OPINION OF ADVOCATE GENERAL GEELHOED

delivered on 7 February 2002 [1]

I — Introduction

1. In the present infringement proceedings the Commission seeks a declaration from the Court that France has failed to implement fully and correctly 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 [2] (hereinafter: 'the Directive').

2. According to Article 1 the Directive aims to ensure that the provisions laid down by law, regulation or administrative provisions in the Member States for the protection of animals used for experimental or other scientific purposes are approximated, so as to avoid affecting the establishment and functioning of the common market. According to its recitals, the Directive aims to ensure that the number of animals used for experimental or other scientific purposes is reduced to a minimum, that such animals are adequately cared for and that no pain, suffering, distress or lasting harm are inflicted unnecessarily. In particular, the unnecessary duplication of animal experiments must be avoided.

3. In accordance with Article 25 of the Directive the Member States should have taken the measures necessary to comply with the Directive by 24 November 1989.

II — Procedure

4. The French authorities informed the Commission on 8 December 1989 of a number of measures implementing the Directive. The notified measures concerned in particular Decree No 87-848 of 19 October 1987 [3] and three interministerial decisions of 19 April 1988 that served to implement Decree No 87-848. On 24 April 1998 the Commission sent the French

1 — Original language: Dutch.

2 — OJ 1986 L 358, p. 1.

3 — Décret no. 87-848 du 19 octobre 1987 pris pour l'application de l'article 454 du code pénal et du troisième alinéa de l'article 276 du code rural et relatif aux expériences pratiquées sur les animaux, JO of 20 October 1987 (Decree of 19 October 1987 regarding the application of Article 454 of the Penal Code and of Article 276(3) of the Agricultural Code and relating to animal experiments).

Government a letter of formal notice to which it received no reply. Subsequently on 18 December 1998 the Commission issued a reasoned opinion requesting the French Government to inform it within two months of the measures to be taken. The application was lodged at the Court Registry on 19 April 1999.

5. The Commission puts forward six pleas in law with regard to the non-implementation or incomplete implementation of a number of the provisions of the Directive. These relate to the choice of species and of experiments, the freeing of animals used in experiments, the notification procedure for experiments, the identification marking of animals and also the mutual recognition of the results of experiments carried out on the territory of the Member States.

6. The Commission claims that the Court should:

— declare that, by failing to implement fully and correctly 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, and in particular Articles 4, 7, 11, 12, 18 and 22 thereof, the French Republic has failed to fulfil its obligations under that Directive and under the EC Treaty;

— order the French Republic to pay the costs.

7. The French Republic asks the Court to take into account the stringent national rules regarding animal experiments.

8. In August and September 2001 the French Government informed the Commission and the Court of the publication of a decree [4] and of a decision [5] which in its opinion brought the French rules into conformity with the Directive.

9. On 25 October 2001 an oral hearing took place at which the French Government and the Commission were represented. In the course of this hearing the Commission indicated that it did not wish to discontinue proceedings.

4 — Decree No 2001-464 of 29 May 2001 amending Decree No 87-848 of 19 October 1987, JO of 31 May 2001.

5 — Decision of 20 June 2001 regarding good laboratory practices for veterinary medicines, JO of 4 July 2001.

10. According to settled case-law, the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion and the Court cannot take account of any subsequent changes, even where the default has been remedied after the time-limit given in the reasoned opinion has expired. [6] In this case the reasoned opinion was served on 18 December 1998. The existence of the alleged failure to fulfil obligations must therefore be determined on the basis of the situation as it stood on 18 February 1999. The decree of 29 May 2001 and the Decision of 20 June 2001 notified by the French Government cannot be taken into consideration.

III — The Commission's pleas in law and the assessment

A — *The first plea in law: failure to implement Article 4*

11. Article 4 of the Directive reads as follows:

'Each Member State shall ensure that experiments using animals considered as endangered under Appendix I of the Convention on International Trade in Endangered Species of Fauna and Flora and Annex C.I. of Regulation (EEC) No 3626/82 are prohibited unless they are in conformity with the above Regulation and the objects of the experiment are:

— research aimed at preservation of the species in question,

or

— essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.'

12. The Commission states that the French Republic has failed to prohibit experiments involving endangered species as defined in this provision.

6 — See Case C-207/00 *Commission* v *Italy* [2001] ECR I-4571, paragraphs 27 and 28.

