OPINION OF ADVOCATE GENERAL FENNELLY

delivered on 23 October 1997 *

1. The present infringement proceedings concern the transposition into Italian law of two pairs of Council Directives broadly speaking in the field of animal health. The Commission has withdrawn its claim in respect of one of the Directives, while Italy has not contested its failure to transpose two of the others, but has done so in respect of the fourth measure.

I — Pre-litigation proceedings

2. The Directives at issue in the present proceedings are the following:

— Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases (hereinafter 'Directive 93/53/EEC'); [1]

— Council Directive 93/54/EEC of 24 June 1993 amending Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products (hereinafter 'Directive 93/54/EEC'); [2]

— Council Directive 93/113/EC of 14 December 1993 concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition (hereinafter 'Directive 93/113/EC'); [3] and

— Council Directive 93/114/EC of 14 December 1993 amending Directive 70/524/EEC concerning additives in feedingstuffs (hereinafter 'Directive 93/114/EC'). [4]

3. Following the adoption of a Ministerial Decree of 29 January 1997, [5] the Commission withdrew its claim as regards Directive

* Original language: English.

1 — OJ 1993 L 175, p. 23.

2 — Ibid., p. 34.

3 — OJ 1993 L 334, p. 17.

4 — Ibid., p. 24.

5 — *Gazzetta Ufficiale dello Stato Italiano* (hereinafter 'GURI') No 92 of 21 April 1997, p. 29.

93/54/EEC, which will therefore not be dealt with in the remainder of this Opinion.

4. Article 20(1) of Directive 93/53/EEC reads as follows:

'Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1994. They shall forthwith inform the Commission thereof.'

For Directive 93/113/EC, the deadlines for transposition set by Article 8 were 1 January 1995 as regards Article 7 (concerning the imposition of labelling requirements), and 1 October 1994 as regards the other provisions. Article 2 of Directive 93/114/EC set the deadline for transposition at 1 October 1994. In each case, the Member States were required to include a reference to the Directive in the national provisions, or in the official publication in which they were announced.

5. In the absence of any indication that the Directives had been transposed into Italian law, the Commission opened the pre-litigation stage of the procedure provided by Article 169 of the Treaty establishing the European Community ('the Treaty') by sending a letter of formal notice on 20 January 1995, inviting the Italian Government to send it a complete table of the national provisions which, in the latter's view, ensured the transposition of the Directives. By letter of 27 February 1995, Italy informed the Commission that the Directives had all been included in the annual 'Community law' for 1994, and that the necessary implementing provisions had been drafted, pending the adoption of this law. As there was no further communication from Italy in this regard, the Commission sent a reasoned opinion on 22 January 1996, concluding that Italy had failed in its obligations under the Treaty and the Directives, and setting a further two-month deadline for compliance. By letter of 15 March 1996, Italy informed the Commission that the implementation of Directives 93/53/EEC and 93/54/EEC was imminent, and that the legislative office of the department responsible in the Ministry of Health had transmitted the sole implementing provision for the remaining Directives to the department responsible for European Union policies.

6. The present proceedings were initiated by an application lodged at the Court on 26 September 1996. The Commission relies upon the obligation of the Member States, in accordance with Articles 189 and 5 of the Treaty, to comply with deadlines set by Directives and argues that this obligation is not fulfilled unless all the provisions of the relevant Directives have been transposed into the law of the Member State. As Italy has not communicated the provisions transposing these Directives to it, the Commission

considers that it has not respected its obligations under the Treaty and the Directives. It therefore requests the Court to declare that, in failing to bring the necessary national provisions into force within the deadlines set, Italy is in breach of these obligations, and to order it to pay the costs.

