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REPORT

on Directive 86/609 on the protection of animals used for experimental and other scientific purposes
(2001/2259(INI))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Jillian Evans

CONTENTS

| | Page |
|------------------------------|-------------|
| PROCEDURAL PAGE | 4 |
| MOTION FOR A RESOLUTION..... | 5 |
| EXPLANATORY STATEMENT | 11 |

PROCEDURAL PAGE

At the sitting of 17 January 2002 the President of Parliament announced that the Committee on the Environment, Public Health and Consumer Policy had been authorised to draw up an own-initiative report, pursuant to Rule 163 of the Rules of Procedure, on Directive 86/609 on the protection of animals used for experimental and other scientific purposes.

The Committee on the Environment, Public Health and Consumer Policy appointed Jillian Evans rapporteur at its meeting of 22 January 2002.

The committee considered the draft report at its meetings of 2 October 2002 and 5 November 2002.

At the latter meeting it adopted the motion for a resolution by 24 votes to 17, with 3 abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Alexander de Roo and Anneli Hulthén, vice-chairmen; Jillian Evans, rapporteur; and María del Pilar Ayuso González, Jean-Louis Bernié, David Robert Bowie, John Bowis, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Chris Davies, Avril Doyle, Anne Ferreira, Marialiese Flemming, Karl-Heinz Florenz, Cristina García-Orcóyen Tormo, Laura González Álvarez, Robert Goodwill, Françoise Grossetête, Cristina Gutiérrez Cortines, Marie-Thérèse Hermange (for Raffaele Costa), Marie Anne Isler Béguin, Eija-Riitta Anneli Korhola, Bernd Lange, Giorgio Lisi (for Christa Kläß), Torben Lund, Minerva Melpomeni Malliori, Patricia McKenna, Emilia Franziska Müller, Riitta Myller, Giuseppe Nisticò, Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Giacomo Santini (for Peter Liese), Karin Scheele, Horst Schnellhardt, María Sornosa Martínez, Catherine Stihler, Nicole Thomas-Mauro, Antonios Trakatellis and Phillip Whitehead.

The report was tabled on 13 November 2002.

MOTION FOR A RESOLUTION

European Parliament resolution on Directive 86/609 on the protection of animals used for experimental and other scientific purposes (2001/2259(INI))

The European Parliament,

- having regard to Directive 86/609/EEC on the Approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes¹,
 - having regard to the Treaty establishing the European Community, and in particular the amendment of the Treaty on European Union which includes a Protocol requiring the European Union and Member States to pay full regard to the welfare of animals when drawing up agriculture, transport, single market and research policies,
 - having regard to the 31 March 1986 Council of Europe Convention ETS 123 for the protection of vertebrate animals used for experimental and other scientific purposes, to which the Community became a Party,
 - having regard to Council Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes²,
 - having regard to the Sixth Environmental Action Programme which aims at taking positive steps towards the development of a coherent system that minimises the need for animal testing and developing alternative testing methods,
 - having regard to Rule 163 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (A5-0387/2002),
- A. Whereas an infringement procedure was launched against Austria in 2000 for failing to completely transpose the Directive into national legislation,
- B. Whereas a judgement was handed down against Belgium in 1998 for failing to completely transpose the Directive into its national legislation - in particular for insufficient recognition of data from experiments in other Member States; and whereas a reasoned opinion was sent to Belgium in 2001 for allowing widespread use of stray cats and dogs for research,
- C. Whereas a reasoned opinion was sent to France for incorrect implementation of Article 4, 7(3), 12(2), 18(1), 18 (3) and 22 (1),
- D. Whereas judgement was handed down against Ireland in 2001 for failing to implement

¹ OJL 358, 18.12.1986, p. 1

² OJ L 222, 24.08.1999, p. 29.

the Directive - in particular Articles 2(d), 11, 12, and a letter of formal notice has also been sent for implementing too narrow a definition of an “experiment”,