13. The French Government relies notably upon Article 7 of Decree No 87-848, which states that all species of animals may be used for experiments, subject to the restrictions laid down in the applicable rules regarding endangered species. According to the French Government, under Decree No 87-848 each animal experiment must be either generally or specifically approved, and in every request for permission the competent national authorities take the prohibition in Article 4 of the Directive into account. The species of animals referred to are seldom bred and captured in France, and for species from third countries the authorities competent to approve import rely upon the requirements of Articles 4 and 8 of Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein. [7]

14. It is well established that Article 249 EC does not necessarily require a literal and formal implementation of a directive and a general legal context may be sufficient to fully and effectively implement a directive in the national legal order. Nevertheless, each Member State is bound to implement the provisions of directives in a manner that fully meets the requirements of clarity and legal certainty imposed by the Community legislature. To that end, the provisions of a directive must be implemented with unquestionable legal certainty and with the requisite specificity, precision and clarity. A purely administrative practice, which can be changed as and when the authorities please and which is not publicised widely enough, cannot be regarded as constituting proper performance of the obligations which, under Article 249 EC, fall upon the Member States to whom directives are addressed. [8]

15. In the light of this settled case-law, I share the Commission's opinion that the provisions and procedures cited by the French Government do not ensure the full implementation in national law of Article 4 of the Directive. Article 7 of Decree No 87-848 contains a general reference to the legislative restrictions regarding endangered species. Such a general reference does not suffice to implement the Directive. Neither this nor any other national provision provides for a specific and unquestionable prohibition on the use of endangered species for experiments unless the conditions set out in Article 4 are met. In addition, the argument that for every permit application, the competent authorities take the requirements of the Directive into account, is ineffective. This is a

7 — OJ 1997 L 61, p. 1.

8 — See for example Case C-354/99 *Commission* v *Ireland* [2001] ECR I-7657, paragraphs 27 and 28.

purely administrative practice, which is not sufficient to properly implement the prohibition under Article 4.

Experiments on animals taken from the wild may not be carried out unless experiments on other animals would not suffice for the aims of the experiment.'

17. The French Government has claimed that its national legislation provides for an obligation to submit an administrative application requesting permission for the experiment. The competent national authorities then examine this request in the light of Article 7(3) of the Directive.

B — *The second plea in law: incomplete implementation of Article 7(3)*

18. Here also I agree with the Commission that such a procedure does not represent an unquestionable and definite implementation. The national legislation does not contain a provision setting out specifically, precisely and clearly the conditions of Article 7(3) regarding the choice of species and serving as a guideline for the competent authorities when they grant permission for any necessary experiments on animals. The French Government essentially invokes an administrative practice. That such practices are insufficient has already been established in the assessment of the first plea in law.

16. Article 7(3) of the Directive relates to the choice of species and of methods and states:

'When an experiment has to be performed, the choice of species shall be carefully considered and, where necessary, explained to the authority. In a choice between experiments, those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected.

C — *The third plea in law: failure to implement Article 11*

19. 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.'

20. The French Government claims that Article 2(b) of Decree No 87-848 implements Article 11 of the Directive. According to this provision the observation of animals under conditions that do not cause them any suffering is not to be regarded as an experiment within the meaning of the Decree.

21. In addition the French Government has argued that the freeing of laboratory animals can only be envisaged for animals that had previously been taken from the natural environment. It seldom occurs that animals are taken in this way. The animals used in experiments in France are bred or originate from intra-Community exchange or import, whilst the use of wild animals for scientific purposes is strictly controlled by the French authorities. For animals that have previously been taken from the natural environment Article 13-II of Law No 76-629 of 10 July 1976 makes the voluntary abandoning of (wild) domesticated animals that have been captured a criminal offence, with the exception of animals intended for repopulation. Furthermore, the French Government has pleaded that according to the 'Code rural' (Agricultural Code) the capture and transport of wild animals and all the endangered species is subject to an administrative approval.

22. According to the Commission, Article 2(b) of Decree No 87-848 cannot be regarded as a correct implementation of Article 11 of the Directive: the freeing of a laboratory animal involved in an experiment within the meaning of the Directive is not subject to binding rules. The Commission considers the response of the French Government, that the freeing of animals involved in experiments either never or seldom occurs in France, to be unsatisfactory. Article 11 obliges the Member States to adopt legal, regulatory or administrative rules on the basis of which the responsible authority may grant permission for the freeing of the animal used in the experiment providing the conditions laid down are met. The conditions of Article 11 are absent in the French regulation in question.

23. Finally the Commission has argued that the term 'set free' within the meaning of

Article 11 is not limited to just returning animals to their natural environment. In view of the broad definition of the term 'experiment', freeing can also be interpreted as no longer using for experimental purposes, and this can also cover, for example, the return of the animal used in the experiment to its original owner.

