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COUNCIL DIRECTIVE

►C1 of 7 June 1988 ◄

on the inspection and verification of Good Laboratory Practice (GLP)

(88/320/EEC)

(OJ L 145, 11.6.1988, p. 35)

Corrected by:

►C1 Corrigendum, OJ L 174, 6.7.1988, p. 55 (88/320)

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on the inspection and verification of Good Laboratory Practice (GLP)

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100A thereof,

Having regard to the proposal from the Commission [1],

In cooperation with the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

Whereas the application of standardized organizational processes and conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing of chemicals for the protection of man, animals and the environment, hereinafter referred to as 'Good Laboratory Practice' (GLP), contributes to the reassurance of Member States as to the quality of the test data generated;

Whereas, in Annex 2 to its Decision on 12 May 1981 on the mutual acceptance of data in the assessment of chemicals, the council of the Organization for Economic Cooperation and Development (OECD) adopted principles of good laboratory practice which are accepted within the Community and are specified in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances [4];

Whereas, in the conduct of tests on chemicals, it is desirable that specialist manpower and testing laboratory resources should not be wasted owing to the need to duplicate tests because of differences in laboratory practices from one Member State to another; whereas this applies especially for animal protection which requires that the number of experiments on animals be restricted in accordance 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 [5]; whereas mutual recognition of the results of tests obtained using standard and recognized methods is an essential condition for reducing the number of experiments in this area;

Whereas, however, in order to ensure that test data generated by laboratories in one Member State are also recognized by other Member States, it is necessary to provide for a harmonized system for study audit and inspection of laboratories to ensure that they are working under GLP conditions;

Whereas Member States designate the authorities responsible for carrying out monitoring on compliance with GLP;

Whereas a committee, the members of which will be appointed by the Member States, would be of assistance to the Commission in the technical application of this Directive and would cooperate in its efforts to encourage the free movement of goods by the mutual recognition by Member States of procedures for monitoring compliance with GLP;

(1) OJ No C 13, 17. 1. 1987, p. 5.
(2) OJ No C 156; 15. 6. 1987, p. 190 and OJ No C 122, 9. 5. 1988.
(3) OJ No C 232, 31. 8. 1987, p. 1.
(4) OJ No L 15, 17. 1. 1987, p. 29.
(5) OJ No L 358, 18. 12. 1986, p. 1.

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whereas the committee set up by Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]), as last amended by Directive 87/432/EEC ([2]), may be used for this purpose;

Whereas this committee may assist the Commission not only in the application of this Directive but also in contributing to the exchange of information and experience in this field,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive applies to the inspection and verification of the organizational processes and the conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing, carried out in accordance with the rules and regulations, of all chemicals (e. g. cosmetics, industrial chemicals, medicinal products, food additives, animal feed additives, pesticides) in order to assess the effect of such products on man, animals and the environment.

2. For the purposes of this Directive, the GLP, is described in Directive 87/18/EEC.

3. This Directive is not concerned with the interpretation and evaluation of test results.

Article 2

1. Using the procedure laid down in Article 3, Member States shall verify the compliance with GLP of any testing laboratory within their territory claiming to use GLP in the conduct of tests on chemicals.

2. Where the provisions of paragraph 1 have been complied with, and the results of the inspection and verification are satisfactory, the Member State in question may provide endorsement of a claim by a laboratory that it and the tests that it carries out comply with GLP, using the formula 'Assessment of conformity with GLP according to Directive 88/320/EEC on … (date)'.

Article 3

1. Member States shall designate the authorities responsible for the inspection of laboratories within their territories and for the audit of studies carried out by laboratories to assess compliance with GLP.

2. The authorities referred to in paragraph 1 shall inspect the laboratory and audit the studies in accordance with the provisions laid down in the Annex.

Article 4

1. Each year, Member States shall draw up a report relating to the implementation of GLP within their territory.

This report shall contain a list of laboratories inspected, the date on which such inspection was carried out and a brief summary of the conclusions of the inspections.

2. The reports shall be forwarded to the Commission each year, not later than 31 March. The Commission shall communicate them to the committee referred to in Article 7. The committee may request information in addition to those elements mentioned in paragraph 1.

3. Member States shall ensure that commercially sensitive and other confidential information to which they gain access as a result of GLP compliance monitoring activities is made available only to the Commis-

([1]) OJ No 196, 16. 8. 1967, p. 1/67.
([2]) OJ No L 239, 21. 8. 1987, p. 1.

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sion, to national regulatory and designated authorities and to a laboratory or study sponsor directly concerned with a particular inspection or study audit.

4. The names of laboratories subject to inspection by a designated authority, their GLP compliance status and the dates upon which laboratory inspections or study audits have been conducted shall not be considered to be confidential.

Article 5

1. Without prejudice to Article 6, the results of laboratory inspections and study audits on GLP compliance carried out by a Member State shall be binding on the other Member States.

2. Where a Member State considers that a laboratory within its territory claiming GLP compliance does not in fact comply with GLP to the extent that the integrity or authenticity of the studies it performs might be compromised, it shall forthwith inform the Commission. The Commission shall inform the other Member States.

Article 6

1. Where a Member State has sufficient reason to believe that a laboratory in another Member State claiming GLP compliance has not carried out a test according to GLP, it may request further information from that Member State and in particular may request a study audit, possibly in conjunction with a new inspection.

Should it not be possible for the Member States concerned to reach agreement, the Member States in question shall immediately inform the other Member States and the Commission, giving reasons for their decision.

2. The Commission shall examine as soon as possible the reasons put forward by the Member States within the Committee; it shall then take the appropriate measures in accordance with procedure laid down in Article 8. It may in this connection ask for expert opinions from the designated authorities in the Member States.

3. If the Commission considers that amendments to this Directive are necessary in order to resolve the matters to in paragraph 1, it shall initiate the procedure laid down in Article 8 with a view to adopting those amendments.

Article 7

1. The committee set up by Article 20 of Directive 67/548/EEC, hereinafter called 'the Committee', may examine any question which is referred to it by its chairman either on his own initiative or at the request of a representative of a Member State, concerning the implementation of this Directive and in particular regarding:

— cooperation between the authorities designated by the Member States in technical and administrative matters arising from the implementation of GLP, and

— the exchange of information on the training of inspectors.

2. The amendments necessary for the adaptation of the formula referred to in Article 2 (2) and of the Annex to this Directive to take account of technical progress shall be adopted in accordance with the procedure set out in Article 8.

Article 8

1. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the

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Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

2. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

3. If within three months of submission of the proposal the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 9

Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive not later than 1 January 1989. They shall forthwith inform the Commission thereof.

Article 10

This Directive is addressed to the Member States.

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ANNEX

Programme for the inspection of laboratories and audit of studies

The provisions concerning the inspection of laboratories and audit of studies are those contained in Annexes 4 (Guide for Compliance of Monitoring Procedures for Good Laboratory Practice) and 6 (Guidance for the Conduct of Laboratory Inspections and Study Audits) of the final report of the Working Party of the OECD Environment Committee on the mutual of recognition of compliance with GLP (OECD ENV/CHEM/CM/87.7).