STATUTORY INSTRUMENTS

2016 No. 1107

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016

PART 1

Preliminary

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 and come into force on 8th December 2016 ("the commencement date").

(2) These Regulations extend to England, Wales and Scotland.

Commencement Information

I1 Reg. 1 in force at 8.12.2016, see **reg. 1(1)**

Interpretation

2.—(1) In these Regulations—

the "1974 Act" means the Health and Safety at Work etc Act 1974(**1**);

the "1994 Directive" means Directive 94/9/EC of the European Parliament and of the Council on the approximation of the laws of the member States concerning equipment and protective systems intended for use in potentially explosive atmospheres(**2**)**[**F1(as it has effect immediately before IP completion day)**]**;

"the 1996 Regulations" means the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996(**3**);

[F2"approved body" has the meaning given to it in regulation 42;**]**

F3...

"ATEX Directive" means Directive 2014/34/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)(**4**);

"attestation of conformity" means a declaration of conformity required to be drawn up in accordance with regulation 7(3) (F4... declaration of conformity and **[**F5UK**]** Marking);

(**1**) 1974 c.37.
(**2**) OJ L 100, 19.4.1994, p.1.
(**3**) S.I. 1996/192; amended by S.I. 1998/81, S.I. 2001/3766, S.I. 2005/830, S.I. 2011/1043, S.I. 2012/1809, S.I. 2014/469 and S.I. 2014/3248.
(**4**) OJ L 96, 29.3.2014, p. 309.

"authorised representative" means a person appointed in accordance with regulation 17(1);

F6…

F7…

"component" means any item essential to the safe functioning of equipment and protective systems but with no autonomous function;

"conformity assessment" means the process demonstrating whether the essential health and safety requirements relating to a product have been fulfilled;

[F8"conformity assessment activities" means any activities connected with conformity assessment including calibration, testing, certification and inspection;**]**

"conformity assessment body" means a person that performs conformity assessment activities, including calibration, testing, certification and inspection;

[F9"conformity assessment procedure" means a procedure referred to in regulation 39 (conformity assessment procedures);**]**

[F9"declaration of conformity" means a declaration of conformity required to be drawn up in accordance with regulation 7(1)(a) (declaration of conformity and UK marking);**]**

[F9"designated standard" has the meaning given to it in regulation 2A;**]**

"distributor" means any person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

"economic operator" means a manufacturer, authorised representative, importer or distributor;

"equipment" means machines, apparatus, fixed or mobile devices, control components and their instrumentation and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy or the processing of material or both and which are capable of causing an explosion through their own potential sources of ignition;

[F10"equipment category" means the classification of equipment, within each equipment group, specified in Schedule 1A to these Regulations;**]**

"equipment-group I" means equipment intended for use in underground parts of mines, and in those parts of surface installations of such mines, liable to be endangered by firedamp or combustible dust or both, comprising equipment categories M 1 and M 2 **[**F11as set out in Schedule 1A to these Regulations**]**;

"equipment-group II" means equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising equipment categories 1, 2 and 3 **[**F12as set out in Schedule 1A to these Regulations**]**;

"essential health and safety requirements" means the requirements set out in Schedule 1 (essential health and safety requirements);

F13…

F14…

"explosive atmosphere" means a mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture;

F15…

[F16"importer" means a person who—

(a) is established in the United Kingdom and places a product from a country outside of the United Kingdom on the market; or

(b) is established in Northern Ireland and places a product on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;**]**

"intended use" means the use of a product prescribed by the manufacturer by assigning the equipment to a particular equipment-group and category or by providing all the information which is required for the safe functioning of a protective system, device or component;

"make available on the market" means any supply of a product for distribution, consumption or use on the **[**F17market of Great Britain**]** in the course of a commercial activity, whether in return for payment or free of charge, and related expressions are to be construed accordingly;

"manufacturer" means a person who—

(a) manufactures a product, or has a product designed or manufactured, and

(b) markets that product—

(i) under that person's name or trade mark, or

(ii) uses such product for that person's own purposes;

"market surveillance authority" has the meaning set out in regulation 51 (designation of market surveillance authority);

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F19...

F20...

"place on the market" means make a product available on the **[**F21market of Great Britain**]** for the first time, and related expressions are to be construed accordingly;

"potentially explosive atmosphere" means an atmosphere which could become explosive due to local and operational conditions;

"protective systems" means devices other than components of equipment which are intended to halt incipient explosions immediately or to limit the effective range of an explosion or both, and which are separately made available on the market for use as autonomous systems;

"putting into service" means the first use of a product by an end-user F22..., for the purposes for which it was intended, and related expressions are to be construed accordingly;

"RAMS" means Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93(**5**);

"recall" means taking any measure aimed at achieving the return of a product that has already been made available to the end-user and related expressions must be construed accordingly;

"relevant conformity assessment procedure" means a conformity assessment procedure referred to in regulation 39 (conformity assessment procedures);

"relevant economic operator" means, in relation to a product, an economic operator with obligations in respect of that product under Part 2;

"technical documentation" has the meaning given in regulation 6 (technical documentation and conformity assessment);

"technical specification" means a document that prescribes technical requirements to be fulfilled by a product;

[F23"UK marking" means the marking in the form set out in Annex 2 of RAMS;**]**

(**5**) OJ L 218, 13.8.2008, p. 30.

[[F23]"UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;**]**

"withdraw" when used in relation to a product, means taking any measure aimed at preventing a product in the supply chain from being made available on the market and related expressions must be construed accordingly.

[[F24](1A) Schedule 1A reproduces the provisions of Annex I to the ATEX Directive with amendments to correct deficiencies in retained EU law.

(1B) A reference to a provision of Schedule 1A is a reference to the equivalent provisions of Annex I to the ATEX Directive as set out in Schedule 1A.

(1C) Schedule 3A reproduces the provisions of Annexes III to IX to the ATEX Directive with amendments to correct deficiencies in retained EU law.

(1D) A reference to any provision of Schedule 3A is a reference to the equivalent provisions of Annex III to IX of the ATEX Directive.**]**

(2) In these Regulations, a reference to a product being "in conformity with Part 2" means that—

(a) the product is in conformity with the essential health and safety requirements; and

(b) each relevant economic operator has complied with the obligations imposed on them under Part 2 which must be satisfied at or before the time at which they make the product available on the market.

[F25](3) . . . . . .

(4) In regulations 10(1) and 24(1) (monitoring) and Schedule 1 (essential health and safety requirements), "risk" means a risk which could arise from lawful and readily predictable human behaviour.

(5) In the other provisions of these Regulations, "risk" means a risk—

(a) which could arise from lawful and readily predictable human behaviour, and

(b) which may result in harm to any of the following interests—

(i) health and safety of persons, in particular workers,

(ii) domestic animals, or

(iii) property.

[F26](6) . . . . . .