- E. Whereas the Commission has taken action against Luxembourg for not adequately transposing the Directive into its national legislation,
- F. Whereas an application against the Netherlands was submitted to the European Court of Justice on 18th May 2001,
- G. Whereas formal legal proceedings were initiated against Portugal for incorrectly implementing the Directive - in particular the use of stray cats and dogs for research,
- H. Whereas a reasoned opinion has been sent to Spain for incorrect implementation of the Directive in Andalucia,
- I. Whereas proceedings against the UK were terminated in August 1998 when the law on Scientific Procedures involving animals was amended,
- J. Whereas there is evidence in at least one case in the UK of research facilities having received licences for experiments far less intrusive and painful than those actually undertaken,
- K. Whereas there is evidence in at least one case in the UK of researchers exceeding the number of animals for which they have been licensed yet not reporting this,
- L. Whereas there is evidence in at least one case in the UK of animals are being left unsupervised for long periods of time - even whilst recovering from traumatic experiments and food and/or water deprivation is being practised,
- M. Whereas Directive 86/609/EEC has not been satisfactorily implemented in all Member States and the implementation of the requirements and longer term objectives have at best been a slow process,
- N. Whereas five Member States (Austria, Ireland, Italy, Luxembourg, Portugal) have not yet completed the ratification or accession to the Convention,
- O. Whereas the collection and collation of statistical information on the use of animals in experiments remains problematic,
- P. Whereas the required statistical data does not provide the details required to monitor the implementation of Article 7 of the Directive,
- Q. Whereas Member States still apply differing standards to authorising, monitoring and review of experimental projects, and a formal system for critical ethical review is often lacking,
- R. Whereas the effectiveness of controls varies between Member States,
- S. Whereas the application of the three Rs – Replacement, Reduction and Refinement

varies widely between research establishments,

- T. Whereas the requirement that unnecessary duplication of experiments be avoided is not adequately enforced,
- U. Whereas even though there has been progress through the work of ECVAM, the development and implementation of alternative methods has not been adequately encouraged throughout the Member States,
- V. Whereas new knowledge on the physical, behavioural and psychological needs of laboratory animals makes improvements in their husbandry and care and thus the standards in Appendix II essential,
- W. Whereas developments in science and technology resulting in new uses of animals make the revision of Directive 86/609/EEC urgent,
- X. Whereas not all animals used for scientific purposes are included in the Directive and, in particular, the very large numbers of animals used in fundamental research are not covered,
- Y. Whereas the variety of potential applications of genetic manipulation were not fully known in 1986, but statistics show a significant rise in the numbers of animals used in these experiments and an annual increase is predicted,
- Z. Whereas there has been rapid growth in research linked to the development of xenotransplantation a technology which raises questions about the status of animals,
- AA. Whereas the continued use of non-human primates for experimental and other scientific purposes causes great concern and bearing in mind that Council Decision 1999/575/EC has already stated that use of such beings/animals must be reduced,
- BB. Whereas techniques for the recognition of animal pain, suffering and distress, and pain management systems are inadequate in many research establishments,
- CC. Whereas, in its recommendation for second reading amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, the European Parliament, considers the prohibition of animal experiments for cosmetics as essential,
- DD. Whereas the UK Guidance on the Operation of Animals (Scientific Procedures) Act 1986 already states that a procedure should be considered as severe “if is expected that even one animal would suffer substantial effects” ,
- EE. Whereas consideration of the ethological needs of the animals is still not obligatory,
- FF. Whereas the minimum housing and care standards are still not mandatory,

1. Calls on the Commission in connection with the revision of legislation on animal experiments to take account of the Council of Europe's recommendations and make the best possible provision for the physiological and ethological needs of animals used in experiments;
2. Calls on the Commission to fulfil its commitments, pursuant to the Protocol of amendment to the European Convention, to present, before the end of 2003, a proposal in order to adapt the provisions of Directive 86/609/EEC¹, and to incorporate the following amendments and rules of procedure;
3. Considers that the scope of the Directive needs to be aligned to the scope of the Council of Europe Convention which also covers animals used for education and training purposes;
4. Considers that Member States should be obliged to set up an ethical review procedure as part of the authorisation system for approving animal experiments;
5. Considers that animal experimentation is a contentious issue which raises ethical problems, and due regard should be paid to the circumstances in which its use is appropriate.
6. Considers that certain ethically unacceptable purposes for animal experiments should not be permitted. These should include:
 - development and testing of weapons including chemical agents on animals
 - development and testing of cosmetics including ingredients of cosmetics
 - the use of wild-caught primates;
7. Considers that to obtain a licence to perform experiments on animals, the applicant must be able clearly to substantiate and justify the purpose of the experiment in terms of the criterion that the experiments will be of benefit to animals or humans. In addition, a licence may be issued only where the applicant can show that the desired outcome can only be achieved by using live animals and that there are no alternative testing methods. Before a licence is issued, an ethical and animal-welfare assessment must be carried setting limits to the level of stress to which the animals may be subjected. Even if it can be shown that certain experiments may be of benefit to animals or humans, they should not be authorised if the stress on the animals used in the experiment exceeds the maximum level;
8. Considers that experiments on animals considered as endangered under Appendix 1 of the CITES and Annex C. I No 3626/82 should be prohibited;
9. Considers that the need for the continued use of non-human primates in research and testing should be critically evaluated in the light of scientific knowledge, with the

