion, a temporary prohibition on collecting molluscs in such polluted waters is an appropriate measure for the purpose of the Directive.

28. In view of the Commission's submissions in response to the Court's written question concerning the relationship between Decree No 256 and Directive 79/923, Italy's position may be rejected altogether. Directive 79/923 was in fact implemented in Italy's internal legal system by means of Legislative Decree No 131 of 27 January 1992, [22] which regulates generally the health requirements relating to waters intended for the cultivation of molluscs. Although the preamble to Decree No 256 does contain a reference to Directive 79/923, the Decree does not even partially implement the Directive because it merely strengthens the procedures for the sampling and periodic inspection of waters intended for the cultivation of molluscs, in accordance with the Italian legislation prior to the Directive, so as to monitor the level of biotoxins in molluscs and the suitability of the molluscs for human consumption. In contrast, the ambit of Directive 79/923 is much wider as it sets up a complex system for the classification of waters intended for the cultivation of molluscs according to the parameters specified in the annex, together with a programme for the gradual cleaning-up of such waters.

29. Secondly, the Italian Republic observes that Directive 91/492 was adopted prior to

21 — Council Directive 79/923/EEC of 30 October 1979 on the quality required of shellfish waters (OJ 1979 L 281, p. 3).

22 — GURI No 41, 19 February 1992.

the delivery of the reasoned opinion concerning Decree No 257 of 1 August 1990 and the Decree of 1 September 1990 concerning the production and marketing of molluscs. In its submission, both decrees were converted into measures applying Directive 91/492 and therefore it was unnecessary, pursuant to Article 10 of Directive 83/189, to notify them to the Commission. This argument cannot be accepted because the provisions of the two decrees show that they are insufficient to constitute internal measures implementing Directive 91/492, which contains far more detailed and exhaustive rules concerning the marketing of molluscs. This conclusion is confirmed by the enactment by Italy of Legislative Decree No 530 of 30 December 1992 implementing Directive 91/492 in the Italian legal system, which derogates from the earlier ministerial decrees on the marketing of molluscs. Accordingly Article 10 of Directive 83/189 does not apply to the two Italian decrees in question since they are not measures implementing Community rules.

30. I therefore take the view that, by failing to notify to the Commission the four ministerial decrees in question at the draft stage, the Italian Republic has failed to comply with Articles 8 and 9 of Directive 83/189.

31. Since the defendant's submissions cannot succeed, the Italian Republic must be ordered to pay the costs pursuant to the first subparagraph of Article 69(2) of the Rules of Procedure.

Conclusion

32. For the foregoing reasons, I am of the opinion that the Court should:

(1) rule that, by adopting Decrees Nos 256 and 257 of 1 August 1990 concerning edible lamellibranch molluscs, the Decree of 1 September 1990 concerning bivalve molluscs, and the Decree of 7 June 1991 concerning proprietary medicinal products made from cattle organs and tissues, without notifying them to the Commission at the draft stage, the Italian Republic has failed to fulfil its obligations under Articles 8 and 9 of 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;

(2) order the Italian Republic to pay the costs.