JUDGMENT OF THE COURT (Fifth Chamber)
18 October 2001 *

In Case C-354/99,

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

applicant,

v

Ireland, represented initially by M.A. Buckley, and subsequently by L.A. Farrell, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for a declaration that, by failing to take all the measures necessary to ensure the correct implementation of Articles 2(d), 11 and 12 of Council Directive 86/609/EEC of 24 November 1986 on 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 (OJ 1986 L 358, p. 1) and by failing to provide for an adequate system

* Language of the case: English.

of penalties for non-compliance with the requirements of Directive 86/609, Ireland has failed to comply with the Directive, in particular Article 25 thereof, and has failed to fulfil its obligations under the EC Treaty, in particular Article 5 thereof (now Article 10 EC),

THE COURT (Fifth Chamber),

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

Advocate General: L.A. Geelhoed,
Registrar: R. Grass,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 5 April 2001,

gives the following

Judgment

1 By an application lodged at the Registry of the Court on 23 September 1999, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by failing to take all the measures necessary to ensure

the correct implementation of Articles 2(d), 11 and 12 of Council Directive 86/609/EEC of 24 November 1986 on 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 (OJ 1986 L 358, p. 1), 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 comply with the Directive, in particular Article 25 thereof, and has failed to fulfil its obligations under the EC Treaty, in particular Article 5 thereof (now Article 10 EC).

The Community legislation

2 The Directive seeks to establish minimum standards for the use of animals for experimental and other scientific purposes relating to the development, manufacture and testing of drugs, foodstuffs and other substances or products and the protection of the environment. Endangered species may only be used in research aimed at the preservation of the species, or essential biomedical purposes where the species in question is the only one suitable.

3 The Directive lays down general and specific requirements for animals' housing, restriction of movement, monitoring, avoidance of pain or stress and the elimination of possible discomfort or suffering. It requires that animals subjected to experiments be killed in a humane manner. Experiments may only be performed by authorised persons and must be designed and carried out so as to minimise suffering. Experiments likely to cause severe pain must be notified to the competent national authorities in advance or receive specific authorisation. Laboratory staff must be properly trained. Annex II to the Directive contains guidelines for the accommodation and care of animals.

4 Breeding and supplying establishments and user establishments must be approved or registered and maintain records of all animals used. Dogs, cats and non-human primates must be given identification marks. Certain animals listed in Annex I, including mice, rats, dogs and cats, must be bred animals unless prior authorisation has been obtained. In order to avoid duplication of testing, the Member States are to recognise as far as possible the validity of data generated by experiments carried out in other Member States.

5 Article 2(d) of the Directive provides as follows:

'For the purposes of this Directive the following definitions shall apply:

...

(d) "*experiment*" means any use of an animal for experimental or other scientific purposes which may cause 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 to be 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 practices are excluded.'

6 Article 11 of the Directive 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(1) of the Directive provides as follows:

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

8 Under Article 25 of the Directive, the Member States were to adopt the laws, regulations and administrative provisions necessary to comply with the Directive by 24 November 1989 and to inform the Commission thereof forthwith. They were also to communicate to the Commission the provisions of national law which they adopt in the field covered by the Directive.

National law

9 The Irish legislation in the field governed by the Directive is the Cruelty to Animals Act 1876 (hereinafter 'the 1876 Act'). According to the Irish

Government, the Directive was initially implemented in domestic law by an amendment to the procedures for authorisation and registration laid down by the 1876 Act and then by the adoption of the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 1994 (hereinafter 'the amending legislation').

10 The 1876 Act as amended by the amending legislation (hereinafter 'the amended Act') lays down, *inter alia*, the circumstances in which and the conditions on which experiments may be carried out on animals. Thus, Section 2 prohibits any experiment calculated to give pain to live animals subject to the exceptions laid down in that Act.

11 The first sentence of Section 12A of the Act as amended provides: 'In particular, the following provisions shall be observed in relation to experiments provided for in this Act'.

12 Section 12A(9) of the amended Act provides as follows:

'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.'

13 Section 12A(10)(i) of the amended Act provides that '[t]he Minister [for Health] shall establish procedures whereby experiments themselves or the details of persons conducting such experiments shall be notified in advance to the authority'. Furthermore, '[w]here 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' and '[t]he 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'.

