
STATUTORY INSTRUMENTS

2018 No. 390

**The Personal Protective Equipment
(Enforcement) Regulations 2018**

PART 1

Preliminary

Citation, commencement and interpretation **N.I.**

1.—(1) These Regulations may be cited as the Personal Protective Equipment (Enforcement) Regulations 2018 and come into force on 21st April 2018.

(2) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974 ^{M1};

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978 ^{M2};

“the 1987 Act” means the Consumer Protection Act 1987 ^{M3};

“the 2002 Regulations” means the Personal Protective Equipment Regulations 2002 ^{M4};

“district council” means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 ^{M5};

“EU Regulation 2016/425” means Regulation (EU) No 2016/425 ^{M6} of the European Parliament and of the Council on personal protective equipment, repealing Council Directive 89/686/EEC^{M7}, as amended from time to time;

“RAMS” means Regulation (EC) No 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^{M8}, as amended from time to time;

“risk” means a risk which may result in harm to the health or safety of persons, domestic animals or property, if personal protective equipment (“PPE”) is used in a normal and predictable manner; and

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985 ^{M9}.

(3) In these Regulations a reference to—

(a) a numbered regulation, paragraph or Schedule is a reference to the regulation, paragraph or Schedule as numbered in these Regulations unless otherwise stated;

(b) an Article, paragraph of an Article or Annex is a reference to the Article, paragraph of an Article or Annex as numbered in EU Regulation 2016/425;

(c) a “relevant economic operator” in relation to PPE means an economic operator with obligations in respect of PPE under EU Regulation 2016/425; and

(d) an “enforcement authority” is to be construed in accordance with regulation 4.

(4) Expressions and words used in these Regulations which are used in EU Regulation 2016/425 have the same meaning as in EU Regulation 2016/425.

Extent Information

E1 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Marginal Citations

M1 1974 c.37.

M2 S.I. 1978/1039 (N.I. 9).

M3 1987 c.43.

M4 S.I. 2002/1144 as amended by S.I. 2004/693, 2012/1848 and 2015/1630.

M5 1972 Chapter 9.

M6 OJ No L81, 31.3.2016, p.51.

M7 OJ No L399, 30.12.1989, p.18.

M8 OJ No L 218, 13.8.2008, p.30.

M9 1985 c.72; section 69 was amended by the Local Government (Wales) Act 1994 (c.19), section 66 and Schedule 16, paragraph 75; the Local Government etc. (Scotland) Act 1994 (c.39), section 180 and Schedule 13, paragraph 144; and the Statute Law (Repeals) Act 1989 (c.43) Schedule 1, Part 1.

Citation, commencement and interpretation **E+W+S**

1.—(1) These Regulations may be cited as the Personal Protective Equipment (Enforcement) Regulations 2018 and come into force on 21st April 2018.

(2) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974 ^{F10};

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978 ^{F11};

“the 1987 Act” means the Consumer Protection Act 1987 ^{F12};

“the 2002 Regulations” means the Personal Protective Equipment Regulations 2002 ^{F13};

“district council” means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 ^{F14};

“EU Regulation 2016/425” means Regulation (EU) No 2016/425 ^{F15} of the European Parliament and of the Council on personal protective equipment, repealing Council Directive 89/686/EEC^{F16}, as amended from time to time;

[^{F17}“Regulation 2016/425 (pre-exit)” means Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC, as it had effect immediately before IP completion day;]

“RAMS” means Regulation (EC) No 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^{F18}, as amended from time to time;

“risk” means a risk which may result in harm to the health or safety of persons, domestic animals or property, if personal protective equipment (“PPE”) is used in a normal and predictable manner; and

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985 ^{F19}.

(3) In these Regulations [^{F20}(unless otherwise stated)] a reference to—

- (a) a numbered regulation, paragraph or Schedule is a reference to the regulation, paragraph or Schedule as numbered in these Regulations ^{F21} ...;
 - (b) an Article, paragraph of an Article [^{F22}, Chapter] or Annex is a reference to the Article, paragraph of an Article [^{F22}, Chapter] or Annex as numbered in EU Regulation 2016/425;
 - (c) a “relevant economic operator” in relation to PPE means an economic operator with obligations in respect of PPE under EU Regulation 2016/425; and
 - (d) an “enforcement authority” is to be construed in accordance with regulation 4.
- (4) Expressions and words used in these Regulations which are used in EU Regulation 2016/425 have the same meaning as in EU Regulation 2016/425 [^{F23}unless otherwise stated].

Extent Information

- E7** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F10** 1974 c.37.
- F11** S.I. 1978/1039 (N.I. 9).
- F12** 1987 c.43.
- F13** S.I. 2002/1144 as amended by S.I. 2004/693, 2012/1848 and 2015/1630.
- F14** 1972 Chapter 9.
- F15** OJ No L81, 31.3.2016, p.51.
- F16** OJ No L399, 30.12.1989, p.18.
- F17** Words in [reg. 1\(2\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(a\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F18** OJ No L 218, 13.8.2008, p.30.
- F19** [1985 c.72](#); [section 69](#) was amended by the [Local Government \(Wales\) Act 1994](#) (c.19), [section 66](#) and [Schedule 16](#), paragraph 75; the [Local Government etc. \(Scotland\) Act 1994](#) (c.39), [section 180](#) and [Schedule 13](#), paragraph 144; and the [Statute Law \(Repeals\) Act 1989](#) (c.43) [Schedule 1](#), Part 1.
- F20** Words in [reg. 1\(3\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(b\)\(i\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F21** Words in [reg. 1\(3\)\(a\)](#) omitted (E.W.S.) (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. 35 para. 1\(2\)\(b\)\(ii\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F22** Word in [reg. 1\(3\)\(b\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(b\)\(iii\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F23** Words in [reg. 1\(4\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(c\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Application, transitional provisions, savings and revocation **N.I.**

- 2.—(1) These Regulations apply to PPE placed on the market on or after 21st April 2018.
- (2) These Regulations do not apply to PPE—
- (a) designed for the uses specified in Article 2(2)(a) to (d); or
 - (b) that falls within Article 2(2)(e).

