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)

Article 1

1 This Directive shall apply to the inspection and verification of the organisational 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, 'good laboratory practice' (GLP), shall mean laboratory practice conducted in accordance with the principles set out in Directive 2004/10/EC.

3 This Directive does not concern 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 2004/9/EC 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 Annex I.

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(1). The Committee may request information in addition to those elements mentioned in paragraph 1 of this Article.

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 Commission, 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 in accordance with 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 referred to in Article 7(1); it shall then take the appropriate measures in accordance with procedure referred to in Article 7(2). It may in this connection ask for expert opinions from the designated authorities in the Member States.

[F1 3 If the Commission considers that amendments to this Directive are necessary in order to resolve the matters referred to in paragraph 1, it shall adopt those amendments.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

***[**F1 Article 7*

1 The Commission shall be assisted by the Committee established by Article 29(1) of Council Directive 67/548/EEC[(1)], hereinafter ‘the Committee’.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

Article 8

1 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.

[F1 2 The Commission shall adopt implementing measures for the following:

a the adaptation of the formula referred to in Article 2(2);

b the adaptation of Annex I to take account of technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

Article 9

Directive 88/320/EEC is hereby repealed, without prejudice to the obligations of the Member States concerning the time limits for transposition of the said Directives as set out in Annex II, Part B.

References made to the repealed Directive shall be construed as being made to this Directive and shall be read in accordance with the correlation table in Annex III.

Article 10

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 11

This Directive is addressed to the Member States.

(1) **[**[F1]OJ 196, 16.8.1967, p. 1.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.