EXPLANATORY NOTE

(This note is not part of the Regulations)
These Regulations contain the legislative measures necessary for the implementation within the United Kingdom of Council Directive 87/18/EEC 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, as amended by Commission Directive 1999/11/EC adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC, and for the implementation of 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 a second time the Annex to Council Directive 88/320/EEC.
Regulation 2 is an interpretation provision. Amongst other definitions, there is a definition of the principles of good laboratory practice, a concept which is defined with reference to the principles set out in Schedule 1 to the Regulations and the operating procedures set out in Schedule 2.
Regulation 3 sets out the arrangements for enforcing compliance with the Regulations by the good laboratory practice monitoring authority (“GLPMA").
Regulation 4 contains a requirement that regulatory studies must only be conducted at test facilities which are part of the United Kingdom good laboratory practice compliance programme.
Regulation 5 deals with prospective membership of the programme by test facility operators in respect of particular test facility premises, and Regulation 6 deals with full membership of the programme.
Regulation 7 contains a requirement that regulatory studies shall be conducted in accordance with the principles of good laboratory practice. Where there are serious deviations from the principles, there is a procedure for serving warning notices on test facility operators requiring them to ensure that the serious deviation will not recur. Breach of such a notice is an offence, although there is an appeals procedure contained in Regulation 8, if an operator of a test facility is aggrieved by a decision to serve a warning notice on him.
Regulation 9 contains the powers to enable persons duly appointed by the GLPMA to enforce compliance with the provisions of the Regulations, including powers of entry. Regulation 10 contains rules relating to the disclosure of commercially sensitive or other confidential information which may come to light as a result of enforcement action taken under the Regulations. Impeding the work of a person duly appointed by the GLPMA who is acting in pursuance of any of his functions under the Regulations is made an offence under Regulation 11.
Regulation 12 contains offences relating to the production and supply to regulatory authorities of false good laboratory practice instruments. Regulation 13 relates to offences committed with the consent or connivance, or attributable to, bodies corporate or Scottish partnerships, and Regulation 14 is a general defence of due diligence in relation to any of the offences under the Regulations.
Regulation 15 is a penalties provision, and Regulation 16 gives the GLPMA powers to charge fees for inspections and services under the Regulations. Regulation 17 revokes the Good Laboratory Practice Regulations 1997.
A Regulatory Impact Assessment in relation to these Regulations has been prepared and copies may be obtained from the GLPMA, Room 1808, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. A copy has also been placed in the library of each of the Houses of Parliament.

Changes to legislation:
There are currently no known outstanding effects for the The Good Laboratory Practice Regulations 1999.