(3) Nothing in these Regulations prevents the showing of PPE at trade fairs, exhibitions, demonstrations or the like, which is not in compliance with the provisions of EU Regulation 2016/425, provided that a visible sign clearly indicates that such PPE does not comply with those provisions and that it is not for sale until it is made compliant.

(4) The 2002 Regulations continue to apply, as if they had not been revoked, to PPE placed on the market before 21st April 2019^{M10}, and in any such case the consequential amendments made by Schedule 5 do not apply.

(5) If, before 21st April 2019—

(a) an EC type-examination certificate is issued by an approved body under the 2002 Regulations, pursuant to the EC type-examination procedure set out in Schedule 7 to those Regulations, or

(b) an approval decision is made under, and in accordance with, Part B of Schedule 8 (system for ensuring EC quality of production by means of monitoring) to the 2002 Regulations,

that certificate or decision remains valid until 21st April 2023^{M11}, or until its' expiry date if earlier, for the purpose of satisfying the requirements of an EU declaration of conformity set out in paragraphs 7 or 8 of Annex IX.

(6) The 2002 Regulations are revoked save to the extent required to give effect to paragraphs (4) and (5).

Extent Information

E2 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Marginal Citations

M10 [Article 47\(1\)](#) of EU Regulation 2016/425 provides for PPE which is in conformity with Council Directive 89/686/EEC to be placed on the market until 21 April 2019. The 2002 Regulations transposed Council Directive 89/686/EEC.

M11 [Article 47\(2\)](#) of the EU Regulation 2016/425 provides for EC type-examination certificates and approval decisions issued under Council Directive 89/686/EEC to remain valid until 21 April 2023 unless they expire before that date.

Application, transitional provisions, savings and revocation **E+W+S**

2.—(1) These Regulations apply to PPE placed on the market on or after 21st April 2018.

(2) These Regulations do not apply to PPE—

(a) designed for the uses specified in Article 2(2)(a) to (d); or

(b) that falls within Article 2(2)(e).

(3) Nothing in these Regulations prevents the showing of PPE at trade fairs, exhibitions, demonstrations or the like, which is not in compliance with the provisions of EU Regulation 2016/425, provided that a visible sign clearly indicates that such PPE does not comply with those provisions and that it is not for sale until it is made compliant.

(4) [^{F24}Subject to the modifications made in paragraph (4A),] the 2002 Regulations continue to apply, as if they had not been revoked, to PPE placed on the market before 21st April 2019^{F25}, and in any such case the consequential amendments made by Schedule 5 do not apply.

[^{F26}(4A) The modifications referred to in paragraph (4) are as follows—

(a) any reference to “Community” is to be read as including the United Kingdom;

- (b) any reference to “Member State” is to be read as including the United Kingdom;
- (c) in Schedule 7—
 - (i) in paragraph 5—
 - (aa) omit from “The Commission” to “conducted”;
 - (bb) before “file shall be held” insert “ manufacturer's technical ”;
 - (ii) in paragraph 6, omit from “An inspection body” to the end;
- (d) in Schedule 10, in paragraph 2, omit from “with a view” to “the Commission]
- (5) If, before 21st April 2019—
 - (a) an EC type-examination certificate is issued by an approved body under the 2002 Regulations, pursuant to the EC type-examination procedure set out in Schedule 7 to those Regulations, or
 - (b) an approval decision is made under, and in accordance with, Part B of Schedule 8 (system for ensuring EC quality of production by means of monitoring) to the 2002 Regulations, that certificate or decision remains valid until 21st April 2023 ^{F27}, or until its' expiry date if earlier, for the purpose of satisfying the requirements of an EU declaration of conformity set out in paragraphs 7 or 8 of Annex IX [^{F28}of Regulation 2016/425 (pre-exit) or a declaration of conformity set out in paragraphs 7 or 8 of Annex IX].
- (6) The 2002 Regulations are revoked save to the extent required to give effect to paragraphs [^{F29}(4) to (5)].

