

OPINION OF ADVOCATE GENERAL
MISCHO

delivered on 27 February 2003¹

1. The Commission of the European Communities seeks a declaration from the Court that, by applying to drinks manufactured and marketed in other Member States rules prohibiting the marketing in Italy of energy drinks containing caffeine in excess of a certain limit, without showing how such a limit is necessary and proportionate for the protection of public health, the Italian Republic has failed to fulfil its obligations under Articles 28 EC and 30 EC.

I — Legal background

A — Community legislation

2. There is no Community legislation which lays down the conditions governing the addition of nutrients to common food-stuffs.

¹ — Original language: French.

B — National legislation

3. Article 15(3) of Presidential Decree No 719 of 18 May 1958 (GURI No 178 of 24 July 1958, p. 3081, hereinafter ‘PD No 719/58’), entitled ‘Regulation laying down the general health provisions relating to the production and marketing of sparkling water, and sparkling or still non-alcoholic drinks produced in sealed containers’, provides:

‘The addition of substances other than those listed in this regulation, which have not received prior approval by the High Commissioner for Hygiene and Public Health, must, at the request of the health authority of the district in which the factory is established and following an opinion from the district health council, be duly authorised in each case by the High Commissioner.’

II — Facts and pre-litigation procedure

4. The Commission’s attention was drawn to the existence of barriers to the import

into and marketing in Italy of certain energy drinks lawfully produced and marketed in other Member States. These drinks, including the Red Bull, CULT and GUVI brands, are characterised by the fact that they contain caffeine in quantities which vary from 250 mg/l to 320 mg/l and often contain other substances such as taurine.

5. On the basis of Legislative Decree No 111 of 27 January 1992 and in accordance with the opinion of 13 December 1995 of the Consiglio Superiore della Sanità (the Board of Health, the 'CSS'), the Italian authorities initially prohibited the marketing of these drinks, in particular those containing taurine.

6. However, the Italian authorities subsequently altered their position and authorised the marketing in Italy of such drinks on condition that the caffeine content did not exceed 125 mg/l.

7. On the basis that this limit represented a measure having equivalent effect to a quantitative restriction on imports, contrary to Article 28 EC and not justified by Article 30 EC in the absence of scientific data demonstrating the extent to which

exceeding that limit would be harmful to public health, the Commission addressed a letter of formal notice, dated 4 October 1996, to the Italian Government.

8. By letter of 8 January 1997 the Italian authorities responded, observing that following the decisions of the Minister for Health of 13 December 1995, there was no longer any barrier to the marketing in Italy of drinks of the type in question which were lawfully marketed in other Member States, provided that the caffeine content did not exceed 125 mg/l, a limit soon to be raised to 150 mg/l, in accordance with the Italian legislation in force, in particular PD No 719/58.

9. The Commission considered this response to be unsatisfactory and addressed a reasoned opinion to the Italian authorities on 23 September 1997.

10. By letter of 11 December 1997, the Italian authorities stated that the Minister for Health had requested a new opinion from the CSS and asked that the Commission provisionally suspend the infringement procedure in order to await the reply of the CSS.

11. By letter of 6 March 1998, the Italian authorities informed the Commission that the CSS had determined that, according to

current levels of knowledge, the drinks in question raised no public health concerns and that a circular (a copy of which was enclosed) had authorised that they be placed on the market for consumption and provided for the communication of certain information to the consumer by means of a label containing instructions and warnings.

firmed that, in practice, the free movement in Italy of drinks originating in other Member States was being ensured as a result of Circular No 5 of 3 April 1998.

12. By letter of 2 April 1998, the Commission replied, amongst other things, that while a circular is an appropriate means of guaranteeing immediate compliance with Community provisions on free movement of goods, the Italian authorities nevertheless remained under the obligation to amend the legislation in question as soon as possible definitively and by the usual procedure.

