OPINION OF ADVOCATE GENERAL JACOBS
delivered on 23 November 1995 *

1. The present case arises from an application made by the Commission pursuant to Article 169 of the EC Treaty for a declaration that the Grand Duchy of Luxembourg, by failing to adopt within the prescribed period the measures necessary to comply with 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 Directive') [1] and/or by failing to notify the Commission of those measures, has failed to fulfil its obligations under Article 25 of the Directive and Articles 5 and 189 of the EC Treaty.

The course of the procedure

2. Pursuant to the first paragraph of Article 169 the Commission served a letter of formal notice on Luxembourg on 4 September 1990 and a reasoned opinion on 20 May 1992. The Commission received no response from the Luxembourg Government to either communication. It therefore brought the matter before the Court by an application of 10 May 1993.

3. Since Luxembourg failed to lodge a defence, the Court Registry informed the parties, by letters of 18 August 1993, that the procedure for giving judgment by default under Article 94 of the Rules of Procedure would apply. By a letter of 30 September 1993 the Commission informed the Court that by a letter of 28 May 1993, that is to say, shortly after the Commission's application had been brought, Luxembourg's Agent had communicated to the Commission a Luxembourg Law pre-dating the Directive and giving partial effect to it. The Commission nevertheless considered that a number of the provisions of the Directive remained unimplemented in Luxembourg Law. By a subsequent letter of 8 December 1994 it sought a judgment by default pursuant to Article 94. Modifying its claims slightly, it asserted that Luxembourg had failed to adopt, within the prescribed period, *all* the measures necessary to comply with the Directive; it added that, since no measures had been taken, it was no

* Original language: English.

1 — OJ 1986 L 358, p. 1.

longer necessary to seek a declaration that Luxembourg had failed to notify them to the Commission.

4. By a letter of 22 June 1995 the Court asked the Commission to explain, in the light of its reasoned opinion, the relationship between the claims put forward in its application and those contained in its letter of 8 December 1994. By a letter of 27 July 1995 the Commission stated that, in the absence of implementation, the claims put forward in its application remained valid. It had nevertheless modified slightly its original claims in order to take account of developments in the case.

The procedure under Article 94

5. Article 94(2) of the Rules of Procedure provides:

'Before giving judgment by default the Court shall, after hearing the Advocate General, consider whether the application initiating proceedings is admissible, whether the appropriate formalities have been complied with, and whether the application appears well founded. The Court may order a preparatory inquiry.'

6. In order to give judgment against Luxembourg by default the Court must therefore satisfy itself that:

(a) the originating application is admissible;

(b) the appropriate formalities have been complied with;

(c) the application appears well founded.

I shall consider those requirements in turn.

Admissibility

7. There is nothing in the documents before the Court to suggest that the Commission, in bringing its action, failed to comply with the requirements of Article 169. Before instituting proceedings before the Court the Commission duly served on Luxembourg a letter of formal notice and a reasoned opinion. The claims made in the application to the Court reproduce the conclusions set out in the reasoned opinion. The only question which

may arise therefore is whether the modification by the Commission of its claims in its letter of 8 December 1994 renders its application inadmissible.

8. In my view it does not. While the Commission may not extend the scope of its claims, it may limit them. [2] It may also specify its claims in more detail during the proceedings before the Court in order to take account of information produced by the defendant. [3] Moreover, under Article 42(2) of the Rules of Procedure the applicant may introduce new pleas in law in order to take account of matters of law or of fact coming to light during the proceedings.

9. It is clear that here the Commission is merely limiting its claim. In its reasoned opinion and its application to the Court the Commission made the general assertion that Luxembourg had not adopted the measures necessary to comply with the Directive or had failed to communicate such measures to the Commission. Having received notice of the Luxembourg Law from Luxembourg's Agent the Commission concluded that the Law gave partial effect to the Directive and limited its action to the provisions which it still considered to be unimplemented.

