STATUTORY INSTRUMENTS.

S.I. No. 18 of 2020

EUROPEAN COMMUNITIES (GOOD LABORATORY PRACTICE) REGULATIONS, 2020

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I, Heather Humphreys, Minister for Business, Enterprise and Innovation, in the 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 Directive 2004/9/EC[1] and Directive 2004/10/EC[2], both of the European Parliament and of the Council of 11 February 2004, hereby make the following Regulations:

1. These Regulations may be cited as the European Communities (Good Laboratory Practice) Regulations, 2020.

2. In these Regulations—

"Accreditation Board" means the Irish National Accreditation Board, a committee of the Authority under section 56A (1) of the Act of 2005, (inserted by section 32 of the Industrial Development (Forfás Dissolution) Act 2014 (Number 13 of 2014));

"Act of 2005" means the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005);

"authorised person" means an officer of the Accreditation Board or other person authorised in writing by the Manager of the Accreditation Board on behalf of the Authority to exercise for the purpose of these Regulations, Directive 2004/10/EC and Directive 2004/9/EC, the powers conferred on an authorised person by these Regulations;

"Authority" means the Health and Safety Authority;

"Directive 2004/9/EC" means Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (codified version);

"Directive 2004/10/EC" means Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions

[1] OJ No. L 050, 20/02/2004, p28 – 43.
[2] OJ No. L 050, 20/02/2004, p44 – 59.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 28*th January*, 2020.

relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version);

"Manager of the Accreditation Board" shall be construed in accordance with section 56A (6) of the Act of 2005;

"The Minister" means the Minister for Business, Enterprise and Innovation;

"the principles of good laboratory practice" means the principles of good laboratory practice laid down in Annex I to Directive 2004/10/EC.

3. (1) Laboratories carrying out tests and/or studies on chemical products in accordance with Regulation (EC) No 1272/2008[3] or any other Community provision shall comply with the principles of good laboratory practice.

(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 and/or studies on chemical products to evaluate their safety for humans or the environment or both.

(3) If the Accreditation Board has reasonable grounds for believing that there is a contravention of this Regulation by a laboratory it may serve a notice on the owner and/or person in charge of the laboratory (referred to in these Regulations as a "Regulation 3 warning notice"):

(i) identifying the alleged contravention;

(ii) specifying the measures required to correct the alleged contravention; and

(iii) requiring the owner and/or person in charge of the laboratory to take those measures or measures which are at least equivalent to them, within such period as may be specified in the warning notice.

(4) Service of a Regulation 3 warning notice shall be effected in accordance with section 3 of the Act of 2005.

(5) Any owner and/or person in charge of a laboratory who fails to comply with a Regulation 3 warning notice shall be guilty of an offence.

[3] OJ No. L 353, 31/12/2008, p1 - 1355

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

(2) Where a laboratory fails to give the confirmation referred to in paragraph (1) of this Regulation, the Accreditation Board may serve upon the owner and/or person in charge of the laboratory a notice (referred to in these Regulations as a "Regulation 4 warning notice") requiring the laboratory to give such confirmation within such period as may be specified within the notice.

(3) Service of a Regulation 4 warning notice shall be effected in accordance with section 3 of the Act of 2005.

(4) Where a laboratory fails to comply with a Regulation 4 warning notice, the owner and/or person in charge of the laboratory shall be guilty of an offence.

(5) Where a laboratory gives confirmation in purported compliance with paragraph 1 of this Regulation that is false or misleading in a material particular, the owner and/or the person in charge of the laboratory shall be guilty of an offence.

(6) Where a laboratory gives confirmation in purported compliance with paragraph (1) of this Regulation that is false or misleading with the intention that it shall be used to induce the regulatory authority of any EU member state charged with the oversight and enforcement of good laboratory practice to accept the confirmation as evidence of compliance with good laboratory practice by the laboratory the owner and/or the person in charge of the laboratory shall be guilty of an offence.

5. (1) For the purpose of assessing compliance with Regulations 3 and 4 of these Regulations, the Accreditation Board shall have the right to and shall inspect laboratories and audit tests and/or studies carried out by laboratories.

(2) The inspections and audits shall be carried out in accordance with the provisions of Annex I to Directive 2004/9/EC and shall be directed to the inspection and verification of the organisational processes and the conditions under which laboratory tests and/or studies are planned, performed, recorded and reported for the non-clinical testing and/or studying, 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 humans, animals and the environment.

