JUDGMENT OF THE COURT (Sixth Chamber)
9 October 1997 *

In Case C-21/96,

Commission of the European Communities, represented by Thomas F. Cusack, Legal Adviser, and Isabel Martínez del Peral, of its Legal Service, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of the same service, Wagner Centre, Kirchberg,

applicant,

v

Kingdom of Spain, represented by Alberto José Navarro González, Director-General for Legal and Institutional Coordination in Community Affairs, and Rosario Silva de Lapuerta, Abogado del Estado, of the State Legal Service, acting as Agents, with an address for service in Luxembourg at the Spanish Embassy, 4-6 Boulevard E. Servais,

defendant,

APPLICATION for a declaration that, by failing to adopt the laws, regulations or administrative provisions necessary to comply with 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 (OJ 1984 L 265, p. 1) or by failing to inform the Commission of the measures it has adopted for the transposition of the Directive, the Kingdom of Spain has failed to fulfil its obligations under the Euratom Treaty,

* Language of the case: Spanish.

THE COURT (Sixth Chamber),

composed of: H. Ragnemalm, President of the Chamber, G. F. Mancini, P. J. G. Kapteyn (Rapporteur), J. L. Murray and G. Hirsch, Judges,

Advocate General: A. La Pergola,
Registrar: L. Hewlett, Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 24 April 1997

after hearing the Opinion of the Advocate General at the sitting on 27 May 1997,

gives the following

Judgment

1 By application lodged at the Court Registry on 24 January 1996, the Commission of the European Communities brought an action under Article 141 of the Euratom Treaty for a declaration that, by failing to adopt the laws, regulations or administrative provisions necessary to comply with 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 (OJ 1984 L 265, p. 1, hereinafter 'the Directive') or by failing to inform the Commission of the measures it has adopted for the transposition of the Directive, the Kingdom of Spain has failed to fulfil its obligations under the Euratom Treaty.

2 While recognizing the beneficial effects of ionizing radiation at a diagnostic, therapeutic and preventive level, the Directive aims to improve protection of patients and of the general public against undue radiation levels.

3 To that end the Directive provides in particular as follows:

— The competent authorities are to draw up an inventory of medical and dental radiological equipment and nuclear medical installations and 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 are to implement the necessary measures to improve inadequate or defective features of installations subject to such surveillance. They are to 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 are to be carried out only in exceptional circumstances (Article 3);

— Each Member State is to take such steps as it may consider necessary to discourage the unnecessary proliferation of equipment for radiotherapy, radiodiagnosis and nuclear medicine (Article 4);

— A qualified expert in radiophysics is to be available to sophisticated departments of radiotherapy and nuclear medicine (Article 5).

4 Article 7 provides that the Member States are to take the measures necessary to comply with the Directive before 1 January 1986 and to inform the Commission of those measures.

5 Article 399 of the Act concerning the Conditions of Accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties (OJ 1985 L 302, p. 23) fixed 1 April 1986 as the date by which the Kingdom of Spain was to communicate to the Commission, in accordance with Article 33 of the Euratom Treaty, the provisions laid down by law, regulation, or administrative action designed to ensure the protection of the health of workers and the general public in the territory of Spain against the dangers arising from ionizing radiations.

6 By letters of 27 November 1987, 8 March 1988 and 5 October 1990 the Kingdom of Spain informed the Commission of the national provisions which were intended to transpose the Directive. The basic instrument for that transposition is Royal Decree No 1132 of 14 September 1990 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (hereinafter 'Royal Decree 1132/1990').

7 In the Commission's view, the measures adopted by the Kingdom of Spain in order to implement the Directive did not adequately transpose some of its articles and, by letter of 5 August 1991, the Commission invited the Spanish Government to submit its observations in accordance with the first paragraph of Article 141 of the Euratom Treaty within a period of two months from the receipt of that letter.

