

SCHEDULE 35

Amendment of Regulation (EU) 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018

PART 1

Amendment of subordinate legislation

Amendment of the Personal Protective Equipment (Enforcement) Regulations 2018

1.—(1) The Personal Protective Equipment (Enforcement) Regulations 2018 are amended as follows.

(2) In regulation 1—

(a) in paragraph (2), at the appropriate place, insert the following [^{F1}definition]—

““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 [^{F2}IP completion day];

^{F3} ...”;

(b) in paragraph (3)—

(i) after “In these Regulations”, insert “ (unless otherwise stated) ”;

(ii) in sub-paragraph (a), omit “unless otherwise stated”;

(iii) in sub-paragraph (b), after “paragraph of an Article” in both places insert “ , Chapter ”;

(c) in paragraph (4), after “EU Regulation 2016/425” in the second place it occurs, insert “ unless otherwise stated ”.

(3) In regulation 2—

[^{F4}(a) at the beginning of paragraph (4) insert “ Subject to the modifications made in paragraph (4A), ”]

[^{F5}(b) after paragraph (4), insert—

“(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”.]

[^{F6}(c) in paragraph (5), at the end, insert “ of Regulation 2016/425 (pre-exit) or a declaration of conformity set out in paragraphs 7 or 8 of Annex IX ”;]

^{F7}(d)

- (e) in paragraph (6), for “(4) and (5)” substitute “ (4) to ([^{F8}5]) ”.
- (4) After regulation 2, insert—

“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).

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).

[^{F9}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 12 months 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 12 months 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).

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 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.

Changes to legislation: There are currently no known outstanding effects for the *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, PART 1.* (See end of Document for details)

- (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.”].
- (5) In regulation 6, for the words from “or other matter within its knowledge” to the end, substitute “in accordance with Chapter 6 ”.
- (6) In regulation 7(1), in both places, for “CE” substitute “ UK ”.
- (7) In regulation 12(1), omit “at national level”.

^{F10}(8)

^{F10}(9)

F1	Word in Sch. 35 para. 1(2)(a) substituted (31.12.2020 immediately before IP completion day) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246) , regs. 1(3), 9(a)(i) ; 2020 c. 1, Sch. 5 para. 1(1)
F2	Words in Sch. 35 para. 1(2)(a) substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/852) , regs. 2(2), 4(2), Sch. 1 para. 1(u)(i)
F3	Words in Sch. 35 para. 1(2)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246) , regs. 1(3), 9(a)(ii) ; 2020 c. 1, Sch. 5 para. 1(1)
F4	Sch. 35 para. 1(3)(a) substituted (31.12.2020 immediately before IP completion day) 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)
F5	Sch. 35 para. 1(3)(b) substituted (31.12.2020 immediately before IP completion day) 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)
F6	Sch. 35 para. 1(3)(c) substituted (31.12.2020 immediately before IP completion day) 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)
F7	Sch. 35 para. 1(3)(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246) , regs. 1(3), 9(b)(iv) ; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, PART 1. (See end of Document for details)

F8	Word in Sch. 35 para. 1(3)(e) substituted (31.12.2020 immediately before IP completion day) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(3), 9(b)(v) ; 2020 c. 1, Sch. 5 para. 1(1)
F9	Words in Sch. 35 para. 1(4) inserted (31.12.2020 immediately before IP completion day) 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. 24(2)
F10	Sch. 35 para. 1(8)(9) omitted (31.12.2020 immediately before IP completion day) by virtue of The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(3), 9(c) ; 2020 c. 1, Sch. 5 para. 1(1)
Commencement Information	
I1	Sch. 35 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Consequential amendments to subordinate legislation

- 2.—(1) The following consequential amendments are made to subordinate legislation.
- (2) In the Personal Protective Equipment at Work Regulations 1992 ^{M1}, in regulation 4(5)(b), omit “(OJ No L81, 31.3.2016, p51)”.
- (3) In the Control of Lead at Work Regulations 2002 ^{M2}, in regulation 6(11), omit “(OJ No L81, 31.3.2016, p51)”.
- (4) In the Control of Substances Hazardous to Health Regulations 2002 ^{M3}, in regulation 7(12), omit “(OJ No L81, 31.3.2016, p51)”.
- ^{F11}(5)
- ^{F12}(6)
- (7) In the Control of Noise at Work Regulations 2005 ^{M4}, in regulation 7(5), omit “(OJ No L81, 31.3.2016, p51)”.
- ^{F13}(8)
- (9) In Schedule 5B to the REACH Enforcement Regulations 2008 ^{M5}, in paragraph 5, omit “(OJ No L81, 31.3.2016, p51)”.
- (10) In the Control of Asbestos Regulations 2012 ^{M6}, in regulation 11(6), omit “(OJ No L81, 31.3.2016, p51)”.
- ^{F14}(11)
- (12) In the Ionising Radiations Regulations 2017 ^{M7}, in regulation 10(3), omit “(OJ No L81, 31.3.2016, p51)”.
- ^{F15}(13)

F11	Sch. 35 para. 2(5) omitted (31.12.2020 immediately before IP completion day) by virtue of 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. 24(3)
F12	Sch. 35 para. 2(6) omitted (31.12.2020 immediately before IP completion day) by virtue of 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. 24(3)
F13	Sch. 35 para. 2(8) omitted (31.12.2020 immediately before IP completion day) by virtue of 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. 24(3)

Changes to legislation: There are currently no known outstanding effects for the *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, PART 1*. (See end of Document for details)

- F14** Sch. 35 para. 2(11) omitted (31.12.2020 immediately before IP completion day) by virtue of *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. 24(3)**
- F15** Sch. 35 para. 2(13) omitted (31.12.2020 immediately before IP completion day) by virtue of *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. 24(3)**

Commencement Information

- I2** Sch. 35 para. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

- M1** S.I. 1992/2966. There are amendments not relevant to this instrument.
- M2** S.I. 2002/2676. There are amendments not relevant to this instrument.
- M3** S.I. 2002/2677. There are amendments not relevant to this instrument.
- M4** S.I. 2005/1643. There are amendments not relevant to this instrument.
- M5** S.I. 2008/2852. There are amendments not relevant to this instrument.
- M6** S.I. 2012/632. There are amendments not relevant to this instrument.
- M7** S.I. 2017/1075. There are amendments not relevant to this instrument.

Changes to legislation:

There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, PART 1.