15. However, by fax of 14 April 1999, the Commission reminded the Italian authorities of their undertaking to adopt an appropriate measure, in the form of a legislative amendment, to govern the matter.

16. The Italian authorities forwarded to the Commission a draft regulation drawn up by the Minister for Industry, Trade and Crafts relating to 'rules for the manufacturing and marketing of bottled water and non-alcoholic drinks'.

13. By letter of 18 June 1998, the Minister for Health notified the Commission of the publication of Circular No 5 of 3 April 1998 (GURI No 101, General series, 4 May 1998, p. 72), entitled 'Drinks of Community origin characterised by high levels of caffeine and taurine', stating that the observations of the Commission had been taken into account in the application of the circular.

17. While the Commission was of the opinion that the draft regulation called for a number of observations regarding the scope of the mutual recognition clause, it noted, by letter of 22 November 1999, that the proposal, once adopted, would result in the infringement procedure being closed.

14. In the meantime, the Commission had contacted the complainants, who con-

18. Following further reminders by the Commission to the Italian authorities as to the need for a legislative amendment of the provision in question, the authorities

notified the Commission, on 13 November 2000, of a draft regulation containing the text of PD No 719/58 in an annex; this proposal was intended to update the legislation on the production and sale of non-alcoholic drinks generally, including those containing caffeine, and included in Article 9 a mutual recognition clause excluding from its scope non-alcoholic drinks lawfully produced and marketed in other Member States or in countries signatories to the European Economic Area Agreement.

19. The Commission reminded the Italian authorities of the observation it had made in its letter of 22 November 1999, that the mutual recognition clause needed to be altered in some respects in order to eliminate all ambiguity. Having received no response from the Italian Republic, the Commission, by letter of 9 April 2001 and referring back to its letter of 22 November 1999, asked the Italian authorities whether they had received the observations on the draft and when the Italian Government expected to adopt the regulation.

20. Given that the original text of PD No 719/58 was still in force and that no amendment had been made in order to bring the matter of recognition of non-alcoholic drinks produced and marketed in other Member States into line with Community law, the Commission brought the present proceedings.

III — Forms of order sought

21. In its application, lodged at the Court Registry on 23 October 2001, the Commission claims that the Court should:

- declare that, by applying to drinks produced and marketed in other Member States a rule prohibiting the marketing in Italy of energy drinks containing caffeine in excess of a certain limit, without showing that that limit is necessary and proportionate for the protection of public health, the Italian Republic has failed to fulfil its obligations under Articles 28 EC and 30 EC; and

- order the Italian Republic to pay the costs.

22. The Italian Republic contends that the Court should dismiss the case as unfounded.

IV — Analysis

A — Arguments of the parties

23. The Commission asserts that, while it may not be possible to identify clearly the legal basis for the prohibition on importing into and marketing in Italy non-alcoholic drinks with a caffeine content in excess of 125 mg/l, it is indisputable that such a prohibition exists. That is confirmed by the complaints addressed to the Commission by a number of Community manufacturers of non-alcoholic energy drinks, by the wording of Article 15(3) of PD No 719/58, and by the fact that the Italian authorities have (as evidenced by the adoption of Circular No 5 of 3 April 1998 and the draft regulation notified to the Commission) themselves recognised the necessity, if not the obligation, to amend and/or repeal certain provisions of the legislation currently in force in the non-alcoholic drinks sector.

24. The Commission considers that in view of the case-law of the Court in relation to Articles 28 EC and 30 EC, and in particular the judgment in *Commission v Germany*, known as the 'Beer Purity Law' judgment,² the merits of the case are not in dispute.

25. As regards a possible justification based on the protection of human health and life, the Commission argues that in any event it is difficult to see how the Italian authorities can assert on the one hand that drinks with a high caffeine content pose a risk to health and, on the other hand, authorise their distribution, as the Italian Republic did by means of Circular No 5 of 3 April 1998.