8 The Spanish Government replied to that request by letters of 3 and 10 December 1991.

9 After considering those letters, the Commission took the view that Articles 3, 4 and 5 of the Directive had been incompletely transposed. Consequently, on 25 May 1993 it delivered a reasoned opinion inviting the Spanish Government to adopt the necessary measures to comply with those provisions within a period of two months of the date of notification.

10 By letter of 15 September 1993 the Spanish Government submitted its observations on that opinion to the Commission. Then, by letter of 2 December 1994, it sent it a draft Royal Decree establishing quality criteria for radiodiagnosis.

11 On 8 March 1995 the Commission sent to the Spanish authorities its recommendations in regard to that draft, pursuant to the second paragraph of Article 33 of the Euratom Treaty. The Commission claims that, if that draft had been adopted, it would have satisfied part of its objections concerning Article 3 of the Directive.

12 By letter of 24 October 1995 the Spanish authorities informed the Commission of their reaction to its recommendations.

13 Since it was not satisfied by that reply, and noting that more than nine years had elapsed since the date on which the Kingdom of Spain should have brought its national legislation into line with the Directive, the Commission brought the present action.

14 In support of its action, the Commission claims that the Kingdom of Spain has not yet correctly and fully transposed Articles 3, 4 and 5 of the Directive into national law. It has thereby infringed the third paragraph of Article 161 of the Euratom Treaty, under which directives are binding upon the Member States as to the result to be achieved, and the first paragraph of Article 192 of the same Treaty, which requires the Member States to take all appropriate measures to ensure fulfilment of the obligations arising out of the Treaty. The Commission observes, moreover, that the principles laid down by the Directive must be regarded as basic standards within the meaning of the first paragraph of Article 33 of the Euratom Treaty, which requires Member States to lay down the appropriate provisions, whether by legislation, regulation or administrative action, to ensure compliance with those standards and to take the necessary measures with regard to teaching, education and vocational training.

Incomplete transposition of Article 3 of the Directive

15 The Commission submits that Article 4 of Royal Decree 1132/1990, which provides that 'equipment for radiotherapy, radiodiagnosis and nuclear medicine must be kept under strict surveillance by the competent authority with regard to the qualitative criteria of appliances for radiotherapy, radiodiagnosis and nuclear medicine in order to guarantee the radiation protection of the patient' does not satisfactorily transpose Article 3 of the Directive. It merely establishes a framework which is to be supplemented by implementing measures.

16 The Commission adds that, although Article 6 of Royal Decree 1132/1990 does provide for certain obligations on the Minister for Health and Consumer Affairs in regard to a survey of national radiological equipment and the national inventory, it does not guarantee that criteria of acceptability for radiological installations and nuclear medical installations are to be fixed; that defects in installations are to be corrected; that those installations are to be taken out of service when they no longer meet the defined criteria; or that there will be strict surveillance of the institutions with regard to radiological protection and the quality control of appliances. In the course of the proceedings the Commission did, however, withdraw its action in so far as it seeks a declaration by the Court that the defendant insufficiently transposed the obligation to keep radiological installations under surveillance, as required by Article 3 of the Directive.

17 The Spanish Government claims that Royal Decree No 2071 of 22 December 1995 establishing the quality criteria in the field of radiodiagnosis ('Royal Decree 2071/1995'), approved and published in the *Boletín Oficial del Estado* on 23 January 1996 and notified to the Commission on 26 February 1996, as well as drafts of similar Royal Decrees concerning radiotherapy and nuclear medicine, which are on the point of being approved, contain measures which are sufficient to implement the provisions of Article 3 of the Directive.

18 The Spanish Government states, moreover, that, in addition to those Royal Decrees, there are various earlier provisions relating to the control and surveillance of radioactive installations, which already applied to radiotherapy and nuclear medicine installations. Those provisions, which impose obligations in regard to the disclosure and registration of appliances in X-ray installations, the authorization of radioactive installations, surveillance, control and inspection, as well as evidence of acceptance of the appliances listed in the purchase specifications, guarantee the radiological protection of all persons concerned by the use of ionizing radiation in the medical field.

