OPINION OF ADVOCATE GENERAL TIZZANO

delivered on 26 September 2002 [1]

1. In the present action, brought by the Commission under Article 226 EC, the Court of Justice is called upon to determine whether the Kingdom of the Netherlands has failed to adopt the measures necessary in order to implement in national law Articles 11 and 22(1) of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions regarding the protection of animals used for experimental and other scientific purposes (hereinafter: 'Directive 86/609' or 'the Directive') (OJ L 358, p. 1).

Legal background

Community law

2. Directive 86/609 establishes minimum standards of protection of animals used for experimental or scientific purposes relating to the development, manufacture and testing of drugs, foodstuffs and other substances or products and the protection of the environment. The primary objective of the harmonisation intended by the Directive, as expressly declared by the preamble (first recital) and Article 1, is to eliminate disparity between the relevant laws in Member States so as to avoid affecting the functioning of the common market, especially by causing distortion in competition and obstacles to trade.

3. According to the preamble (second recital), harmonisation is to be pursued by reducing the number of animals used for the abovementioned purposes to a minimum, and in any case by ensuring that such animals are adequately cared for and that no pain, suffering, distress or lasting harm is inflicted unnecessarily, or, if unavoidable, that they be restricted to the minimum.

4. As regards the specific provisions whose implementation in the national law of the

1 — Original language: Italian.

Netherlands is in dispute in the present case, it should be noted that Article 11 of the Directive provides:

'Notwithstanding the other provisions of this Directive, where it is necessary for the legitimate purposes of the experiment, the authority [responsible for checking experiments] 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.'

5. 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.'

6. Lastly, Article 25 of the Directive provides:

'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.'

National law

7. The principal measures aimed at implementing the Directive which the Kingdom of the Netherlands notified to the Commission are the Wet op de dierproeven (Law on animal experiments) of 12 January 1977,[2] as amended by the Law of 12 September 1996,[3] and the Dierproevenbesluit (Animal experiments order) of 31 May 1985, as amended, which gives effect to certain provisions of that law.[4]

2 — Wet van 12 januari 1977, houdende regelen met betrekking tot het verrichten van proeven op dieren (Stbl. 1977, 67).

3 — Wet tot wijziging van de Wet op de dierproeven (Stbl. 1996, 500).

4 — Besluit van 31 mei 1985 tot uitvoering van de artikelen 3, tweede lid, 9, 12, 14 en 15 van de Wet op de dierproeven (Stbl. 1985, 336).

Facts and procedure

8. By letter of 9 June 1998 the Commission informed the Kingdom of the Netherlands that it considered that the notified measures did not constitute a full and proper transposition of certain provisions of the Directive and invited the latter to submits its observations within two months. The Government of the Netherlands replied by letter of 29 July 1998, denying that it had failed to fulfil its obligations. However, examination of the arguments advanced by the Netherlands did not lead the Commission to change its position. On 1 August 2000 the Commission therefore issued a reasoned opinion requiring the Kingdom of the Netherlands to comply with its obligations under Articles 4, 5, 7(3), 8(2),(3) and (4), 11, 18(1) and 22(1) of the Directive within two months.

9. By letter of 3 October 2000 the Government of the Netherlands submitted its observations in response to the reasoned opinion. By letter of 14 March 2001 the Netherlands informed the Commission of further measures it had adopted and published subsequent to the reasoned opinion in order to implement the Directive, namely the Beleidsregels ontheffingen Wet op de dierproeven (Orders relating to derogations from the Law on animal experiments) [5] and the Regeling huisvesting en verzorging proefdieren (Regulation on the housing and welfare of animals used for experimental purposes). [6] At the same time the Netherlands informed the Commission of a series of measures amending the Order on animal experiments.

10. On the basis of the above information, the Commission withdrew some complaints but maintained those relating to Articles 8(2), 11, 18(1) and 22(1) of the Directive. It commenced the present proceedings on 18 May 2001. Subsequently, at the hearing before the Court of Justice on 11 June 2002, in view of the adoption of the amendment to the Order on animal experiments [7] and of the Nadere regeling merken proefdieren (Additional standards of identification marking of animals used for experimental purposes), [8] the Commission dropped the claims relating to Articles 8(2) and 18(1) of the Directive but maintained those in respect of Articles 11 and 22(1) as well as its position on costs. [9]

Legal analysis

11. As we have seen, the Commission claims that the Kingdom of the Netherlands

5 — Stert. 2000, 507.

6 — Stert. 2001, 27.

7 — Besluit van 26 Juni 2001 tot wijziging van het Dierproevenbesluit (Stbl. 2001, 310).

8 — Stert. 2001, 119.

9 — The Commission confirmed the withdrawal of some of its claims by letter to the Court Registry on 12 June 2002.

has not ensured the full and proper implementation of the Directive, albeit now only in respect of Articles 11 and 22(1). The Government of the Netherlands argues that, while those provisions of the Directive have not been literally transposed into the national law on animal experiments, the achievement of the objectives which they set is nevertheless ensured by that law and in general by the national rules in force. According to the Kingdom of the Netherlands, that is in line with the criteria outlined by the Court of Justice for verifying whether Member States have fulfilled their obligations in transposing directives.