F1 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**, and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F4 Word in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(d)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F5 Word in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(d)(ii)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(f)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(g)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(h)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(j)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(k)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(l)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(m)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(n)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(o)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(p)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 17(2)); 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 2(2)(q) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(13)(a)**)

F18 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(r)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(s)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F20 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(t)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F21 Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 2(2)(u) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(13)(b)**)

F22 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(v)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F23 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(w)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F24 Reg. 2(1A)-(1D) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(3)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F25 Reg. 2(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(4)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F26 Reg. 2(6) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(5)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I2 Reg. 2 in force at 8.12.2016, see **reg. 1(1)**

[F27Designated standard

2A.—(1) Subject to paragraphs (6) and (7), in these Regulations a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body **[**F28or an international standardising body**]**, for repeated or continuous application, with which compliance is not compulsory; and

(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a product, service or system, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and

(ii) the requirements applicable to the product, service or system as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and

(b) production methods and processes relating to the product, where these have an effect on the characteristics of the product, service or system.

(3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—

(a) the European Committee for Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenelec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI).

[

F29(3A) In this regulation "international standardising body" has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).**]**

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with **[**[F30]such**]** technical specifications adopted by the other recognised standardisation bodies **[**[F31]or by international standardising bodies as the Secretary of State considers to be relevant.**]**

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) The Secretary of State may by regulations amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.

(9) Regulations made under paragraph (8) are to be made by statutory instrument.

(10) A statutory instrument containing regulations made under paragraph (8) is subject to annulment in pursuance of a resolution of either House of Parliament.**]**

F27 Reg. 2A inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 3** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in reg. 2A(1)(a) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(a)**; S.I. 2020/1662, reg. 2(ee)

F29 Reg. 2A(3A) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(b)**; S.I. 2020/1662, reg. 2(ee)

F30 Word in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(c)(i)**; S.I. 2020/1662, reg. 2(ee)

F31 Words in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(c)(ii)**; S.I. 2020/1662, reg. 2(ee)

Scope

3.—(1) These Regulations apply to products which—

(a) fall within the meaning of "product" in paragraph (2); and

(b) are not excluded by paragraph (3).

(2) A "product" means—

(a) equipment and protective systems intended for use in potentially explosive atmospheres;

(b) safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;

(c) components intended to be incorporated into equipment and protective systems referred to in sub-paragraph (a).

(3) The following products are excluded from the definition in paragraph (2)—

(a) medical devices intended for use in a medical environment;

(b) equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;

(c) equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas;

(d) personal protective equipment covered by Council Directive 89/686/EEC on the approximation of the laws of the member States relating to personal protective equipment(**6**);

(e) seagoing vessels and mobile offshore units together with equipment on board such vessels or units;

(f) means of transport (other than vehicles intended for use in a potentially explosive atmosphere), including vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks and means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water;

[F32(g) products connected with the production of trade in arms, munitions and war material;**]**

(h) products which have been placed on the market before the commencement date.

F32 Reg. 3(3)(g) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 4** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I3 Reg. 3 in force at 8.12.2016, see **reg. 1(1)**

Exceptions for trade fairs, exhibitions and demonstrations

4. The provisions of Part 2 (and of Part 5, so far as applying in relation to obligations under Part 2) do not apply to the showing of a product which is not in conformity with Part 2, at a trade fair, exhibition or demonstration, provided that a visible sign clearly indicates that—

(a) the product is not in conformity with Part 2, and

(b) the product is not available for sale until brought into conformity with Part 2.

Commencement Information

I4 Reg. 4 in force at 8.12.2016, see **reg. 1(1)**

(**6**) OJ L 399, 30.12.1989, p. 18.

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 must ensure that it has been designed and manufactured in accordance with the essential health and safety requirements.

Commencement Information
I5 Reg. 5 in force at 8.12.2016, see **reg. 1(1)**

Technical documentation and conformity assessment

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

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

[[F33](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 paragraph 3(c) of Part 1 of Schedule 3A to these Regulations;

(ii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(b) is being carried out, in paragraph 3(c) of Part 1 of Schedule 3A to these Regulations;

(iii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(c) is being carried out, in paragraph 2 of Part 6 of Schedule 3A to these Regulations;

(iv) for a product in respect of which the conformity assessment procedure in regulation 39(1)(d) is being carried out, in paragraph 2 of Part 7 of Schedule 3A to these Regulations.**]**

F33 Reg. 6(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 5** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I6 Reg. 6 in force at 8.12.2016, see **reg. 1(1)**

[[F34]**Declaration] of conformity and [**[F35]**UK] 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 must, before placing the product on the market—

(a) draw up a declaration of conformity in accordance with regulation 40 (F36... declaration of conformity), and

(b) affix the **[**F37UK**]** Marking in accordance with regulation 41 (**[**F37UK**]** Marking).

(2) The manufacturer must keep the F38... 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 must, 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 must ensure that each product is accompanied by a copy of the F39... 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 F40... declaration or attestation of conformity as appropriate.

[F41(6) Where a product is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.**]**

F34 Word in reg. 7 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(a)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F35 Word in reg. 7 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(a)(ii)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F36 Word in reg. 7(1)(a) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F37 Word in reg. 7(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F38 Word in reg. 7(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F39 Word in reg. 7(4) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F40 Word in reg. 7(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F41 Reg. 7(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(e)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I7 Reg. 7 in force at 8.12.2016, see **reg. 1(1)**

Retention of technical documentation and [F42]... declaration of conformity

8. A manufacturer must keep the technical documentation and the [F43]... 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.

F42 Word in reg. 8 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 7** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F43 Word in reg. 8 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 7** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I8 Reg. 8 in force at 8.12.2016, see **reg. 1(1)**

Compliance procedures for series production

9.—(1) A manufacturer of a product which is manufactured by series production must 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 must take adequate account of—

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

(b) any change in a **[**[F44]designated**]** standard or in another technical specification by reference to which the [F45]... declaration of conformity or attestation of conformity was drawn up.

F44 Word in reg. 9(2)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 8(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F45 Word in reg. 9(2)(b) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 8(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I9 Reg. 9 in force at 8.12.2016, see **reg. 1(1)**

Monitoring

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

(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 must 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 must 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.

Commencement Information
I10 Reg. 10 in force at 8.12.2016, see **reg. 1(1)**

Labelling and packaging of products

11.—(1) Before placing a product on the market, a manufacturer must ensure that it bears a type, batch or 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 must ensure that the information is provided on the packaging or in a document accompanying the product.

Commencement Information
I11 Reg. 11 in force at 8.12.2016, see **reg. 1(1)**

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 must 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.

Commencement Information
I12 Reg. 12 in force at 8.12.2016, see **reg. 1(1)**

Information identifying manufacturer

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

(a) on the product packaging, or

(b) in a document accompanying the product.

[[F46](3) The information specified in paragraph (1) must be in a language which can be easily understood by end users and the market surveillance authority.**]**

F46 Reg. 13(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 9** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I13 Reg. 13 in force at 8.12.2016, see **reg. 1(1)**

[F47Provision of instructions and safety information

14. When placing a product on the market, a manufacturer must ensure that a product is accompanied by instructions and safety information that are clear, legible and in easily understandable English.]

F47 Reg. 14 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 10** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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, must 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 must immediately inform the market surveillance authority[F48]... 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.

F48 Words in reg. 15(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 11** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I14 Reg. 15 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

16.—(1) A manufacturer must, 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 must, 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 manufacturer has placed on the market.

Commencement Information

I15 Reg. 16 in force at 8.12.2016, see **reg. 1(1)**

Authorised representatives

17.—(1) A manufacturer may, by written mandate, appoint a person established in the **[**[F49]United Kingdom**]** 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) must not form part of an authorised representative's mandate.