Extent Information

- E8** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F24** Reg. 2(4)(a) inserted (31.12.2020) by S.I. 2019/696, Sch. 35 para. 1(3)(a) (as substituted by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(3), **9(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1))
- F25** Article 47(1) of EU Regulation 2016/425 provides for PPE which is in conformity with Council Directive 89/686/EEC to be placed on the market until 21 April 2019. The 2002 Regulations transposed Council Directive 89/686/EEC.
- F26** Reg. 2(4A) inserted (31.12.2020) by S.I. 2019/696, **Sch. 35 para. 1(3)(b)** (as substituted by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(3), **9(b)(ii)**; 2020 c. 1, **Sch. 5 para. 1(1)**)
- F27** Article 47(2) of the EU Regulation 2016/425 provides for EC type-examination certificates and approval decisions issued under Council Directive 89/686/EEC to remain valid until 21 April 2023 unless they expire before that date.
- F28** Words in reg. 2(5) inserted (31.12.2020) by S.I. 2019/696, Sch. 35 para. 1(3)(c) (as substituted by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(3), **9(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1))
- F29** Words in reg. 2(6) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 35 para. 1(3)(e)** (as amended by S.I. 2020/676, regs. 1(1), 2, 3); 2020 c. 1, Sch. 5 para. 1(1))

[^{F1}Obligations which are met by complying with obligations in Regulation 2016/425 (pre-exit)

2A.—(1) In this regulation, “harmonised standard” has the meaning in Article 3(10) of Regulation 2016/425 (pre-exit).

- (2) Paragraph (3) applies where before placing PPE on the market, the manufacturer—
- (a) ensures that the PPE has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II of Regulation 2016/425 (pre-exit);
 - (b) carries out the applicable conformity assessment procedure referred to in Article 19 of Regulation 2016/425 (pre-exit), or has it carried out;
 - (c) draws up the technical documentation referred to in Annex III of Regulation 2016/425 (pre-exit);
 - (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in, or translated into, English;
 - (e) affixes a CE marking in accordance with Articles 16 and 17(1) to (4) of Regulation 2016/425 (pre-exit);
 - (f) draws up an EU declaration of conformity, in accordance with Article 15 of Regulation 2016/425 (pre-exit); and
 - (g) ensures that the EU declaration of conformity is prepared in, or translated into, English.
- (3) Where this paragraph applies—
- (a) the requirements of Articles 8(1) and (2), 15, 16, 17 and 19 are to be treated as being satisfied;
 - (b) Articles 8(3), (4), (7) and (8), 9(2) and regulation 7(1) apply, subject to the modifications in paragraph (8);
 - (c) Article 41 does not apply.
- (4) Paragraph (5) applies, where before placing PPE on the market, the importer ensures that—
- (a) the applicable conformity assessment procedure referred to in Article 19 of Regulation 2016/425 (pre-exit) has been carried out;
 - (b) the manufacturer has drawn up the technical documentation referred to in Annex III of Regulation 2016/425 (pre-exit); and
 - (c) the PPE bears the CE marking in accordance with Articles 16 and 17(1) to (4) of Regulation 2016/425 (pre-exit).
- (5) Where this paragraph applies—
- (a) the requirements in Article 10(2), to ensure that—
 - (i) the appropriate conformity assessment procedure referred to in Article 19 has been carried out;
 - (ii) the manufacturer has drawn up the technical documentation;
 - (iii) the PPE bears the UK marking,are to be treated as being satisfied; and
 - (b) the second subparagraph of Article 10(2), Article 10(4), (5) and (8), and regulation 7(1) apply, subject to the modifications in paragraph (8).
- (6) Paragraph (7) applies where, before placing PPE on the market, a distributor ensures that the PPE bears the CE marking in accordance with Articles 16 and 17(1) to (4) of Regulation 2016/425 (pre-exit).
- (7) Where this paragraph applies—

- (a) the requirement for the distributor to verify that the PPE bears the UK marking, referred to in Article 11(2), is to be treated as being satisfied; and
 - (b) (excluding the requirement mentioned in sub-paragraph (a)), Article 11(2), 11(3) and regulation 7(1) apply, subject to the modifications in paragraph (8).
- (8) The modifications referred to in subparagraphs (3)(b), (5)(b) and (7)(b) are that—
- (a) any reference to a “declaration of conformity” is to be read as a reference to an EU declaration of conformity, referred to in Article 15 of Regulation 2016/425 (pre-exit);
 - (b) any reference to point 1.4 of Annex II is to be read as a reference to point 1.4 of Annex II of Regulation 2016/425 (pre-exit);
 - (c) any reference to “essential health and safety requirements” is to be read as a reference to the essential health and safety requirements referred to in Annex II of Regulation 2016/425 (pre-exit);
 - (d) any reference to “designated standard” is to be read as a reference to a harmonised standard;
 - (e) any reference to “technical documentation” is a reference to the technical documentation referred to in Annex III of Regulation 2016/425 (pre-exit);
 - (f) in regulation 7(1), any reference to a numbered Article is to be read as a reference to the equivalent Article of Regulation 2016/425 (pre-exit).

Textual Amendments

- F1** Regs. 2A, 2B inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 35 para. 1\(4\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2, 3); 2020 c. 1, Sch. 5 para. 1(1)

Conformity assessment procedure obligation which is met by complying with Regulation 2016/425 (pre-exit)

- 2B.**—(1) Paragraph (2) applies where—
- (a) PPE is classified under Article 18 of Regulation 2016/425 (pre-exit) as falling within risk category II or risk category III, as set out in Annex I to Regulation 2016/425 (pre-exit); and
 - (b) prior to manufacture of that PPE, the manufacturer ensures that the conformity assessment procedure set out in Annex V to Regulation 2016/425 (pre-exit), and referred to in Article 19(b) and (c) of Regulation 2016/425 (pre-exit) as EU type-examination, has been carried out in accordance with Article 19(b) or (c).
- (2) Where this paragraph applies—
- (a) the requirement in Article 19(b) or (c) to follow the conformity assessment procedure referred to in those provisions as type-examination, and set out in Annex V, is to be treated as being satisfied;
 - (b) any reference to “conformity assessment procedure” in Articles 8(2) and 10(2) is to be read as including the conformity assessment procedure referred to in Article 19(b) and (c) of Regulation 2016/425 (pre-exit) as EU type-examination;
 - (c) any reference to “technical documentation” in Articles 8(2), 8(3), 10(2) and 10(8) is to be read as including the technical documentation relating to the design of the PPE as referred to in Annex V to Regulation 2016/425 (pre-exit).]

