OPINION OF ADVOCATE GENERAL GEELHOED

delivered on 5 April 2001 [1]

I — Introduction

1. This case concerns an application by the Commission under Article 226 EC for a declaration that, by failing to take all necessary measures required by 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] Ireland has failed to fulfil its obligations under that directive, in particular Article 25 thereof, and its obligations under the EC Treaty, in particular Article 10 thereof.

II — The legal background

A — *The Community legislation*

2. Article 1 states as follows:

'The aim of this Directive is to ensure that where animals are used for experimental or other scientific purposes the provisions laid down by law, regulation or administrative provisions in the Member States for their protection are approximated so as to avoid affecting the establishment and functioning of the common market, in particular by distortions of competition or barriers to trade.'

3. At issue are the provisions for the transposition of Articles 11 and 12 of the Directive and the concept of 'experiment' as defined in Article 2 of the Directive. The case also concerns the scheme of penalty provisions in force.

4. 'Experiment' is defined in Article 2 as 'any use of an animal for experimental or other scientific purposes which may cause

1 — Original language: Dutch.
2 — OJ 1986 L 358, p. 1 (hereinafter 'the Directive').

it pain, suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition, but excluding the least painful methods accepted in modern practice (i.e. "humane" methods) of killing or marking an animal; an experiment starts when an animal is first prepared for use and ends when no further observations are made for that experiment; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition. Non-experimental agricultural or clinical veterinary practice are excluded'.

5. Article 3 provides that the Directive is to apply to the use of animals in experiments which are undertaken for one of the following purposes:

'(a) the development, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products:

(i) for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects on man, animals or plants;

(ii) for the assessment, detection, regulation or modification of physiological conditions in man, animals or plants;

(b) the protection of the natural environment in the interests of the health or welfare of man or animal.'

6. Article 11 provides as follows:

'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.'

7. Article 12 provides:

'1. Member States shall establish procedures whereby experiments themselves or the details of persons conducting such experiments shall be notified in advance to the authority.

2. 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.'

8. Article 25 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.'

B — *The national legislation*

9. The Irish legislation relating to the matters covered by Directive 86/609/EEC is contained in the Cruelty to Animals Act 1876 and the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 1994 (hereinafter also referred to jointly as 'the Act'). The regulations contain a new Section 12A by which the Irish Government attempts to give full effect to the Directive.

10. The Act sets out *inter alia* when experiments may or may not be held on animals and the conditions under which they may take place. Section 2 thus provides that an experiment calculated to inflict pain may not be performed unless it is covered by one of the exceptions set out in the Act.

11. Section 12A(9) of the Act reads almost identically to Article 11 of the Directive:

'Notwithstanding the other provisions of these regulations where it is necessary for the legitimate purposes of the experiment, the animal concerned may be set free, provided 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.'

12. Section 12A(10)(i) of the Act provides that the Minister is to establish procedures whereby experiments or the details of persons conducting such experiments are to be notified in advance to the authority. It is also laid down that 'where it is planned to subject the 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 Minister for Health. The Minister shall take appropriate judicial or administrative action if he is not satisfied that the experiment is of sufficient importance for meeting the essential needs of man or animal.'

13. The Act contains some penalty provisions. Section 2 provides that penalties may be imposed on persons who perform or take part in performing an experiment. The maximum penalty for a first offence is IEP 50 and the maximum penalty for a second offence is IEP 100 or imprisonment for a period not exceeding three months.

Section 13 provides that a penalty may be imposed for the obstruction of certain investigations. The maximum fine which can be awarded in such a case is IEP 5.

III — Arguments of the parties

14. In these proceedings the Commission seeks to establish that Ireland has failed to fulfil its obligations because the measures adopted by the Irish Government do not go far enough and do not correctly transpose the Directive.

15. The Commission's first complaint relates to the term 'experiment'. That term is defined in the Directive and thereby indicates the area of application *ratione materiae* of the Directive. The Commission submits that it is therefore important that the definition in the national legislation should be the same as in the Directive. However, the Irish law uses the term without defining it. Moreover, the 1876 Act relates only to experiments which cause

pain and the amended 1994 version has not altered the position in that respect. The Directive, on the other hand, extends not only to experiments calculated to cause pain to the animal but also to experiments which may cause suffering, distress or lasting harm if such experiments are performed for one of the purposes specified in Article 3 of the Directive. In other words, the Directive extends to situations in which there is an objective possibility that pain, suffering, distress or lasting harm may be caused, whereas the Irish legislation, according to its wording, only relates to cases in which the experiment in question is calculated to cause pain.