14 Section 2 of the amended Act provides for penalties in respect of persons 'performing or taking part in performing any experiment calculated to give pain, in contravention of this Act'. The penalty applicable is a fine of a maximum of IEP 50 for a first offence and IEP 100 for a second offence or imprisonment for a period not exceeding three months.

15 There is also a maximum penalty of IEP 5 for the obstruction of certain investigations under Section 13 of the amended Act.

The pre-litigation procedure

16 The Commission, having invited Ireland to submit observations on the incorporation of the Directive into national law, addressed to Ireland, by letters

of 27 May 1993 and 17 December 1998 respectively, a reasoned opinion and a supplementary reasoned opinion, requesting on each occasion that it take the measures necessary to comply with its obligations under the Directive within two months of receipt of the opinion.

17 Since it was apparent from the information sent to the Commission by the Irish Government in response to the supplementary reasoned opinion that the Directive had still not been incorporated into Irish law, the Commission decided to bring this action.

The action

18 Bearing in mind the obligations which bind the Member States under the first paragraph of Article 5 of the Treaty, the third paragraph of Article 189 of the EC Treaty (now the third paragraph of Article 249 EC), and Article 25 of the Directive, the Commission submits that Ireland had failed to fulfil its obligations by not adopting the measures necessary to comply with that directive and/or by not informing the Commission of such measures.

19 The Commission has put forward four pleas in law relating to the implementation of the Directive by Ireland which it is appropriate to consider in turn:

— there is no definition of 'experiment' (incorrect implementation of Article 2(d) of the Directive);

— no national competent authority has been designated to authorise the setting free of animals (incorrect implementation of Article 11 of the Directive);

— there are no procedures for notification in advance of experiments or the details of persons conducting such experiments to the competent national authority (incorrect implementation of Article 12(1) of the Directive); and

— there is no adequate system of penalties for non-compliance with the requirements of the Directive.

Absence of a definition of the term 'experiment'

20 By its first plea, the Commission argues that the term 'experiment', as defined in Article 2(d) of the Directive, delimits the scope of application of the Directive, whereas the Irish implementing legislation uses the term without any explanation of its content. As is clear from the first sentence of Section 12A of the amended Act, the Act only applies to such experiments on animals as were already covered by the 1876 Act, that is to say, those which are calculated to inflict pain. The kinds of experiments covered are thus expressly confined to those situations where there is a subjective intention ('calculated') linked to a single result ('pain').

21 In contrast, according to the Commission, the Directive applies to experiments in which there is an objective possibility ('may') of causing pain, suffering, distress

or lasting harm; in other words there is a wider range of results than that envisaged by the amended Act, in so far as those experiments are carried out for one of the purposes specified in Article 3. It would therefore be possible for an animal used for experimental purposes to suffer 'lasting harm' such as a shortening of its life expectancy as a result of genetic changes, but not to feel any pain.

22 In addition, the Commission argues, the absence of a clear definition of 'experiment' in the national legislation means that there is legal uncertainty as to how far other elements of the definition in the Directive, such as the duration of an intervention or when it starts and ends, are reflected in the national legal order.

23 The Commission observes that under the Directive the term 'experiment' also covers 'any course of action intended, or liable, to result in the birth of an animal in any such condition', that is, any course of action affecting animals not yet born. Accordingly, the Directive covers, *inter alia*, genetic modifications or cloning experiments resulting in the birth of animals which will then suffer lasting harm, such as physical malformations, mental deficiencies or the appearance of cancers or other diseases due to foreign genes. The same is not true of the amended Act, which only covers animals already in being.

24 The Irish Government argues that the Commission's concern over the definition of 'experiment' is largely semantic. Since all experiments on animals inflict some pain or discomfort on the animal, all such experiments come within the definition of 'experiment' provided for in the Directive.

25 In that connection the Irish Government argues that persons wishing to conduct research using live animals must be licensed by the Minister for Health and conduct their work in registered premises. Further, the Minister may not only refuse a licence if he considers that the health and welfare of the animals is not taken into account but also withdraw a licence if the conditions attached to it are not being observed and refuse the issue of any further licences.