10. Moreover that limitation did not entail any impediment to Luxembourg's rights of defence. Since the Commission's remaining claims were encompassed by the claims made in the reasoned opinion and application, Luxembourg was given every opportunity to refute them during the pre-litigation phase and in the proceedings before the Court. It is only because Luxembourg did not submit the Law during the pre-litigation phase that the Commission was not able to limit its application to the Court. The litigation might even have been avoided if Luxembourg had been able to demonstrate that the remaining provisions of the directive would shortly be implemented. Even if Luxembourg, although not responding during the pre-litigation phase, had entered a defence to which the Law was annexed, the Commission's remaining complaints could have been fully debated before the Court in the remainder of the written phase of the procedure and at the hearing. The unsatisfactory position in which the Court now finds itself stems not from the Commission's failure to respect Luxembourg's rights of defence but from the failure by the Luxembourg Government to cooperate with the Commission and the Court.

2 — See most recently Case C-257/94 *Commission* v *Italy* [1995] ECR I-3041, judgment of 12 October 1995, and the Opinion of Advocate General La Pergola in Case C-17/95 *Commission* v *France* [1995] ECR I-4895, at paragraph 2, note 4.

3 — Case C-243/89 *Commission* v *Denmark* [1993] ECR I-3353, paragraph 20 of the judgment.

11. In any event the fact that the proceedings must be conducted as default proceedings under Article 94 of the Rules of Procedure owing to Luxembourg's failure to enter a defence has no bearing on the admissibility of the Commission's application. It would be bizarre if a Member State which had failed to lodge a defence were to be put in a better position than a Member State which had done so.

12. Moreover, to regard the modification of the claim as rendering the action inadmissible in such cases would have serious disadvantages. Member States would have an incentive to produce legislative texts only at a very late stage in the hope that the Commission's resultant modification of its claim would render the action inadmissible. The Commission for its part might be discouraged from bringing matters to the notice of the Court in circumstances such as the present. Such a view would therefore be contrary to the principles of procedural economy and proper administration of justice.

Completion of the appropriate formalities

13. There is nothing to suggest that the appropriate formalities, such as proper service on the defendant, have not been complied with. I can therefore now turn to the substance.

Substance

14. Before giving judgment by default it is sufficient, as mentioned above (paragraph), that the application 'appears well founded'. I can therefore deal with the substance relatively briefly.

The Community Directive

15. Article 1 of the Directive explains the purpose of the Directive in the following terms:

'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.'

16. By virtue of Article 3 the Directive applies to the use of animals in experiments undertaken in connection with the development and production of certain drugs and other medicinal products or with the protection of the natural environment in the interests of the health or welfare of man or animals. Article 4 regulates the use of animals belonging to endangered species. Article 5, in conjunction with Annex II, lays down provisions concerning the general care and accommodation of animals used for experiments. Article 6 requires Member States to designate the authority or authorities responsible for supervising compliance with the Directive. Articles 7 and 8 regulate the conduct of experiments. Articles 9 to 11 lay down provisions concerning the treatment of animals after the completion of experiments. Article 12 requires Member States to establish general procedures for notifying the competent authorities of experiments and specific procedures for experiments involving severe pain over a prolonged period. Article 13 provides for the collection and publication of statistical information by the competent authorities. Article 14 concerns the education and training of persons involved in experiments.

17. Articles 15 to 18 lay down provisions concerning the approval and registration of breeding and supplying establishments, the records to be kept by such establishments and the application of identification marks to animals held there. Articles 19 to 21 lay down provisions concerning the approval and registration of user establishments, their design, administration and staffing, the records which must be kept and the source of animals used for experimentation.

18. Article 22 requires Member States to recognize as far as possible the validity of data generated by experiments in other Member States in order to avoid unnecessary duplication and for that purpose to provide the Commission with information on their legislation and administrative practice and factual information on experiments carried out; the Commission is to establish a permanent consultative committee to assist in information exchange. Article 23 requires the Commission and the Member States to encourage research into alternative techniques involving fewer animals or less pain. By virtue of Article 24 the Directive is not to restrict the right of Member States to apply stricter measures.