12. In this regard I also note first of all that, according to the case-law of the Court, the transposition of a directive into national law 'does not necessarily require the provisions of the directive to be enacted in precisely the same words in a specific express provision of a law or regulation, [but] the general legal situation may be sufficient if it actually ensures the full application of the directive' provided in particular that it 'is sufficiently precise, clear and transparent for the persons concerned to know the full extent of their rights and obligations'. [10]

10 — Settled case-law; the citation is from Case C-214/98 *Commission* v *Greece* [2000] ECR I-9601, paragraphs 49 and 50.

13. Thus, in order to assess the complaints brought by the Commission, it has to be determined whether the above conditions have been satisfied and, in particular, whether the national law relating to animal experiments meets the requirements of Articles 11 and 22(1) of the Directive. It should be noted from the outset that this is far from straightforward since in effect, as will be seen later, the national law in question appears for the most part to comply with the Community provisions, and where it does fall short it does so in ways which are of little or merely formal significance. Nevertheless, the fact remains that, to the extent that these shortcomings continue to exist, they justify the Commission's action, especially where they jeopardise the complete achievement of the objectives contained in the above provisions of the Directive.

Article 11 of the Directive

14. As has been seen, Article 11 of the Directive establishes the conditions by which the authority responsible for checking experiments on animals can authorise an animal to be set free during an experiment. For that purpose the competent authority must be satisfied that the maximum possible care has been taken to safeguard the animal's well-being, that its health allows this to be done and that there is no danger for public health and the environment. According to the Commis-

sion, Netherlands law does not ensure the exact implementation of that provision. In particular, it does not agree with the Government of the Netherlands' argument that the conditions laid down by that provision are ensured by Articles 10a, 12 and 13 of the Law on animal experiments. Those articles in fact are of general scope and do not deal with the specific situation of freeing the animals.

15. The Government of the Netherlands, for its part, insists that it is precisely the application of the above articles of the Law on animal experiments which achieves the result intended by Article 11 of the Directive. In its view, the freeing of animals envisaged by that provision is but one stage in the experiment and as such it is subject to the preventive checking of the competent national authorities which ensures that the conditions laid down by the Directive are complied with. The Netherlands emphasise in particular that, according to Article 10a of the Law on animal experiments, in order to carry out an experiment it is necessary to obtain the favourable opinion of a commission authorised by the Centrale Commissie dierproeven (Central commission for animal experiments) or of the Central commission itself, which is issued subject to a research plan which shows the various stages of the experiment. In this context, under Articles 12 and 13 of the national law, the relevant bodies must take into account the requirements to protect the well-being and the health of the animal used for experiments. Moreover, and more generally, those bodies must ensure that the experiment complies with all existing legislative obligations, especially with regard to public health and the environment. All of that, in the view of the Government of the Netherlands, ensures compliance with the conditions laid down by Article 11 of the Directive, without it being necessary to reproduce those conditions in national law in a literal and specific way.

16. I must confess that I do not find the arguments advanced by the Government of the Netherlands convincing. Article 11 of the Directive requires compliance with precise conditions whose continuing existence, as is clear from the wording of the provision, has to be the subject of a specific assessment in each particular case where it is proposed to set an animal free. [11] It is only where such conditions are met that the competent authority can allow the animal to be set free. Even in this respect, I therefore doubt whether the preventive assessment of the experiment undertaken by the commissions for animal experiments, as envisaged by national law, constitutes an adequate means of ensuring that the above conditions are fully complied with.

17. Even if, as the Government of the Netherlands argues, the commissions also form a view as to the setting free of the animal in assessing research plans, it is in any case logical to presume that the animal is freed at the end of a stage of the experiment (for example the administration of a pharmaceutical product) in which problems for the animal and risks for the protection of public health and the environ-

11 — See on this point Case C-152/00 *Commission* v *France* [2002] ECR I-6973, paragraphs 41 and 42.

ment referred to by Article 11 of the Directive could arise. In this regard, an assessment ex ante of the experiment conducted solely on the basis of the research plan does not seem to me sufficient to enable the competent authority to establish that the maximum has been done to safeguard the animal's well-being, that its state of health allows it to be set free and that there is no danger for public health and the environment, as specifically required by Article 11.

18. Aside from that however, it certainly does not seem sufficient as a way of ensuring compliance with Article 11 of the Directive to refer to the requirements to safeguard the well-being and health of the animals which the national authorities should meet under Articles 12 and 13 of the Law on animal experiments. Even if the Netherlands legislation is to be interpreted in this sense, the fact remains that Article 11 of the Directive specifies that the requirements in a particular case in which an animal is set free can only be met where the competent authority 'is satisfied that the maximum possible care has been taken to safeguard the animal's well-being' and 'its state of health allows this to be done'. On the basis of the measures adopted by the national government, however, it does not appear at all that the relevant legislation requires the competent authorities, when deciding whether to free an animal, to adhere to conditions of equivalent rigour and clarity.