26. The Commission also draws attention to the fact that the CSS opinion of 13 December 1995, to which the Italian authorities refer, has been superseded, the CSS itself having rendered a subsequent opinion which states that the drinks in question pose no health risks. The Commission contends that this latter opinion is, moreover, confirmed by the opinion issued by the Scientific Committee for Food on 21 January 1999.

27. It is the opinion of the Commission that the disputed issue relates rather to the measure adopted by the Italian Republic in order to bring its legislation into line with the principles of Community law, once it had been found to be incompatible with Community law. Given that a Member State cannot discharge its obligations under a directive by means of a mere circular which can be amended by the administration at will, the Commission considers that in the light of the judgment in *Commission v Germany*³ Circular No 5

2 — Case 178/84 [1987] ECR 1227.

3 — Case C-96/95 [1997] ECR I-1653.

of 3 April 1998 is not sufficient to amend the contested provisions in Article 15 of PD No 719/58.

28. The Italian Government states in its defence that the fixing of an upper limit for caffeine content is justified in particular by the evaluations undertaken by the relevant health authorities. It contends that the whole matter must be resolved from the point of view of the lawfulness of the scientific position adopted by the Italian health authorities. Any other solution would, according to the Italian Government, deprive Article 30 EC of its content by replacing the non-arbitrary discretion of the Member State with the subjective opinion of the health authorities of another Member State, which although legitimate cannot, by its very nature, be considered as indisputable.

29. The Italian Government considers that it is for the Commission to produce scientific evidence that, given the prevailing environmental conditions in Italy, the fixing of a maximum authorised caffeine level, which is considered in the majority of cases not to be harmful to the consumer, does not satisfy the criteria of a proper balancing of the interests in question.

30. The Italian Government adds, however, that it still intends to formalise its position as regards the maximum accept-

able level of caffeine in alcoholic drinks and the introduction of rules governing the composition of non-alcoholic drinks. However, it stresses that this intention is not the result of either a legal obligation or an absolute necessity inasmuch as technical rules, such as the one envisaged, inevitably reflect current scientific knowledge and take no account of any possible interaction with ingredients of specified alcoholic drinks, whether cited in the relevant provisions or not. Reserving the right to issue a specific authorisation for the use of ingredients other than those envisaged serves rather to evaluate that interaction and, as a result, to protect the life and health of consumers, which should not be subject to considerations relating to profit or to abstract interpretations of the EC Treaty.

31. The Italian Government also notes that the rule which applies to drinks imported from other Member States applies equally to drinks produced in Italy.

32. In its rejoinder, the Italian Government affirms once again that a legislative text amending the provisions which were considered not to have been brought into line with the approach taken by the health authorities of other Member States had been drawn up and was submitted in April 2002 for examination by the authority representing all relevant local bodies. Moreover, the Italian Government contends that Circular No 5 of 3 April 1998

permitted the marketing in Italy of products with a higher caffeine content than that authorised by the relevant rules in force in this sector.

Italian Government has never sought to deny the existence thereof as at the date mentioned above. On the contrary, it specifically recognised it in its response of 8 January 1997 to the letter of formal notice.

B — Assessment

33. The documents in the file show that at the end of the period laid down in the reasoned opinion, which according to settled case-law⁴ is the date at which the existence of a failure to fulfil obligations must be assessed and which in this case is the end of November 1997,⁵ there existed a prohibition on the marketing in Italy of energy drinks lawfully for sale in other Member States but having a caffeine content in excess of 125 mg/l.

34. Despite the fact that, even after a written question on the matter put by the Court, some doubt remains as to the basis in national law for this prohibition (Article 15(3) of PD No 719/58 does not, in fact, contain any such prohibition), the

35. Nevertheless, even if the prohibition was simply in the form of an administrative practice it may still constitute a failure to fulfil obligations.⁶

36. Given that this prohibition on marketing, in so far as it applies to imported products, constitutes a measure having equivalent effect to a quantitative restriction on imports contrary to Article 28 EC, the question arises as to whether this prohibition is justified by one of the interests laid down in Article 30 EC and in particular that of the protection of human health and life.