Textual Amendments

- F1** Regs. 2A, 2B inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 1(4)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2, 3); 2020 c. 1, Sch. 5 para. 1(1)

[^{F2}Expiry of regulations 2A and 2B

2C.—(1) Subject to paragraph (2), regulation 2A ceases to have effect at the end of the period of [^{F3}four years] beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 2A—

- (a) any PPE which was placed on the market pursuant to regulation 2A may continue to be made available on the market on or after the expiry of regulation 2A;
- (b) any obligation to which a person was subject under regulation 2A in respect of PPE placed on the market pursuant to regulation 2A continues to have effect after the expiry of regulation 2A, in respect of that PPE.

(3) Subject to paragraph (4), regulation 2B ceases to have effect at the end of the period of [^{F4}four years] beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 2B in relation to a product prior to the expiry of regulation 2B, regulation 2B continues to apply in respect of that product where—

- (a) the manufacturer arranges for the EU-Type examination certificate and any annexes to that certificate 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 procedure referred to in regulation 2B(1)(b) has been carried out in relation to that PPE, in accordance with Article 19(b) or (c) of Regulation 2016/425 (pre-exit).

Textual Amendments

- F2** Regs. 2C, 2D inserted (E.W.S.) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), **Sch. 35 para. 1(4)** (as amended (31.12.2020) by [S.I. 2020/1460](#), reg. 1(4), **Sch. 3 para. 24(2)**)
- F3** Words in [reg. 2C\(1\)](#) 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 para. (f)**
- F4** Words in [reg. 2C\(3\)](#) 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 para. (f)**

Qualifying Northern Ireland Goods

2D.—(1) In this regulation—

“EU Regulation 2016/425 (Northern Ireland)” means Regulation (EU) No. 2016/425 of March 2016 of March 2016 of the European Parliament and of the Council on personal protective

equipment, repealing Council Directive [89/686/EEC](#), as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement;

“applicable conformity assessment procedure” means the conformity assessment procedure applicable to the PPE in accordance with Article 19 of EU Regulation 2016/245 (Northern Ireland);

“CE marking” has the meaning given to it in Article 3(18) of EU Regulation 2016/425 (Northern Ireland);

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

“technical documentation” means the documentation referred to in Annex III of Regulation 2016/425 (Northern Ireland).

(2) Where paragraph (3) applies—

- (a) PPE is to be treated as being in conformity with the essential safety requirements within the meaning given in EU Regulation 2016/425; and
- (b) each relevant economic operator is to be treated as having complied or as complying with the obligations imposed on them under Chapter II of EU Regulation 2016/425.

(3) This paragraph applies where—

- (a) PPE is—
 - (i) in conformity with the essential requirements within the meaning given in EU Regulation 2016/245 (Northern Ireland); and
 - (ii) qualifying Northern Ireland goods; and
- (b) each relevant economic operator has complied or is complying with the obligations imposed on them under Chapter II of EU Regulation 2016/425 (Northern Ireland); and
- (c) an importer has complied with the obligations set out in paragraph (4).

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

- (a) complies with Article 10(3) of EU Regulation 2016/425;
- (b) ensures that—
 - (i) the applicable conformity assessment procedure has been carried out in relation to the PPE;
 - (ii) the manufacturer has drawn up the technical documentation; and
 - (iii) the PPE bears the CE marking.]

Textual Amendments

- F2** Regs. 2C, 2D inserted (E.W.S.) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [Sch. 35 para. 1\(4\)](#) (as amended (31.12.2020) by [S.I. 2020/1460](#), [reg. 1\(4\)](#), [Sch. 3 para. 24\(2\)](#))

PART 2

Market Surveillance and Enforcement

Designation of market surveillance authorities

- 3.—(1) The market surveillance authority is—
- (a) in the case of PPE for private use or consumption (other than that referred to in paragraph (2)(b))—
 - (i) in Great Britain, within its area, a weights and measures authority; and
 - (ii) in Northern Ireland, within its area, a district council;
 - (b) in the case of PPE for use or operation in the circumstances set out in paragraph (2)—
 - (i) subject to paragraph (3), in Great Britain, the Health and Safety Executive; and
 - (ii) in Northern Ireland, the Health and Safety Executive for Northern Ireland.
- (2) The circumstances referred to in paragraphs (1)(b) are where the PPE is designed—
- (a) for use or operation, whether exclusively or not, by persons at work; or
 - (b) for use, otherwise than at work, in non-domestic premises made available to persons at a place where they may use the PPE provided for their own use there.
- (3) In so far as these Regulations apply to PPE intended exclusively or primarily for use on relevant nuclear sites, the market surveillance authority is the Office for Nuclear Regulation.
- (4) In paragraph (3) “relevant nuclear site” means a site which is—
- (a) a GB nuclear site (within the meaning given in section 68 of the Energy Act 2013 ^{M12});
 - (b) an authorised defence site (within the meaning given in regulation 2(1) of the Health and Safety (Enforcing Authority) Regulations 1998 ^{M13}); or
 - (c) a new nuclear build site (within the meaning given in regulation 2A of those Regulations ^{M14}).

