

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 definitions—

““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 exit day;

“the relevant period” means the period of time beginning on exit day and ending at midnight on 20th April 2019;”;

(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—

(a) in paragraph (4), for “21st April 2019” substitute “exit day”;

(b) after paragraph (4), insert—

“(4A) The 2002 Regulations continue to apply, as if they had not been revoked, to PPE placed on the market during the relevant period, and in any such case—

(a) the 2002 Regulations apply subject to the modifications set out in Schedule 6; and

(b) the consequential amendments made by Schedule 5 do not apply.”;

(c) in paragraph (5)—

(i) for “21st April 2019” substitute “exit day”;

(ii) for “an EU” (at the end), substitute “a”;

(d) after paragraph (5), insert—

“(5A) If, during the relevant period—

(a) a type-examination certificate is issued by an approved body under the 2002 Regulations (as modified by Schedule 6), pursuant to the type-examination procedure set out in Schedule 7 to those Regulations, or

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- (b) an approval decision is made under, and in accordance with, Part B of Schedule 8 (system for ensuring quality of production by means of monitoring) to the 2002 Regulations (as modified by Schedule 6),
that certificate or decision remains valid until 21st April 2023, or until its expiry date, if earlier, for the purpose of satisfying the requirements of a declaration of conformity set out in paragraphs 7 or 8 of Annex IX.”;
 - (e) in paragraph (6), for “(4) and (5)” substitute “(4) to (5A)”.
- (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;

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- (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).”.
- (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”.
- (8) After regulation 19, insert—
- “20. Schedule 6 makes modifications to the 2002 Regulations that apply in the case of PPE which is placed on the market during the relevant period.”.**
- (9) After Schedule 5, insert—

“SCHEDULE 6

Regulation 20

Modifications to the 2002 Regulations

1. In the case of PPE which is placed on the market during the relevant period, the 2002 Regulations apply subject to the modifications set out in paragraph 2.
2. The following provisions of the 2002 Regulations apply as if—
 - (a) in regulation 2—
 - (i) paragraph (1)(b) were omitted;
 - (ii) in paragraph (2)—
 - (aa) the definitions of “CE marking”, “the Commission”, “harmonised standard” and “transposed harmonised standard” were omitted;
 - (bb) in the definition of “responsible person”, for “European Union” in both places, there were substituted “United Kingdom”;
 - (cc) in the definition of “supply”, for “European Union” there were substituted “United Kingdom”;
 - (dd) at the appropriate places, the following definitions were inserted—
 - ““designated standard” has the meaning given in Article 7A of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council [Directive 89/686/EEC](#).”;
 - ““placing on the market” means the first supply of PPE for distribution or use on the United Kingdom market in the course of a commercial activity, whether in return for payment or free of charge.”; and
 - ““UK marking” means the marking in the form set out in Annex 2 of 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) [339/93](#).”;
 - (b) in regulation 5—
 - (i) at the end of paragraph (1), “or” were omitted;

- (ii) paragraph (2) were omitted;
- (c) in regulation 8(2)—
 - (i) in sub-paragraph (a), for “transposed harmonised standard” there were substituted “designated standard”;
 - (ii) for “European Union”, in both places, there were substituted “United Kingdom”;
 - (iii) in sub-paragraph (c), for “CE” there were substituted “UK”;
- (d) in regulation 10—
 - (i) for “European Union”, in each place it occurs, there were substituted “United Kingdom”;
 - (ii) for “CE” there were substituted “UK”;
- (e) in regulation 11, “EC” in each place it occurs, were omitted;
- (f) in regulation 12—
 - (i) in the heading, and in each place it occurs in paragraphs (1) to (4), for “CE” there were substituted “UK”;
 - (ii) in paragraph (2), for “European Union” there were substituted “United Kingdom”;
 - (iii) in paragraph (3)—
 - (aa) for “directive or directives”, in both places, there were substituted “enactment”;
 - (bb) the words “in addition to the PPE Directive” were omitted;
 - (iv) in paragraph (4)—
 - (aa) for “directives”, in the first place it occurs, there were substituted “enactments”;
 - (bb) for “directive or directives”, in each place it occurs, there were substituted “enactment”;
 - (cc) the words “as published in the Official Journal of the European Union” were omitted;
- (g) for regulation 13 there were substituted—

“Approved Bodies

- 13.—**(1) For the purposes of these Regulations, an approved body is a body which—
- (a) has been appointed as an approved body pursuant to regulation 14 to carry out one or more of the conformity assessment procedures specified in regulation 11; or
 - (b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action under regulation 14(2)(e), as it had effect immediately before exit day, to terminate the appointment.
- (2) In this regulation, “notified body” means a body which, before exit day, had been—
- (a) appointed as an approved body pursuant to regulation 14, as it had effect immediately before exit day; and
 - (b) notified by the Secretary of State to the European Commission and other member States pursuant to Article 9(1) of the PPE Directive.”;
- (h) in regulation 14—
 - (i) in paragraph (6)—

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- (aa) for “an EC” in both places, there were substituted “a”;
- (bb) “EC” in the second place it occurs, were omitted;
- (ii) in paragraph (7), for “an EC”, there were substituted “a”;
- (i) after regulation 14, there were inserted—