37. In this respect it is important to recall the settled case-law to the effect that it is for the competent national authorities to show, in each case, that their rules are necessary to properly protect the interests

4 — See *inter alia* Case C-133/94 *Commission v Belgium* [1996] ECR I-2323, paragraph 17, and Case C-122/02 *Commission v Belgium* [2003] ECR I-833, paragraph 11.

5 — In this case the reasoned opinion laid down a period of two months from its communication to the Italian Government for the latter to adopt the measures necessary to comply with its obligations under Community law. The reasoned opinion was communicated to the Italian Government in a letter of 23 September 1997. The end of the period laid down by the reasoned opinion is therefore at the end of November 1997.

6 — See, for example, Case 21/84 *Commission v France* [1985] ECR 1355, paragraph 12; Case C-187/96 *Commission v Greece* [1998] ECR I-1095, paragraph 23; and Case C-185/96 *Commission v Greece* [1998] ECR I-6601, paragraph 35.

referred to in Article 30 EC and, in particular, that the marketing of the product in question poses a risk for public health.⁷

marketing in Italy of energy drinks lawfully sold in other Member States but having a caffeine content in excess of 125 mg/l was in fact necessary to protect human health and life.

38. However, I agree with the Commission that the Italian Government has not proved that the prohibition which was in force at the end of November 1997 was justified by a need to protect human life and health.

42. In response to a written question by the Court, the Italian Government contended once again that the issue which formed the basis of the action for failure to fulfil obligations had been resolved by the adoption of Circular No 5 of 3 April 1998.

39. In fact, the only piece of evidence advanced by the Italian Government is the opinion rendered by the CSS on 13 December 1995.

43. This fact does not, however, lead to the conclusion that the action for failure to fulfil obligations is unfounded. As already noted above, it is 'settled case-law that the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion, and that *the Court cannot take account of any subsequent changes...*'.⁸

40. However, independently of the fact that, as stated in the letter of the Italian authorities of 6 March 1998, the CSS itself subsequently overruled this opinion, a reading of that original opinion reveals that in any event it related to drinks containing a high level of caffeine *and* taurine as well as a caffeine content as high as 320 mg/l, more than double the limit of 125 mg/l.

41. It therefore cannot be concluded from that CSS opinion that a prohibition on the

44. On the other hand, it is not possible to agree with the argument presented by the Commission in its application, according to which the disputed issue relates principally to the measure adopted by the Italian State in order to bring its legislation into line with the principles of Community law after

⁷ — See, in particular, Case 304/84 *Ministère public v Muller and Others* [1986] ECR 1511, paragraph 25; the '*Beer Purity Law*' judgment, cited above; Case C-42/90 *Bellon* [1990] ECR I-4863, paragraph 16; and Joined Cases C-13/91 and C-113/91 *Debus* [1992] ECR I-3617, paragraphs 17 and 18.

⁸ — Case C-122/02 *Commission v Belgium*, cited above, paragraph 11.

it was found to be incompatible with Community law, and therefore to the question of whether by adopting Circular No 5 of 3 April 1998 the Italian Government has remedied the incompatibility.

and effects of the tax system introduced by the Decree-Law in question to the point where they asked the Court to consider the resulting situation as a whole.

45. I am of the opinion that that question is not relevant to the case in hand.

46. It is appropriate in this respect to refer to the judgment in *Commission v Italy*,⁹ which dealt with facts similar to those in the present case.

47. In that case, the Commission had brought an action before the Court against the Italian Republic for failure to fulfil obligations as a result of a system of turnover tax which it considered constituted an infringement of Article 95 of the EEC Treaty (now, after amendment, Article 90 EC).

