STATUTORY RULES OF NORTHERN IRELAND

2017 No. 90

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017

PART 2

OBLIGATIONS OF ECONOMIC OPERATORS

CHAPTER 1

MANUFACTURERS

Design and manufacture in accordance with essential health and safety requirements

5. Before placing a product on the market or using a product for their own purposes, a manufacturer shall ensure that it has been designed and manufactured in accordance with the essential health and safety requirements.

Technical documentation and conformity assessment

6. Before placing a product on the market or using it for their own purposes, a manufacturer shall—

(a) carry out the relevant conformity assessment procedure or have a relevant conformity assessment procedure carried out; and

(b) draw up the technical documentation referred to—

(i) for a product in respect of which the conformity assessment procedure in regulation 39(1)(a) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);

(ii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(b) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);

(iii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(c) is being carried out, in point 2 of Module A of Annex VIII to the ATEX Directive (as amended from time to time);

(iv) for a product in respect of which the conformity assessment procedure in regulation 39(1)(d) is being carried out, in point 2 of Module G of Annex IX to the ATEX Directive (as amended from time to time);

EU declaration of conformity and CE marking

7.—(1) Save for where a product is a component, where the conformity of a product with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer shall, before placing the product on the market—

(a) draw up a declaration of conformity in accordance with regulation 40 (EU declaration of conformity); and

(b) affix the CE marking in accordance with regulation 41 (CE marking).

(2) The manufacturer shall keep the EU declaration of conformity up-to-date.

(3) Where the conformity of a component with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer shall, before placing the component on the market, draw up a written attestation of conformity in accordance with regulation 39(3) (Conformity assessment procedures).

(4) Subject to paragraph (5), before placing a product on the market, the manufacturer shall ensure that each product is accompanied by a copy of the EU declaration of conformity or attestation of conformity as appropriate.

(5) Where a large number of products are delivered to a single user, the batch or consignment may be accompanied by a single copy of the EU declaration or attestation of conformity as appropriate.

(6) Where a product is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer shall draw up a single declaration of conformity, which—

(a) identifies the EU instruments; and

(b) includes references to the publication of those EU instruments in the Official Journal.

Retention of technical documentation and EU declaration of conformity

8. A manufacturer shall keep the technical documentation and the EU declaration of conformity (or where applicable, the attestation of conformity) drawn up in respect of a product for a period of 10 years beginning on the day on which the product is placed on the market.

Compliance procedures for series production

9.—(1) A manufacturer of a product which is manufactured by series production shall ensure that, before placing a product on the market, procedures are in place to ensure that any product so manufactured will be in conformity with Part 2.

(2) In doing so, the manufacturer shall take adequate account of—

(a) any change in the product design or characteristics; and

(b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity or attestation of conformity was drawn up.

Monitoring

10.—(1) When appropriate, with regard to the risks to the health and safety of end-users presented by a product, a manufacturer shall—

(a) carry out sample testing of a product manufactured by the manufacturer made available on the market;

(b) investigate complaints that a product manufactured by the manufacturer is not in conformity with Part 2; and

(c) keep distributors informed of any actions carried out under sub-paragraphs (a) and (b).

(2) A manufacturer shall keep a register of—

(a) complaints that a product is not in conformity with Part 2;

(b) products which are found not to be in conformity with Part 2; and

(c) product recalls.

(3) A manufacturer shall keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Labelling and packaging of products

11.—(1) Before placing a product on the market, a manufacturer shall ensure that it bears a type, batch, serial number or other element allowing its identification.

(2) If the size or nature of the product does not provide sufficient space for the labelling requirements in paragraph (1), the manufacturer shall ensure that the information is provided on the packaging or in a document accompanying the product.

Labelling and packaging of products, other than components

12. Save for where a product is a component, before placing a product on the market a manufacturer shall ensure that it—

(a) bears the specific marking of explosion protection as referred to at paragraph 5(1)(f) of Schedule 1; and

(b) where applicable, bears the other markings and information referred to at paragraph 5 of Schedule 1.

Information identifying manufacturer

13.—(1) Before placing a product on the market, a manufacturer shall indicate on the product—

(a) the name, registered trade name or registered trade mark of the manufacturer; and

(b) a postal address at which the manufacturer can be contacted.

(2) Where it is not possible to indicate the information specified in paragraph (1) on the product, the manufacturer shall indicate that information—

(a) on the product packaging; or

(b) in a document accompanying the product.

(3) The information specified in paragraph (1) shall be in a language which can be easily understood by end-users and the competent national authority in the Member State in which it is to be made available to such end-users.

Instructions and safety information

14.—(1) When placing a product on the market, a manufacturer shall ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users in the Member State in which it is to be made available on the market.

(2) The instructions and safety information referred to in paragraph (1) and any labelling shall be clear and understandable.

(3) Where the Member State referred to in paragraph (1) is the United Kingdom, the language referred to in that paragraph shall be English.

Duty to take action in respect of a product placed on the market which is considered not to be in conformity

15.—(1) A manufacturer who considers, or has reason to believe, that a product which the manufacturer has placed on the market is not in conformity with Part 2, shall immediately take the corrective measures necessary to—

(a) bring the product into conformity;

(b) withdraw the product; or

(c) recall the product.