7. Italy's defence, broken down by Directive, is as follows:

— the national provisions to implement Directive 93/53/EEC will be adopted as soon as possible. Italy also contended in its written pleadings that the Directive had been partially transposed into Italian law by a Ministerial Order of 2 September 1996, which contains provisions concerning viral haemorrhagic septicaemia and infectious hematopoietic necrosis in farm fish, though this plea was in effect abandoned at the hearing. In a letter registered at the Court on 27 August 1997, Italy drew the Court's attention to the adoption, on 3 July 1997, of Presidential Decree No 263, [6] which in its view ensured the transposition of Directive 93/53/EEC. While indicating at the hearing that the withdrawal of its claim in respect of this Directive was under active consideration, at the time of drafting of the present Opinion the Commission had not yet so decided;

— Directive 93/113/EC should be considered fully implemented in Italy. In accordance with Article 3, on 20 December 1994 Italy forwarded to the Commission a list of enzymes and micro-organisms and their preparations permitted for use in animal nutrition, which was subsequently included in the Community list of such products drawn up by the Commission and published on 11 September 1996. [7] In the meantime, in conformity with Article 2, Italy has temporarily admitted the use and marketing of the products on the list sent to the Commission in December 1994, subject to a number of restrictions introduced at the Commission's behest. The corrected list of permitted products was notified to all the regional health representative offices ('assessorati regionali della Sanità') and professional associations and organizations by means of a ministerial circular of 26 July 1995, and has since been replaced by the Commission list. The labelling obligations of Article 7 have been implemented in part by Presidential Decree No 228 of 1 March 1992, [8] which transposes different Community Directives concerning additives in animal

6 — GURI No 184 of 8 August 1997, p. 4.

7 — OJ 1996 C 263, p. 3.

8 — Supplemento Ordinario alla GURI No 66 of 19 March 1992, p. 22.

feedingstuffs, and in part by the instructions sent to the services and bodies concerned along with the list of permitted products;

— the adoption of the regulation required to implement Directive 93/114/EC is under way.

II — Analysis of the Commission complaints

8. Italy has not contested the complaint regarding its failure to bring into force within the deadline set the requisite provisions to comply with Directive 93/53/EEC, and the Commission has not withdrawn its complaint in this regard. Whatever the content of Presidential Decree No 263 of 3 July 1997, it follows from the established case-law of the Court that 'the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation in the Member State as it stood at the end of the period laid down in the reasoned opinion, and the Court cannot take account of any subsequent changes', [9] other than in the case of a withdrawal of claim. Similarly, Italy has not sought to contest the complaint regarding its failure to transpose Directive 93/114/EC. I therefore recommend that the Commission's complaint be upheld in respect of these Directives.

9. The situation regarding the Commission's complaint in respect of Directive 93/113/EC is somewhat more complicated, and it becomes necessary to examine briefly certain of its substantive provisions. The basic Community rule in this area, which was laid down in Article 3(1) of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs, [10] is that 'only those additives which are listed in Annex I [to the Directive] may be incorporated in feeding-stuffs and only subject to the requirements set out therein'. By way of derogation from this provision, Article 2(1) of Directive 93/113/EC requires Member States 'temporarily [to] allow the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition within their territory, provided that, on the basis of the information available, the products do not present a danger to human or animal health, and that they are included in the list established by virtue of Article 3' of this Directive. Article 3 required the Member States to forward to the Commission before 1 November 1994 a list of the enzymes, micro-organisms and preparations (hereinafter, for convenience, 'products') it permitted on the basis of Article 2, while those requesting the inclusion of a given product on the list were to transmit the dossiers justifying

9 — See, for example, Case C-302/95 *Commission* v *Italy* [1996] ECR I-6765, paragraph 13 of the judgment.

10 — OJ, English Special Edition, First Series 1970 (III), p. 840.

inclusion to the Commission and the Member States by 1 January 1996. [11]

10. On the basis of this information, the Commission was under an obligation to publish, before 31 March 1996, a provisional list of the products then permitted in the Member States (Article 4(3)), and then, before 1 January 1997, a definitive Community list of permitted products (Article 5). Article 7 sets out quite detailed labelling requirements for different categories of products.

11. As noted above, the Commission only published the provisional list of permitted products in September 1996. It was also unable to meet the deadline of 1 January 1997 for the adoption of the definitive list; as a result, Council Directive 97/40/EC of 25 June 1997 amending Directive 93/113/EC concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition [12] extended the deadline to 1 July 1998.