¹ Proposal for a Council decision concerning the conclusion of the Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (COM (2001) 704)

intention of reducing and eventually ending their use;

10. Considers that the definition of an animal should be widened to include Cephalopods and Decapods;
11. Considers that a central database for approved experiments on animals should be set up including information on all current and all completed animal experiments to ensure that there is no repeat testing. The database should also contain information on animal experiments with no directly applicable results so that not only published studies are registered. Finally, the database should also contain information on alternative testing methods which may replace or reduce the use of animals in experiments;
12. Considers that the data that must be collected under Directive 86/609 should be more detailed and include the number of transgenic animals used as well as taking into account the level of pain suffered;
13. Considers that the use of the uniform format for presenting data collected from the Member States should be made mandatory, and data presentation should occur yearly rather than every three years;
14. Considers that Article 22 should be better implemented so that there be no unnecessary duplication of experiments nor should there be any legal need to duplicate experiments in order for a product to be marketed in a particular country;
15. Considers that transgenic animals must be included in the Directive and be fully recorded and traceable throughout their lives;
16. Considers that GM animals and animals born bearing debilitating deformities as a result of previous experiments that cause the animal to suffer sporadic or continuous pain or discomfort must be killed humanely at the earliest possible opportunity;
17. Considers that licensing procedures should be stricter than in Directive 86/609/EEC - licence applications should include a cost benefit analysis and state the degree of pain to be caused by experiments;
18. Considers that a central EU inspectorate should be established to guide inspectors within the Member States with the power to visit facilities where animal experiments are being undertaken - both private and public, without any prior warning, and have the power to revoke any licence that is not being adhered to;
19. Considers that an EU-wide training course for those undertaking research using animals as well as for those responsible for the care of animals used for experiments should be introduced as a mandatory requirement. The training course should also ensure that researchers and carers make provision, where appropriate, for the training and socialisation of animals for use in experiments so that the animals are familiar with other animals, people and the relevant procedure for the experiment;
20. Considers that only qualified technicians should be allowed to look after animals used

for experiments and a minimum staff to animal ratio must be adhered to – especially when an animal is recovering from experimentation and/or anaesthetised procedures;

21. Considers that analgesics or other appropriate methods of pain management should be used to ensure that an animal is not subject to moderate or even mild pain or suffering as well as severe pain, distress or suffering;
22. Considers that the minimum housing and care-taking standards which are in Appendix II must be made mandatory;
23. Given that up to 9 million “surplus” animals are born and culled each year in the EU, a revision and improvement of breeding procedures is essential;
24. Instructs its President to forward this resolution to the Council and Commission.

EXPLANATORY STATEMENT

It is estimated that some 12 million vertebrate animals are used each year in the EU in the development and testing of chemicals, biological material and other products. The use of animals for such purposes is, rightly, the subject of extensive debate and public interest, especially as the Directive controlling such experiments - 86/609/EEC as well as the scientific basis and the political impetus behind it are almost twenty years old.

A great deal has changed since the Directive was adopted - science has developed significantly in ways unforeseen by the original Directive, and public opinion towards animals has changed, with the result that more people now list animal welfare as an issue that causes them concern.

It is inappropriate therefore that this Directive on *The Protection of Animals Used for Experimental and other Scientific Purposes* has as its original basis, not the welfare of such animals, but undistorted trade between Member States. As a result, certain types of experiments - such as those for basic research and teaching or training are not covered by the Directive.

The Commission itself has acknowledged a necessity to update Directive 86/609 and has agreed to begin this process before the end of 2003. Evidence regarding implementation and enforcement unearthed during the research for this report highlights the need for these reforms to be made sooner rather than later. There are basic failures of implementation - whilst some Member States have adopted laws stronger than those of 86/609/EEC into their national legislation, others have failed to implement and enforce some of the more basic principles behind the Directive - a fact highlighted by the current infringement actions that the European Commission is taking against certain Member States.