(2) Where the product presents a risk , the manufacturer shall immediately inform the market surveillance authority, and the competent national authorities of any other Member State in which the manufacturer made the product available on the market, of the risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Provision of information and cooperation

16.—(1) A manufacturer shall, further to a reasoned request from the market surveillance authority, and within such period as the market surveillance authority may specify, provide the authority with the information and documentation necessary to demonstrate that the product is in conformity with Part 2—

(a) in paper or electronic form; and

(b) in a language which can be easily understood by the market surveillance authority.

(2) A manufacturer shall, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (Evaluation of products presenting a risk);

(b) eliminate the risks posed by a product which the manufacturer has placed on the market.

Authorised representatives

17.—(1) A manufacturer may, by written mandate, appoint a person established in the EU as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) A manufacturer who has appointed an authorised representative to perform, on the manufacturer's behalf, a task under these Regulations remains responsible for the proper performance of that task.

(3) The obligations laid down in regulation 5 (Design and manufacture in accordance with essential health and safety requirements) and regulation 6(b) (Technical documentation and conformity assessment) shall not form part of an authorised representative's mandate.

(4) The mandate shall allow the authorised representative to do at least the following in relation to a product covered by the mandate—

(a) perform the manufacturer's obligations under regulation 8 (Retention of technical documentation and EU declaration of conformity); and

(b) perform the manufacturer's obligations under regulation 16 (Provision of information and cooperation);

(5) An authorised representative shall comply with all duties imposed on the manufacturer in relation to each obligation under these Regulations that the authorised representative is appointed by the mandate to perform and, accordingly as far as those duties are concerned, as well as the penalties

for failure to comply with those duties, references in these Regulations (except in this regulation) to the manufacturer is to be taken as including a reference to the authorised representative.

CHAPTER 2

IMPORTERS

Prohibition on placing on the market products which are not in conformity

18. An importer shall not place a product on the market unless it is in conformity with the essential health and safety requirements.

Requirements which shall be satisfied before an importer places a product on the market

19.—(1) Before placing a product on the market, an importer shall ensure that—

(a) a relevant conformity assessment procedure has been carried out by the manufacturer;

(b) the manufacturer has drawn up the technical documentation;

(c) the product—

(i) bears the CE marking where applicable;

(ii) is accompanied by the EU declaration of conformity or the attestation of conformity as appropriate; and

(iii) is accompanied by the required documents; and

(d) the manufacturer has complied with the requirements set out in regulation 11 (Labelling and packaging of products), regulation 12 (Labelling and packaging of products, other than components) and regulation 13 (Information identifying manufacturer).

(2) In paragraph (1)(c)(iii), "required documents" means any documents that are required to be provided with a product pursuant to—

(a) regulation 11(2) (Labelling and packaging of products);

(b) regulation 13(2)(b) (Information identifying manufacturer);

(c) regulation 14(1) (Instructions and safety information).

Prohibition on placing on the market products considered not to be in conformity with the essential health and safety requirements

20.—(1) Where an importer considers, or has reason to believe, that a product is not in conformity with the essential health and safety requirements, the importer shall not place the product on the market.

(2) Where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authority of that risk.

Information identifying importer

21.—(1) Before placing a product on the market, an importer shall indicate on the product—

(a) the name, registered trade name or registered trade mark of the importer; and

(b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) shall be in a language which can be easily understood by end-users and by the competent national authority in the Member State in which it is to be made available to end-users.

(3) Where it is not possible to indicate the information specified in paragraph (1) on the product, the importer shall indicate that information—

(a) on the packaging; or

(b) in a document accompanying the product.

Instructions and safety information

22.—(1) When placing a product on the market, an importer shall ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users in the Member State in which the product is to be made available.

(2) Where the Member State referred to in paragraph (1) is the United Kingdom, the language referred to in that paragraph shall be English.

Storage and transport

23. Each importer shall ensure that, whilst a product is under that importer's responsibility, its storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements.

Monitoring

24.—(1) When deemed appropriate, with regard to the risks to the health and safety of end-users presented by a product, an importer shall—

(a) carry out sample testing of a product made available by the importer on the market;

(b) investigate complaints that a product placed on the market by the importer is not in conformity with Part 2; and

(c) keep distributors informed of actions carried out under sub-paragraphs (a) and (b).

(2) An importer shall keep a register of—

(a) complaints that a product is not in conformity with Part 2;

(b) products which are found not to be in conformity with Part 2; and

(c) product recalls.

(3) An importer shall keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Duty to take action in respect of a product placed on the market which is considered not to be in conformity

25.—(1) An importer who considers, or has reason to believe, that a product which the importer has placed on the market is not in conformity with Part 2 shall immediately take the corrective measures necessary to—

(a) bring the product into conformity;

(b) withdraw the product; or

(c) recall the product.