Marginal Citations

M12 2013 c.32.

M13 S.I. 1998/494 amended by S.I. 2014/469. There are other amendments not relevant to these Regulations.

M14 Regulation 2A was inserted by S.I. 2014/469 and amended by S.I. 2015/51 (regulation 38, Schedule 5).

Enforcement Authorities

- 4.—(1) Subject to paragraph (2), EU Regulation 2016/425, these Regulations and RAMS (in its application to PPE) must be enforced by the market surveillance authority.
- (2) Notwithstanding paragraph (1), the Secretary of State may enforce EU Regulation 2016/425, these Regulations and RAMS (in its application to PPE).
- (3) In Scotland only the Lord Advocate may commence proceedings for an offence under these Regulations.

Enforcement Powers

5.—(1) Schedule 1 makes provision for enforcement powers under the 1987 Act where the enforcement authority is—

- (a) a weights and measures authority;
- (b) a district council; or
- (c) the Secretary of State.

(2) Schedule 2 makes provision for enforcement powers under the 1974 Act where the enforcement authority is the Health and Safety Executive or the Office for Nuclear Regulation.

(3) Schedule 3 makes provision for enforcement powers under the 1978 Order where the enforcement authority is the Health and Safety Executive for Northern Ireland.

(4) In addition to the powers available to an enforcement authority by virtue of paragraph (1), (2) or (3), as appropriate, the enforcement authority may use the powers in Schedule 4 (compliance, withdrawal and recall notices).

Notification to the Secretary of State of enforcement action etc **E+W+S**

6. A market surveillance authority must immediately notify the Secretary of State of any action taken by it, evaluation made or other opinion formed by it, [^{F5}in accordance with Chapter 6].

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F5 Words in [reg. 6](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 35 para. 1\(5\)](#) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Notification to the Secretary of State of enforcement action etc **N.I.**

6. A market surveillance authority must immediately notify the Secretary of State of any action taken by it, evaluation made or other opinion formed by it, or other matter within its knowledge which is required by Article 38 to be communicated to the Commission or the ^{F30}... member States.

Extent Information

E9 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F30 Word in [reg. 6](#) omitted (N.I.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 17 para. 1\(2\)](#)

[^{F6}Information obligations

6A.—(1) Nothing in EU Regulation 2016/425 requires any market surveillance authority or the Secretary of State to inform the Commission or member States of any matter in relation to PPE on the market of Great Britain only.]

Textual Amendments

F6 Reg. 6A inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 17 para. 1(3)**

Offences **E+W+S**

7.—(1) It is an offence for an economic operator to contravene the requirements and obligations set out in—

- (a) Article 8 (obligations of manufacturers);
- (b) Article 10 (obligations of importers);
- (c) Article 11 (obligations of distributors);
- (d) Article 13 (identification of economic operators);
- (e) Article 16 (general principles of [^{F7}UK] marking); and
- (f) Article 17 (rules and conditions for affixing the [^{F7}UK] marking).

(2) It is an offence for an economic operator to fail to—

- (a) cooperate with;
- (b) provide information to; and
- (c) comply with any of the requirements of,

the market surveillance authority acting under Article 38.

(3) It is an offence for an economic operator to fail to take the action required under—

- (a) Article 40 (compliant PPE which presents a risk); or
- (b) Article 41 (formal non-compliance).

(4) It is an offence for a person—

- (a) to intentionally obstruct an enforcement authority acting in the execution or enforcement of EU Regulation 2016/425;
- (b) without reasonable cause, to fail to give such an enforcement authority any assistance or information which that person may reasonably require for those purposes;
- (c) to knowingly or recklessly furnish to such an enforcement authority any information knowing it to be false or misleading in a material particular; or
- (d) to fail to produce a document or record for such an enforcement authority when required to do so.

(5) Proceedings must not be commenced against an economic operator under paragraph (1), (2) or (3) if the economic operator has been given a time period within which to comply or take action, and that time period has not expired.

Extent Information

- E4** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F7** Word in [reg. 7\(1\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 35 para. 1\(6\)](#) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2, 3](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

Modifications etc. (not altering text)

- C1** [Reg. 7\(1\)](#) modified (W.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Wales\) Regulations 2020 \(S.I. 2020/1489\)](#), [regs. 1\(1\)](#), [4\(1\)](#) (with [reg. 4\(4\)](#))
- C2** [Reg. 7\(1\)](#) modified (E.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(England\) Regulations 2020 \(S.I. 2020/1484\)](#), [regs. 1\(1\)](#), [4\(1\)](#) (with [reg. 4\(4\)](#))
- C3** [Reg. 7\(1\)](#) modified (S.) (1.2.2021) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Scotland\) Regulations 2021 \(S.S.I. 2021/50\)](#), [regs. 1](#), [4\(1\)](#) (with [reg. 4\(4\)](#))
- C4** [Reg. 7\(3\)](#) modified (E.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(England\) Regulations 2020 \(S.I. 2020/1484\)](#), [regs. 1\(1\)](#), [4\(2\)\(3\)](#) (with [reg. 4\(4\)](#))
- C5** [Reg. 7\(3\)](#) modified (W.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Wales\) Regulations 2020 \(S.I. 2020/1489\)](#), [regs. 1\(1\)](#), [4\(2\)\(3\)](#) (with [reg. 4\(4\)](#))
- C6** [Reg. 7\(3\)](#) modified (S.) (1.2.2021) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Scotland\) Regulations 2021 \(S.S.I. 2021/50\)](#), [regs. 1](#), [4\(2\)\(3\)](#) (with [reg. 4\(4\)](#))