(4) The mandate must 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 [F50]... declaration of conformity), and

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

(5) An authorised representative must 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 are to be taken as including a reference to the authorised representative.

F49 Words in reg. 17(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 12(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F50 Word in reg. 17(4)(a) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 12(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I16 Reg. 17 in force at 8.12.2016, see **reg. 1(1)**

Chapter 2

Importers

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

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

Commencement Information
I17 Reg. 18 in force at 8.12.2016, see **reg. 1(1)**

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

19.—(1) Before placing a product on the market, an importer must 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 **[**F51UK**]** marking where applicable,

(ii) is accompanied by the F52... 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 **[**F53**]**14 (provision of instructions and safety information)**]**.

F51 Word in reg. 19(1)(c)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F52 Word in reg. 19(1)(c)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F53 Words in reg. 19(2)(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I18 Reg. 19 in force at 8.12.2016, see **reg. 1(1)**

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 must not place the product on the market.

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

Commencement Information

I19 Reg. 20 in force at 8.12.2016, see **reg. 1(1)**

Information identifying importer

21.—(1) Before placing a product on the market, an importer must 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) must be in a language which can be easily understood by end-users and **[**[F54]the market surveillance authority**]**.

[[F55](3) Paragraph (1) does not apply where—

(a) either—

(i) it is not possible to set out the information referred to in paragraph (1) on the product, or

(ii) the importer has imported the product from an EEA state or Switzerland and places it on the market within the period of **[**[F56]seven years**]** beginning with IP completion day, and

(b) before placing the product on the market, the importer sets out the information referred to in paragraph (1)—

(i) on the packaging; or

(ii) in a document accompanying the product.**]**

F54 Words in reg. 21(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 14(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F55 Reg. 21(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 14(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2019/1246, regs. 1(3), **5** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 2(1)(i)** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F56 Words in reg. 21(3)(a)(ii) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 4, **Sch. 3**

Modifications etc. (not altering text)

C1 Reg. 21 modified (temp.) (10.9.2019) by S.I. 2019/392, reg. 6 (as inserted by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2)(4), **2(3)** (with reg. 18))

Commencement Information
I20 Reg. 21 in force at 8.12.2016, see **reg. 1(1)**

[F57Provision of Instructions and safety information

22. When placing a product on the market, an importer must ensure that the product is accompanied by instructions and safety information that are clear, legible and in easily understandable English.**]**

F57 Reg. 22 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 15** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Storage and transport

23. Each importer must 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.

Commencement Information
I21 Reg. 23 in force at 8.12.2016, see **reg. 1(1)**

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 must—

(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 must 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 must 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.

Commencement Information
I22 Reg. 24 in force at 8.12.2016, see **reg. 1(1)**

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 must 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 must immediately inform the market surveillance authority[F58]... 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.

F58 Words in reg. 25(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 16** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I23 Reg. 25 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

26.—(1) An importer must, 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 must, 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.

Commencement Information

I24 Reg. 26 in force at 8.12.2016, see **reg. 1(1)**

Retention of technical documentation and [F59]... declaration of conformity

27. An importer must, 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 [F60]... declaration of conformity or, where applicable, the attestation of conformity, and

(b) the technical documentation.

F59 Word in reg. 27 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 17** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F60 Word in reg. 27 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 17** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I25 Reg. 27 in force at 8.12.2016, see **reg. 1(1)**

Chapter 3

Distributors

Duty to act with due care

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

Commencement Information

I26 Reg. 28 in force at 8.12.2016, see **reg. 1(1)**

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

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

(a) the product—

(i) bears a **[**[F61]UK**]** marking where applicable;

(ii) is accompanied by the [F62]... declaration of conformity or the attestation of conformity;

(iii) is accompanied by the required documents;

[[F63](iv) is accompanied by instructions and safety information that are clear, legible and in easily understandable English;**]**

(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);

(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).

F61 Word in reg. 29(1)(a)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F62 Word in reg. 29(1)(a)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F63 Reg. 29(1)(a)(iv) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I27 Reg. 29 in force at 8.12.2016, see **reg. 1(1)**

Storage and transport

30. Each distributor must 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.

Commencement Information

I28 Reg. 30 in force at 8.12.2016, see **reg. 1(1)**

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 must not make the product available on the market.

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

(a) the manufacturer or the importer, and

(b) the market surveillance authority.

Commencement Information

I29 Reg. 31 in force at 8.12.2016, see **reg. 1(1)**

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 must 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 must immediately inform the market surveillance authority[F64]... 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.

F64 Words in reg. 32(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 19** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I30 Reg. 32 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

33.—(1) A distributor must, 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 must, 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.

Commencement Information

I31 Reg. 33 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information

I32 Reg. 34 in force at 8.12.2016, see **reg. 1(1)**

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, must, 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.

Commencement Information

I33 Reg. 35 in force at 8.12.2016, see **reg. 1(1)**

Prohibition on improper use of [F65UK] marking

36.—(1) An economic operator must not affix the **[**F66UK**]** 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 must not affix to a product a marking (other than the **[**F66UK**]** marking) which purports to attest that the product is in conformity with the essential health and safety requirements.

(3) An economic operator must 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 **[**F66UK**]** marking.

(4) An economic operator must not affix to a product any other marking if the visibility, legibility and meaning of the **[**F66UK**]** marking would be impaired as a result.

F65 Word in reg. 36 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 20** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F66 Word in reg. 36 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 20** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I34 Reg. 36 in force at 8.12.2016, see **reg. 1(1)**

[F67Obligations which are met by complying with obligations in the ATEX Directive

36A.—(1) In this regulation—

(a) any reference to an Article or an Annex is a reference to an Article or an Annex of the ATEX Directive;

(b) "CE marking" has the meaning given to it in Article 2(26); and

(c) "harmonised standard" has the meaning given to in in Article 2(18).

(2) Subject to paragraphs (6) and (7) paragraph (3) applies where, before placing the product on the market, the manufacturer—

(a) ensures that the product has been designed and manufactured in accordance with the essential safety requirements set out in Annex II;

(b) ensures that the relevant conformity assessment procedures that apply to that product in accordance with Article 13(1) and (2) have been carried out;

(c) draws up the technical documentation referred to in Annexes III to IX;

(d) ensures that the records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;

(e) affixes a CE marking and the inscriptions in accordance with Articles 15 and 16(1) to (4);

(f) draws up an EU declaration of conformity, in accordance with Article 14; and

(g) ensures that the declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

(a) the requirements of regulations 5, 6, 7(1), (3) and 7(6) are to be treated as being satisfied;

(b) regulations 2(a), 7(6), 8, 9(2), 17(4), 36 and 59 apply subject to the modifications in paragraph (10);

(c) Part 3 does not apply; and

(d) regulation 57 does not apply.

(4) Subject to paragraphs (6) and (7) paragraph (5) applies where, before placing a product on the market, the importer ensures that—

(a) the relevant conformity assessment procedure referred to in Article 13 has been carried out;

(b) the manufacturer has drawn up the technical documents relevant to the conformity assessment procedure followed; and

(c) the product bears the CE marking and inscriptions referred to in point 1.0.5 of Annex II.