Data Collection

One of the most basic examples of the shortcomings of the current Directive has been the difficulty incurred in collating and interpreting the data that should be collected under the provisions of Directive 86/609. Although the format for collecting the data has been to some extent standardised, it remains almost impossible to find out the exact number of animals used for each type of experimental procedure, and there is no provision for listing the degree of severity of experiments undertaken on animals. At present, it is impossible to glean from the data submitted whether article 7, paragraph 2 of the Directive is being adequately implemented. Statistical evidence published must demonstrate that there was no other scientifically satisfactory method not involving an animal available. All Member States do not collect the data at the same intervals - whilst some go beyond the existing requirement of every three years, others stick to this timeline and do not publish internal results in the meantime. The major failings with data collection should be rectified when the Directive is revised. For any such data to be useful, the figures should be published annually across the Member States, with a detailed breakdown, and in a uniform format. As those experimenting on animals - pharmaceutical companies in particular, already keep such data, this should not prove difficult.

Differing Standards Across Member States

It has become apparent that standards differ across Member States on several aspects of implementation and enforcement of Directive 86/609. Animal welfare would appear to have a different degree of importance in some Member States with the result that the authorisation, monitoring and the review of experimental projects differs within. Whilst some Member States attempt to regulate and enforce their national legislation through ad hoc inspector visits to facilities where experiments are undertaken, other have implemented the Directive in a far more far less stringent manner. The harmonisation of standards has obviously failed in this respect, and any review of Directive 86/609 should strive not only to ensure the lowest standards are raised, but also that all Member States progress to a more efficient level of monitoring animal experimentation.

The three Rs - *Replacement*, *Reduction* and *Refinement* approach to animal experimentation as defined by Russell and Burch¹, now plays a more important role when the European Union debates the subject. And whilst this is to be welcomed, it is essential that the approach be one that is accepted and equally applied in all Member States. Far from reducing experiments, the fact that experiments are being duplicated demonstrates that the principle of *Reduction* is not being followed, nor is the provision against unnecessary duplication of experiments in Directive 86/609 being adhered to.

Scope of Directive 86/609

One contentious issue since this Directive was passed has been that not all animals are covered by its provision. Since 1986, there have been major developments in the field of animal experimentation - one of these has been the unforeseen yet substantial increase in the number of transgenic animals being created and used. That a Directive intended to regulate the use of animals used for experimental and other scientific purposes does not include all animals which are experimented upon is inadmissible. Transgenic animals should be included in any revision of Directive 86/609 as should all animal forms - including embryonic and foetal forms and beings with the capability to feel pain - such as Cephalopods and Decapods. The acceptable criterion for regulation should be susceptibility to pain. Experiments should also not be undertaken.

It is censurable that the scope of this Directive also omits experiments undertaken by certain bodies or institutions, and as a result, millions of animals used annually in education and basic scientific research remain unaccounted for. Given recent debate about the ethics of animal experimentation for educational purposes, this is an area of the Directive that needs urgent attention. The future of experiments on non-human primates needs also to be reconsidered.

Care and Treatment of Animals

It has come to light that there are several shortcomings in the way that animals are being cared for whilst subject to experimentation. Although voluntary guidelines exist on the education and training of persons working with laboratory animals (FELASA)², there is currently no

¹ Russell, William M.S. and Rex L. Burch, *Principles of Humane Experimental Technique*. Methuen, London, 1959.

² Federation of European Laboratory Animal Science Associations

EU-wide standard course that can be followed. A recent report on Cambridge University, UK lists a catalogue of animal suffering. That this could happen in the country which is often cited as having the most stringent welfare legislation is lamentable evidence of the shortcomings of the way in which Directive 86/609 is implemented and enforced.

All people, not only those named as competent persons or on-site veterinary surgeons, should undergo a certified animal welfare course including the ethics of scientific and other experiments on animals. A standard course leading to such a certificate, valid and recognised throughout the Member States would not only raise the standard of care offered, but also enable employers to ensure that qualified animal technicians could be employed from any EU country.

Revision of Directive 86/609

The Animal Welfare Protocol of Amsterdam which entered into force on 1st May 1999 requires that full regard be paid to the welfare needs of animals. This, coupled with the fact that Convention ETS 123 has been signed by the EC, makes the urgent revision of the Directive paramount and the extension of its legal basis essential. This report should be seen as a precursor to this, and its comments and recommendations taken aboard.