Offences **N.I.**

7.—(1) It is an offence for an economic operator to contravene the requirements and obligations set out in—

- (a) Article 8 (obligations of manufacturers);
- (b) Article 10 (obligations of importers);
- (c) Article 11 (obligations of distributors);
- (d) Article 13 (identification of economic operators);
- (e) Article 16 (general principles of CE marking); and
- (f) Article 17 (rules and conditions for affixing the CE marking).

(2) It is an offence for an economic operator to fail to—

- (a) cooperate with;
- (b) provide information to; and
- (c) comply with any of the requirements of,

the market surveillance authority acting under Article 38.

(3) It is an offence for an economic operator to fail to take the action required under—

- (a) Article 40 (compliant PPE which presents a risk); or
- (b) Article 41 (formal non-compliance).

(4) It is an offence for a person—

- (a) to intentionally obstruct an enforcement authority acting in the execution or enforcement of EU Regulation 2016/425;
 - (b) without reasonable cause, to fail to give such an enforcement authority any assistance or information which that person may reasonably require for those purposes;
 - (c) to knowingly or recklessly furnish to such an enforcement authority any information knowing it to be false or misleading in a material particular; or
 - (d) to fail to produce a document or record for such an enforcement authority when required to do so.
- (5) Proceedings must not be commenced against an economic operator under paragraph (1), (2) or (3) if the economic operator has been given a time period within which to comply or take action, and that time period has not expired.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Penalties

- 8.** A person guilty of an offence under these Regulations is liable on summary conviction—
- (a) in England and Wales, to a fine or imprisonment for a term not exceeding three months, or to both;
 - (b) in Scotland and Northern Ireland, to a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding three months, or to both;

Defence of due diligence

9.—(1) In proceedings for an offence under these Regulations, 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 notice in accordance with paragraph (3); or
 - (b) obtained leave of the court.
- (3) The notice must—
- (a) give any information in the possession of P which identifies or assists in identifying the person who—
 - (i) is alleged to have committed the act or default; or
 - (ii) supplied the information on which P relies; and
 - (b) be served on the person bringing the proceedings not less than seven clear days before—
 - (i) the hearing of the proceedings in England, Wales and Northern Ireland;
 - (ii) the trial date in Scotland.

(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 in all the circumstances to have relied on 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 to—

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

(b) reliance on information supplied by another person.

Liability of persons other than the principal offender

10.—(1) Where the commission by a person (“P”) of an offence under these Regulations is due to anything which another person (“S”) did or failed to do in the course of business, S is guilty of that offence and may be proceeded against and punished, whether or not proceedings are taken against P.

(2) Where a body corporate commits an offence under these Regulations, a relevant person is also guilty of the offence where the offence was committed by the body corporate—

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

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

(3) In paragraph (2) a “relevant person” means—

(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 performing managerial functions;

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

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

Time limit for prosecution of offences

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

(2) In Scotland—

(a) summary proceedings for an offence may only be commenced within 12 months after the date on which evidence sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge, and

(b) section 136(3) of the Criminal Procedure (Scotland) Act 1995 ^{M15} (time limit for certain offences) applies for the purpose of this paragraph as it applies for the purpose of that section.

(3) In Northern Ireland summary proceedings for an offence may be instituted within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify proceedings comes to the knowledge of the prosecutor.

(4) No proceedings are to be brought more than three years after the commission of the offence.

(5) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which such evidence as is referred to above came to their notice is conclusive evidence of that fact.

(6) This regulation has effect subject to paragraph (1)(n) of Schedule 2 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act) and to

paragraph (1)(n) of Schedule 3 (enforcement powers of the Health and Safety Executive for Northern Ireland under the 1978 Order).

Marginal Citations

M15 1995 c.46.

Written notice under Article 38 and service of documents **N.I.**

12.—(1) In a case falling within Article 38 (procedure at national level for dealing with PPE presenting a risk), a market surveillance authority must provide notice when requiring the economic operator to, within a reasonable period—

- (a) take appropriate corrective action;
- (b) withdraw the PPE from the market [^{F8}in Northern Ireland]; or
- (c) recall the PPE.

(2) The notice given under paragraph (1) must—

- (a) give reasons for the action required;
- (b) provide a time limit for compliance; and
- (c) be served in accordance with paragraphs (3) to (6).

(3) Any document required or authorised by EU Regulation 2016/425 or these Regulations to be served on a person may be served by—

- (i) delivering it to that person in person;
- (ii) leaving it at the person's proper address; or
- (iii) sending it by post or electronic means to that person's proper address.

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

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

(6) If a person 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.

(7) 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; or
 - (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; or
 - (ii) the email address of a partner or a person having that control or management;
- (c) in any other case, a person's last known address, which includes an email address.

(8) In this regulation, “partnership” includes a Scottish partnership.

