

Directive 2004/10/EC of the European Parliament and of the Council 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 (codified version) (Text with EEA relevance)

DIRECTIVE 2004/10/EC OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

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 (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 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of principles of good laboratory practice and the verification of their applications for tests on chemical substances⁽³⁾ has been significantly amended. In the interests of clarity and rationality the said Directive should be codified.
- (2) 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⁽⁴⁾ requires tests to be carried out on chemical substances in order to enable their potential risk to man and the environment to be determined.
- (3) When the active substances in pesticides undergo tests they should do so in accordance with Directive 67/548/EEC.
- (4) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products⁽⁵⁾ and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁽⁶⁾ lay down that non-clinical tests on pharmaceutical products are to be carried out in accordance with the

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principles of good laboratory practice (GLP) in force in the Community for chemical substances, compliance with which is also required by other Community legislation.

- (5) The methods to be used for these tests are laid down in Annex V to Directive 67/548/EEC.
- (6) It is necessary to comply with the principles of GLP in carrying out the tests laid down by Directive 67/548/EEC so as to ensure that the results are comparable and of high quality.
- (7) The resources devoted to the tests should not be wasted by having to repeat tests owing to differences in laboratory practice from one Member State to another.
- (8) The Council of the Organisation for Economic Cooperation and Development (OECD) took a Decision on 12 May 1981 on the mutual acceptance of data for the evaluation of chemical products. It issued a recommendation on 26 July 1983 concerning the mutual recognition of compliance with GLP. The principles of GLP have been modified by OECD Council Decision (C(97) 186 (final)).
- (9) Animal protection requires that the number of experiments conducted on animals be restricted. 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.
- (10) It is necessary to set up a procedure allowing rapid adaptation of the principles of GLP.
- (11) 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. 138.](#)
- (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 15, 17.1.1987, p. 29.](#) Directive as amended by Commission Directive 1999/11/EC ([OJ L 77, 23.3.1999, p. 8.](#))
- (4) [OJ 196, 16.8.1967, p. 1.](#) Directive as last amended by Regulation (EC) No 807/2003 ([OJ L 122, 16.5.2003, p. 36.](#))
- (5) [OJ L 311, 28.11.2001, p. 1.](#)
- (6) [OJ L 311, 28.11.2001, p. 67.](#) Directive as amended by Commission Directive 2003/63/EC ([OJ L 159, 27.6.2003, p. 46.](#))