(5) Where this paragraph applies—

(a) the requirements of regulation 19(1)(a) to (c) are to be treated as being satisfied; and

(b) regulations 2(a),18, 23 and 27 apply subject to the modifications in paragraph (10).

(6) This paragraph applies where there is no designated standard or part of a designated standard which corresponds exactly to a harmonised standard or part of a harmonised standard referred to in Article 12.

(7) Where paragraph (6) applies, paragraphs (2)(b) and (4)(a) are to be treated as requiring the manufacturer to carry out—

(a) the conformity assessment procedure set out in Article 13(1)(b); and

(b) the relevant conformity assessment procedure that applies to that product in accordance with Article 13(2).

(8) Paragraph (9) applies where, before making a product available on the market, a distributor ensures that the product bears the CE marking and inscriptions referred to in point 1.0.5 of Annex II.

(9) Where this paragraph applies—

(a) regulation 29(1)(a)(i) is to be treated as being satisfied; and

(b) regulations 2(a), 30 and 31(1) apply subject to the modifications in paragraph (10).

(10) The modifications referred to in subparagraphs (3)(b), (5)(b) and (9)(b) are that—

(a) any reference to “declaration of conformity” is to be read as a reference to the EU declaration of conformity;

(b) any reference to “UK marking” is to be read as reference to the CE marking;

(c) any reference to "essential safety requirements" is to be read as a reference to the essential safety requirements referred to in Annex II;

(d) any reference to "designated standard" is to be read as a reference to a harmonised standard;

(e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures referred to in Article 13;

(f) any reference to "technical documentation" is a reference to the technical documentation referred to in Annexes III to IX.

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Conformity assessment procedure obligation which is met by complying with the ATEX Directive

36B.—(1) In this regulation any reference to an Article or Annex is a reference to an Article or an Annex of the ATEX Directive;

(2) Paragraph (3) applies where, prior to the manufacture of a product, the manufacturer ensures that the conformity assessment procedure that applies to that product in accordance with Annex III as referred to in Article 13(1)(a) and (b) has been carried out.

(3) Where this paragraph applies—

(a) any requirement to follow the Type-examination set out in Part 1 of Schedule 3A in regulation 39 is to be treated as being satisfied;

(b) any reference to "relevant conformity assessment procedure" in regulations 6(a), 7(1), 19(a), 36(1)(b), 40(c) and 41(3) is to be read as including the conformity assessment procedure set out in Annex III as referred to in Article 13(1)(a) and (b); and

(c) any reference to "technical documentation" in regulations 6(b), 8, 19(b) and 27(b) is to be read as including the technical documentation relating to the design of the product referred to in Annex III.

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Expiry of regulations 36A and 36B

36C.—(1) Subject to paragraph (2), regulation 36A ceases to have effect at the end of the period of **[**F68four years**]** beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 36A—

(a) any product which was placed on the market pursuant to regulation 36A may continue to be made available on the market on or after the expiry of regulation 36A;

(b) any obligation to which a person was subject under regulation 36A in respect of any product placed on the market pursuant to regulation 36A continues to have effect after the expiry of regulation 36A, in respect of that product.

(3) Subject to paragraph (4), regulation 36B ceases to have effect at the end of the period of **[**[F69]four years**]** beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 36B in relation to a product prior to the expiry of regulation 36B, regulation 36B continues to apply in respect of that pressure equipment or assembly where—

(a) the manufacturer arranges for the EU-Type examination certificate and any annexes to be transferred to an approved body;

(b) the approved body referred to in sub-paragraph (a) accepts responsibility for the EU-Type examination certificate; and

(c) the approved body issues a Type-examination certificate relying, or relying in part, on any examinations or tests undertaken prior to the issue of the EU-Type examination certificate.

(5) In paragraph (4) "EU-Type examination certificate" means a certificate issued after the conformity assessment referred to in regulation 36B(2) has been carried out.

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

F68 Words in reg. 36C(1) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1**

F69 Words in reg. 36C(3) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1**

Qualifying Northern Ireland Goods

36D.—(1) In this regulation—

"the 2017 Regulations" means the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017;

"CE marking" has the meaning given to it in regulation 2(1) of the 2017 Regulations;

"qualifying Northern Ireland goods" has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

"relevant conformity assessment procedure" has the meaning given to it in regulation 2(1) of the 2017 Regulations;

"technical documentation" has the meaning given to it in regulation 2(1) of the 2017 Regulations.

(2) Where paragraph (3) applies, a product is to be treated as being in conformity with Part 2.

(3) This paragraph applies where—

(a) a product—

(i) is in conformity with Part 2, within the meaning of regulation 2(2) of the 2017 Regulations; and

(ii) is qualifying Northern Ireland goods; and

(b) an importer has complied with the obligations set out in paragraph (4).

(4) The obligations referred to in paragraph (3)(b) are that, before placing the product on the market, the importer—

(a) complies with regulation 21;

(b) ensures that—

(i) the relevant conformity assessment procedure has been carried out in relation to the product;

(ii) the manufacturer has drawn up the technical documentation; and

(iii) the product bears the CE marking.**]**

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Translation of declaration of conformity

[F70]37. . . . . . .

F70 Reg. 37 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 22** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

PART 3

Conformity assessment

Presumption of conformity

38.—(1) A product which is in conformity with a **[**[F71]designated**]** standard (or part of such a standard) [F72]... is presumed to be in conformity with the essential health and safety requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

F71 Word in reg. 38(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 23(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F72 Words in reg. 38(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 23(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I35 Reg. 38 in force at 8.12.2016, see **reg. 1(1)**

Conformity assessment procedures

39.—(1) For the assessment of conformity of equipment, and where necessary those devices referred to at regulation 3(2)(b), the manufacturer must follow one of the following procedures—

[F73(a) for equipment-groups I and II, equipment-categories M1 and 1, the manufacturer must follow either—

(i) the Type-examination set out in Part 1 of Schedule 3A, in conjunction with either the procedure set out in—

(aa) Part 2 of Schedule 3A, or

(bb) Part 3 of Schedule 3A; or

(ii) the conformity based on unit verification referred to in Part 7 of Schedule 3A;**]**

[F74(b) for equipment-groups I and II, equipment-categories M2 and 2, the manufacturer must follow—

(i) for internal combustion engines and electrical equipment in these groups and categories the Type examination set out in Part 1 of Schedule 3A, in conjunction with either the procedure set out in either Part 4 or Part 5 of Schedule 3A;

(ii) for other equipment in these groups and categories the procedures set out in Part 6 of Schedule 3A;**]**

[F75(c) for equipment group II, equipment-category 3, the procedure relating to internal production control referred to in Part 6 of Schedule 3A;**]**

[F76(d) for equipment-groups I and II, instead of the procedures referred to in paragraphs (1)(a), (b) and (c), the manufacturer may follow conformity based on unit verification referred to in Part 7 of Schedule 3A.**]**

(2) The procedure referred to in paragraph (1)(a) or (d) must be used for the conformity assessment of protective systems.

(3) For the assessment of conformity of components, the manufacturer must—

(a) follow the procedures referred to in paragraph (1), with the exception of—

(i) affixing the **[**F77UK**]** marking;

(ii) drawing up of the F78... declaration of conformity;

(b) issue a written attestation of conformity which must—

(i) confirm conformity of the component with Part 2 of these Regulations,

(ii) state the characteristics of the component, and

(iii) explain how the component must be incorporated into equipment or protective systems to comply with the essential health and safety requirements.

