S.I. No. 4 of 1991.

EUROPEAN COMMUNITIES (GOOD LABORATORY PRACTICE) REGULATIONS, 1991.

I, DESMOND O'MALLEY, Minister for Industry and Commerce, 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 Council Directive 87/18/EEC(1) of 18 December, 1986, Council Directive 88/320/EEC(2) of 9 June, 1988 and Commission Directive 90/18/EEC (3) of 18 December, 1988, hereby make the following Regulations:

1. (1) These Regulations may be cited as the European Communities (Good Laboratory Practice) Regulations, 1991.

(2) In these Regulations—

"the Board" means the Irish Laboratory Accreditation Board;

"the Directive of 1986" means Council Directive 87/18/EEC of 18 December, 1986;

"the Directive of 1988" means Council Directive 88/320/EEC of 9 June, 1988 as amended by Commission Directive 90/18/EEC of 18 December, 1989;

"The Minister" means the Minister for Industry and Commerce;

"the principles of good laboratory practice" means the principles of good laboratory practice specified in Annex 2 to the Decision (as amended) of 12 May, 1981 of the Council of the Organisation for Economic Cooperation and Development on the mutual acceptance of data for the evaluation of chemical products.

2. (1) Laboratories carrying out tests on chemical products in accordance with Council Directive 67/548/EEC(4) or any other Community provision shall comply with the principles of good laboratory practice.

(4) O.J. No. 196, 16.8.67.

(1) O.J. No. L 15/29, 17.1.1987.

(2) O.J. No. L 145/35, 11.6.1988.

(3) O.J, No. L 11 13.1.1990.

(2) In paragraph (1) of this Regulation "any other Community provision" means any other Community provision providing for the application of the principles of good laboratory practice in respect of tests on chemical products to evaluate their safety for man or the environment or both.

(3) Where there is a contravention of this Regulation by a laboratory, the owner and the person in charge of the laboratory shall be guilty of an offence.

3. (1) Where a laboratory has carried out a test in accordance with Regulation 2 of these Regulations, it shall give a notice in writing to the person who commissioned the test and to the Board stating that the test has been carried out in conformity with the principles of good laboratory practice.

(2) Where there is a contravention of this Regulation by a laboratory or a laboratory, in purported compliance therewith, gives a notice in writing to the person who commissioned the test or to the Board that is false or misleading in a material particular, the owner and the person in charge of the laboratory shall be guilty of an offence.

4. (1) For the purpose of assessing compliance with Regulations 2 and 3 of these Regulations, the Board shall inspect laboratories and audit studies carried out by laboratories.

(2) The inspection and audits shall be carried out in accordance with the provisions referred to in the Annex to the Directive of 1988 and shall be directed 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 and animal feed additives, pesticides) in order to assess the effect of such products on man, animals and the environment.

(3) The Board may, for the purposes of its functions under these Regulations, request a laboratory to furnish it with a copy of any report of the laboratory of, or in connection with, a study made by the laboratory in relation to a chemical.

(4)O.J. No. 196, 16.8.67.

(4) The Board shall communicate to the laboratory concerned the results of any inspection or audits of studies referred to in paragraph (1) of this Regulation and, in making any decision consequent upon those results, the Board shall take into account any representations made to it by the laboratory in relation to the results not later than 28 days after the day on which they were communicated to the laboratory.

(5) (a) The Board may, in respect of an inspection of a laboratory or of an audit of a study carried out by a laboratory, charge the laboratory, and the laboratory shall pay to the Board, a fee of such amount as the Board considers to be equal to the amount of the costs incurred by it in relation to the inspection.

(b) A fee payable to the Board under this Regulation may be recovered by it from the laboratory concerned as a simple contract debt in any court of competent jurisdiction.
(c) The Public Offices Fees Act, 1879, shall not apply to a fee payable under this Regulation.
(6) If a laboratory fails or refuses to comply with a request under paragraph (3) of this Regulation, the owner and the person in charge of the laboratory shall be guilty of an offence.

5. (1) In this Regulation "authorised person" means—

(a) an officer of the Minister authorised in writing by the Minister, or
(b) an officer of the Board or other person authorised in writing by the chief executive officer of the Board,
to exercise for the purpose of these Regulations, the Directive of 1986 and the Directive of 1988 the powers conferred on an authorised person by these Regulations.

(2) An authorised person may, for the purposes of these Regulations, on production, if so requested by any person affected, of his authorisation—

(a) enter any premises which he reasonably believes to be a laboratory in which tests referred to in Regulation 2 of these Regulations are carried out,
(b) carry out on the premises or elsewhere such inspections, examinations, tests and analyses (including the inspections and study checks referred to in Article 3 of the Directive of 1986) as he considers necessary,

(c) inspect and take copies of, or of extracts from, any books, records or other documents found on the premises.
(d) take, without payment, samples of any substances found on the premises,
(e) request any person found on the premises to furnish them with such information as they may reasonably require for the purposes of these Regulations.
(3) A person who obstructs or impedes an authorised person in the exercise of a power or, without reasonable excuse, does not comply with a request under this Regulation or who, in purported compliance with such a request, gives information to an authorised person that he knows to be false or misleading in a material particular, shall be guilty of an offence.

6. (1) A person who has gained access to commercially sensitive or other confidential information by virtue of these Regulations shall not disclose the information to a person (other than the Commission of the European Communities or the Board) unless it is necessary to do so for the purpose of the enforcement of these Regulations.

(2) A person who contravenes this Regulation shall be guilty of an offence.

7. (1) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,000 or imprisonment for a term not exceeding 6 months or both.

(2) An offence under these Regulations may be prosecuted by the Minister.

(3) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in such capacity, that person shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against and punished as if he were guilty of the first-mentioned offence.

GIVEN under my Official Seal, this 7th day of January, 1991.

DESMOND O'MALLEY,

Minister for Industry and Commerce.

EXPLANATORY NOTE.

The purpose of these Regulations is to give effect to Council Directives

(a) 87/18/EEC on the harmonisation of laws, regulations and administrative provisions of Member States relating to the application of the principles of good laboratory practice and verification of their applications for tests on chemical substances.

(b) 88/320/EEC and amending Commission Directive 90/18/EEC on the inspection and verification of Good Laboratory Practice (GLP).

These Regulations require the carrying out of laboratory tests in accordance with GLP in compliance with the Directives and designate the Irish Laboratory Accreditation Board as the Competent Authority for verifying compliance for the purposes of these Directives.

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