

Directive 2004/9/EC of the European Parliament and of the Council
of 11 February 2004 on the inspection and verification of good
laboratory practice (GLP) (Codified version) (Text with EEA relevance)

DIRECTIVE 2004/9/EC OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

of 11 February 2004

on the inspection and verification of good laboratory practice (GLP)

(Codified version)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽²⁾,

Whereas:

- (1) Council Directive 88/320/EEC of 7 June 1988 on the inspection and verification of Good Laboratory Practice (GLP)⁽³⁾ has been significantly amended several times. In the interests of clarity and rationality the said Directive should be codified.
- (2) The application of standardised organisational 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.
- (3) In Annex 2 to its Decision of 12 May 1981 on the mutual acceptance of data in the assessment of chemicals, the Council of the Organisation for Economic Cooperation and Development (OECD) adopted principles of good laboratory practice which are accepted within the Community and are specified in the European Parliament and Council Directive 2004/10/EC of 11 February 2004 on the harmonisation 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⁾.
- (4) 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.

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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⁾. Mutual recognition of the results of tests obtained using standard and recognised methods is an essential condition for reducing the number of experiments in this area.

- (5) However, in order to ensure that test data generated by laboratories in one Member State are also recognised by other Member States, it is necessary to provide for a harmonised system for study audit and inspection of laboratories to ensure that they are working under GLP conditions.
- (6) Member States should designate the authorities responsible for carrying out monitoring on compliance with GLP.
- (7) 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 through the mutual recognition by Member States of procedures for monitoring compliance with GLP. 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⁽⁶⁾ should be used for this purpose.
- (8) That 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.
- (9) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁷⁾.
- (10) This Directive should be without prejudice to the obligations of the Member States concerning the time-limits for transposition of the Directives set out in Annex II, Part B,

HAVE ADOPTED THIS DIRECTIVE:

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- (1) [OJ C 85, 8.4.2003, p. 137.](#)
- (2) Opinion of the European Parliament of 1 July 2003 (not yet published in the Official Journal) and Decision of the Council of 20 January 2004.
- (3) [OJ L 145, 11.6.1988, p.35.](#) Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1.](#)).
- (4) See page 44 of this Official Journal.
- (5) [OJ L 358, 18.12.1986, p. 1.](#)
- (6) [OJ 196, 16.8.1967, p. 1.](#) Directive as last amended by Council Regulation (EC) No 807/2003 ([OJ L 122, 16.5.2003, p. 36.](#)).
- (7) [OJ L 184, 17.7.1999, p. 23.](#)