19. Article 25(1) requires Member States to implement the Directive by 24 November 1989 and to inform the Commission forthwith. Article 25(2) imposes an obligation on Member States to communicate to the Commission the provisions of national law which they adopt in the field covered by the Directive. In addition Article 26 requires Member States to make regular reports to the Commission on the measures taken in the area and to provide a suitable summary

of the information collected under Article 13. The Commission is to prepare a report for the Council and the European Parliament.

The Luxembourg Law

20. The Law of 15 March 1983 on the protection of the life and well-being of animals, communicated to the Commission by Luxembourg's Agent, does not deal solely with the use of animals in experiments but, as its title suggests, is concerned with animal welfare in general. Article 1 of the Law lays down a general prohibition on the killing, injuring or infliction of pain on animals.

21. Articles 2 to 4 are concerned with the keeping of animals. Article 2 requires any person keeping an animal to ensure that it is properly fed, cared for and accommodated and that its requirements regarding exercise and movement are met. Minimum conditions may be laid down by Grand-Ducal regulations. Article 3 concerns intensive rearing of animals. Article 4 provides that non-domestic animals may be kept only in establishments designed for teaching or scientific purposes and for the preservation of threatened species. The competent Minister is given powers to derogate from Article 4 in the case of certain species and also to prohibit the keeping of certain species. General or specific conditions regarding the keeping of animals, and conditions regarding the authorization, functioning, cleanliness, safety and supervision of establishments may be laid down by Grand-Ducal regulations. The persons responsible for the establishments must hold a certificate evidencing their ability to look after animals. The conditions for the issue of the certificate are to be laid down by Grand-Ducal regulation. Persons operating establishments are required to obtain authorization within six months of the entry into force of the Law.

22. Article 5 of the Law requires any person carrying on a trade in animals, rearing them for commercial purposes, hiring them out, using them as a means of transport or exhibiting them for commercial purposes to seek authorization from the Minister, who may lay down conditions to ensure their well being. Article 6 gives the Minister power to restrict the importation, exportation and transit of animals for reasons connected with the protection of animals and the preservation of species.

23. Article 7 concerns the transport of animals, Article 8 their slaughter. Subject to certain exceptions, Article 9 requires painful operations on animals to be carried out under anaesthetic and by a veterinarian. Article 10 permits amputations to be carried out on animals only on instructions from a veterinarian or on imperative zootechnical grounds to be determined by Grand-Ducal regulation.

24. Articles 11 to 19, concerning experiments on live animals, are the most directly relevant to the present case. They provide as follows:

'Article 11

Experiments may be carried out on an animal only with the following aims:

1. (a) Prevention of diseases, deficiencies or any other anomaly or of their effects on humans, animals or plants, including testing of medicaments, substances or products;

(b) diagnosis or treatment of illnesses, deficiencies or any other anomaly or of their effects on humans, animals or plants;

2. Diagnosis and appraisal of physiological state;

3. Prolonging the life of humans, animals or plants;

4. Protection of the environment;

5. Production and testing of foodstuffs;

6. Rearing of animals;

7. Study of animal behaviour;

8. Teaching and training.

Article 12

Any person who proposes to conduct experiments on live animals on one of the grounds listed in Article 11 must seek the authorization of the Minister for each experiment.

The application must state the aim of the experiment, the method by which it is to be performed, any anaesthetics that are to be used and the kind and number of animals used.

Experiments may be authorized by the Minister only if the Minister of Health has given his prior authorization to the programme of experiments.

Such authorization may be limited in time. It may be revoked at any moment.

The person responsible for conducting the experiments must possess a university qualification in medicine, veterinary medicine or biology and possess the necessary practical experience.

Article 13

Experiments on animals may be conducted only in approved institutes or laboratories possessing qualified staff and appropriate facilities permitting the animals in question to be kept in such a way as to prevent them as far as possible from suffering pain, distress or injury.

Experiments connected with a study of behaviour may be conducted outside such premises.

Article 14

Educational experiments may only be conducted in higher level education.

Article 15

No animals shall be used in an experiment if there is another animal of lower sensitivity or psychological development or if a reasonable alternative meeting the needs of the experiment is available.