(3) The Accreditation Board may, for the purposes of its functions under these Regulations, request a laboratory to furnish it with a copy of any report, document, data or record (in whatever form held) of the laboratory of, or in connection with, any test and/or study made by the laboratory in relation to a chemical substance, and the laboratory shall furnish the requested report, document, data or record within such time frame as the Accreditation Board

may specify or, in the absence of a specified time frame, within a reasonable period of time from the making of the request.

(4) The Accreditation Board shall communicate to the laboratory concerned the results of any inspection or audits of tests and/or studies referred to in paragraph (1) of this Regulation and, in making any decision consequent upon those results, the Accreditation 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 Authority, acting on behalf of the Accreditation Board may, in respect of an inspection of a laboratory or of an audit of a test and/or study carried out by a laboratory, charge the laboratory, and the laboratory shall pay to the Authority, a fee of such amount as the Accreditation Board considers to be equal to the amount of the costs incurred by it in relation to the inspection

(*b*) The fee shall be so charged in accordance with the provisions of section 47 of the Act of 2005 (amended by section 33 of the Industrial Development (Forfás Dissolution) Act 2014), and is payable to the Authority in accordance with the terms and conditions of the invoice issued by the Authority.

(*c*) Fees referred to in subparagraph (a) and (b) are payable in accordance with any terms or conditions stated on the invoice issued by the Authority.

(*d*) A fee payable to the Authority, acting on behalf of the Accreditation Board, under this Regulation may be recovered by it from the laboratory concerned as a simple contract debt in any court of competent jurisdiction.

(6) If a laboratory:

(*a*) obstructs, impedes or fails to co-operate with the Accreditation Board in the exercise by the Accreditation Board of any right conferred upon the Accreditation Board by this Regulation;

(*b*) fails or refuses to comply with a request under paragraph (3) of this Regulation; and/or

(*c*) knowingly or recklessly furnishes the Accreditation Board with information which is false or misleading in a material particular,

the owner and/or the person in charge of the laboratory shall be guilty of an offence.

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

(*a*) enter any premises which s/he reasonably believes to be a laboratory in which tests and/or studies referred to in Regulation 3 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 Articles I and III of Directive 2004/10/EC) as s/he considers necessary;

(*c*) request the production of, inspect and take copies of, or of extracts from, any documentation or records, either electronic or hard copy, found on the premises;

(*d*) take, without payment, samples of any substances found on the premises; and/or

(*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.

(2) 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.

7. (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 Accreditation 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.

8. It shall be a defence for a person charged with an offence under any of the preceding provisions of these Regulations to prove that s/he took all reasonable precautions and exercised all due diligence to avoid the commission of an offence.

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

(2) An offence under these Regulations may be brought and prosecuted by the Authority.

(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.

(4) For the purpose of this Regulation, a company within the meaning of the Companies Acts shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body of persons shall be deemed to be ordinarily resident at its principal office or place of business.

(5) Where a person is convicted of an offence under these Regulations in proceedings brought by the Authority, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority the costs and expenses, measured by the court, incurred by the Authority in relation to the investigation, detection and prosecution of the offence including—

(*a*) the costs and expenses incurred in taking samples;

(*b*) the carrying out of examinations, tests, inspections, analyses or checks; and

(*c*) the remuneration and expenses of consultants and advisors engaged by the Authority.

10. The European Communities (Good Laboratory Practice) Regulations 1991 (S.I. No. 4 of 1991) and the European Communities (Good Laboratory Practice) (Amendment) Regulations, 1999 (S.I. No. 294 of 1999) are hereby revoked.

L.S.

GIVEN under my Official Seal,
23 January, 2020.

HEATHER HUMPHREYS,
Minister for Business, Enterprise and Innovation.

EXPLANATORY NOTE

(*This note is not part of the Instrument 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. These were amended in 1999 by the European Communities (Good Laboratory Practice) (Amendment) Regulations, 1999 (S.I. No. 294 of 1999).

The purpose of these new Regulations is:

(i) to take account of the integration of the Irish National Accreditation Board (formerly a Committee of Forfás), in to the Health and Safety Authority (HSA), as a Committee thereof, with effect from 31st July 2014;

(ii) to clarify the powers of the Accreditation Board and the enforcement provisions available to the Accreditation Board; and

(iii) to revoke the above Regulations to reflect the codification of previous Good Laboratory Directives by –

(a) Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (codified version); and

(b) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 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 (codified version).

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