JUDGMENT OF THE COURT (Fifth Chamber)

12 September 2002 *

In Case C-152/00,

Commission of the European Communities, represented by L. Ström and J.-F. Pasquier, acting as Agents, with an address for service in Luxembourg,

applicant,

v

French Republic, represented initially by K. Rispal-Bellanger and C. Vasak, and subsequently by C. Vasak and G. de Bergues, acting as Agents,

defendant,

APPLICATION for a declaration that, by failing to transpose 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

* Language of the case: French.

(OJ 1986 L 358, p. 1), and in particular Articles 4, 7, 11, 12, 18 and 22 thereof, the French Republic has failed to fulfil its obligations under the EC Treaty,

THE COURT (Fifth Chamber),

composed of: P. Jann, President of the Chamber, S. von Bahr and A. La Pergola (Rapporteur), Judges,

Advocate General: L.A. Geelhoed,
Registrar: H.A. Rühl, Principal Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 25 October 2001, at which the Commission was represented by L. Ström and J.-F. Pasquier and the French Republic by C. Isidoro and C. Chevallier, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 7 February 2002,

gives the following

Judgment

1 By application lodged at the Registry of the Court on 19 April 2000, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by failing to transpose 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 (OJ 1986 L 358, p. 1, hereinafter 'the Directive'), and in particular Articles 4, 7, 11, 12, 18 and 22 thereof, the French Republic has failed to fulfil its obligations under the EC Treaty.

Relevant provisions and pre-litigation procedure

2 Article 4 of the Directive provides:

'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 [OJ 1982 L 384, p. 1] 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.'

3 Under Article 7(3) of the Directive:

'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.

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.'

4 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 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 12(2) of the Directive provides as follows:

'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.'

6 Article 18 of the Directive provides:

'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.

...'

7 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.'

8 Under Article 25(1) of the Directive, the Member States were to adopt the measures necessary to comply with the Directive by 24 November 1989 and to inform the Commission thereof forthwith.

9 The French authorities notified the Commission of the measures adopted to transpose the Directive, namely, first, Decree No 87-848 of 19 October 1987 regarding the application of Article 454 of the Criminal Code and of Article 276(3) of the Agricultural Code and relating to animal experiments

(JORF, 20 October 1987, p. 12246), secondly, three Interministerial Orders of 19 April 1988 applying that decree and laying down, respectively, the conditions for the supply to approved laboratories of animals used for the purposes of scientific or experimental research, the conditions for the allocation of licences to carry out experiments on animals, and the conditions for approval, equipping and functioning of establishments for animal experiments (JORF, 27 April 1988, pp. 5607 and 5608 respectively) and, thirdly, Article R. 5118 of the Code of Public Health.

10 Since it considered that those provisions did not ensure a full and correct transposition of Articles 4, 7, 11, 12, 18 and 22 of the Directive, the Commission, by letter dated 24 April 1998, gave the French Government formal notice to submit its observations in that regard within a period of two months.

11 Having received no reply from the French Republic, the Commission, on 18 December 1998, sent a reasoned opinion to that Member State requesting it to adopt the measures necessary to comply with it within two months from the date of notification of the opinion.

12 By letter of 28 June 1999, the French Republic rejected the complaints made against it in the reasoned opinion.

13 Since it considered that that Member State had not complied with the reasoned opinion within the period laid down therein, the Commission brought this action.

The action

Preliminary observations

14 In the course of the proceedings the French Government notified the Commission of, and produced before the Court, Decree No 2001-464 of 29 May 2001, amending Decree No 87-848 (JORF, 31 May 2001, p. 8682), and the Order of 20 June 2001 regarding good laboratory practices for veterinary medicines (JORF, 4 July 2001, p. 10684). It also referred, in its defence, to the Order of 14 March 2000 regarding good laboratory practices (JORF, 23 March 2000, p. 4465). According to that Government, those various provisions effected a complete transposition of the Directive.

15 It must be remembered, in that regard, that it is settled case-law that whether a Member State has failed to fulfil its obligations must be determined by reference to the situation 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 (see, in particular, Case C-354/99 *Commission* v *Ireland* [2001] ECR I-7657, paragraph 45). It follows that none of the national provisions mentioned in the preceding paragraph can be taken into account by the Court in its consideration of this action.