24. Article 11 of the Directive aims to protect the animal used in the experiment also after it has been used for experimental purposes by attaching a number of conditions to the freeing of the animal concerned. Prior to the freeing, the competent authority must give permission, and in each case examine, whether the requirements mentioned in this provision, with regard to freeing, are fulfilled. It is therefore obvious that the conditions set out in Article 11 must be apparent in national legislation. Since this was not the case in the French legal order by the deadline established in the reasoned opinion, the Commission's plea in law is already justified on this ground. The argument of the French Government that one can only speak of freeing when the animals used in the experiment have in fact ever been removed from the natural environment, is not, in my view, convincing. Nowhere does the Directive make such a distinction and, as the Commission has stated, it is conceivable that at the end of the experiment animals are returned to surroundings other than the natural environment.

D — *The fourth plea in law: failure to implement Article 12(2)*

25. Article 12(2) states that:

'Where it is planned to subject an animal to an experiment in which it will, or may, experience severe pain which is likely to be prolonged, that experiment must be specifically declared and justified to, or specifically authorised by, the authority. The authority shall take appropriate judicial or administrative action if it is not satisfied that the experiment is of sufficient importance for meeting the essential needs of man or animal.'

26. The Commission found that the French Republic had not introduced any regulation that would make the experiments mentioned in this provision subject to supervision by the competent authority. The French Government has not denied this. The plea in law of the Commission must therefore be upheld.

E — *The fifth plea in law: incomplete implementation of Article 18(1) and (3)*

27. Article 18 reads as follows:

'1. Each dog, cat or non-human primate in any breeding, supplying or user establishment shall, before it is weaned, be provided with an individual identification mark in the least painful manner possible except in the cases referred to in paragraph 3.

...

3. Where a dog, cat or non-human primate is transferred from one establishment as referred to in paragraph 1 to another before it is weaned, and it is not practicable to mark it beforehand, a full documentary record, specifying in particular its mother, must be maintained by the receiving establishment until it can be so marked.

...'

28. In the pre-litigation procedure the French Government pointed out various provisions that oblige the institutions carrying out the experiments both to register the origin and the identification of the animals held by them and to mark these animals. These are Articles 9, 25 and 26 of Decree No 87-848, a 1988 Decision regarding the conditions for the recognition, planning and functioning of institutions carrying out animal experiments, the 'Code rural' and a Decision of 25 October 1995, as amended on 26 October 1996.

29. The Commission does not contest that the regulations mentioned implement obligations that arise from Article 18 of the Directive. However, it does not consider that the provisions represent a full implementation of Article 18(1) and (3). In particular the marking provisions do not cover animals prior to weaning as is required by Article 18(1). The marking of dogs and cats is covered by a general regulation that is not exclusively intended for animal experiments and does not make it obligatory to mark before the animals are weaned. Furthermore, the regulations do not relate to non-human primates. At the same time, the Commission considers that

insufficient attention is given to the exceptional provision in Article 18(3) whereby an animal that has not yet been weaned may be marked at a later date. Nowhere is a provisional registration provided for prior to marking taking place.

30. In this regard the French Government has limited itself in its statement of defence to referring to an intended modification of national legislation in order to fully implement Article 18. This plea in law must therefore also be upheld.

F — *The sixth plea in law: failure to implement Article 22(1)*

31. Article 22(1) of the Directive states:

'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 health and safety.'

32. In the pre-litigation phase the French Government referred to Article R. 5118 of the Public Health Code ('Code de la santé publique'), according to which the Minister determines the rules and the methods for the testing of medicines and on the basis of which tests must be carried out according to 'good laboratory practices' ('bonnes pratiques de laboratoire').

33. In my opinion the Commission is correct in stating that such a general provision cannot constitute implementation of Article 22(1) of the Directive. That provision aims to avoid the duplication of experiments that comply with national or Community legislation, by providing for the recognition of the validity of experiments carried out elsewhere. The plea in law is thus valid in its own right. Both in its statement of defence and in the court hearing the French Government has invoked decisions adopted after 18 February 1999 which aim to transpose Article 22(1). However, as already stated the Court cannot take into account amendments that have been made after this date.

IV — Conclusion

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

— declare that, by failing to implement fully and correctly 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, and in particular Articles 4, 7, 11, 12, 18 and 22 thereof, the French Republic has failed to fulfil its obligations under that Directive and under the EC Treaty;

— order the French Republic to pay the costs.