The Commission claims further that the definition of 'experiment' contains a number of important elements which may cause legal uncertainty in the absence of an equivalent definition in the Irish legislation. Reference is made to the fact that the scope of the Irish legislation is restricted to experiments on living animals, while the Directive includes also experiments in the pre-natal phase (and from which the animal suffers the consequences after its birth) and furthermore that this legislation does not make it clear as to when an experiment begins and when it ends.

16. The second complaint voiced by the Commission concerns the provision in the Irish legislation corresponding to Article 11 of the Directive. Section 12A(9) of the Irish law omits the reference to the authority. No provision is therefore made for the requirement that the authority must satisfy itself, before an animal is set free, that a number of pre-conditions has been met, and so there is a failure to comply with Article 11 of the Directive.

17. The third complaint relates to the fact that even though the Act provides that the Minister is to establish procedures, Ireland has not established those procedures for the purposes of Article 12(1) of the Directive, or at any rate has not informed the Commission of them.

18. Lastly, the Commission considers that the system of penalties in the Irish legislation is ineffective. First, the penalties apply to only a limited number of offences; second, the penalties which can be imposed do not have sufficient deterrent effect. The amounts of the fines have not been adjusted since 1876. Moreover, the Irish Government does not penalise infringements of the Directive in the same way as infringements of national law that are of comparable nature and importance. The Commission submits that the transposition of a directive into national law without providing for adequate enforcement of those rules, with appropriate, adequate penalties, conflicts with Article 10 EC.

19. The Irish Government recognises the problem concerning the definition of 'experiment' and that the Irish legislation does not satisfy all requirements, as submitted by the Commission. It also intends to bring about the desired adjustments by means of a legislative amendment. Although it recognises that there may be uncertainties regarding the scope of the legislation currently applicable, it submits that the current practice, including the application of the definition of 'experiment' in the Act, does in fact fulfil the requirements of the Directive relating to distress or lasting harm. Furthermore, it argues that experiments which may cause suffering, distress or lasting harm also fall within the term 'experiments calculated to inflict pain' in the Irish legislation and regulations.

20. The Irish Government has indicated that it will introduce amendments in its legislation in order to dispel the concerns expressed by the Commission with regard to the implementation of Articles 11 and 12 of the Directive. Nevertheless, the Irish Government has emphasised that the current Irish system is restrictive with regard to persons who wish to conduct scientific experiments upon animals. It states that Irish legislation prohibits any experiment likely to cause pain, except where the Minister considers that such experiments are necessary for the furtherance of medical science. Moreover, it emphasises that in the application for a licence to carry out experiments details must be given of the fate of the animals used for the experiments. If an animal is to be released or returned to a herd this must be indicated in the application. Moreover, conditions are attached to the licence. Lastly, the Irish Government states that the vast majority of animals are killed humanely after an experiment.

21. As regards the procedure, the Irish Government has pointed out that the procedure in Ireland requires applicants to notify the ministry in advance of details of the experiments and procedures involved. That follows from the general rules applicable to licencing procedures. According to the Irish Government, a licence application must contain information concerning the nature of the experiment and its objectives and a detailed protocol must be submitted. Applicants must also state where the experiments are to be carried out, what qualifications they have and what position they hold in the research establishment for which they are undertaking the experiments.

22. As regards the penalties, the Irish Government has indicated that it accepts the Commission's complaints and will take that aspect into account in the proposed amending legislation. It nevertheless takes the view that a licencing system with the associated possibility of revoking an existing licence has an adequate deterrent effect.

IV — Legal analysis

However, the Commission heard nothing since and that has led to the present proceedings.