48. The Italian Republic, in its defence, observed that a Decree-Law which had amended the tax system in dispute was, in its opinion, of such a nature as to justify the withdrawal of the application. The Commission disagreed, and a debate ensued between the parties relating to the impact

49. In response to this request, the Court declared, at paragraph 4 of the judgment, that '... in so doing the applicant has thus amended the subject-matter of its application so that it is no longer concerned only with the question whether at the time when the application was lodged there was a failure on the part of the Italian Republic to fulfil its obligations under Article 95, but principally with the question whether this failure still continues after the coming into force of the Decree-Law...'.

50. The Court continued, at paragraphs 5 and 6 of that judgment, in the following terms:

'5 ... the Court cannot give judgment in the present case on the failure to fulfil an obligation occurring after legislation has been amended during the course of the proceedings without thereby adversely affecting the rights of the Member State to put forward its arguments in defence based on complaints formulated according to the procedure laid down by Article 169.

9 — Case 7/69 [1970] ECR 111.

6 In such circumstances *it is for the Commission to commence new proceedings under Article 169 with regard to the effects of Decree-Law No 319, and if necessary to refer to the Court the specific shortcoming upon which it desires the Court to pronounce...*¹⁰

51. This judgment represents the precursor to what has since become settled case-law, to the effect that the application introduced under Article 226 EC must be based on the same grounds and pleas as the reasoned opinion.¹¹

52. However, in the case at hand, the allegation by the Commission that the Italian Republic has failed to fulfil its obligations under Articles 28 EC and 30 EC by lifting a prohibition on marketing which was contrary to the Treaty by means of the adoption of a circular amounts to a different ground of failure to that made against the same Member State for having failed to fulfil the same obligations by reason of the very existence of that prohibition.

53. The reasoned opinion is founded exclusively on that second ground of failure. The first ground is therefore inadmissible.

54. In any event, I wonder whether there is sufficient information available to the Court to permit a useful examination of that first ground of failure in the absence of any pre-litigation procedure, the proper conduct of which, according to the Court, 'constitutes an essential guarantee required by the Treaty not only in order to protect the rights of the Member State concerned, but also so as to ensure that any contentious procedure will have a clearly defined dispute as its subject-matter (see Case C-1/00 *Commission v France* [2001] ECR I-9989, paragraph 53)'.¹²

55. It is appropriate to recall the lack of clarity as regards the legislative basis in Italian law for the disputed prohibition. Whilst the Commission considered that Circular No 5 of 3 April 1998 is not sufficient to amend Article 15 of PD No 719/58, it recognised in its response to a written question put by the Court that the disputed prohibition may not result in fact from that provision, but simply from administrative practice.

56. However, this question of the legislative basis for the disputed prohibition

10 — Emphasis added.

11 — See, in particular, Case C-347/88 *Commission v Greece* [1990] ECR I-4747, paragraph 16; Case C-439/99 *Commission v Italy* [2002] ECR I-305, paragraph 11; and Case C-287/00 *Commission v Germany* [2002] ECR I-5811, paragraph 18.

12 — Case C-287/00 *Commission v Germany*, cited above, paragraph 17.

seems to me to be of fundamental importance to the assessment of the manner in which the Italian Republic must remedy its failure which has, in my opinion, been established and is based on the existence of the prohibition at the end of the period laid down in the reasoned opinion.

57. While a Member State may not 'repeal' a domestic legislative provision giving rise to a failure to fulfil obligations by means of a circular, I cannot see *prima facie*, on the other hand, why a Member State may not (other than in the context of the implementation of a directive, which is not the case here) convert by means of a circular an administrative practice which breaches the Treaty into a practice which conforms to the Treaty.

V — Conclusion

58. In the light of the foregoing, I propose that the Court:

- declare that, by applying to drinks produced and marketed in other Member States rules prohibiting the marketing in Italy of energy drinks containing caffeine in excess of a certain limit, without showing how such a limit is necessary and proportionate for the protection of human health, the Italian Republic has failed to fulfil its obligations under Articles 28 EC and 30 EC;
- order the Italian Republic to pay the costs.