(4) In respect of the safety aspects referred to in paragraph 13 of Schedule 1, instead of the conformity assessment procedures referred to in paragraphs (1) and (2), the manufacturer may follow the procedure referred to in **[**F79Part 6 of Schedule 3A**]**.

(5) Where the procedures referred to in paragraphs (1), (2) and (4) have not been applied, the market surveillance authority, may authorise the placing on the market and the putting into service, of a product other than a component, F80... where—

(a) the market surveillance authority is in receipt of a duly justified request, requesting the placing on the market and the putting into service of a product, other than a component, and

(b) the use of that product is in the interests of protection.

(6) The manufacturer must ensure that the documents and correspondence relating to the conformity assessment procedures referred to in paragraphs (1) to (4) are in **[**F81English**]**.

F73 Reg. 39(1)(a) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F74 Reg. 39(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F75 Reg. 39(1)(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F76 Reg. 39(1)(d) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F77 Word in reg. 39(3)(a)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(e)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F78 Word in reg. 39(3)(a)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(f)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F79 Words in reg. 39(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(g)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F80 Words in reg. 39(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(h)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F81 Word in reg. 39(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I36 Reg. 39 in force at 8.12.2016, see **reg. 1(1)**

F82... Declaration of conformity

40. The F83... declaration of conformity for a product must—

(a) state that the fulfilment of the essential health and safety requirements have been demonstrated in respect of the product;

(b) have the model structure set out in Schedule 6;

(c) contain the elements specified in **[**F84Schedule 3A to these Regulations**]** for the relevant conformity assessment procedure followed in respect of the product.

F82 Word in reg. 40 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 25(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F83 Word in reg. 40 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 25(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F84 Words in reg. 40(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 25(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I37 Reg. 40 in force at 8.12.2016, see **reg. 1(1)**

[F85UK] Marking

41.—[F86(1) The UK marking must be affixed visibly, legibly and indelibly—

(a) to the product;

(b) to its data plate; or

(c) where paragraph (1A) applies, to—

(i) a label affixed to the product; or

(ii) a document accompanying the product.]

[F87(1A) For a period of [F88seven years] beginning with IP completion day, the UK marking may be affixed to—

(a) a label affixed to the product; or

(b) a document accompanying the product.]

(2) Where [F89paragraph (1A) does not apply and] it is not possible or warranted, on account of the nature of the product, to affix the [F90UK] marking in accordance with [F91paragraph (1)(a) or (b)], the [F90UK] marking must be affixed to—

(a) the packaging, and

(b) the accompanying documents.

(3) The [F90UK] marking must be followed by the identification number of the [F92approved body] which carried out the relevant conformity assessment procedure for the product, where that body is involved in the production control phase.

(4) The identification number of the [F92approved body] must be affixed—

(a) by the [F92approved body] itself, or

(b) under the instructions of the [F92approved body], by the manufacturer or the authorised representative.

(5) The [F90UK] marking and, where applicable, the identification number of the [F92approved body] must be followed by—

(a) the specific marking of explosion protection as referred to in paragraph 5(1)(f) of Schedule 1,

(b) the symbols of the equipment-group and category, and

(c) where applicable, the other markings and information referred to in paragraph 5 of Schedule 1.

(6) Products designed for a particular explosive atmosphere must be marked accordingly.

F85 Word in reg. 41 heading substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ac) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F86 Reg. 41(1) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(a) (as substituted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(a)**)

F87 Reg. 41(1A) inserted by S.I. 2019/696, Sch. 25 para. 26(aa) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F88 Words in reg. 41(1A) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 3, **Sch. 2**

F89 Words in reg. 41(2) inserted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ab)(i) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F90 Word in reg. 41(2)-(5) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ac) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F91 Words in reg. 41(2) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ab)(ii) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F92 Words in reg. 41 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 26(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I38 Reg. 41 in force at 8.12.2016, see **reg. 1(1)**

[F93PART 4

Approval of Conformity Assessment Bodies

F93 Pt. 4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 27** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(iv)(v)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Approved bodies

42.—(1) An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 43 (approval of conformity assessment bodies); or

(b) immediately before IP completion day was a notified body in respect of which the Secretary of State has taken no action under regulation 48(1) or (2) as it had effect immediately before IP completion day to restrict, suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 46 (restriction, suspension or withdrawal of approval).

(3) In this Part—

"notified body" means a body—

(a) which the Secretary of State had before IP completion day notified to the European Commission and the member States of the European Union, in accordance with Article 17 of the ATEX Directive; and

(b) in respect of which no objections had been raised as referred to in regulation 42(1)(b) as it had effect immediately before IP completion day.

"approved body requirements" means the requirements set out in Schedule 2.

Approval of conformity assessment bodies

43.—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

(2) A conformity assessment body qualifies for approval if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) When deciding whether to approve a conformity assessment body that applies for approval, the Secretary of State may—

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.

(7) For the purposes of this regulation "accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

Presumption of conformity of approved bodies

44.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Monitoring

45. The Secretary of State must monitor each approved body with a view to verifying that the body—

(a) continues to meet the approved body requirements;

(b) meets any conditions set—

(i) in accordance with regulation 43(6)(b), or

(ii) in the case of an approved body which was a notified body immediately before IP completion day, in accordance with regulation 43(6)(b) as it applied immediately before IP completion day; and

(c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval

46.—(1) Where the Secretary of State determines that an approved body—

(a) no longer meets an approved body requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 45(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 42 (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 45(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 42.

(3) In deciding what action is required under paragraph (1) or (2) the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2) the Secretary of State must—

(a) give notice in writing to the approved body of the proposed action and the reasons for it;

(b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations made by the approved body.

(5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—

(a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State, or

(b) keep its files relating to the activities it has undertaken as an approved body available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.

(6) The activities undertaken by an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.

Operational matters in relation to approved bodies

47.—(1) Subject to the terms of its appointment, an approved body must carry out the conformity assessment activities and procedures—

(a) in respect of which the body's approval was given under regulation 43, or

(b) in respect of which the body's notification as a notified body was made.

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 3.

(3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—

(a) to issue a Type examination certificate referred to in Part 1 of Schedule 3B;

(b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 41 (UK marking).

Subsidiaries and contractors

48.—(1) An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

(a) the body is satisfied that the subcontractor or subsidiary meet the approved body requirements;

(b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meet those requirements; and

(c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documents concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006;

Register of approved bodies

49.—(1) The Secretary of State must—

(a) assign an approved body identification number to each approved body; and

(b) compile and maintain a register of—

(i) approved bodies;

(ii) their approved body notification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.

UK national accreditation body

50. The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the approved body requirements;

(b) monitoring approved bodies in accordance with regulation 45; and

(c) compiling and maintaining the register of approved bodies, in accordance with regulation 49.**]**

PART 5

Market surveillance and enforcement

Designation of market surveillance authority

51.—(1) Save where paragraph (2) applies, the market surveillance authority in Great Britain for a product is the Health and Safety Executive.

(2) The market surveillance authority in Great Britain for a product is the Office for Nuclear Regulation, in so far as these Regulations apply to—

(a) any person who places on the market or supplies a product intended exclusively or primarily for use on a GB nuclear site;

(b) any person who puts into service a product on a relevant nuclear site.

