JUDGMENT OF THE COURT (Fifth Chamber)
15 October 1998 *

In Case C-268/97,

Commission of the European Communities, represented by Hendrik van Lier, Legal Adviser, and Lena Ström, of its Legal Service, acting as Agents, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, also of its Legal Service, Wagner Centre, Kirchberg,

applicant,

v

Kingdom of Belgium, represented by Jan Devadder, General Adviser at the Legal Service of the Ministry of Foreign Affairs, External Trade and Cooperation with Developing Countries, acting as Agent, with an address for service in Luxembourg at the Belgian Embassy, 4 Rue des Girondins,

defendant,

APPLICATION for a declaration that, by not adopting within the prescribed period all the measures necessary to comply with Articles 14 and 22 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States relating to the protection of animals used for experimental and other scientific purposes (OJ 1986 L 358, p. 1), the Kingdom of Belgium has failed to fulfil its obligations under that directive and the EC Treaty,

* Language of the case: French.

THE COURT (Fifth Chamber),

composed of: J.-P. Puissochet, President of the Chamber, P. Jann, C. Gulmann, D. A. O. Edward and L. Sevón (Rapporteur), Judges,

Advocate General: F. G. Jacobs,
Registrar: R. Grass,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 14 May 1998,

gives the following

Judgment

1 By application lodged at the Court Registry on 22 July 1997, the Commission of the European Communities brought an action under Article 169 of the EC Treaty for a declaration that, by not adopting within the prescribed period all the measures necessary to comply with Articles 14 and 22 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States relating to the protection of animals used for experimental and other scientific purposes (OJ 1986 L 358, p. 1, hereinafter 'the Directive'), the Kingdom of Belgium has failed to fulfil its obligations under that directive and the Treaty.

2 Article 14 of the Directive provides:

'Persons who carry out experiments or take part in them and persons who take care of animals used for experiments, including duties of a supervisory nature, shall have appropriate education and training.

In particular, persons carrying out or supervising the conduct of experiments shall have received instruction in a scientific discipline relevant to the experimental work being undertaken and be capable of handling and taking care of laboratory animals; they shall also have satisfied the authority that they have attained a level of training sufficient for carrying out their tasks.'

3 Article 22(1) of the Directive provides:

'In order to avoid unnecessary duplication of experiments for the purposes of satisfying national or Community health and safety legislation, Member States shall as far as possible recognise the validity of data generated by experiments carried out in the territory of another Member State unless further testing is necessary in order to protect public health and safety.'

4 Under Article 25 the Member States were to take the measures necessary to comply with the Directive by 24 November 1989 and were forthwith to inform the Commission thereof.

5 The Belgian authorities notified the Commission of the Law of 14 August 1986 on the protection of the welfare of animals (*Moniteur Belge* of 3 December 1986), and the Royal Decree of 14 November 1993 on the protection of test animals (*Moniteur Belge* of 5 January 1994).

6 However, as it considered that those provisions did not correctly and fully transpose Articles 14 and 22 of the Directive, the Commission, by letter of 23 January 1995, gave the Belgian Government notice to submit its observations in that connection within two months.

7 By letter of 6 April 1995 the Belgian Government first contested those allegations, then notified the Commission of the Law of 4 May 1995, amending that of 14 August 1986.

8 On 6 August 1996, as it considered that Articles 14 and 22 of the Directive had still not been correctly and fully transposed, the Commission sent a reasoned opinion to the Kingdom of Belgium, calling on it to take the measures necessary to comply with that opinion within two months of its notification.

9 The Kingdom of Belgium replied by letter of 18 October 1996, stating that a draft Royal Decree was being prepared to meet the requirements of Article 14 of the Directive. As regards Article 22, it drew the Commission's attention to two Royal Decrees of 22 and 25 September 1992, one amending the Royal Decree of 16 September 1985 concerning the standards and procedures applicable in trials of medicines for human consumption and the other amending that of 12 March 1985 concerning the standards and procedures applicable in trials of veterinary medicines (*Moniteur Belge* of 5 December 1992). It then notified a consolidated version of

the Royal Decree of 3 July 1969 concerning the registration of medicines which, it argued, ensured mutual recognition of the validity of data generated by experiments carried out in the territory of another Member State.

10 Taking the view that those documents still did not constitute transposition of Articles 14 and 22 of the Directive, the Commission brought this action.

11 The Commission submits that Article 14 of the Directive has not been fully transposed since Article 26 of the Law of 14 August 1986, as amended by the Law of 4 May 1995, only lays down a requirement regarding appropriate education and training for a 'maître d'expérience' (master of experiments), rather than for all the persons covered by the Directive. As regards Article 22 of the Directive, it has not been fully transposed by the Royal Decrees of 22 and 25 September 1992, since they only concern experiments for the production of medicines for human and veterinary use, rather than all experiments on animals.

12 The Kingdom of Belgium acknowledges that Article 14 of the Directive has not been fully transposed, but states that a draft Royal Decree amending the Royal Decree of 14 November 1993 has been prepared to remedy the situation. As regards Article 22 of the Directive, it observes that the Royal Decrees of 22 and 25 September 1992 expressly provide that tests must be carried out in accordance with the Directive. Moreover, Article 6a of the Royal Decree of 3 July 1969, inserted by Royal Decree of 1 February 1996 (*Moniteur Belge* of 28 March 1996), made provision for a system of mutual recognition as regards the registration of cases dealt with in another Member State.

13 In that connection it must be held that Article 14 of the Directive has not been fully transposed because the relevant national provisions only provide for appropriate education and training in the case of a 'maître d'expérience' rather than for all the persons referred to in that article.

14 As regards Article 22 of the Directive, it must be pointed out that it concerns the recognition by the Member States of the validity of data generated by experiments carried out in the territory of another Member State for one of the purposes listed in Article 3 of the Directive, that is to say, the development, manufacture, quality, effectiveness and safety testing not only of drugs but also of foodstuffs and other substances or products and the protection of the environment. As the Decrees of 22 and 25 September 1992 only concern tests on medicines for human or veterinary use and Article 6a of the Royal Decree of 3 July 1969, inserted by Royal Decree of 1 February 1996, only concerns the medicines registered, those provisions do not constitute a full transposition of Article 22 of the Directive.

15 As regards the draft Royal Decree amending the Royal Decree of 14 November 1993, suffice it to note that no provisions transposing the Directive fully and correctly were enacted within the period prescribed by the reasoned opinion.

16 It must therefore be held that, by not adopting within the prescribed period all the measures necessary to comply with Articles 14 and 22 of the Directive, the Kingdom of Belgium has failed to fulfil its obligations under the Directive.

Costs

17 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been asked for in the successful party's pleadings. The Commission asked for an order for costs against the Kingdom of Belgium. Since that party has been unsuccessful, it must be ordered to pay the costs.

On those grounds,

THE COURT (Fifth Chamber),

hereby:

1) **Declares that by not adopting within the prescribed period all the measures necessary to comply with Articles 14 and 22 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States relating to the protection of animals used for experimental and other scientific purposes, the Kingdom of Belgium has failed to fulfil its obligations under that directive.**

2) **Orders the Kingdom of Belgium to pay the costs.**

Puissochet Jann Gulmann

Edward Sevón

Delivered in open court in Luxembourg on 15 October 1998.

R. Grass J.-P. Puissochet

Registrar President of the Fifth Chamber