Extent Information

- E5** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F8** Words in [reg. 12\(1\)\(b\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 17 para. 1\(4\)](#)

Written notice under Article 38 and service of documents **E+W+S**

12.—(1) In a case falling within Article 38 (procedure ^{F31}... for dealing with PPE presenting a risk), a market surveillance authority must provide notice when requiring the economic operator to, within a reasonable period—

- (a) take appropriate corrective action;
 - (b) withdraw the PPE from the market; or
 - (c) recall the PPE.
- (2) The notice given under paragraph (1) must—
- (a) give reasons for the action required;
 - (b) provide a time limit for compliance; and
 - (c) be served in accordance with paragraphs (3) to (6).
- (3) Any document required or authorised by EU Regulation 2016/425 or these Regulations to be served on a person may be served by—
- (i) delivering it to that person in person;
 - (ii) leaving it at the person's proper address; or
 - (iii) sending it by post or electronic means to that person's proper address.
- (4) In the case of a body corporate, a document may be served on a director of that body.
- (5) In the case of a partnership, a document may be served on a partner or person having control or management of the partnership business.
- (6) If a person 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.
- (7) 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; or
 - (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; or
 - (ii) the email address of a partner or a person having that control or management;
 - (c) in any other case, a person's last known address, which includes an email address.
- (8) In this regulation, “partnership” includes a Scottish partnership.

Extent Information

- E11** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F31** Words in [reg. 12\(1\)](#) omitted (E.W.S.) (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. 35 para. 1\(7\)](#) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2, 3](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

Appeals against notices

13.—(1) An application for an order to vary the terms of, or set aside, a notice served under regulation 5 (enforcement powers) or 12 (Article 38 notices) may be made—

- (a) by the economic operator on whom the notice has been served; and
- (b) in the case of a notice other than a recall notice, by a person having an interest in the PPE 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 regulation 5 or 12 if satisfied—

- (a) that no contravention of EU Regulation 2016/425 or these Regulations has occurred; or
- (b) that the enforcement authority failed to comply with Article 14 (presumption of conformity of PPE) when serving the notice.

(4) On an application to vary the terms of the notice, 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 14; and
- (b) “notice” means—
 - (i) a notice served under regulation 12;
 - (ii) a prohibition notice, a notice to warn or a suspension notice served in accordance with Schedule 1; or
 - (iii) a compliance notice, a withdrawal notice, or a recall notice served in accordance with Schedule 4.

Appropriate court for appeals against notices etc and further appeals

14.—(1) In England and Wales, or Northern Ireland, the appropriate court for the purposes of regulation 13 is—

- (a) the court in which proceedings have been brought for an offence under regulation 7 (offences);
- (b) an employment tribunal seized of appeal proceedings against a notice which relates to PPE which has been served under or by virtue of paragraph 1 of Schedule 2;
- (c) an industrial tribunal seized of appeal proceedings against a notice which relates to PPE which has been served under or by virtue of paragraph 1 of Schedule 3 (enforcement powers of the Health and Safety Executive for Northern Ireland under the 1978 Order); or

- (d) in any other case, a magistrates' court in England and Wales, or Northern Ireland.
- (2) In Scotland the appropriate court for the purposes of regulation 13 is—
 - (a) the sheriff of a sheriffdom in which the person making the appeal resides or, as the case may be, has a registered or principal office; or
 - (b) an employment tribunal seized of appeal proceedings against a notice which relates to PPE which has been served under or by virtue of paragraph 1 of Schedule 2.
- (3) A person aggrieved by an order made by a magistrates' court in England and Wales, or Northern Ireland, pursuant to an application under regulation 13, or by a decision of such a court not to make such an order, may appeal against that order or decision—
 - (a) in England and Wales, to the Crown Court;
 - (b) in Northern Ireland, to the county court.

Compensation

15.—(1) Where an enforcement authority other than the Health and Safety Executive, the Health and Safety Executive of Northern Ireland or the Office for Nuclear Regulation, serves a relevant notice in respect of PPE, that authority is liable to pay compensation to a person having an interest in the PPE in respect of any loss or damage caused by reason of the notice if both conditions mentioned in paragraph (2) are met.

- (2) The conditions are that—
 - (a) the PPE in respect of which the relevant notice was served neither—
 - (i) presents a risk; nor
 - (ii) contravenes any requirement of EU regulation 2016/425; and
 - (b) any neglect or default on the part of the economic operator was not the reason for service of the relevant notice.
- (3) In this regulation, “relevant notice” means a suspension, withdrawal or recall notice as referred to in regulation 13(5)(b).

Recovery of expenses of enforcement

16.—(1) This regulation applies where a person commits an offence under regulation 7 (offences).

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

Action by enforcement authority

17.—(1) An enforcement authority may itself take any action which an economic operator could have been required to take by a notice served under regulation 5 (enforcement powers) where the conditions for serving such a notice are met and either—

- (a) the enforcement 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 enforcement authority has taken action under paragraph (1) following the failure of an economic operator to comply with a notice, the authority may recover from that person as a civil debt any costs or expenses incurred by the enforcement authority in taking the action.
- (3) A civil debt recoverable under paragraph (2) may be recovered summarily—

- (a) in England and Wales, by way of a complaint pursuant to section 58 of the Magistrates' Courts Act 1980;
- (b) in Northern Ireland, in proceedings under Article 62 of the Magistrates' Court (Northern Ireland) Order 1981.