Article 16

Any experiment on an animal which is liable to cause it pain or anxiety must be con-

ducted under general or local anaesthetic or by similar methods unless they are:

(a) more traumatic for the animal than the experiment itself;

(b) incompatible with the aim of the experiment and authorized by the Minister.

Article 17

Where an animal has been subject to severe pain, distress or injury, it may not be used for further experiments.

If an animal can survive only in a state of pain or suffering it must be killed immediately even if the object of the experiment has not been achieved.

Article 18

For each experiment on animals that is authorized a record must be made indicating the aim of the experiment, the method by which it is carried out, any anaesthetics used and the kind and number of animals used.

Records shall be kept for three years and shall be available for inspection by the supervisory bodies.

Article 19

The Minister shall confer responsibility for the control and supervision of the articles of Chapter VII on a veterinarian.'

25. Article 20 prohibits a series of practices involving cruelty or danger to other animals. Article 21 imposes criminal penalties for infringement of the Law or implementing regulations. Articles 22 to 25 concern the powers and responsibilities of the authorities responsible for enforcing the Law.

The Commission's claims

26. By its letter of 8 December 1994 the Commission claimed that the following

provisions of the Directive had not yet been implemented in Luxembourg law:

(1) Article 7(3) and (4),

(2) Article 8(4) (since Article 17 of the Law only implements Articles 9(1) and 10 of the Directive),

(3) Article 9(2) and (3) and Article 11 (which are not implemented by Article 17 of the Law),

(4) Articles 15 to 18,

(5) Article 19(4),

(6) Article 22.

In addition the Commission stated that it had no knowledge of the measures taken under Article 4 of the Directive and had not received notification of the Grand-Ducal regulations mentioned in Articles 9(3) [actually fourth paragraph, point 3] and 10 of the Law.

27. As already noted, Article 94(2) of the Rules of Procedure requires the Court to verify 'whether the applicant's submissions appear well founded'. I shall therefore consider each point in turn.

Article 7(3) and (4)

28. Article 7(3) and (4) of the Directive provide:

'3. 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. All experiments shall be designed to avoid distress and unnecessary pain and suffering to the experimental animals. They shall be subject to the provisions laid down in Article 8. The measures set out in Article 9 shall be taken in all cases.'

29. It may be noted that Article 15 of the Law prohibits the use of an animal if there is another animal of lesser sensitivity and psychological development or if a suitable alternative solution is available. It seems to me that that provision achieves, at least in part, the result intended by the first subparagraph of Article 7(3). There does not, on the other hand, appear to be any provision in the Law which corresponds to the second subparagraph of Article 7(3).

30. Article 7(4) is not implemented by any single provision. However, in so far as it entails a separate obligation from those laid down by Articles 8 and 9 with regard to the use of anaesthetics and the treatment of animals after completion of experiments, it is of a general nature. It seems to me that, taken together, Articles 13, 15, 16, 17 and 18 of the Law are designed to ensure that animals used in experiments do not suffer distress and unnecessary pain.

Article 8(4)

31. With respect to the use of anaesthetics the Commission's claim is limited to non-implementation of Article 8(4). That provision states:

'Provided such action is compatible with the object of the experiment, an anaesthetized animal, which suffers considerable pain once anaesthesia has worn off, shall be treated in good time with pain-relieving means or, if this is not possible, shall be immediately killed by a humane method.'

32. Article 17 of the Law partially implements that provision by providing that an animal is to be killed immediately where survival will entail pain and suffering. Unlike Article 8(4) it does not however provide, at least not expressly, for the treatment of animals with pain-relieving means once anaesthesia has worn off.

Article 9(2) and (3) and Article 11

33. Article 9(2) and (3) provide:

'2. The decisions referred to in paragraph 1 [i. e. the decisions concerning the treatment of animals at the end of experiments] shall be taken by a competent person, preferably a veterinarian.

3. Where, at the end of an experiment:

(a) an animal is to be kept alive, it shall receive the care appropriate to its state of health, be placed under the supervision of a veterinarian or other competent person and shall be kept under conditions conforming to the requirements of Article 5. The conditions laid down in this subparagraph may, however, be waived where, in the opinion of a veterinarian, the animal would not suffer as a consequence of such exemption;

(b) an animal is not to be kept alive or cannot benefit from the provisions of Article 5 concerning its well-being, it shall be killed by a humane method as soon as possible.'