(3) In paragraph (2), "relevant nuclear site" means a site which is—

(a) a GB nuclear site;

(b) an authorised defence site (within the meaning given in regulation 2(1) of the Health and Safety (Enforcing Authority) Regulations 1998);

(c) a new nuclear build site (within the meaning given in regulation 2A of the Health and Safety (Enforcing Authority) Regulations 1998).

(4) In paragraphs (2) and (3), "GB nuclear site" means a nuclear site in Great Britain (within the meaning given in section 68 of the Energy Act 2013(**7**)).

Commencement Information
I39 Reg. 51 in force at 8.12.2016, see **reg. 1(1)**

Enforcement

52.—(1) The market surveillance authority must enforce these Regulations and RAMS in its application to a product.

(2) In Scotland, only the Lord Advocate may prosecute an offence under these Regulations.

Commencement Information
I40 Reg. 52 in force at 8.12.2016, see **reg. 1(1)**

Enforcement powers

53.—(1) Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act) is to have effect.

(2) In addition to the powers available to the market surveillance authority under paragraph (1), the authority may use the powers set out in Schedule 5 (compliance, withdrawal and recall notices).

(**7**) 2013 c.32.

Commencement Information
I41 Reg. 53 in force at 8.12.2016, see **reg. 1(1)**

Exercise of enforcement powers

54. When enforcing these Regulations, the market surveillance authority must exercise its powers in a manner which is consistent with—

(a) regulation 55 (evaluation of a product presenting a risk);

(b) regulation 56 (enforcement action in respect of products which are not in conformity and which present a risk);

F94(c) . . . . . .

(d) regulation 58 (enforcement action in respect of products which are in conformity, but present a risk);

(e) regulation 59 (enforcement action in respect of formal non-compliance);

(f) regulation 60 (restrictive measures).

F94 Reg. 54(c) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 28** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I42 Reg. 54 in force at 8.12.2016, see **reg. 1(1)**

Evaluation of a product presenting a risk

55. Where the market surveillance authority has sufficient reason to believe that a product presents a risk, the market surveillance authority must carry out an evaluation in relation to the product covering the relevant requirements of Part 2.

Commencement Information
I43 Reg. 55 in force at 8.12.2016, see **reg. 1(1)**

Enforcement action in respect of products which are not in conformity and which present a risk

56.—(1) Where, in the course of the evaluation referred to in regulation 55, the market surveillance authority finds that the product is not in conformity with Part 2, it must, without delay, require a relevant economic operator to—

(a) take appropriate corrective action to bring the product into conformity with those requirements within a prescribed period,

(b) withdraw the product within a prescribed period, or

(c) recall the product within a prescribed period.

(2) The market surveillance authority must inform the **[**F95approved**]** body which carried out the conformity assessment procedure in respect of the product of—

(a) the respect in which the product is not in conformity with Part 2, and

(b) the actions which the market surveillance authority is requiring the relevant economic operator to take.

(3) Where the market surveillance authority considers that the lack of conformity referred to in paragraph (1) is not restricted to Great Britain, it must notify the Secretary of State of—

(a) the results of the evaluation, and

(b) the actions which it has required the economic operator to take.

(4) Where the Secretary of State receives a notice under paragraph (3), or otherwise considers that the lack of conformity referred to in paragraph (1) is not restricted to Great Britain, the Secretary of State must inform the **[**F96Health and Safety Executive for Northern Ireland**]** of—

(a) the results of the evaluation, and

(b) the actions which the market surveillance authority has required the economic operator to take.

(5) Where the relevant economic operator does not take adequate corrective action within the prescribed period, the market surveillance authority must take appropriate measures to—

(a) prohibit or restrict the product being made available on the market in Great Britain,

(b) withdraw the product from the market in Great Britain, or

(c) recall the product.

(6) Where the market surveillance authority takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.

(7) Where the Secretary of State receives a notice under paragraph (6), the Secretary of State must notify the **[**F97Health and Safety Executive for Northern Ireland**]** of those measures without delay.

(8) The notices in paragraphs (6) and (7) must include details about the product and, in particular—

(a) the data necessary for the identification of the product which is not in conformity with Part 2;

(b) the origin of the product;

(c) the nature of the lack of conformity alleged and the risk involved;

(d) the nature and duration of the measures taken;

(e) the arguments put forward by the relevant economic operator;

(f) whether the lack of conformity is due to either of the following—

(i) failure of the product to meet requirements relating to a risk;

(ii) shortcomings in the **[**F98designated**]** standards referred to in regulation 38 (presumption of conformity) conferring a presumption of conformity.

(9) In this regulation, "prescribed period" means a period which is—

(a) prescribed by the market surveillance authority;

(b) reasonable and commensurate with the nature of the risk presented by the product.

F95 Word in reg. 56(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F96 Words in reg. 56(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F97 Words in reg. 56(7) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F98 Word in reg. 56(8)(f)(ii) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I44 Reg. 56 in force at 8.12.2016, see **reg. 1(1)**

EU safeguard procedure

[F99]57. . . . . . .

F99 Reg. 57 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 30** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Enforcement action in respect of products which are in conformity, but present a risk

58.—(1) Where, having carried out an evaluation under regulation 55, the market surveillance authority finds that although a product is in conformity with Part 2, it presents a risk, the market surveillance authority must require a relevant economic operator to take appropriate measures to—

(a) ensure that the product concerned, when placed on the market, no longer presents a risk,

(b) withdraw the product within a prescribed period, or

(c) recall the product within a prescribed period.

(2) Where the market surveillance authority takes measures under paragraph (1), it must notify the Secretary of State immediately.

(3) Where the Secretary of State receives a notice under paragraph (2), the Secretary of State must notify **[**[F100]the Health and Safety Executive for Northern Ireland**]** immediately.

(4) The notices referred to in paragraphs (2) and (3) must include details about the product and, in particular—

(a) the data necessary for the identification of the product concerned;

(b) the origin and the supply chain of the product;

(c) the nature of the risk involved;

(d) the nature and duration of the measures taken by the market surveillance authority.

(5) In this regulation, "prescribed period" means a period which is—

(a) prescribed by the market surveillance authority;

(b) reasonable and commensurate with the nature of the risk presented by the product.

F100 Words in reg. 58(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 31** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I45 Reg. 58 in force at 8.12.2016, see **reg. 1(1)**

Enforcement action in respect of formal non-compliance

59.—(1) Where the market surveillance authority makes one of the following findings relating to a product, it must require a relevant economic operator to remedy the non-compliance concerned within a specified period—

(a) the **[**F101UK**]** marking—

(i) where required, has not been affixed;

(ii) has been affixed otherwise than in accordance with regulations 36 (prohibition on improper use of **[**F101UK**]** marking) and 41 (**[**F101UK**]** marking);

(b) where **[**F102an approved**]** body is involved in the production control phase for the product, the identification number of the notified body—

(i) has not been affixed;

(ii) has been affixed otherwise than in accordance with regulation 41;

(c) the F103... declaration of conformity or the attestation of conformity as appropriate—

(i) does not accompany the product;

(ii) has been drawn up otherwise than in accordance with regulations 7 (F103... declaration of conformity and **[**F104UK**]** marking) and 40 (F103... declaration of conformity);

(d) the technical documentation is either not available or not complete;

(e) the following product information has not been affixed or has been affixed otherwise than in accordance with paragraph 5 of Schedule 1—

(i) specific marking of explosion protection in accordance with paragraph 5(1)(f) of Schedule 1;

(ii) the symbols of the equipment-group and category in accordance with paragraph 5(1)(g) of Schedule 1;

(iii) where applicable, the other markings and information required by paragraph 5(1) of Schedule 1;

(f) the following information that is required to be included in the labelling of the product is absent, false or incomplete—

(i) the information specified in regulation 13 (information identifying manufacturer)

(ii) the information specified in regulation 21 (information identifying importer);

(g) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.