19 Lastly, the Spanish Government observes that the Directive, while providing that the competent national authorities are to establish criteria of acceptability for installations, does not itself give any guidelines for establishing those criteria.

20 The Court notes, first of all, that the Kingdom of Spain has not contested that Article 4 of Royal Decree 1132/1990 had to be supplemented by implementing measures and that in that regard it has referred to Royal Decree 2071/1995 and to certain similar draft Royal Decrees concerning radiotherapy and nuclear medicine.

21 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 that the Court cannot take account of any subsequent changes (see, *inter alia*, Case C-289/94 *Commission* v *Italy* [1996] ECR I-4405, paragraph 20, and Case C-302/95 *Commission* v *Italy* [1996] ECR I-6765, paragraph 13).

22 In the present case, the period given in the reasoned opinion expired on 10 September 1993. Royal Decree 2071/1995 was notified to the Commission only on 26 February 1996 and the drafts of similar Royal Decrees concerning radiotherapy and nuclear medicine to which the Spanish Government refers had not yet been adopted at the moment when the present action was brought.

23 In those circumstances, when appraising this action, the Court cannot take into account either Royal Decree 2071/1995 or the draft royal decrees.

24 As regards the pre-existing provisions on the control and surveillance of radioactive installations, which are claimed already to govern radiotherapy and nuclear medicine installations, it suffices to point out that, although they provide a means to ensure the surveillance of radiotherapy and nuclear medicine installations, it has not been shown that, as Article 3 of the Directive requires, they establish criteria of acceptability for those types of installations and adequately ensure the rectification of defects in them or their withdrawal from service where they no longer meet the criteria specified.

25 Lastly, the Spanish Government's assertion that the Directive does not lay down guidelines for the purpose of establishing the criteria of acceptability for the installations does not justify its failure to establish those criteria.

26 Consequently, it must be held that, by failing to adopt the laws, regulations or administrative provisions necessary to establish criteria of acceptability for radiological installations and nuclear medical installations and to have those installations rectified when they are defective or inadequate or taken out of service where they no longer meet the criteria specified, the Kingdom of Spain has failed to transpose Article 3 of the Directive in full.

Incomplete transposition of Article 4 of the Directive

27 The Commission submits that Article 6 of Royal Decree 1132/1990, pursuant to which the Minister of Health and Consumer Affairs 'must include in the national inventory of radiodiagnostic, radiotherapy and nuclear medicine installations all installations of that type on the national territory, so that the inventory is constantly up to date in order to allow planning which discourages the unnecessary proliferation of those installations' does not satisfactorily transpose Article 4 of the Directive. Without appropriate instruments to implement the planning, a national survey is insufficient to discourage the unnecessary proliferation of the installations.

28 The Spanish Government considers that it has complied with its obligations under Article 4 of the Directive by adopting Article 6 of Royal Decree 1132/1990, which, when read in conjunction with the criteria for the distribution of the installations, allows each autonomous community to perform its task in regard to authorizing the opening of health centres and the initiation of health services including the installations covered by Article 4 of the Directive. Those distribution criteria have already been established for radiotherapy and hemodynamics and are in the course of being established for medical examinations and nuclear medicine. Moreover, guidelines for clinical practice and the survey of technology have been drawn up by the Technology Development Agency, which is answerable to the Ministry of Health and Consumer Affairs.

29 The Spanish Government adds that the autonomous communities have adopted rules concerning the powers and conditions for the authorization, creation, construction and modification of health centres, services and establishments, including radiology services. As evidence of that claim, the Spanish Government has annexed to its defence the rules concerning the communities of Castilla-La Mancha, Madrid, Catalonia and Galicia.