Article 9(2) complements Article 7(1), which deals with supervision of the experiments themselves. That provision states:

'Experiments shall be performed solely by competent authorized persons, or under the direct responsibility of such a person, or if the experimental or other scientific project concerned is authorized in accordance with the provisions of national legislation.'

34. The Luxembourg Law makes no express provision regarding the person responsible for taking decisions concerning the treatment of animals after completion of experiments. It is possible that Article 12 of the Law, which implements Article 7(1) by requiring experiments to be conducted by a doctor, veterinarian or biologist who has the requisite experience, may apply. However, it is not clear that that is the case.

35. 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.'

36. There is no corresponding provision in the Luxembourg Law. It is however unclear whether Article 11 necessarily requires implementation, in so far as it merely permits the competent authority to allow an animal to be set free on certain conditions.

Articles 15 to 18

37. These provisions, which concern breeding and supplying establishments, have no equivalent in the Luxembourg Law.

Article 19(4)

38. Article 19(4) provides:

'In user establishments, only animals from breeding or supplying establishments shall be used unless a general or special exemption has been obtained under arrangements determined by the authority. Bred animals shall be used whenever possible. Stray animals of domestic species shall not be used in experiments. A general exemption made under the conditions of this paragraph may not extend to stray dogs and cats.'

39. Article 19(4) is not implemented by the Luxembourg Law.

Article 22

40. Article 22 provides:

'1. 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 recognize 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.

2. To that end, Member States shall where practicable, and without prejudice to the requirements of existing Community Directives, furnish information to the Commission on their legislation and administrative practice relating to animal experiments, including requirements to be satisfied prior to the marketing of products; they shall also supply factual information on experiments carried out in their territory and on authorizations or any other administrative particulars pertaining to these experiments.

3. The Commission shall establish a permanent consultative committee within which the Member States would be represented, which will assist the Commission in organizing the exchange of appropriate information, while respecting the requirements of confidentiality, and which will also assist the Commission in the other questions raised by the application of this Directive.'

41. The Law does not contain provisions giving effect to Article 22(1). It is unclear whether Article 22(2), imposing an obligation to furnish information to the Commission, needs to be implemented by legislative provisions. Article 22(3) imposes obligations primarily on the Commission rather than the Member States.

Article 4

42. The Law contains no provisions giving effect to Article 4, which prohibits experiments using endangered species unless certain conditions are met.

Uncertainty as to the existence of Grand-Ducal regulations adopted pursuant to Article 9, fourth paragraph, point 3, and Article 10 of the Law

43. Article 9 of the Law concerns surgical operations on animals. The first paragraph of that article requires painful operations to be performed under anaesthetic. The fourth paragraph provides that the administration of anaesthetics is not required *inter alia* 'in the case of minor operations to be determined by Grand-Ducal regulation' (point 3).

44. It is unclear why the Commission considers that the regulations adopted under that provision fall within the scope of the Directive. Article 9 is concerned with surgical operations rather than experiments on animals. As already noted, the use of anaesthetics in connection with experiments is dealt with separately by Article 16 of the Law.

45. Similar considerations apply to Article 10 of the Law, which provides:

'An amputation or partial amputation may be carried out on an animal only on instructions from a veterinarian or on imperative zootechnical grounds to be determined by Grand-Ducal regulation.'

46. In conclusion, therefore, it appears that, although some of the Commission's claims are unfounded, a number of the provisions of the Directive remain wholly or partly unimplemented. That conclusion is sufficient to support a finding that Luxembourg has failed to fulfil its obligations under the Directive.

Conclusion

47. Accordingly, I am of the opinion that the Court should:

(1) declare that, by failing to adopt within the prescribed period all the measures necessary to comply with Council Directive 86/609/EEC of 26 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, Luxembourg has failed to fulfil its obligations under the Treaty;

(2) order Luxembourg to pay the costs.