(2) The market surveillance authority must not take any enforcement action against the relevant economic operator under these Regulations in respect of the non-compliance concerned until the period referred to in paragraph (1) has elapsed.

(3) Where the non-compliance referred to in paragraph (1) persists, the market surveillance authority must take appropriate measures to—

(a) restrict or prohibit the product being made available on the market,

(b) ensure that the product is withdrawn, or

(c) ensure that the product is recalled.

(4) This regulation does not apply where a product presents a risk.

F101 Word in reg. 59(1)(a) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F102 Words in reg. 59(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F103 Word in reg. 59(1)(c) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F104 Word in reg. 59(1)(c)(ii) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I46 Reg. 59 in force at 8.12.2016, see **reg. 1(1)**

Restrictive measures

60. When enforcing these Regulations, the market surveillance authority must comply with the requirements of Article 21 of RAMS (as amended from time to time) in relation to any measure to—

(a) prohibit or restrict a product being made available on the market,

(b) withdraw a product, or

(c) recall a product.

Commencement Information

I47 Reg. 60 in force at 8.12.2016, see **reg. 1(1)**

Offences

61.—(1) It is an offence for a person to contravene or fail to comply with any requirement of regulations 5 to 15, 16(2), 18 to 25, 26(2), 27 to 32, 33(2), 35 or 36.

(2) It is an offence for any person to contravene or fail to comply with any requirement of a withdrawal or recall notice served on that person by the market surveillance authority under these Regulations.

Commencement Information

I48 Reg. 61 in force at 8.12.2016, see **reg. 1(1)**

Penalties

62. A person guilty of an offence under regulation 61 is liable—

(a) on summary conviction—

(i) in England and Wales, to a fine or imprisonment for a term not exceeding 3 months or to both;

(ii) in Scotland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding 3 months, or to both;

(b) on conviction on indictment, to a fine or imprisonment for a term not exceeding 2 years or to both.

Commencement Information
I49 Reg. 62 in force at 8.12.2016, see **reg. 1(1)**

Defence of due diligence

63.—(1) Subject to paragraphs (2) and (4), in proceedings for an offence under regulation 61, it is a defence for a person ("P") to show that P took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) P may not rely on a defence under paragraph (1) which involves a third party allegation unless P has—

(a) served a notice in accordance with paragraph (3), or

(b) obtained the leave of the court.

(3) The notice must—

(a) give any information in P's possession which identifies or assists in identifying the person who—

(i) committed the act or default, or

(ii) supplied the information on which P relied;

(b) be served on the person bringing the proceedings not less than 7 clear days before—

(i) in England and Wales, the hearing of the proceedings;

(ii) in Scotland, the trial diet.

(4) P may not rely on a defence under paragraph (1) which involves an allegation that the commission of the offence was due to reliance on information supplied by another person unless it was reasonable for P to have relied upon the information, having regard in particular to—

(a) the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information, and

(b) whether P had any reason to disbelieve the information.

(5) In this regulation, "third party allegation" means an allegation that the commission of the offence was due—

(a) to the act or default of another person; or

(b) to reliance on information supplied by another person.

Commencement Information
I50 Reg. 63 in force at 8.12.2016, see **reg. 1(1)**

Liability of persons other than principal offender

64.—(1) Where the commission of an offence by one person ("A") under regulation 61 is due to anything which another person ("B") did or failed to do in the course of business, B is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against A.

(2) Where a body corporate commits an offence, a relevant person is also guilty of the offence where the body corporate's offence was committed—

(a) with the consent or connivance of the relevant person, or

(b) as a result of the negligence of the relevant person.

(3) In paragraph (2), "relevant person" means any of the following—

(a) a director, manager, secretary or other similar officer of the body corporate;

(b) in relation to a body corporate managed by its members, a member of that body corporate performing managerial functions;

(c) in relation to a Scottish partnership, a partner;

(d) a person purporting to act as a person described in sub-paragraphs (a), (b) or (c).

Commencement Information

I51 Reg. 64 in force at 8.12.2016, see **reg. 1(1)**

Time limit for prosecution of offences

65.—(1) Subject to paragraph (3), in England and Wales, information relating to an offence under regulation 61 that is triable by a magistrates' court may be so tried if it is laid within 12 months after the date on which evidence which is sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.

(2) Subject to paragraph (3), in Scotland—

(a) summary proceedings for an offence under regulation 61 may be commenced before the end of 12 months after the date on which evidence which is sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge;

(b) section 136(3) of the Criminal Procedure (Scotland) Act 1995 (time limit for certain offences) applies for the purpose of this paragraph as it applies for the purpose of that section.

(3) No proceedings may be brought more than 3 years after the commission of the offence.

(4) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which the evidence referred to paragraphs (1) and (2) came to light, is conclusive evidence.

(5) This regulation has effect subject to paragraphs 1(n) and 2(o) of Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act).

Commencement Information

I52 Reg. 65 in force at 8.12.2016, see **reg. 1(1)**

Service of documents

66.—(1) Any document required or authorised by these Regulations to be served on a person may be served by—

(a) delivering it to that person in person,

(b) leaving it at that person's proper address, or

(c) sending it by post or electronic means to that person's proper address.

(2) In the case of a body corporate, a document may be served on a director of that body.

(3) In the case of a partnership, a document may be served on a partner or a person having control or management of the partnership business.

(4) For the purposes of this regulation, "proper address" means—

(a) in the case of a body corporate or its director—

(i) the registered or principal office of that body;

(ii) the email address of the secretary or clerk of that body;

(b) in the case of a partnership, a partner or person having control or management of the partnership business—

(i) the principal office of the partnership;

(ii) the email address of a partner or person having that control or management;

(c) in any other case, a person's last known address, which includes an email address.

(5) If a person to be served with a document has specified an address in the United Kingdom (other than that person's proper address) at which that person or someone on that person's behalf will accept service, that address must also be treated as that person's proper address.

(6) In this regulation, "partnership" includes a Scottish partnership.

Commencement Information

I53 Reg. 66 in force at 8.12.2016, see **reg. 1(1)**

Recovery of expenses of enforcement

67.—(1) This regulation applies where a person commits an offence under regulation 61.

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person to reimburse the market surveillance authority for any expenditure which the market surveillance authority has incurred in investigating the offence.

Commencement Information

I54 Reg. 67 in force at 8.12.2016, see **reg. 1(1)**

Action by the market surveillance authority

68.—(1) The market surveillance authority may itself take action which an economic operator could have been required to take by a notice served under these Regulations where the conditions for serving such a notice are met and either—

(a) the market surveillance authority has been unable to identify any economic operator on whom to serve such a notice, or

(b) the economic operator on whom such a notice has been served has failed to comply with it.

