

S.I. No. 294 of 1999.

EUROPEAN COMMUNITIES (GOOD LABORATORY PRACTICE) (AMENDMENT)
REGULATIONS, 1999.

I. MARY HARNEY, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Commission Directive 1999/11/EC of 8 March 19991, and Commission Directive 1999/12/EC of 8 March 19992, hereby make the following regulations:

2 O.J. No. L77, 23.3.99, p.22.

1 O.J. No. L77, 23.3.99, p. 8.

1. These Regulations may be cited as the European Communities (Good Laboratory Practice) (Amendment) Regulations, 1999.

2. Regulation 1(2) of the European Communities (Good Laboratory Practice) Regulations, 1991 (S.I. No. 4 of 1991), is hereby amended by the substitution for—

(a) the definition of "the Board" of the following definition:

" 'the Board' means the National Accreditation Board;"

(b) the definition of "the Directive of 1986" of the following definition:

" 'the Directive of 1986' means Council Directive 87/18/EEC of 18 December 19863 as amended by Commission Directive 1999/11/EC of 8 March 19991;"

1 O.J. No. L77, 23.3.99, p. 8.

3 O.J. No. L15, 17.1.87, p.29.

(c) the definition of "the Directive of 1988" of the following definition:

" 'the Directive of 1988' means Council Directive 88/320/EEC of 9 June 19884 as amended by Commission Directive 90/18/EEC of 18 December 19895 and Commission Directive 1999/12/EC of 8 March 19992;" and

2 O.J. No. L77, 23.3.99, p.22.

5 O.J. No. L11, 13.1.90, p. 37.

4 O.J. No. L145, 11.6.88, p. 35.

(d) the definition of "the principle of good laboratory practice" of the following definition:
" 'the principles of good laboratory practice' means the principles of good laboratory practice as laid down in the Annex to the Directive of 1986.".

GIVEN under my Official Seal, this 17th day of September, 1999.

MARY HARNEY,

Minister for Enterprise, Trade and Employment.

EXPLANATORY NOTE.

(This note is not part of the Regulations and does not purport to be a legal interpretation.)

The European Communities (Good Laboratory Practice) Regulations, 1991 (S.I. No. 4 of 1991) implemented in Ireland the provisions of a number of European Directives which require that any test facilities carrying out tests on chemical products shall comply with the OECD Principles of Good Laboratory Practice.

The purpose of the present Regulations is to amend the 1991 Regulations to give legal effect to Commission Directives:

(a) 1999/11/EC adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC (S.I. No. 4 of 1991) and the verification of their applications for tests on chemical substances.

(b) 1999/12/EC adapting to technical progress the Annex to Council Directive 88/320/EEC (S.I. No. 4 of 1991) on the inspection and verification of good laboratory practice.

The Regulations also take account of the change of name of the Irish Laboratory Accreditation Board to the National Accreditation Board.

These Regulations should be read together with the relevant Council Directives.