JUDGMENT OF THE COURT (Fifth Chamber)

16 January 2003 *

In Case C-205/01,

Commission of the European Communities, represented by R.B. Wainwright, acting as Agent, and J. Stuyck, advocaat, with an address for service in Luxembourg,

applicant,

v

Kingdom of the Netherlands, represented by H.G. Sevenster, acting as Agent,

defendant,

APPLICATION for a declaration that, by failing to adopt, or in any event to communicate to the Commission, all the laws, regulations and administrative provisions necessary in order to transpose into national law Articles 8(2), 11, 18(1) and 22(1) of Council Directive 86/609/EEC of 24 November 1986 on the

* Language of the case: Dutch.

approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ 1986 L 358, p. 1), the Kingdom of the Netherlands has failed to fulfil its obligations under that directive,

THE COURT (Fifth Chamber),

composed of: C.W.A. Timmermans, President of the Fourth Chamber, acting for the President of the Fifth Chamber, D.A.O. Edward, A. La Pergola (Rapporteur), P. Jann and S. von Bahr, Judges,

Advocate General: A. Tizzano,
Registrar: H. von Holstein, Deputy Registrar,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 11 June 2002,

after hearing the Opinion of the Advocate General at the sitting on 26 September 2002,

gives the following

Judgment

1 By application lodged at the Court Registry on 18 May 2001, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by failing to adopt, or in any event to communicate to the Commission, all the laws, regulations and administrative provisions necessary in order to transpose into national law Articles 8(2), 11, 18(1) and 22(1) of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ 1986 L 358, p. 1; 'the Directive'), the Kingdom of the Netherlands has failed to fulfil its obligations under that directive.

Legal context and pre-litigation procedure

2 Article 11 of the Directive states:

'Notwithstanding the other provisions of this Directive, where it is necessary for the legitimate purposes of the experiment, the authority may allow the animal concerned to be set free, provided that it is satisfied that the maximum possible care has been taken to safeguard the animal's well-being, as long as its state of health allows this to be done and there is no danger for public health and the environment.'

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 Article 25 of the Directive states:

'1. Member States shall take the measures necessary to comply with this Directive by 24 November 1989. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.'

5 The main measures transposing the Directive which the Kingdom of the Netherlands notified to the Commission are the Wet houdende regelen met betrekking tot het verrichten van proeven op dieren (Law regulating the carrying out of experiments on animals, *Staatsblad* 1977, No 67) of 12 January 1977, as amended by the Law of 12 September 1996 (*Staatsblad* 1996, No 500) ('the Law

on Animal Experiments'), and the Besluit tot uitvoering van de artikelen 3, tweede lid, 9, 12, 14 en 15 van de Wet op de dierproeven (Order implementing Articles 3(2), 9, 12, 14 and 15 of the Law on Animal Experiments) of 31 May 1985 ('the Animal Experiments Order').

6 Since the Commission took the view that those measures did not secure a complete and correct transposition of Articles 4, 5 and 7(3), the second subparagraph of Article 8(2), Article 8(3) and (4) and Articles 11, 18(1) and 22(1) of the Directive, by letter of 9 June 1998 it gave the Kingdom of the Netherlands formal notice to submit its observations to it in that regard.

7 By letter of 29 July 1998, the Netherlands Government contested the alleged infringements. Since the Commission was not satisfied with the explanations provided by the Netherlands Government, on 1 August 2000 it sent the Kingdom of the Netherlands a reasoned opinion essentially repeating the complaints set out in its letter of formal notice and adding that, in any event, the Kingdom of the Netherlands had not informed it of the measures adopted to comply with the Directive. The Commission therefore called on that Member State to adopt the measure necessary to comply with the reasoned opinion within two months of notification thereof.