PART 3

Miscellaneous

Review and consequential amendments **E+W+S**

18.—(1) The Secretary of State must—

- (a) carry out a review of the regulatory provision contained in these Regulations; and
- (b) publish a report setting out the conclusions of that review.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how EU Regulation 2016/425 (which is enforced and supplemented by means of these Regulations) is executed and enforced in other member States.

(3) The first report must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(4) Subsequent reports under this regulation are to be published at intervals not exceeding five years.

(5) Section 30(4) of Small Business, Enterprise and Employment Act 2015 ^{M16} requires that the reports published under this regulation must, in particular—

- (a) set out the objectives intended to be achieved by the regulatory provision referred to in paragraph (1)(a),
- (b) assess the extent to which those objectives are achieved,
- (c) assess whether those objectives remain appropriate, and
- (d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(6) In this regulation, “regulatory provision” has the same meaning as in sections 28 to 32 of the 2015 Act (see section 32 of that Act).

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Marginal Citations

M16 2015 c.26.

Review and consequential amendments **N.I.**

18.—(1) The Secretary of State must—

- (a) carry out a review of the regulatory provision contained in these Regulations; and
- (b) publish a report setting out the conclusions of that review.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how EU Regulation 2016/425 (which is enforced and supplemented by means of these Regulations) is executed and enforced in [^{F32}any] member States.

(3) The first report must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(4) Subsequent reports under this regulation are to be published at intervals not exceeding five years.

(5) Section 30(4) of Small Business, Enterprise and Employment Act 2015 ^{F33} requires that the reports published under this regulation must, in particular—

- (a) set out the objectives intended to be achieved by the regulatory provision referred to in paragraph (1)(a),
- (b) assess the extent to which those objectives are achieved,
- (c) assess whether those objectives remain appropriate, and
- (d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(6) In this regulation, “regulatory provision” has the same meaning as in sections 28 to 32 of the 2015 Act (see section 32 of that Act).

Extent Information

E12 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F32 Word in [reg. 18\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 17 para. 1\(5\)](#)

F33 [2015 c.26](#).

19. Schedule 5 (consequential amendments) makes amendments to legislation which are consequential to these Regulations (subject to regulation 2(4)).

[^{F9}PART 4

Provisions in respect of the UK(NI) indication

Textual Amendments

F9 [Pt. 4](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1460\)](#), [reg. 1\(2\)](#), [Sch. 2 para. 15\(2\)](#)

Interpretation

20. In this Part “UK(NI) indication” means the marking in the form set out in Schedule 1 to the [Product Safety and Metrology etc. \(Amendment etc.\) \(UK\(NI\) Indication\) \(EU Exit\) Regulations 2020](#).

UK(NI) indication

21.—(1) Where the CE marking is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the PPE, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

- (a) visibly, legibly and indelibly; and
- (b) before PPE is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with Article 17.

(4) The UK(NI) indication must be affixed by—

- (a) the manufacturer; or
- (b) the manufacturer's authorised representative.

(5) When placing PPE on the market in Northern Ireland, an importer must ensure that the manufacturer has complied with their obligations under this regulation.

United Kingdom notified bodies

22.—(1) The reference in Article 28(5) to “objections” does not include objections on the grounds that—

- (a) the conformity assessment body is established in the United Kingdom; or
- (b) the accreditation certificate was issued by the United Kingdom's national accreditation body.

(2) Where a notified body established in the United Kingdom is involved in a conformity assessment procedure pursuant to Article 19, the notified body identification number referred to in Article 17(3) is the notified body identification number assigned to the notified body pursuant to regulation 23.

Register of notified bodies established in the United Kingdom

23.—(1) The Secretary of State must ensure that—

- (a) each notified body established in the United Kingdom is assigned an identification number; and
- (b) there is a register of—
 - (i) notified bodies established in the United Kingdom;
 - (ii) their notified body identification number;
 - (iii) the activities for which they have been notified;
 - (iv) any restrictions on those activities.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).

Offence in relation to the UK(NI) indication

24.—(1) Where an enforcement authority finds that the UK(NI) indication—

- (a) has not been affixed, in contravention of regulation 21; or

(b) has been affixed otherwise in accordance with regulation 21

it must require a manufacturer to put an end to the non-compliance within such reasonable period as the authority specifies.

(2) Until the specified period has elapsed, the enforcement authority must not commence proceedings under these Regulations, or take any other enforcement action under these Regulations, against the manufacturer in respect of the non-compliance referred to in paragraph (1).

(3) Where the non-compliance referred to in paragraph (1) persists beyond the specified period, the enforcement authority must take appropriate measures to—

- (a) restrict or prohibit the PPE being available on the market;
- (b) ensure that the PPE is withdrawn;
- (c) ensure that the PPE is recalled.

(4) It is an offence for any person to contravene or fail to comply with any requirement of a withdrawal or recall notice that relates to the UK(NI) indication served on that person under these Regulations.

(5) A person guilty of an offence under paragraph (4) shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(6) This regulation does not apply where PPE presents a risk.]

Department for Business, Energy and Industrial
Strategy

Andrew Griffiths
Minister for Small Business, Consumer and
Corporate Responsibility

Changes to legislation:

There are currently no known outstanding effects for the The Personal Protective Equipment (Enforcement) Regulations 2018.