OPINION OF MR ADVOCATE GENERAL DARMON
delivered on 8 February 1994 *

Mr President,
Members of the Court,

1. In this action, the Court of Justice is asked to declare that, by failing to give notice to the Commission of the laws, regulations and administrative provisions needed to give effect to Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of Good Laboratory Practice (GLP), [1] the Kingdom of Spain has failed to fulfil its obligations under the EEC Treaty.

2. The matters covered by the directive are 'the inspection and verification of the organizational processes and the conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing, carried out in accordance with the rules and regulations, of all chemicals (e. g. cosmetics, industrial chemicals, medicinal products, food additives, animal feed additives, pesticides) in order to assess the effect of such products on man, animals and the environment'. [2]

3. Under Article 9, the directive was to be brought into force by the Member States not later than 1 January 1989, and the Commission was to be informed thereof forthwith.

4. Since it had received no notification of any measures adopted by the Kingdom of Spain to implement the directive, the Commission initiated the procedure under Article 169 of the Treaty on 4 April 1990 against that State. Next, as the letter before action went unanswered, the Commission sent a reasoned opinion on 10 February 1992.

5. The Kingdom of Spain contends that the action should be dismissed, and observes that 'transposition of Directive 88/320/EEC is linked to the transposition of Directive 87/18/EEC [3] because the latter constitutes a measure preliminary to the former in so far as the inspection and verification made compulsory by Directive 88/320/EEC are based on the principles laid down by Directive 87/18/EEC'. [4]

* Original language: French.

1 — OJ 1988 L 145, p. 35.

2 — Article 1 of the directive.

3 — Council Directive of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances (OJ 1987 L 15, p. 29).

4 — Defence, p. 2 of the French translation.

6. The latter directive has just been transposed into national law, and it should be possible to adopt the royal decree transposing Directive 88/320 and notify it to the Commission 'very shortly'.

7. Directive 87/18/EEC was to be transposed by 30 June 1988 and an action was brought against the Kingdom of Spain under Article 169 for failure to comply with that time-limit. [5] According to the Commission, that directive gave rise to adequate implementing measures adopted by Royal Decree 822/1993 of 28 May 1993. Following the applicant's withdrawal, the case was removed from the register by order of the President of the Court of 22 September 1993.

8. However, it has by no means been shown that Directive 88/320/EEC, the only one in question here, has been transposed. On the contrary, the Kingdom of Spain acknowledges that the Directorate-General for Pharmacy of the Ministry of Health and for Consumers [6] is currently making preparations for the adoption of a draft decree.

9. The Court has consistently held that:

'... a Member State may not plead provisions, practices or circumstances existing in its internal legal [or financial] system in order to justify a failure to comply with obligations and time-limits resulting from Community law ...' [7]

10. I would add, for the sake of completeness, that a Member State may not justify its failure to transpose one directive by its delay in adopting measures to implement an earlier directive.

11. It follows that the Commission's claim that the Kingdom of Spain has failed to fulfil its obligations is proved. I propose, therefore, that the Court so declare and order the defendant State to pay the costs.

5 — Case C-294/93.

6 — Rejoinder, p. 2 of the French translation.

7 — Judgment in Case C-290/89 *Commission* v *Belgium* [1991] ECR I-2851, paragraph 9.