8 On 3 October 2000 the Netherlands authorities provided the Commission with their observations on the reasoned opinion. By letter of 14 March 2001, they informed the Commission that new provisions implementing the Directive had been published, namely the Beleidsregels ontheffingen Wet op de dierproeven (Instructions on derogations from the Law on Animal Experiments) of 10 October 2000 (*Nederlandse Staatscourant* 2000, No 207) and the Regeling huisvesting en verzorging proefdieren (Regulation on the accommodation and

care of animals used for experiments) of 30 January 2001 (*Nederlandse Staatscourant* 2001, No 27).

9 Since the Commission took the view that there was still a failure to transpose Articles 8(2), 11, 18(1) and 22(1) of the Directive, it brought the present action.

10 Following the adoption, in the course of the proceedings, of further measures transposing the Directive, namely the Besluit tot wijziging van het Dierproevenbesluit (Order amending the Animal Experiments Order) of 26 June 2001 (*Staatsblad* 2000, No 310) and the Nadere regeling merken proefdieren (Supplementary regulation concerning the marking of animals used for experiments) of 21 June 2001 (*Nederlandse Staatscourant* 2001, No 119), the Commission partially withdrew its action, retaining only the complaints concerning Articles 11 and 22(1) of the Directive.

The action

The failure to transpose Article 11 of the Directive

11 By its first complaint, the Commission maintains that the Kingdom of the Netherlands has not transposed Article 11 of the Directive correctly.

12 In its defence, the Netherlands Government contends that strict word-for-word repetition in national legislation of the express and precise terms in which the

provisions of a directive are couched is not necessary, provided that the effectiveness of the directive is ensured and the requirements of legal certainty and of clarity are met, so that persons concerned can be aware of the rights and obligations flowing from the directive (see, in particular, Case C-144/99 *Commission* v *Netherlands* [2001] ECR I-3541, paragraph 17).

13 In its submission, that is the case with Article 11 of the Directive inasmuch as its objective is achieved by means of Article 10a of the Law on Animal Experiments.

14 It states that, as provided in Article 10a(1) of the Law, any animal experiment requires a favourable opinion given in advance by an authorised animal experiments committee ('the authorised committees') or, in the event of an adverse opinion from such a committee, a favourable decision by the Centrale Commissie dierproeven (Central Committee for Animal Experiments; 'the Central Committee').

15 Under Article 10a(2) of the Law on Animal Experiments, the authorised committees are obliged, when drawing up their opinions, to consider the research plan ('onderzoeksplan') which must be submitted to them and to take account at that time of the requirements resulting from various provisions of the Law, including Article 12 which imposes an obligation on all researchers to ensure that animals used for experiments are treated and cared for properly, in particular by taking account of all the rules laid down in that regard.

16 According to the Kingdom of the Netherlands, it follows from that legislation that the research plan must mention and justify any setting free of animals in so far as that forms part of the proposed experiment. It also follows therefrom that the authorised committees and the Central Committee must, when authorising

such an experiment, take account of the provisions obliging the researcher to ensure that the animals used are treated and cared for properly and to comply with all other applicable legal provisions, such as those adopted in relation to public health in the broad sense or the environment.

17 The effectiveness of Article 11 of the Directive is accordingly ensured in particular by the fact that, if legal provisions in a field other than that of animal experiments oppose an animal's being at large having regard to its state at that stage of the experiment, the committee's opinion or decision can only be adverse.

18 Those arguments cannot be upheld.

19 Article 11 of the Directive lays down strict conditions for the setting free of any animals in the context of experiments within the meaning of the Directive (Case C-152/00 *Commission* v *France* [2002] ECR I-6973, paragraph 41). Such setting free requires an authorisation from the competent authority, which may be granted only where that is necessary for the legitimate purposes of the experiment, the authority is satisfied that the maximum possible care has been taken to safeguard the well-being of the animal concerned, the animal's state of health allows it to be set free as proposed and there is no danger for public health and the environment by reason of its being set free.

20 It must be stated, first, that Articles 10a and 12 of the Law on Animal Experiments, upon which the Netherlands Government relies, do not refer at all to the setting free of animals in the context of scientific experiments and, a

fortiori, do not specify that such setting free can be authorised only under the strict conditions laid down in Article 11 of the Directive.