(2) Where the product presents a risk, the importer shall immediately inform the market surveillance authority, and the competent national authorities of any other Member State in which the importer made the product available on the market, of the risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Provision of information and cooperation

26.—(1) An importer shall, further to a reasoned request from the market surveillance authority and within such period as the market surveillance authority may specify, provide the authority with the information and documentation necessary to demonstrate that the product is in conformity with Part 2—

(a) in paper or electronic form; and

(b) in a language which can be easily understood by the market surveillance authority.

(2) An importer shall, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (Evaluation of a product presenting a risk);

(b) eliminate the risks posed by the product which the importer has placed on the market.

Retention of technical documentation and EU declaration of conformity

27. An importer shall, for a period of ten years beginning on the day on which the product was placed on the market, keep and, upon request, make available to the market surveillance authority—

(a) a copy of the EU declaration of conformity or, where applicable, the attestation of conformity; and

(b) the technical documentation.

CHAPTER 3

DISTRIBUTORS

Duty to act with due care

28. When making a product available on the market, a distributor shall act with due care to ensure that it is in conformity with Part 2.

Requirements which shall be satisfied before a distributor makes a product available on the market

29.—(1) Before making a product available on the market, the distributor shall verify that—

(a) the product—

(i) bears a CE marking where applicable;

(ii) is accompanied by the EU declaration of conformity or the attestation of conformity;

(iii) is accompanied by the required documents; and

(iv) is accompanied by instructions and safety information in a language which can be easily understood by end-users in the Member State in which the product is to be made available on the market;

(b) the manufacturer has complied with the requirements set out in regulation 11 (Labelling and packaging of products), regulation 12 (Labelling and packaging of products, other than components) and regulation 13 (Information identifying manufacturer); and

(c) the importer has complied with the requirements set out in regulation 21 (Information identifying importer).

(2) In paragraph (1)(a)(iii), "required documents" means the documents that the manufacturer or importer is required to provide with the product pursuant to—

(a) regulation 11(2) (Labelling and packaging of products);

(b) regulation 13(2)(b) (Information identifying manufacturer);

(c) regulation 21(3)(b) (Information identifying importer).

Storage and transport

30. Each distributor shall ensure that, whilst a product is under that distributor's responsibility, its storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements.

Prohibition on making available on the market where product not considered to be in conformity with safety objectives

31.—(1) Where a distributor considers, or has reason to believe, that a product is not in conformity with the essential health and safety requirements, the distributor shall not make the product available on the market.

(2) Where the product presents a risk, the distributor shall inform the following persons of the risk—

(a) the manufacturer or the importer; and

(b) the market surveillance authority.

Duty to take action in respect of products made available on the market which are not in conformity

32.—(1) A distributor who considers, or has reason to believe, that a product which the distributor has made available on the market is not in conformity with Part 2 shall make sure that the necessary corrective measures are taken to—

(a) bring that product into conformity;

(b) withdraw the product; or

(c) recall the product.

(2) Where the product presents a risk, the distributor shall immediately inform the market surveillance authority, and the competent national authorities of the other Member States in which the distributor has made the product available on the market, of that risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Provision of information and cooperation

33.—(1) A distributor shall, further to a reasoned request from the market surveillance authority and within such period as the authority may specify, provide the authority with the information and documentation, in paper or electronic form, necessary to demonstrate that the product is in conformity with Part 2.

(2) A distributor shall, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (Evaluation of a product presenting a risk);

(b) eliminate the risks posed by a product which the distributor has made available on the market.

CHAPTER 4

IMPORTERS AND DISTRIBUTORS

Cases in which obligations of manufacturers apply to importers and distributors

34. An economic operator ("A") who would, but for this regulation, be considered an importer or distributor, is to be considered a manufacturer for the purposes of these Regulations and is subject to the obligations of the manufacturer under this Part, where A—

(a) places a product on the market under A's own name or trademark; or

(b) modifies a product already placed on the market in such a way that it may affect whether the product is in conformity with Part 2.

CHAPTER 5

ALL ECONOMIC OPERATORS

Identification of economic operators

35.—(1) An economic operator ("E") who receives a request from the market surveillance authority before the end of the relevant period, shall, within such period as the authority may specify, identify to the authority—

(a) any economic operator who has supplied E with a product; and

(b) any economic operator to whom E has supplied a product.

(2) The relevant period is—

(a) for information under paragraph (1)(a), a period of 10 years beginning on the day on which E was supplied with the product;

(b) for information under paragraph (1)(b), a period of 10 years beginning on the day on which E supplied the product.

Prohibition on improper use of CE marking

36.—(1) An economic operator shall not affix the CE marking to a product unless—

(a) that economic operator is the manufacturer; and

(b) the conformity of the product with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator shall not affix to a product a marking (other than the CE marking) which purports to attest that the product is in conformity with the essential health and safety requirements.

(3) An economic operator shall not affix to a product a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking.

(4) An economic operator shall not affix to a product any other marking if the visibility, legibility and meaning of the CE marking would be impaired as a result.

Translation of declaration of conformity

37.—(1) Before making a product available on the market, an economic operator shall ensure that the EU declaration of conformity is prepared in, or translated into, the language required by the Member State in which it is to be made available on the market.

(2) Where the product is to be made available on the market in the United Kingdom, the language required is English.