
STATUTORY INSTRUMENTS

2004 No. 994

**The Good Laboratory Practice (Codification
Amendments Etc.) Regulations 2004**

Amendment of the Good Laboratory Practice Regulations 1999

2. The Good Laboratory Practice Regulations 1999⁽¹⁾ are amended as follows:—
- (a) in regulation 2 (interpretation), in paragraph (1)—
 - (i) for the definition of “principles of good laboratory practice” there is substituted the following definition—

““principles of good laboratory practice” means—

 - (a) the principles of good laboratory practice set out in Schedule 1, which are based on the Good Laboratory Practice Principles set out in Section II of Annex I to the European Parliament and Council Directive [2004/10/EC](#)⁽²⁾ 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; read with
 - (b) the revised guidance for the conduct of test facility inspections and study audits set out in Schedule 2, which is based on part of the Revised Guidance for the Conduct of Test Facility Inspections and Study Audits in Annex I to the European Parliament and Council Directive [2004/9/EC](#)⁽³⁾ on the inspection and verification of good laboratory practice;”;
 - (ii) in the definition of “regulatory studies”, at the start of paragraph (c) there is inserted “in respect of which”;
 - (b) in regulation 5 (prospective membership of the United Kingdom good laboratory practice compliance programme), in paragraph (4) the word “that” is omitted;
 - (c) in regulation 9 (powers of entry etc.), in paragraph (6) for “the Annex to Council Directive [88/320/EEC](#) on the inspection and verification of good laboratory practice (GLP), as amended by Commission Directive [1999/12/EC](#) adapting to technical progress for the second time the annex to Council Directive [88/320/EEC](#)” there is substituted “Annex I to the European Parliament and Council Directive [2004/9/EC](#)”;
 - (d) in Schedule 1 (good laboratory practice principles), in the heading for “(BASED ON SECTION II OF THE ANNEX TO COUNCIL DIRECTIVE [87/18/EEC](#), AS AMENDED BY COMMISSION DIRECTIVE [1999/11/EC](#))” there is substituted “(BASED ON SECTION II OF ANNEX I TO THE EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE [2004/10/EC](#))”;
 - (e) in Schedule 2 (revised guidance for the conduct of test facility inspections and study audits), in the heading for “(BASED ON PART OF PART B OF THE ANNEX TO

⁽¹⁾ S.I.1999/3106.

⁽²⁾ OJNo. L50, 20.2.2004, p.44.

⁽³⁾ OJ No. L50, 20.2.2004, p.28.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

COUNCIL DIRECTIVE [88/320/EEC](#), AS AMENDED BY COMMISSION DIRECTIVE [1999/12/EC](#)” there is substituted “(BASED ON PART OF PART B OF ANNEX I TO THE EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE [2004/9/EC](#))”.