12. The Commission did not specify during the written procedure which aspects of Directive 93/113/EC it considered Italy had not complied with, and a large part of Italy's pleadings was devoted to demonstrating that it had complied with the substantive obligations imposed by Articles 2 and 3. At the hearing, however, the Commission clarified that its complaint in regard to this Directive concerned Italy's failure to bring into force the necessary provisions to transpose Articles 2 and 7. In its view, the adoption and communication to the relevant authorities of the ministerial circular of 26 July 1995 establishing the Italian list of permitted products, upon which Italy relies, does not constitute a proper transposition of Article 2. Similarly, the Commission argues that neither the circular nor Presidential Decree No 228 of 1 March 1992 constitutes a sufficient transposition of the labelling requirements of Article 7; in particular, Article 7 introduces new requirements and criteria for products not covered by the 1992 Decree. The Commission adds that, in any case, Italy failed to communicate any transposition measures to it, as it was required to do by Article 8(2) of the Directive.

13. In respect of Article 2, Italy has accused the Commission of being excessively formalistic. The national list it forwarded to the Commission in December 1994 was provisional in character, pending the adoption of the definitive Community list of permitted products; furthermore, a national transposition was no longer indispensable following the publication of the consolidated national lists by the Commission in September 1996.

14. It follows from Article 8(1) that Italy should have brought into force the national

11 — The English version of paragraph (b) of this provision, which requires the Member States to 'forward ... to the Commission ... the dossiers to justify these authorizations by the person(s) responsible', is rather obscure; it is clear from the French and Italian versions, for example, that what is intended is 'the dossiers on the basis of which the person(s) responsible ... justify' inclusion of their product(s) on the list.

12 — OJ 1997 L 180, p. 21.

provisions to comply with Article 2 by 1 October 1994; it appears from the case-file that it had not done so before the expiry of the deadline set by the Commission's reasoned opinion, in March 1996, nor had it done so by the date of the oral hearing. Even if it were a proper defence, which I doubt, I do not accept that the Commission is being 'excessively formalistic'. A failure properly to transpose Article 2 could, in my view, have important practical consequences, for example, for producers or potential users of such products who wish to market or use a given product in Italy, and who would only have the circular to justify their activities in the face of the general prohibition laid down in Article 3(1) of Council Directive 70/524/EEC, which has, presumably, been enacted into Italian law.

15. The Court has consistently held that 'mere administrative practices, which by their nature are alterable at will by the administration and are not given the appropriate publicity, cannot be regarded as constituting the proper fulfilment of a Member State's obligations under the Treaty'. [13] It has also consistently held that 'it is particularly important, in order to satisfy the requirement for legal certainty, that individuals should have the benefit of a clear and precise legal situation enabling them to ascertain the full extent of their rights and, where appropriate, to rely upon them before the national courts'. [14] In my opinion, the circular of 26 July 1995 on which Italy relies does not create a sufficiently clear legal situation in its territory as regards the marketing and use of the listed products and, hence, does not constitute a proper fulfilment of its transposition obligations under Article 8(1) of Directive 93/113/EC as regards Article 2. Nor does the publication in the 'C' series of the *Official Journal of the European Communities*, which is reserved for Information and Notices, of a consolidated list of products permitted in the Member States correct this situation at the national level or dispense the Member States from their duty to transpose Article 2.

16. Italy has suggested that Article 7 of the Directive had in part been transposed, *ex ante* as it were, by Presidential Decree No 228 of 1 March 1992, [15] in combination with the circular of 26 July 1995. It did not challenge the Commission's contention at the hearing that the 1992 Decree covered different enzymes and imposed different requirements from those governed by the Directive, but argued that the circular expressly required the addressees to respect the terms of the Directive. For the reasons set out in the preceding paragraph concerning the value of an administrative circular as an instrument of transposition, I would reject its arguments on this point too.

13 — Case C-311/95 *Commission* v *Greece* [1996] ECR I-2433, paragraph 7 of the judgment.

14 — Case C-236/95 *Commission* v *Greece* [1996] ECR I-4459, paragraph 13 of the judgment.

15 — Cited in footnote 8 above.

III — Conclusion

17. In view of the foregoing, I would recommend to the Court that it:

(1) Declare that, by failing to bring into force within the deadlines set the laws, regulations and administrative provisions necessary to comply with Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases, Council Directive 93/113/EC of 14 December 1993 concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition, and Council Directive 93/114/EC of 14 December 1993 amending Directive 70/524/EEC concerning additives in feedingstuffs, the Italian Republic has failed to comply with its obligations under these Directives and the Treaty;

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