26 While the Irish Government accepts that it would be appropriate to amend the definition of 'experiment' under the Irish legislation currently in force, it argues that in practice the criteria relating to distress and lasting harm inflicted on animals are covered by the definition of that term under the amended Act.

27 In that regard it must be observed that, according to settled case-law, each Member State is bound to implement the provisions of directives in a manner that fully meets the requirements of clarity and certainty in legal situations imposed by the Community legislature, in the interests of the persons concerned established in the Member States. To that end, the provisions of a directive must be implemented with unquestionable legal certainty and with the requisite specificity, precision and clarity (see Case C-207/96 *Commission* v *Italy* [1997] ECR I-6869, paragraph 26).

28 Thus, mere administrative practices, which by their nature can be changed as and when the authorities please and which are not publicised widely enough cannot be regarded as a proper fulfilment of the obligation imposed on Member States to which the directives are addressed (see, *inter alia*, Case 102/79 *Commission* v *Belgium* [1980] ECR 1473, paragraph 11).

29 In this case it has been established that the definition of 'experiment', as provided for by Article 2(d) of the Directive, was not incorporated into Irish law. In those circumstances, even if in practice the criteria relating to distress and lasting harm inflicted on animals are covered by the definition of the term 'experiment' under the amended Act, as the Irish Government claims, the persons concerned are in a position of uncertainty as regards their legal situation.

30 It must therefore be held that Ireland has failed to fulfil its obligations under Article 2(d) of the Directive.

Failure to designate a competent national authority to authorise the setting free of animals

31 By its second plea the Commission submits that, unlike Article 11 of the Directive, Section 12A(9) of the amended Act, which is the relevant Irish provision, does not make the setting free of an animal subject to the granting of authorisation by a competent national authority whose responsibility it is to verify in advance whether the applicable conditions are met.

32 The Irish Government contends that the fate of the animals being used for experimental purposes must be detailed in the application for a licence to carry out experiments. Further, any licence specifies the conditions that must be complied with in carrying out the experiments. One of the conditions is that the licence holder is to ensure that detailed records are maintained of the source, use and final disposal of all animals accommodated in the establishment for scientific purposes and that these records are available for inspection by the Minister for Health or an inspector appointed by the Minister.

33 In that connection, it must be pointed out that Article 11 of the Directive has not been implemented in full since the relevant national provisions do not provide for any form of supervision by a competent authority of the setting free of animals.

34 In addition, regarding the Irish Government's argument that the vast majority of the animals used for experimental purposes in Ireland are reared for that purpose in authorised establishments and are put to death painlessly at the end of the experiment, 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 Case C-333/99 *Commission* v *France* [2001] ECR I-1025, paragraph 37).

35 It must therefore be held that Ireland has failed to fulfil its obligations under Article 11 of the Directive.

Absence of procedures for notifying a competent authority in advance of experiments or the details of persons conducting such experiments

36 By its third plea the Commission argues that, although Section 12A(10)(i) of the amended Act requires the Minister for Health to establish procedures whereby experiments themselves or the details of persons conducting such experiments are to be notified in advance to the competent authority, it has received no information that such procedures have been set up. Nor does the amended Act specify what person or body constitutes the competent authority to which such experiments and details are to be notified in advance in accordance with Article 12(1) of the Directive.

37 The Irish Government submits that, under the relevant provisions of national law, an applicant has to notify the Minister for Health in advance of the details of the experiments he intends to carry out and of the procedures he intends to apply. That information relates to the nature of the experiments, where they are to be carried out and their objectives, the applicant's qualifications and what position he holds in the research establishment or agency for which he is undertaking the experimental activity. Further, under the applicable Irish legislation, the experimental procedure for which a licence is being sought must also be certified as being essential, with no alternative scientific method reasonably and practically available.

38 In that connection it must be observed that Article 12(1) of the Directive has not been implemented in full since, notwithstanding the provisions of Section 12A(10)(i) of the amended Act, the Minister for Health has failed to establish procedures for notifying a named competent authority in advance of the experiments to be carried out or of the details of the persons conducting such experiments.

