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## REPORT

drawn up on behalf of the Committee on the Environment,  
Public Health and Consumer Protection

on the proposal from the Commission of the European  
Communities to the Council  
(COM(85) 380 final - Doc. C 2-70/85) for a directive on  
the harmonization of the laws, regulations and  
administrative provisions relating to the application of  
the principles of good laboratory practice and the  
verification of their application for tests on chemical  
substances

Rapporteur: Mrs U. SCHLEICHER

WG(VS1)3192E

PE 103.074/fin.  
Or. De.



By letter of 19 August 1985 the President of the Council of the European Communities requested the European Parliament, pursuant to Article 100 of the EEC Treaty, to deliver an opinion on the proposal for a Council directive on the harmonization of the laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

On 9 September 1985 the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs and Industrial Policy for its opinion.

At its meeting of 20 September 1985 the Committee on the Environment, Public Health and Consumer Protection appointed Mrs SCHLEICHER rapporteur.

The committee considered the Commission's proposal and the draft report at its meetings of 22 January and 25 February 1986.

At the last meeting the committee decided unanimously to recommend to Parliament that it approve the Commission's proposal, subject to the following amendment.

The committee then unanimously adopted the motion for a resolution as a whole.

The following took part in the vote: Mrs BLOCH von BLOTTNITZ, vice-chairman and acting chairman; Mrs SCHLEICHER, vice-chairman and rapporteur; Mrs BANOTTI, Mr BOMBARD, Mr ELLIOTT (deputizing for Mr HUGHES), Mr GARCIA (deputizing for Mrs VEIL), Mrs JACKSON, Mr VAN DER LEK, Mrs LENTZ-CORNETTE, Mr MERTENS, Mr NORDMANN, Mr PEREIRA, Mrs PEUS (deputizing for Mr ALBER), Mrs RENAU I MANEN, Mrs SQUARCIALUPI, Ms TONGUE and Mr VITTINGHOFF.

The opinion of the Committee on Economic and Monetary Affairs and Industrial Policy is attached.

The report was tabled on 7 March 1986.

The deadline for tabling amendments to this report will be indicated in the draft agenda for the part-session at which it will be debated.

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following amendment to the Commission's proposal and motion for a resolution, together with explanatory statement, on

the proposal for a Council directive on the harmonization of the laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances:

Text proposed by the Commission of  
the European Communities

Amendment tabled by the Committee on  
the Environment, Public Health and  
Consumer Protection

Preamble and Articles 1-5 unchanged

Amendment No. 1

new Article 5a

'Member States shall take the measures necessary to restrict rigorously the animal experiments used in the tests described in this directive and shall give priority to the other test systems.

When testing products in respect of which animal experiments have been shown to be unnecessary, Member States shall take all measures necessary to prohibit such experiments.'

Articles 6 and 7 unchanged

MOTION FOR A RESOLUTION

closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive on the harmonization of the laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances

The European Parliament,

- having regard to the proposal from the Commission to the Council<sup>1</sup>,
- having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. C 2-70/85),
- having regard to the result of the vote on the Commission's proposal,
- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic and Monetary Affairs and Industrial Policy (Doc. A2-233/85),
- having regard to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>2</sup>, as last amended by Directive 84/449/EEC<sup>3</sup>,
- having regard to its report on the limiting of animal experiments and the protection of laboratory animals (Doc. 1-213/84)<sup>4</sup>,

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<sup>1</sup> OJ No. C 219, 29.8.1985, p. 6

<sup>2</sup> OJ No. L 196, 16.8.1967, p. 1

<sup>3</sup> OJ No. L 251, 19.9.1984, p. 1

<sup>4</sup> OJ No. C 172, 2.7.1984, p. 164

- having regard to the motion for a resolution by Mrs BLOCH von BLOTTNITZ on behalf of the Rainbow Group on the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (Doc. B 2-335/85),
  - having regard to the motion for a resolution by Mr MARTIN and Mr NEWENS on continued Community approval of the use of the LD<sub>50</sub> (lethal dose 50%) test (Doc. B 2-544/85),
- A. whereas both European legislation and the laws of the Member States set certain requirements with regard to the safety of chemical substances and prescribe tests to ensure this safety prior to their being put on the market,
  - B. whereas the Commission has submitted this proposal to bring the Community into line with OECD agreements,
  - C. whereas the incorporation of the OECD decisions into Community law will remove any threat of the European Community's chemical industry, which is the main sector concerned, being at a competitive disadvantage vis-à-vis third countries as a result of different test methods,
  - D. whereas the European Parliament has repeatedly called for a reduction in the number of animal experiments, and whereas the mutual acceptance of tests based on uniform, recognized methods which provide reliable and comparable results is a major step towards achieving this objective,
  - E. having regard to the OECD's definition, according to which 'good laboratory practice' has to do with the organization of experiments and the conditions under which laboratory experiments are planned, carried out, verified and registered and the results thereof disseminated,

1. Welcomes the Commission's proposal, as it will make binding on the Community Member States the application of the principles of good laboratory practice (OECD decision of May 1981) to the conduct of tests provided for by Directive 67/548/EEC and to the control measures associated therewith (OECD recommendation of 26 July 1983);
2. Welcomes the close cooperation between the European Community and the Organization for Economic Cooperation and Development, in accordance with Article 231 of the EEC Treaty, in the field of scientific and economic development;
3. Stresses the benefits for producers and consumers associated with the standardization throughout the OECD of the requirements for putting goods, in this case chemical substances, on the market;
4. Welcomes the fact that the application of the uniform principles of good laboratory practice in all the Member States will make it unnecessary to repeat tests as a result of the application of different methods and will enable the cost and duration of tests, and the number of animal experiments needed in this connection, to be reduced;
5. Expects that animal experiments will be subject to further drastic reductions, over and above those brought about by application of uniform principles of good laboratory practice, and that they will be restricted to an absolute minimum;
6. Expects that animal experiments in the framework of this directive will be prohibited wherever they are shown to be unnecessary;
7. Expects that these OECD principles will not only be implemented in laboratories carrying out tests on chemical substances, but will also be extended to all large laboratories which carry out similar tests;
8. Instructs its President to forward this resolution to the Council and the Commission as Parliament's opinion, the Commission's proposal as voted by Parliament and the corresponding resolution.