23. It must be pointed out first of all that the Member States should, by 24 November 1989, have taken all measures necessary to implement the Directive. On a number of occasions after that date Ireland has had an opportunity to implement it in full. An initial letter was sent by the Commission as long ago as 1990. The Irish Government thereupon let it be known that the Directive would be implemented by means of an amendment to the licencing and registration procedure. The Commission found this to be unsatisfactory and stated that Ireland was in default. The Commission then issued a reason opinion. In reaction the Irish Government amended the law through the European Communities (Amendment to Cruelty to Animals Act 1876) Regulations 1994. After studying that legislative amendment the Commission came to the conclusion that the Directive had still not yet been correctly implemented. The Commission therefore considered that Ireland had failed to fulfil its obligations and gave the Irish Government a period of two months within which to submit its observations. Ultimately a supplementary reasoned opinion was issued on 17 December 1998. In that supplementary reasoned opinion the Commission once again set out the points on which it considered that there had been a failure to fulfil obligations and invited the Irish Government to take the necessary measures within a period of two months. In its letter of reply, dated 16 March 1999, the Irish Government accepted the Commission's point of view and also stated that amending legislation was being prepared and that it would be submitted to the Commission for its opinion by the end of June 1999.

24. The present case concerns individual elements of the Directive. It is settled case-law that the obligations which the Member States have when implementing directives must be strictly construed. Although the Member States are free to choose the means and methods of implementing a directive, that freedom does not alter the fact that a Member State is obliged to take all measures in the framework of its national legal system that are necessary to ensure the full effect of the Directive in accordance with its intended objective. To that end the Member States must provide a precise legal framework in the field in question, so that the national law corresponds with the provisions of the Directive, with wording that cannot give rise to doubt or ambiguity.

25. In my opinion, the Commission has convincingly demonstrated the importance of correctly transposing the concept of 'experiment' into national legislation. That concept is, moreover, a key concept which defines the scope *ratione materiae* of the Directive. That is why it is of great importance that the concept be transposed exactly into national legislation. The Irish Government has ultimately also accepted this complaint by the Commission.

26. It has done the same with regard to the points raised by the Commission regarding Articles 11 and 12 of the Directive. I point out that the Irish Government has agreed to amend its legislation in accordance with the Commission's wishes. That does not alter the fact that I must find that Ireland has failed to fulfil its obligations and that the Commission's application must be upheld on those points too.

27. I can be brief with regard to the penalty system. I agree with the Commission that the level of the fines which can be imposed in Ireland is inadequate. 150 years ago the maximum fines may well have had a deterrent effect but, in the light of subsequent inflation, they have taken on a symbolic character. This is all the more so because animal experiments are also carried out on an industrial scale. Moreover, the Irish Government has not disputed that point and has agreed to amend its legislation.

28. Furthermore, it is settled case-law that where Community legislation does not specifically provide any penalty for an infringement, and in the present case the Directive does not do so, the Member States have a general obligation under Article 10 EC to take all measures necessary to ensure the effective application of Community law. To that end the Member States must in particular ensure that infringements of Community law are penalised under the same substantive and procedural conditions as infringements of national law of a similar nature and importance. Although the Member States are free to choose the penalties to be imposed, fines must in any event be effective, proportionate and dissuasive. [3] I therefore agree with the Commission when it submits that Ireland has, in this case, failed to fulfil its obligations under Article 10 EC.

29. The Irish Government's argument that there is deterrent effect owing to the possibility of revoking a licence is unconvincing. A licencing system can function only when the underlying prohibition can be adequately enforced. Undoubtedly, the severity of the penalty provided for plays a role in the context of that enforcement.

30. All things considered, the Irish Government's defence cannot withstand the Commission's arguments. Moreover, these proceedings have been continuing for some time and Ireland has had several opportunities to achieve the correct implementation of the Directive in its national legal system. The Commission's application should, in my opinion, therefore be upheld.

3 — See, *inter alia*, Case 68/88 *Commission* v *Greece* [1989] ECR 2965 and Case 326/88 *Hansen* [1990] ECR I-2911.

31. In accordance with Article 69(2) of the Rules of Procedure, the unsuccessful party must be ordered to pay the costs, if they are asked for in the other party's pleadings. Since the Commission has applied for costs and Ireland has been unsuccessful, I consider that the application for costs should be granted.

Conclusion

Having regard to the above, I propose that the Court should declare that:

(1) by failing to take all necessary measures to ensure correct transposition into national law of Article 2 (the concept of 'experiment'), Article 11 and Article 12 of Council Directive 86/609/EEC of 24 November 1986 concerning the approximation of the laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, and by failing to provide for an adequate system of penalties for non-compliance with the requirements of Directive 86/609, Ireland has failed to fulfil its obligations under that Directive, in particular Article 25 thereof, and under Article 10 EC.

(2) Ireland is ordered to pay the costs.