30 Lastly, the Spanish Government observes that, according to the actual wording of Article 4 of the Directive, it is for the Member States to take such steps as they may consider necessary to implement that article; consequently, the Directive, which leaves the nature of those steps to be decided by the Member States, does not determine that matter.

31 As the Advocate General has correctly pointed out in point 4 of his Opinion, unless there are specific measures which, in particular, limit the number of installations and regulate their siting, a mere survey of radiodiagnostic, radiotherapy and nuclear medicine installations, as provided for in Article 6 of Royal Decree 1132/1990, does not discourage the unnecessary proliferation of those installations.

32 The criteria for the distribution of the installations and the clinical practice guidelines are not legally binding under Spanish law. Moreover, according to the observations of the Spanish Government, the criteria for the distribution of the installations concern solely radiotherapy and hemodynamics installations and do not cover those for radiodiagnosis and nuclear medicine. It follows that those criteria can, on any view, constitute only a partial transposition.

33 Furthermore, the Spanish Government's reference to the legislation adopted by the autonomous communities is also immaterial. That legislation 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 numbers of installations referred to in Article 4 of the Directive.

34 Lastly, although Article 4 of the Directive does indeed leave the Member States a degree of discretion as regards the choice of steps to be taken, any steps taken must nevertheless be taken in order to achieve the objective of that article. It follows from the foregoing that the steps taken by the Kingdom of Spain do not satisfy that requirement.

35 Consequently, the Kingdom of Spain has not fully transposed Article 4 of the Directive.

Incomplete transposition of Article 5 of the Directive

36 The Commission considers that Article 5 of Royal Decree 1132/1990 does not sufficiently transpose Article 5 of the Directive. The domestic provision provides that the radiodiagnostic, nuclear medicine and radiotherapy installations must have available to them a qualified expert in radiophysics, either specific to their installation or approved, and that the conditions to be satisfied in order to obtain that qualification, the necessary conditions in the event that services are performed in several installations, and the circumstances in which the radiodiagnostic installations must have an expert in radiophysics available to them are to be laid down in a Royal Decree. No such Royal Decree has been adopted.

37 The Spanish Government considers that it has satisfied its obligation under Article 5 of the Directive in view of the fact that since 1993 the notices of competition for access to specialized health training plans also cover posts for hospital radiophysics training and that during the 1996 calendar year the first intake of radiophysics

students will graduate after a three-year programme in university hospital training units. There are already 40 radiophysicians chosen under that system.

38 The Spanish Government adds that, on the basis of Article 5 of Royal Decree 1132/1990, it has also drawn up a draft Royal Decree providing for and governing the award of the official qualification of specialist in hospital radiophysics and that the procedure for the adoption of that draft is at an advanced stage, with only the opinion of the Council of State outstanding before it is approved by the Council of Ministers.

39 Although it is true that the notices of competitions for specialization in radiophysics enable specialists to be trained, those measures are not, however, in the nature of regulations and cannot therefore be regarded as a sufficient transposition of the Directive. For the reasons set out in paragraph 21 above, the existence of a draft Royal Decree, such as that pointed out by the Spanish Government, cannot cure that failure to act.

40 Consequently, it must be held that, by failing to adopt within the prescribed period all the provisions necessary to implement Articles 3, 4 and 5 of the Directive, the Kingdom of Spain has failed to fulfil its obligations under the Euratom Treaty.

Costs

41 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs. Since Spain has been unsuccessful, it must be ordered to pay the costs.

On those grounds,

THE COURT (Sixth Chamber)

hereby:

1. **Declares that, by failing to adopt within the prescribed period 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, the Kingdom of Spain has failed to fulfil its obligations under the Euratom Treaty;**

2. **Orders the Kingdom of Spain to pay the costs.**

Ragnemalm Mancini Kapteyn

Murray Hirsch

Delivered in open court in Luxembourg on 9 October 1997.

R. Grass H. Ragnemalm

Registrar President of the Sixth Chamber