19. The same can be said of the further condition imposed by Article 11 of the Directive according to which an animal used for experimental purposes can be set free only if 'there is no danger for public health or the environment'. In this regard also the Government of the Netherlands places general reliance on a rather heterogenous variety of legislative provisions in different sectors from which, it maintains, compliance with the above conditions can be deduced. In my view, however, it is precisely this kind of argument which confirms that in reality Netherlands law does not offer a response which is as unequivocal as the clear and precise imperative of Article 11 of the Directive.

20. I therefore find the Commission's complaint in respect of Article 11 of the Directive to be well-founded.

Article 22(1) of the Directive

21. The Commission further claims that the Kingdom of the Netherlands has failed to transpose Article 22(1) of the Directive, which, as has been seen, requires the mutual recognition of data generated by experiments carried out in other Member States for the purposes of satisfying national or Community health and safety legislation in order to avoid unnecessary duplication of experiments.

22. The Government of the Netherlands argues that the requirements of Article 22(1) are fully reflected in Article 10(1)(a) of the Law on animal experiments in which, in its view, a clause of mutual recognition can be implied. By prohibiting direct experiments on animals for obtaining data which, according to prevailing and generally accepted expert opinion, can be produced by other means, the national provision also covers the case where the desired data has already been obtained in other Member States and is available to researchers concerned. As is apparent from the various working drafts, it is precisely this latter situation which is at the origin of the provision. The Government of the Netherlands submits finally that Article 10(1) of the Law on animal experiments does not prevent the competent national authorities from authorising an experiment where, in accordance with Article 22(1) of the Directive, further research is necessary for the protection of public health and safety.

23. In my opinion the Government of the Netherlands' argument cannot be accepted on this point either. Even if Article 10(1)(a) of the Law on animal experiments had the scope which the national government attributes to it, the obligation of mutual recognition is not in any event as strict as that required by Article 22(1) of the Directive.

24. It is true that the requirement imposed by the Directive for Member States to recognise 'as far as possible' the validity of data generated by experiments is not an absolute obligation. This can be understood from the fact that, in order to avoid the duplication of experiments, the desired data from experiments must not only be available but also usable, in the sense that it derives from an experiment with an identical or comparable object. [12] Nevertheless, even taking this into account, I am of the view that the conditions laid down by the Netherlands law do not fully comply with the requirements of the Directive since the mutual recognition of the validity of data generated by experiments, although not excluded, is not imposed in the clearer and more strict terms set out in Article 22(1) of the Directive.

25. In my view, this is indicated by the fact that, according to the Government of the Netherlands, the prohibition laid down by Article 10(1)(a) of the national Law on animal experiments ensures both the implementation of the obligation of mutual recognition in Article 22(1) of the Directive and also the exception to that obligation. The prohibition on animal experiments laid down in Article 10(1)(a) in cases where the desired results can be obtained by other means gives rise simultaneously not just to the obligation on the part of the competent authorities in the Netherlands to recognise the validity of data generated by experi-

12 — Even though, in my opinion, it is legitimate to presume that the object is identical or comparable in respect of experiments for the purposes of satisfying *Community* health and safety legislation.

ments in other Member States but also to the possibility for those authorities to derogate from that obligation where further experiments are necessary 'to protect public health and safety' as indicated in the Directive. However, in my opinion, it is precisely this ambivalence, which, far from supporting the argument of the Government of the Netherlands, shows instead that the national law does not clearly correspond to the requirements of Article 22(1) of the Directive.

26. On the other hand, that should not come as a surprise when one considers that Article 10(1)(a) of the Law on animal experiments relied on by the Netherlands Government does not reproduce Article 22(1) but rather Article 7(2) of the Directive, which prohibits experiments on animals 'if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practically available'. There is no question that the obligation of mutual recognition in Article 22(1) of the Directive has the same objective as that prohibition, namely to limit the use of animal experiments to those which are absolutely necessary. However, this does not alter the fact that the prohibition is separate and independent inasmuch as it envisages the particular case of 'experiments for the purposes of satisfying national or Community health and safety legislation' with specific provisions intended to avoid the duplication of experiments. In my opinion, it is therefore the structure of the Directive itself which indicates that full compliance with Article 22(1) cannot be ensured, as the Netherlands Government seeks to do, by means of the prohibition set out in the abovementioned Article 7(2) of that Directive.

27. Therefore, in respect of this point also, the Netherlands law cannot be considered to be in compliance with the Directive.

28. I therefore conclude that this claim and consequently the Commission's action in its entirety are well founded.

Costs

29. 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 view of what I have concluded as to the merits and of the fact that the Commission did so apply, the Kingdom of the Netherlands should pay the costs.

Conclusion

30. In the light of the above I propose that the Court should:

— declare that, by failing to adopt within the prescribed time-limit all the measures necessary to comply with Articles 11 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, the Kingdom of the Netherlands has failed to fulfil its obligations under that Directive;

— order the Kingdom of the Netherlands to pay the costs.