21 Second, it is clear that, even if those national provisions give rise to an obligation to refer to the setting free in the research plan, provisions of that kind are not capable of ensuring that the specific objective of Article 11 of the Directive is attained.

22 The fact that authorised committees or the Central Committee called on to give a favourable opinion or decision respectively on an experiment must take account at that time of the general obligation on the researcher to ensure that animals used for experiments are treated and cared for properly and to comply with all the rules laid down in that regard, in particular in the fields of public health and environmental protection, is not capable of ensuring compliance with the strict and specific conditions for grant of any authorisation to set an animal free imposed by Article 11 of the Directive.

23 In particular, it is not clear from the Law on Animal Experiments that the competent authority is required, before granting such authorisation, to make sure that the maximum possible care has been taken to safeguard the well-being of the animal concerned and to establish that the animal's state of health allows it to be set free as proposed and that setting it free does not give rise to any danger for public health or the environment. In this connection, it should also be pointed out that the Netherlands Government has not precisely indicated the rules laid down in the field of public health and environmental protection mere regard to which by the competent authority would, in its submission, have the effect of preventing that authority from authorising animals subjected to experiments to be set free where there is a risk to public health or the environment.

24 The Commission's first complaint must accordingly be upheld.

The failure to transpose Article 22(1) of the Directive

25 By its second complaint, the Commission maintains that the Kingdom of the Netherlands has not adopted any measure for the purpose of transposing Article 22(1) of the Directive.

26 The Netherlands Government contends that that provision does not call for specific transposition.

27 It also refers to Article 10(1)(a) of the Law on Animal Experiments which prohibits the carrying out of animal experiments for a purpose which, according to prevailing, freely available, expert opinion, can also be achieved in a different manner. In the Netherlands Government's submission, such a prohibition covers, *inter alia*, cases where the experiment proposed in the Netherlands is considered to provide data which already exist following experiments carried out in other Member States and are available to the person wishing to conduct such an experiment.

28 Those arguments cannot be upheld.

29 First, it is clear from the Court's case-law that Article 22 of the Directive, which concerns recognition by Member States of the validity of data generated by animal 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, the manufacture and the quality, effectiveness and safety testing of drugs, foodstuffs or other substances or products and the protection of the environment, does indeed require the adoption of appropriate measures of transposition (see Case C-268/97 *Commission* v *Belgium* [1998] ECR I-6069, paragraph 14, and *Commission* v *France*, cited above, paragraph 59).

30 Second, as the Advocate General has observed in point 26 of his Opinion, Article 10(1)(a) of the Law on Animal Experiments is in actual fact modelled on the wording of Article 7(2) of the Directive, which it accordingly transposes into Netherlands law. The respective provisions of Articles 7(2) and 22(1) of the Directive cannot be confused. Article 7(2) requires preference to be given to any alternative scientific methods to animal experiments which enable the same result to be achieved. Article 22(1), on the other hand, requires the validity of data generated by animal experiments carried out in another Member State to be recognised in order to avoid all pointless repetition of experiments which have already been carried out.

31 The Commission's second complaint must accordingly also be upheld.

32 It must therefore be found that, by failing to adopt all the measures necessary to ensure the correct transposition of Articles 11 and 22(1) of the Directive, the Kingdom of the Netherlands has failed to fulfil its obligations under the Directive.

Costs

33 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Kingdom of the Netherlands has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds,

THE COURT (Fifth Chamber)

hereby:

1. **Declares that, by failing to adopt all the measures necessary to ensure the correct transposition of Articles 11 and 22(1) of Council Directive 86/609/EEC of /yt24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, the Kingdom of the Netherlands has failed to fulfil its obligations under that directive;**

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

Timmermans Edward La Pergola

Jann von Bahr

Delivered in open court in Luxembourg on 16 January 2003.

R. Grass M. Wathelet

Registrar President of the Fifth Chamber