Failure to transpose Article 4 of the Directive

16 By its first complaint, the Commission claims that the French Republic has not transposed Article 4 of the Directive.

17 In answer to that complaint the French Government relies, in the first place, on Articles 5, 7 and 11 of Decree No 87-848, providing respectively that '[a]ny person who carries out experiments on animals must hold... a general or special licence in their name', that '[a]nimals of all species may be used in experiments, subject to the restrictions laid down under the legislation and rules applying to protected species...', and that '[t]he Minister for Agriculture may restrict the scope of the licence requested or subject it to any conditions he thinks fit....'.

18 That Government submits that it follows from the combined effect of those provisions that, if a researcher intends to carry out experiments on animals belonging to an endangered species covered by Article 4 of the Directive, his licence application must make mention of that circumstance and contain evidence to show that the experiment is for an essential medical purpose and that such species is the only one which is suitable, in default of which the licence must be refused, as required by Article 4 of the Directive.

19 In that regard, it is sufficient, first, to observe that such consequences do not follow at all from the wording of the national provisions mentioned in paragraph 17 of this judgment and, second, to point out that mere administrative practices, which by their nature can be changed as and when the authorities please and

which are not published widely enough, cannot be regarded as a proper fulfilment of the obligation imposed on Member States to which the directives are addressed (see, in particular, *Commission* v *Ireland*, cited above, paragraph 28).

20 Second, the French Government submits that the protected species covered by Article 4 of the Directive are only rarely bred in captivity in France, whereas the conditions relating to their importation from third countries, laid down by 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 (OJ 1997 L 61, p. 1), are sufficient to guarantee the result required by that provision.

21 It is unnecessary to rule on the scope of Articles 4 and 8 of Regulation No 338/97. It is sufficient, in this case, to observe that those provisions concern the import of, and trade in, the species they cover and not experiments on such species. With regard to the fact that the protected species covered by the Directive are only rarely bred in captivity in France, it is important to remember that, since failure to comply with an obligation imposed by a rule of Community law is itself sufficient to constitute a breach, the fact that such a failure had no adverse effects is irrelevant (see, in particular, *Commission* v *Ireland*, cited above, paragraph 34).

22 In those circumstances, the Commission's first complaint must be upheld.

Incorrect transposition of Article 7(3) of the Directive

23 By its second complaint, the Commission claims that the French legislation contains no provisions prescribing the taking into account of the criteria which are to govern the choice of experiments, species and animals, criteria which are listed in Article 7(3) of the Directive.

24 The French Government submits that, when the licence application for an experiment under Article 5 of Decree No 87-848 is considered, the competent authority is in a position to check that the conditions set out in Article 7(3) of the Directive are satisfied.

25 In that regard, it is sufficient to observe that, assuming that to be the case, a check such as that cited by the French Government rests on a mere administrative practice, which, as has been pointed out in paragraph 19 of this judgment, is insufficient to bring about a proper transposition of the Directive.

26 In relation, more particularly, to the second subparagraph of Article 7(3) of the Directive, according to which experiments on animals taken from the wild are not permitted unless experiments on other animals would not suffice for the aims of the experiment, the French Government relies on the existence of various national provisions under which the capture or taking, transport or use of numerous species of wild fauna are prohibited, unless a special licence for capture or taking is granted for scientific purposes. According to the Government, in order to decide upon such applications for licences the competent authorities

must, in that event, verify, in the light of the scientific file which is required to be submitted to them, that the purpose of the taking is research with a view to ensuring the conservation of the species concerned or an essential scientific purpose, and that the species concerned is appropriate for that purpose.

27 It is sufficient, in that regard, to observe that the rules so briefly described by the French Government are not such as to ensure the proper transposition of the second subparagraph of Article 7(3) of the Directive. Those rules concern only certain animal species living in the wild and do not relate to their capture or transport unless experiments on such species are envisaged. Furthermore, the possible taking into consideration of the requirements prescribed in Article 7(3) by the relevant competent authorities, if this is in fact what happens, is not prescribed by a binding provision, but comes about as a result of a mere administrative practice.

28 In those circumstances, the Commission's second complaint must be upheld.

Failure to transpose Article 11 of the Directive

29 By its third complaint, the Commission claims that the French legislation contains no provision subjecting, as required by Article 11 of the Directive, every setting free of an animal which is being used for an experiment, to the prior verification, by the competent authority, that the conditions laid down by that provision have been met.

30 In that regard, the French Government relies upon Article 2 of Decree No 87-848 which provides that '[t]he following are not to be regarded as experiments within the meaning of this Decree:... (b) [t]hose that consist of the observation of animals under conditions that do not cause them any suffering'.

31 With regard to the setting free of animals in the course of experiments, the French Government submits that the effect of the applicable national regulations is to exclude it.

