STATUTORY INSTRUMENTS

2004 No. 994

HEALTH AND SAFETY

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

Made - - - -	*30th March 2004*
Laid before Parliament	*6th April 2004*
Coming into force - -	*27th April 2004*

The Secretary of State, being a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act(**2**) in relation to measures relating to good laboratory practice, in exercise of the powers conferred by the said section 2(2)(**3**), and of all other powers enabling him in that behalf, hereby makes the following Regulations—

Citation and commencement

1. These Regulations may be cited as the Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 and shall come into force on 27th April 2004.

Amendment of the Good Laboratory Practice Regulations 1999

2. The Good Laboratory Practice Regulations 1999(**4**) 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/

(**1**) S.I.1999/2788.
(**2**) 1972 c. 68.
(**3**) Measures relating to good laboratory practice are not a reserved matter under the Scotland Act 1998 (c. 46). Therefore, as regards Scotland, see section 57(1) of the 1998 Act which provides that despite the transfer to the Scottish Ministers by virtue of section 53 of that Act of functions in relation to observing and implementing Community law, any function of a Minister of the Crown in relation to any matter (including, therefore, in relation to measures relating to good laboratory practice) shall continue to be exercisable by him as regards Scotland for the purposes specified in section 2(2) of the European Communities Act 1972.
(**4**) S.I. 1999/3106.

EC(**5**) 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(**6**) 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 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)".

Amendment of the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003

3. In Schedule 1 (funded operations) of the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(**7**) for "Council Directive 87/18/EEC of 18th December 1986 as amended and Council Directive 88/320/EEC of 9th June 1988 as amended" there is substituted "the European Parliament and Council Directive 2004/10/EC of 11th February 2004 and the European Parliament and Council Directive 2004/9/EC of 11th February 2004".

Amendment of the Cosmetic Products (Safety) Regulations 2003

4. In regulation 9 (product information) of the Cosmetic Products (Safety) Regulations 2003(**8**), in paragraph (2) for "Article 1 of Council Directive 87/18/EEC" there is substituted "Article 1 of the European Parliament and Council Directive 2004/10/EC".

(**5**) OJNo. L50, 20.2.2004, p.44.
(**6**) OJ No. L50, 20.2.2004, p.28.
(**7**) S.I. 2003/1076.
(**8**) S.I. 2003/835.

Amendment of the Notification of New Substances Regulations 1993

5. In regulation 2 (interpretation) of the Notification of New Substances Regulations 1993(**9**), in paragraph (1) in the definition of "principles of good laboratory practice" for "the Good Laboratory Practice Regulations 1997" there is substituted "the Good Laboratory Practice Regulations 1999".

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health

30th March 2004

(**9**) S.I. 1993/3050; amended by S.I. 1994/3247, 1995/2646, 1997/654 and 2971, 1999/3232, 2001/1055 and 2002/2176.

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations make consequential amendments to the references in the Good Laboratory Practice Regulations 1999, the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 and the Cosmetic Products (Safety) Regulations 2003 following the adoption of the European Parliament and Council Directives 2004/9/EC and 2004/10/EC. Those Codification Directives repealed and re-enacted Council Directive 87/18/EEC as amended by Commission Directive 1999/11/EC and Council Directive 88/320/EEC as amended by Commission Directive 1999/12/EC.

The Notification of New Substances Regulations 1993 are amended to update the definition of the "principles of good laboratory practice".

In addition these Regulations amend the Good Laboratory Practice Regulations 1999 definition of "regulatory study" to improve the clarity of the wording of the definition and make a minor amendment to Regulation 5(4) to correct a drafting error.

A Transposition Note in respect of Directives 2004/9/EC and 2004/10/EC has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines and Healthcare products Regulatory Agency, Room 16-107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. These Regulations do not impose any cost on business.