B  
EXPLANATORY STATEMENT

As the Commission states in its explanatory memorandum to this proposal for a directive, there is a gap in Community legislation, because neither Directive 79/81/EEC, amending for the sixth time Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances, which requires that tests conducted on chemical substances before these are marketed, nor the OECD's 1981 decision on the mutual acceptance of data on the evaluation of chemical products and the OECD's 1983 recommendation on the mutual recognition of compliance with good laboratory practice have yet been incorporated into Community law. All the Member States have approved these international agreements and the Community is a contracting party to both agreements.

The purpose of the proposal for a directive is to close this gap in legislation by making binding on all the Member States of the Community the principles of good laboratory practice and the control measures specified in relation thereto.

The European Parliament has repeatedly called for all substances to be tested before they are marketed to determine their safety with regard to human health and the environment. This was made compulsory for chemical substances for the first time by the sixth amending directive (79/831/EEC), annexes VII and VIII of which contain the list of tests to be carried out and annex V of which describes the test methods to be used.

In order to obtain reliable and comparable test results with regard to the characteristics and safety of substances it is essential to apply the principles of good laboratory practice. This will ensure that test results will be accepted by other countries not only within the Community but also elsewhere.

It also means that tests will not have to be repeated unnecessarily and that the financial resources and number of experimental animals needed to carry out the tests can be reduced as a result. The Commission is furthering the Community's efforts to secure mutual acceptance of national procedures.

The principles of good laboratory practice establish the conditions under which laboratory experiments are planned, carried out, verified and registered and the results thereof disseminated. The OECD's 1983 recommendation, which is not yet binding, specifies the control measures to be implemented in order to ensure compliance with good laboratory practice. This directive will require the Member States to ensure compliance with good laboratory practice by carrying out on-the-spot inspections of laboratories and verifications of studies. These provisions are also in line with the frequently expressed wishes of the European Parliament. The European Parliament would welcome it if this directive were extended to cover all laboratories which are concerned in any way with carrying out tests and, as it has long been demanding, if approval of substances other than chemical substances were also made subject to standardized conditions and procedures.

O P I N I O N

(pursuant to Rule 101 of the Rules of Procedure)

of the Committee on Economic and Monetary Affairs and Industrial Policy

Draftsman: Mr F. GAUTIER

On 25 September 1985 the committee appointed Mr Gautier draftsman for the opinion.

At its meeting of 26-28 November 1985 the committee considered the draft opinion and adopted the conclusions unanimously.

The following took part in the vote: Mr SEAL, chairman; Mr BEAZLEY, vice-chairman; Mr GAUTIER, draftsman of the opinion; Mr BEUMER, Mr KILBY (deputizing for Mr CASSIDY), Mr METTEN, Mrs NIELSEN, Mrs OPPENHEIM, Mr PATTERSON, Ms QUIN, Mrs van ROOY (deputizing for Mr von WOGAU) and Mr STARITA.

## Introduction

1. The Organization for Economic Cooperation and Development (OECD) is responsible for promoting scientific, technical and economic development and the expansion of world trade.

2. To achieve these objectives it can take binding decisions and make recommendations to the Member States.

### I. Substance

3. On 12 May 1981 the Council of the OECD took a 'decision on the mutual acceptance of data on the evaluation of chemical products'. On 26 June 1983 it issued a 'recommendation on the mutual recognition of compliance with Good Laboratory Practice'.

4. The proposal for a Directive is intended to make the decision and recommendation binding on the Member States of the Community. In submitting it the Commission is complying with the explicit requirements of Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>1</sup> and the agreements reached within the framework of the OECD.

### II. Examination of the proposal

5. The OECD principles of Good Laboratory Practice supplement the provisions contained in Annex V to Directive 67/548/EEC - as last amended by Directive 84/449/EEC<sup>2</sup> - on the testing of chemical substances. The aim is to ensure that the results of the tests are reliable and mutually comparable.

6. The introduction of these OECD principles into Community legislation will have the economic advantage of saving money spent on tests, since it will no longer be necessary to repeat tests because of differences in laboratory practice between Member States.

7. The introduction of the principles into Community law will improve the competitiveness of the Community's chemical industry in relation to non-member countries: the uniform OECD rules will facilitate access to the world market and the industry will not find itself at a disadvantage because of differing methods of testing.

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<sup>1</sup>OJ No. 196, 16.8.1967, p. 1

<sup>2</sup>OJ No. 251, 19.9.1984, p. 1

### III. Conclusions

The Committee on Economic and Monetary Affairs and Industrial Policy asks the Committee on the Environment, Public Health and Consumer Protection to take account of the following conclusions:

1. the Community's close cooperation with the Organization of Economic Cooperation and Development (OECD) pursuant to Article 231 of the EEC Treaty in specifically this area of scientific and economic development is to be welcomed;
2. attention is drawn to the benefits for producers and consumers of OECD measures to harmonize the requirements governing the marketing of goods - in this instance, chemical substances.
3. The committee supports the Commission's proposal.