32 First, the scientific purposes for which experiments on animals are permitted under Article 1 of Decree No 87-848 are such as to exclude the conduct of experiments necessitating the setting free of animals.

33 Second, setting free within the meaning of Article 11 of the Directive covers only the return of the animal to its natural environment and covers, therefore, only non-domestic animals which have been taken from the wild. All animals involved in scientific experiments come from breeding establishments or are imported, so that the use of wild French fauna for experimental purposes is exceptional.

34 Third, under Article 13-II of Law No 76-629 of 10 July 1976 on the protection of nature, 'the voluntary abandonment of a domestic or tamed animal which has been held in captivity, with the exception of animals intended for repopulation' is a criminal offence.

35 Fourth, the capture and transport of animals taken from the wild is subject to a regime of prior licensing. Such is the case for certain species protected under the rules mentioned in paragraph 26 of this judgment and for game, under Articles L. 224-8 and R. 224-14 of the Agricultural Code. According to the French Government, the competent authorities ensure, when granting such licences for taking or transport, including those with a view to setting animals free, that the maximum has been done to safeguard the well-being of the animal in the circumstances set out in Article 11 of the Directive.

36 The Commission maintains, for its part, that the setting free of animals used for experiments is not governed by legally binding provisions. It contends, further, that 'setting free' in the sense contemplated in the Directive covers more than the mere return of the animal to its natural environment and that it can cover, among other things, releasing an animal from experimental use, for example by returning it to its owner.

37 In order to adjudicate on the complaint put forward by the Commission, it is necessary, at the outset, to define the scope of Article 11 of the Directive.

38 By specifying that the setting free of an animal may be allowed 'where it is necessary for the legitimate purposes of the experiment', that provision shows, first of all, that the setting free of an animal used for an experiment within the meaning of the Directive may only be allowed when it forms an integral part of the experiment, that is to say, as is apparent from Article 2(d) of the Directive, when further observations are still to be made. Therefore, contrary to the Commission's submission, Article 11 is in no way intended to authorise an animal to be set free after the conclusion of the experiment.

39 Furthermore, and contrary to the French Government's submission, there is nothing to suggest that that provision contemplates the setting free of animals for the purposes of experiments in progress only so far as animals taken from their natural environment are concerned.

40 It is necessary, finally, to point out that the Commission is also wrong in maintaining that Article 11 of the Directive requires the Member States to adopt provisions enabling a designated authority to authorise, at the request of researchers, animals used for an experiment to be set free where it is necessary for the legitimate purposes of the experiment and if the other conditions laid down by that provision are satisfied.

41 On the one hand, Article 11 shows that, where the strict conditions which it lays down are satisfied, the competent authority has a discretion, but not an obligation, to grant a licence to set animals free. On the other hand, it is important to note that, under Article 24 of the Directive, the Member States are free to apply or adopt stricter measures to ensure the protection of animals used for experimental purposes or to control or restrict the use of animals for certain experiments. It follows from the latter provision that the Member States are, in particular, entitled to prohibit any setting free of animals used in an experiment, or even to allow this, under the conditions laid down by Article 11 of the Directive, only so far as concerns animals taken from the wild.

42 With the benefit of that clarification, it must none the less be held that, in this case, the French Republic has not fulfilled its obligations. The national provisions upon which it relies do not in the least ensure that setting free, in the sense contemplated in Article 11 of the Directive, is possible only under the conditions specified by that provision. That provision constitutes, as is clear from the preceding paragraph of this judgment, the minimum protection which Member States are required to ensure for animals used for experiments within the meaning of the Directive.

43 In that regard, it is appropriate, in the first place, to point out that Article 2(b) of Decree No 87-848, a provision relating to the observation of animals put in conditions which involve no suffering, is completely irrelevant to the decision in this case, since Article 11 of the Directive covers only the setting free of animals used for an experiment within the meaning of Article 2(d), that is use for scientific purposes capable of causing pain, suffering, distress or lasting harm to the animal.

44 Second, the French Government has not in any way substantiated its assertion that the scientific purposes for which experiments on animals are allowed under Article 1 of Decree No 87-848 are such as to exclude experiments necessitating animals to be set free.

45 Third, it should be pointed out that Article 13 of Law No 76-629 was repealed by Article 290 of Law No 92-1336 of 16 December 1992 on the entry into force of the new Criminal Code and on the amendment of certain provisions of criminal law and procedure made necessary by that entry into force (JORF, 23 December 1992). It must be added, in that regard, that the meaning of setting free for the purposes of the experiment envisaged in Article 11 of the Directive does not correspond to that of voluntary abandonment.

