OPINION OF ADVOCATE GENERAL LA PERGOLA

delivered on 27 May 1997 *

1. By this action, the Commission is asking the Court for a declaration that, by failing to transpose certain provisions of Council Directive 84/466/Euratom [1] (hereinafter 'the Directive') into national law, the Kingdom of Spain has failed to fulfil its obligations. The Spanish Government submits that the action should be rejected on the ground that it has correctly transposed the normative content of the Directive into national law.

Legislative framework

2. While recognizing the beneficial effects of ionizing radiation at a diagnostic and therapeutic level, the Directive, the transposition of which is in dispute, aims to limit its use as much as possible. To that end, provisions have been adopted to discourage 'any unnecessary proliferation of radiological installations' and to 'ensure that users have the necessary competence and experience to avoid inappropriate uses of these techniques'. [2]

This case relies, in particular, on the failure to transpose Articles 3, 4 and 5 of the Directive. The first of those articles provides that: 'The competent authorities shall draw up an inventory of medical and dental radiological equipment and nuclear medical installations and shall establish criteria of acceptability for radiological installations and nuclear medical installations. All installations in use must be kept under strict surveillance with regard to radiological protection and the quality control of appliances. The competent authorities shall implement the necessary measures to improve inadequate or defective features of installations subject to such surveillance. They shall ensure as soon as possible that all installations which no longer meet the criteria specified in the first paragraph are taken out of service or replaced. Direct fluoroscopic examinations without the use of image intensification shall be carried out only in exceptional circumstances.'

The exact wording of Article 4 is as follows: 'Each Member State shall take such steps as it may consider necessary to discourage the unnecessary proliferation of equipment for radiotherapy, radiodiagnosis and nuclear medicine.'

Finally, Article 5 provides that: 'A qualified expert in radiophysics shall be available to

* Original language: Italian.

1 — Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (OJ 1984 L 265, p. 1).

2 — See the seventh recital in the preamble to the Directive.

sophisticated departments of radiotherapy and nuclear medicine.'

Substance

Article 3 of the Directive

3. In the course of the proceedings the Commission abandoned its action in so far as it related to the obligation, laid down in Article 3 of the Directive, to keep radiological installations under surveillance. Although the reasons for this partial abandonment have not been explained in the written submissions, the Court can only take note of this decision and limit its examination to the other aspects of the alleged failure to fulfil obligations.

As regards the Commission's allegation that Article 3 of the Directive has not been transposed, the Spanish Government claims that this provision was correctly transposed into national law by the adoption of Royal Decree 2071/1995 of 22 December 1995 which establishes the qualitative criteria for the radiodiagnostic field. This decree, published in the Official Journal on 23 January 1996, was notified to the Commission on 26 February 1996.

However, the argument put forward by the defendant cannot be accepted. As the Commission rightly recalls, the Court has consistently held 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'. [3] In this case, Royal Decree 2071/1995 was only notified to the Commission on 26 February 1996, whilst the period laid down in the reasoned opinion expired on 10 September 1993. As a result, even if it is assumed that the Decree amounts to a correct transposition of the Directive — which is disputed by the applicant — that transposition would, in any event, have been late. Consequently, from this point of view there are good grounds for declaring the Commission's action for failure to fulfil obligations to be justified.

Article 4 of the Directive

4. Furthermore, the defendant disputes the Commission's assessment that there has been a failure to transpose Article 4 of the Directive. In its opinion, the purpose of the provision (namely to discourage the unnecessary proliferation of equipment for radiotherapy, radiodiagnosis and nuclear medicine) has been achieved by adopting the following measures: the national survey of existing installations, the development of criteria for the distribution of resources, the guidelines

3 — Judgment in Case C-133/94 *Commission* v *Belgium* [1996] ECR I-2323, at paragraph 17.

for clinical practice as well as a series of provisions adopted by the autonomous communities concerning the authorization, creation and modification of treatment centres.

However, this argument must also be rejected. Firstly, if it is true that compiling a national inventory is a matter of clear importance in view of the planning for the subject-matter in question, as soon as it allows a complete survey of the existing installations, I do not see how this measure can, in itself, discourage 'the unnecessary proliferation of equipment' in existence, as Article 4 of the Directive requires. Unless there are specific measures which limit the number of installations and regulate their siting, a mere survey of the latter is of purely descriptive value.

Moreover, as for the criteria for the allocation of funds, it is enough to point out that, as the Spanish Government has accepted in its defence, they concern solely radiotherapy installations and do not cover those for radiodiagnosis and nuclear medicine, which are nevertheless referred to in Article 4 of the Directive. As a result, even assuming that the policy of allocating funds is a measure aimed at discouraging 'the unnecessary proliferation of installations', it does not, nevertheless, concern all of these, so that transposition would only be partial. The same applies to the guidelines for clinical practice, which do not cover radiology or nuclear medicine.

Reference to the legislation adopted by the autonomous communities is also immaterial. That legislation, in fact, concerns the grant of administrative authorizations for the establishment and management of health centres, but does not contain any provisions regarding planning and restrictions on the number of installations referred to in Article 4 of the Directive. Moreover, those provisions only concern 4 out of the 17 regional communities, giving no indication of the situation in the others.

Finally, the Spanish Government's argument that Article 4 of the Directive leaves the Member States a wide discretionary power as to the measures considered necessary to achieve the objective laid down in the article is no longer tenable. In its opinion, the decision to transpose the article by the measures referred to cannot be challenged. This argument is, however, unconvincing. I do not deny that Article 4 leaves the Member States some discretion in the choice of the measures to adopt. Nevertheless, those measures must be adopted and they must be appropriate to ensure the desired purpose is achieved, which is not the case here or only partly the case. I therefore consider that on this point the Commission's action should be upheld.

Article 5 of the Directive

5. By disputing the failure to transpose Article 5 of the Directive the defendant Government claims that, since 1995, notices of competition for access to specialized health training plans also cover posts for hospital radiophysics training. Moreover, it reports that it has drawn up a draft Royal Decree introducing and regulating the official qualification of specialist in hospital radiophysics and that the procedure for the adoption of that draft is at an advanced stage.

That line of defence is also bad. Likewise the argument to which I have just referred is not worthy of consideration: the draft Decree has not yet been approved and, in any event, transposition is still late and this does not cure the failure to fulfil obligations. As far as the first argument is concerned, it is enough to recall that Article 5 provides that a qualified expert in radiophysics shall be available 'to sophisticated departments of radiotherapy and nuclear medicine'. Even though the notices of competition for specialization in radiophysics may enable specialists to be trained, the measures do not, as a general rule, require an expert in radiophysics and nuclear medicine to be present, as is required by Article 5.

In my view, the action brought by the Commission is therefore well founded in this respect.

Conclusion

In the light of the above considerations, I propose that the Court should:

(1) declare that, by failing to adopt within the prescribed period all the provisions necessary to implement Articles 3, 4 and 5 of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment, except for the obligation to keep radiodiagnostic installations under surveillance as provided for by Article 3 of that Directive, the Kingdom of Spain has failed to fulfil its obligations;

(2) order the Kingdom of Spain to pay the costs.