39 It must therefore be held that Ireland has failed to fulfil its obligations under Article 12(1) of the Directive.

Absence of an adequate system of penalties for non-compliance with the requirements of the Directive

40 By its fourth plea the Commission argues first of all that Sections 2 and 13 of the amended Act, concerning the penalties applicable for non-compliance with the requirements of the Directive, do not cover infringements relating to the

accommodation and care of animals and to the operation of breeding, supplying and user establishments, since the wording of Section 2 refers only to persons performing or taking part in performing experiments and Section 13 provides for a penalty only in respect of the obstruction of investigations.

41 The Commission considers that the absence of penalties applicable to infringements relating to the accommodation and care of animals and to the operation of breeding, supplying and user establishments calls in question the effectiveness of the comprehensive system of protection offered under the amended Act and is contrary to Article 5 of the Treaty. Even where a directive does not provide for any specific penalty or fine for non-compliance with the specific obligations it imposes, the Member States nevertheless have a general duty under Article 5 of the Treaty to take all measures necessary to guarantee the application and effectiveness of Community law.

42 Secondly, the Commission says, because of the decline in monetary values since the fines in question were introduced, the penalties provided for in Sections 2 and 13 of the amended Act are not effective, proportionate or dissuasive. In addition, Ireland does not penalise infringements of the rules laid down in the Directive in the same way as infringements of provisions of national law of a similar nature and importance. In that connection, the Commission points out, by way of illustration, that for certain analogous domestic offences of cruelty to animals the penalty is IEP 1 000.

43 The Irish Government considers that the numerous conditions to which the issue of a licence to carry out experiments is subject and the Minister's power to

withdraw licences awarded are much stronger deterrents to breaching the law in this area than the imposition of fines, which could only be imposed after a successful prosecution.

44 None the less the Irish Government accepts the Commission's arguments regarding the inadequacy of the level of financial penalties currently applicable. It states in its pleadings that it intends to increase the level of fines and that a bill is in the course of being drafted to that end.

45 First, 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-119/00 *Commission* v *Luxembourg* [2001] ECR I-4745, paragraph 14).

46 Secondly, it should be noted that where a Community regulation does not specifically provide for any penalty for an infringement or refers for that purpose to national laws, regulations and administrative provisions, Article 5 of the Treaty requires the Member States to take all measures necessary to guarantee the application and effectiveness of Community law. For that purpose, while the choice of penalties remains within their discretion, they must ensure in particular that infringements of Community law are penalised under conditions, both procedural and substantive, which are analogous to those applicable to infringements of national law of a similar nature and importance and which, in any event, make the penalty effective, proportionate and dissuasive (Case 68/88 *Commission* v *Greece* [1989] ECR 2965, paragraphs 23 and 24; Case C-213/99 *de Andrade* [2000] ECR I-11083, paragraph 19).

47 It must be held that the penalties provided for in the Irish legislation for non-compliance with the requirements of the Directive do not satisfy the conditions set out in the case-law referred to in the previous paragraph.

48 In addition, the Irish Government's argument that the controls carried out in the context of the procedures for issuing licences enable an adequate penalty to be imposed where appropriate is based on the erroneous assumption that all breaches of the requirements under the Directive may be penalised in the context of those procedures. As the Commission has correctly observed, a refusal to issue or withdrawal of a licence cannot in any event be considered to be an effective and dissuasive penalty when the experiment to which the Directive relates is carried out with complete disregard for the national licensing provisions.

49 In those circumstances the Commission's fourth plea must also be upheld.

Costs

50 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 Ireland has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds,

THE COURT (Fifth Chamber)

hereby rules:

1. By failing to adopt all the measures necessary to ensure the correct implementation of Articles 2(d), 11 and 12 of Council Directive 86/609/EEC of 24 November 1986 on 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 the Directive, in particular Article 25 thereof, and under the EC Treaty, in particular Article 5 thereof (now Article 10 EC).

2. Ireland is ordered to pay the costs.

Jann von Bahr Edward

La Pergola Timmermans

Delivered in open court in Luxembourg on 18 October 2001.

R. Grass P. Jann

Registrar President of the Fifth Chamber