(2) If the market surveillance authority has taken action as a result of the condition in paragraph (1)(b) being met, the authority may recover from the economic operator, as a civil debt, any costs or expenses reasonably incurred by the market surveillance authority in taking the action.

(3) A civil debt recoverable under paragraph (2) may be recovered summarily in England and Wales by way of a complaint pursuant to section 58 of the Magistrates' Courts Act 1980(**8**).

(**8**) 1980 c.43; section 58 was amended by the Crime and Courts Act 2013 (c.22), Schedule 10 paragraph 40.

Commencement Information
I55 Reg. 68 in force at 8.12.2016, see **reg. 1(1)**

Appeals against notices

69.—(1) An application for an order to vary or set aside the terms of a notice served under these Regulations may be made—

(a) by the economic operator on whom the notice has been served;

(b) in the case of a notice other than a recall notice, by a person having an interest in the product in respect of which the notice has been served.

(2) An application must be made before the end of the period of 21 days beginning with the day on which the notice was served.

(3) The appropriate court may only make an order setting aside a notice served under these Regulations if satisfied—

(a) that the product to which the notice relates is in conformity with Part 2 and does not present a risk;, or

(b) that the market surveillance authority failed to comply with regulation 54 (exercise of enforcement powers) when serving the notice.

(4) On an application to vary the terms of a notice served under these Regulations, the appropriate court may vary the terms of the notice as it considers appropriate.

(5) In this regulation—

(a) the "appropriate court" is to be determined in accordance with regulation 70 (appropriate court for appeals against notices);

(b) "notice" means any of the following—

(i) a notice to warn served in accordance with Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act);

(ii) a suspension notice served in accordance with Schedule 4 ;

(iii) a compliance notice served in accordance with Schedule 5 (compliance, withdrawal and recall notices);

(iv) a withdrawal notice served in accordance with Schedule 5;

(v) a recall notice served in accordance with Schedule 5.

Commencement Information
I56 Reg. 69 in force at 8.12.2016, see **reg. 1(1)**

Appropriate court for appeals against notices

70.—(1) In England and Wales, the appropriate court for the purposes of regulation 69 is—

(a) the court in which proceedings have been brought in relation to the product for an offence under regulation 61 (offences),

(b) an employment tribunal seized of appeal proceedings against a notice which relates to the product and which has been served under or by virtue of paragraph 1 of Schedule 4

(Enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act), or

(c) in any other case, a magistrates' court.

(2) In Scotland, the appropriate court for the purposes of regulation 69 is—

(a) the sheriff of a sheriffdom in which the person making the appeal resides or has a registered or principal office, or

(b) an employment tribunal seized of appeal proceedings against a notice which relates to the product and which has been served under or by virtue of paragraph 1 of Schedule 4 (Enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act).

(3) A person aggrieved by an order made by a magistrates' court in England and Wales pursuant to an application under regulation 69, or by a decision of such a court not to make such an order, may appeal against that order or decision in England and Wales, to the Crown Court.

Commencement Information

I57 Reg. 70 in force at 8.12.2016, see **reg. 1(1)**

PART 6

Miscellaneous

Review

71.—(1) The Secretary of State must from time to time—

(a) carry out a review of these Regulations,

(b) set out the conclusions of the review in a report, and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other Member States.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations,

(b) assess the extent to which those objectives are achieved, and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.

(4) The first report under this regulation must be published no later than 5 years after the commencement date.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Commencement Information

I58 Reg. 71 in force at 8.12.2016, see **reg. 1(1)**

Transitional provisions

72.—(1) A certificate issued, or approval granted, by a notified body under Schedule 6 to the 1996 Regulations, or any enactment of another Member State which implemented the 1994 Directive, is to be treated as a certificate issued or approval granted under the ATEX Directive.

F105(2) . . . . . .

F105 Reg. 72(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 33** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I59 Reg. 72 in force at 8.12.2016, see **reg. 1(1)**

[F106Transitional provision in relation to EU Exit

72A.—(1) In this regulation—

"pre-exit period" means the period beginning with the commencement date and ending immediately before IP completion day;

(2) Subject to paragraph (3), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 25 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, any obligation to which a person was subject under these Regulations as they had effect immediately before IP completion day, continues to have effect as it did immediately before IP completion day, in relation to that product.

(3) Paragraph (2) does not apply to—

(a) any obligation of any enforcing authority to inform the European Commission or the member States of any matter; or

(b) any obligation to take action outside of the market in respect of that product.

(4) Where during the pre-exit period—

(a) a product has not been placed on the market; and

(b) a manufacturer has taken any action under regulation 38 as it had effect immediately before IP completion day in relation to that product,

that action has effect as if it had been done under regulation 38 as it had effect on and after IP completion day.

[

F107(5) Subject to paragraph (6), where before 11pm on 31st December 2024—

(a) a product has not been placed on the market or put into service; and

(b) a manufacturer has taken any action under the conformity assessment procedure that applies to that product in accordance with Article 13 of the ATEX Directive

that action has effect as if it had been done under the applicable conformity assessment procedure referred to in regulation 39.

(6) Paragraph (5) does not apply—

(a) after the expiry of the validity of any certificate issued pursuant to the applicable conformity assessment procedure; and

(b) in any event, after 31st December 2027.**]]**

F106 Reg. 72A inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 34** (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(vi)**)

F107 Reg. 72A(5)(6) inserted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), **16(2)**

Revocations and savings

73.—(1) Subject to paragraph (3) **[**F108and (3A)**]**, the 1996 Regulations, the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations 2001(**9**) and the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations 2005(**10**) are revoked.

(2) The Electrical Equipment for Explosive Atmospheres (Certification) (Amendment) Regulations 1999(**11**) are revoked.

[F109(3) Subject to the modifications made in paragraph (3A), the Regulations referred to in paragraph (1) continue to apply, as if they had not been revoked, to a product placed on the market before the commencement date.**]**

[F110(3A) The modifications in the 1996 Regulations referred to in paragraph (3) are as follows—

(i) any reference to "the Community" shall be read as including the United Kingdom;

(ii) any reference to "member State" shall be read as including the United Kingdom;

(iii) any reference to "notified body" shall be read as "approved body" as defined in the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016.**]**

F108 Words in reg. 73(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 35(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F109 Reg. 73(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 35(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F110 Reg. 73(3A) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 35(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I60 Reg. 73 in force at 8.12.2016, see **reg. 1(1)**

Consequential Amendments

74.—(1) In paragraph 1 of Schedule 3 to the Dangerous Substances and Explosive Atmospheres Regulations 2002(**12**) for "the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996" substitute "the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016".

(**9**) S.I. 2001/3766.
(**10**) S.I. 2005/830.
(**11**) S.I. 1999/2550.
(**12**) S.I. 2002/2776.

(2) In relation to a product placed on the market before the commencement date, the amendments in paragraph (1) do not apply.

Commencement Information

I61 Reg. 74 in force at 8.12.2016, see **reg. 1(1)**

Margot James
Parliamentary Under Secretary of State Minister for Small Business, Consumers and Corporate Responsibility
Department for Business, Energy and Industrial Strategy

Changes to legislation:
There are currently no known outstanding effects for the The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016.