“Register of approved bodies

14A. 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 identification numbers;
 - (iii) the activities for which they have been approved; and
 - (iv) any restrictions on those activities.”;
- (j) in regulation 16 for “CE”, in each place it occurs, there were substituted “UK”;
- (k) in Schedule 2 (Annex II of the PPE Directive)—
 - (i) in paragraph 1.4—
 - (aa) in the first sentence, (beginning “In addition to”), for “European Union” there were substituted “United Kingdom”;
 - (bb) in sub-paragraph (h), for “the Directives applied in accordance with Article 5(6)(b)” there were substituted, “any other enactments applied”;
 - (cc) in the last sentence (beginning “These notes”), for “at least in the official language(s) of the Member State of destination” there were substituted “in English”;
 - (ii) in paragraph 2.12—
 - (aa) “harmonised” were omitted;
 - (bb) for “the official languages(s) of the Member State where the equipment is to be used” there were substituted “English”;
 - (iii) in paragraph 3.5 for “by Council [Directive 86/188/EEC](#) of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work” there were substituted “in the Control of Noise at Work Regulations 2005 ([S.I. 2005/1643](#)) and the Control of Noise at Work Regulations (Northern Ireland) 2006 ([S.R. 2006 No.1](#))”(1);
- (l) in Schedule 3 (Annex III of the PPE Directive)—
 - (i) in paragraph 1(b)—
 - (aa) for “harmonised” there were substituted “designated”;
 - (bb) “referred to in Articles 3 and 5” were omitted;
 - (ii) in paragraph 2, for “harmonised” there were substituted “designated”;

(1) Council [Directive 86/188/EEC](#) on the protection of workers from the risks related to exposure to noise at work was repealed by Article 15 of Council [Directive 2003/10/EC](#) of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise), (OJ No L42, 15.2.2003, p 38). These Regulations implement, as respects Great Britain and Northern Ireland, [Directive 2003/10/EC](#). There are amendments not relevant to this instrument.

- (iii) in paragraph 3, for “Annex II, 1.4” there were substituted “paragraph 1.4 of Schedule 2”;
- (m) Schedule 4 (Annex IV of the PPE Directive) were omitted;
- (n) in Schedule 5 (Annex VI of the PPE Directive)—
 - (i) and in the heading to that Schedule, “EC” were omitted;
 - (ii) for “European Union” there were substituted “United Kingdom”;
 - (iii) for “Council [Directive 89/686/EEC](#)” there were substituted “this Regulation”;
 - (iv) for “national standard transposing harmonised standard No” there were substituted “designated standard”;
 - (v) for “(for the PPE referred to in Article 8(3))” there were substituted “(for the PPE referred to as simple PPE)”;
 - (vi) for “Article 11 point A or point B of [Directive 89/686/EEC](#)” there were substituted “Paragraph A or B of Schedule 8”;
- (o) in Schedule 6 (Article 13 of the PPE Directive)—
 - (i) for “CE”, in each place, there were substituted “UK”;
 - (ii) in paragraph 1—
 - (aa) “in the form shown in the specimen in Annex IV” were omitted;
 - (bb) for “a notified”, there were substituted “an approved”;
 - (iii) in paragraph 4—
 - (aa) in sub-paragraph (a), for “a Member State” there were substituted, “the enforcement authority”, and for “European Union” there were substituted “United Kingdom”;
 - (bb) in sub-paragraphs (a) and (b), for “the Member State” there were substituted “the enforcement authority”;
 - (cc) in sub-paragraph (b), the words “in accordance with the procedures laid down in Article 7” were omitted;
- (p) in Schedule 7 (Article 10 of the PPE Directive)—
 - (i) in paragraphs 1, 2 and 4, “EC” were omitted;
 - (ii) in paragraph 2, for “European Union” there were substituted “United Kingdom”;
 - (iii) in paragraph 4—
 - (aa) in sub-paragraphs (a) and (b), for “harmonised” in each place it occurs, there were substituted “designated”;
 - (bb) in sub-paragraph (a), “referred to in Article 5” were omitted;
 - (iv) in paragraph 5—
 - (aa) for “an EC” there were substituted “a”;
 - (bb) the second sub-paragraph (beginning “The Commission”), were omitted;
 - (v) paragraph 6 were omitted;
- (q) in Schedule 8 (Article 11 of the PPE Directive)—
 - (i) in part A—
 - (aa) in the heading, “EC” were omitted;
 - (bb) in paragraphs 1, 4, and 5, “EC” were omitted;

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- (cc) in paragraph 2, for “A body of which notification has been given” there were substituted “An approved body”;
- (dd) in paragraphs 3, 4, 5 and 6, for “body of which notification has been given” there were substituted “approved body”;
- (ee) in paragraph 3, for “harmonised” there were substituted “designated”;
- (ff) in paragraph 5, the words from “and inform the Member State” to the end, were omitted;
- (ii) in Part B—
 - (aa) in the heading, “EC” were omitted;
 - (bb) in paragraph 1(a), for “a body of which notification has been given” there were substituted “an approved body”;
 - (cc) in paragraph 1(c), for “relevant harmonised” there were substituted “designated”;
 - (dd) in paragraph 2(e), for “body of which notification has been given” there were substituted “approved body”;
- (r) in Schedule 9 (Article 12 of the PPE Directive)—
 - (i) in the heading, “EC” were omitted;
 - (ii) in the first sentence—
 - (aa) “EC” were omitted;
 - (bb) for “European Union” there were substituted “United Kingdom”;
 - (iii) in paragraph 1—
 - (aa) “using the form laid down on Annex VI” were omitted;
 - (bb) for “this Directive” there were substituted “these Regulations”;
 - (iv) in paragraph 2—
 - (aa) for “CE” there were substituted “UK”;
 - (bb) “provided for by Article 13” were omitted;
- (s) in Schedule 10 (Enforcement), in paragraph 2—
 - (i) for “CE” there were substituted “UK”;
 - (ii) the words from “with a view” to the end were omitted.”.