46 Fourth, and finally, it must be acknowledged that, for reasons essentially similar to those set out in paragraph 27 of this judgment, the fact that the capture and transport of certain protected species as well as game taken from the wild are subject to a regime of prior authorisation is no more likely to ensure the correct implementation of Article 11 of the Directive.

47 In those circumstances, the Commission's third complaint must be upheld.

Failure to transpose Article 12(2) of the Directive

48 Since the French Republic does not dispute that that provision has not been transposed into its national law, the Commission's fourth complaint must therefore be upheld.

Incomplete transposition of Article 18(1) and (3) of the Directive

49 By its fifth complaint, the Commission claims that the French Republic has not fully transposed Article 18(1) and (3) of the Directive concerning the marking of cats, dogs and non-human primates in breeding, supplying or user establishments within the meaning of the Directive.

50 The French Government relies, first of all, on Article 9 of Decree No 87-848 which provides, in particular, that 'weaned dogs, cats and primates in [experimental establishments and establishments breeding or supplying animals for experiments] must be identified by an individual and permanent mark'.

51 It also relies on Article 25 of that Decree and Article 26 of the Order of 19 April 1988 laying down the conditions for approval, equipping and functioning of establishments for animal experiments, provisions which require such establishments to keep a register identifying the animals they are keeping and, in respect of cats, dogs and primates, containing an individual registration number corresponding to their identification mark.

52 Finally, in relation to dogs and cats, the French Government relies on Article 276-2 of the Agricultural Code and Articles 1 to 9 of Decree No 91-823 of 28 August 1991, on the identification of dogs, cats and other domestic carnivores and on the keeping of premises where the activities of breeding for sale, sale, cleaning, transit or keeping of those animals are habitually carried on, adopted pursuant to Articles 276, 276-2 and 276-3 of the Agricultural Code (JORF, 30 August 1991), as well as the Order of 30 June 1992 on the identification by tattooing of dogs and cats (JORF, 9 August 1992), provisions which give rise to an obligation to tattoo dogs and cats which are subject to a change of ownership and those which pass through premises where the activities of breeding for sale, sale, transit or keeping of those animals are carried on.

53 As the Commission correctly claims, those various measures do not provide that the individual marking must take place before weaning and in the least painful manner possible, as required by Article 18(1) of the Directive, or, as a result, lay down the specific regime applicable to cases of transfer of an unweaned animal prescribed by paragraph 3 of that provision.

54 In those circumstances, the Commission's fifth complaint must be upheld.

Failure to transpose Article 22(1) of the Directive

55 By its sixth complaint, the Commission claims that the French Republic has not adopted any measure for the purposes of ensuring the transposition of Article 22(1) of the Directive.

56 In order to refute that complaint, the French Government relies on the two orders mentioned in paragraph 14 of this judgment, explaining that they were adopted on the basis of Article R. 5118 of the Code of Public Health, which enables the Minister responsible for health to prescribe the rules and methods applying to experiments for medicines as well as the principles relating to good laboratory and good clinical practices in accordance with which trials are to take place.

57 For the reasons expressed in paragraph 15 of this judgment, the Court cannot, however, take those orders into consideration.

58 During the hearing, the French Government also submitted that Article 22 of the Directive imposes on Member States only an obligation to use their best endeavours, as is shown by the use of the words 'as far as possible' in paragraph 1 of that provision.

59 It should be pointed out, in that regard, that it is clear from the Court's settled case-law that Article 22 of the Directive, which concerns the recognition by the 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, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and 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).

60 It must be observed that, on the expiry of the period laid down in the reasoned opinion, the French Republic had not adopted any measure aimed at giving effect to Article 22(1) of the Directive, with the result that the Commission's sixth complaint must also be upheld.

61 Consequently, it must be held that, by failing to adopt all the measures necessary to ensure the correct transposition of Articles 4, 7(3), 11, 12(2), 18(1) and (3) and 22(1) of the Directive, the French Republic has failed to fulfil its obligations under that directive.

Costs

62 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 French Republic 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 4, 7(3), 11, 12(2), 18(1) and (3) 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 French Republic has failed to fulfil its obligations under that directive;**

2. **Orders the French Republic to pay the costs.**

Jann von Bahr La Pergola

Delivered in open court in Luxembourg on 12 September 2002.

R. Grass P. Jann

Registrar President of the Fifth Chamber