STATUTORY INSTRUMENTS

2019 No. 1246

The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019

PART 3

Amendments relating to retained EU law

Amendments to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

4. The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019(**1**) are amended in accordance with regulations 5 to 17.

Modifications to importers' obligations to provide contact information

5.—(1) In the provisions set out in paragraph (2) after "EEA state" insert "or Switzerland".

(2) The provisions referred to in paragraph (1) are—

(a) Schedule 15, paragraph 23, the inserted paragraph (2)(a)(iii);

(b) Schedule 16, paragraph 14(a), the inserted paragraph (1A);

(c) Schedule 20, paragraph 14(b), the inserted paragraph (1A)(a)(ii);

(d) Schedule 21, paragraph 15(b), the inserted paragraph (1A)(a)(ii);

(e) Schedule 22, paragraph 18(b), the inserted paragraph (3)(a)(ii);

(f) Schedule 23, paragraph 11(b), the inserted paragraph (3)(a)(ii);

(g) Schedule 24, paragraph 15(b), the inserted paragraph (3)(a)(ii);

(h) Schedule 25, paragraph 14(b), the inserted paragraph (3)(a)(ii);

(i) Schedule 26, paragraph 15(a), the inserted paragraph (2)(a)(ii);

(j) Schedule 27, paragraph 14(a), the inserted paragraph (2)(a)(ii);

(k) Schedule 29, paragraph 19(b), the inserted paragraph (3)(a)(ii);

(l) Schedule 31, paragraph 13(a), the inserted paragraph (1A);

(m) Schedule 32, paragraph 14(b), the inserted paragraph (3)(a)(ii);

(n) Schedule 35, paragraph 3(10)(b), the inserted sub-paragraph (a)(ii);

(o) Schedule 36, paragraph 2(10)(b), the inserted sub-paragraph (a)(ii).

6.—(1) In Schedule 15, in paragraph 23, in the inserted paragraph (2)(b), after "is set out" insert "on the toy's packaging or".

(2) In Schedule 20, in paragraph 14(b), in the inserted paragraph (1A)(b), after "in paragraph (1)" insert "on the packaging of the apparatus or".

(**1**) S.I. 2019/696.

(3) In Schedule 24, in paragraph 15(b)—

(a) in the inserted paragraph (3)(a)(i), for "pressure equipment" substitute "the pressure equipment or assembly";

(b) in the inserted paragraph (3)(a)(ii), after "pressure equipment" insert "or assembly";

(c) in the inserted paragraph (3)(b)—

(i) after "pressure equipment" insert "or assembly" in both places in which it occurs;

(ii) after "in paragraph (1)" insert "on the packaging of the pressure equipment or assembly or".

7.—(1) In Schedule 23, in paragraph 11(b), in the inserted paragraph (3)(b)(ii), for "safety component" substitute "electrical equipment".

(2) In Schedule 29, in paragraph 19(b), in the inserted paragraph (3)(b)(ii), for "safety component" substitute "radio equipment".

Amendments to Schedule 34

8. In Schedule 34—

(a) in paragraph 3(h)—

(i) after the inserted point (v) insert—

"(va) 'CMR' means carcinogenic, mutagenic or toxic for reproduction;";

(ii) after the inserted point (y) insert—

"(ya) 'historic animal testing data' means data from any animal testing that was carried out before the date on which such testing was prohibited in accordance with Article 18 of the EU Regulation (pre-exit);";

(b) in paragraph 13, in the inserted Article 13(1)(f) for "carcinogenic" to "1B" substitute "CMR substances of category 1A or 1B";

(c) in paragraph 15, in the inserted Article 15—

(i) for paragraph 1, substitute—

"**1.** A cosmetic product must not contain a substance classified as a CMR substance of category 1A, 1B or 2 under Regulation (EC) No 1272/2008, unless the substance is included in any of Annexes 3 to 6.";

(ii) for paragraph 2, substitute—

"**2.** Where a CMR substance of category 1A or 1B is permitted for use in cosmetic products, specific labelling in order to avoid misuse of the cosmetic product must be provided in accordance with Article 3 of this Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure.";

(d) in paragraph 17, in the substituted Article 18—

(i) at the beginning of paragraph 1 insert "Except as provided in paragraph 1A,";

(ii) after paragraph 1 insert—

"**1A.** Paragraph 1 does not prevent the use of historic animal testing data in order to meet the requirements of this Regulation.";

(e) in paragraph 27—

(i) in the inserted Article 30, for paragraphs 3 to 7 substitute—

"**3.** Where the conditions in paragraph 4 are met, the Secretary of State may by regulations amend Article 16(1) to extend the provisions of Article 16 to nanomaterials used as colourants, UV-filters or preservatives that are regulated under Article 14.

4. The conditions referred to in paragraph 3 are that the Secretary of State considers that it is necessary to do so in view of—

(a) safety concerns raised by a competent authority; or

(b) scientific or technical evidence that there are safety concerns relating to colourants, UV filters or preservatives regulated under Article 14.

5. The Secretary of State may amend Article 14(1)(c) to extend its scope to hair colouring products.";

(ii) in the inserted Article 31, at the end insert—

"(f) Annex 2 to add a substance classified as a CMR substance of category 1A, 1B or 2 under Regulation (EC) No 1272/2008;

(g) Annexes 3 to 6—

(i) to allow a substance classified as a CMR substance of category 2 under Regulation (EC) No 1272/2008 to be used in cosmetic products where the Secretary of State considers that there is sufficient scientific evidence that the substance is safe for use in cosmetic products;

(ii) to allow a substance classified as a CMR substance of category 1A or 1B under Regulation (EC) No 1272/2008 to be used in cosmetic products where the conditions in point (h) are met;

(iii) to make provision as to labelling in order to implement Article 15(2);

(h) the conditions referred to in point (g)(ii) are that—

(i) the CMR substance complies with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;

(ii) an analysis of alternative substances has been undertaken and concluded that there are no suitable alternative substances available;

(iii) an application to the Secretary of State is made for a particular use of the product category with a known exposure;

(iv) the Secretary of State considers that there is sufficient scientific evidence that the CMR substance has been evaluated and found safe for use in cosmetic products; and

(v) the evaluation referred to in point (iv) took into account exposure to the product and overall exposure to the CMR substance from other sources, particularly for vulnerable population groups".

Amendments to Schedule 35

9. In Schedule 35, in paragraph 1—

(a) in sub-paragraph (2)(a)—

(i) for "definitions" substitute "definition";

(ii) omit the inserted definition of "the relevant period";

(b) in sub-paragraph (3)—

(i) for paragraph (a) substitute—

"(a) at the beginning of paragraph (4) insert "Subject to the modifications made in paragraph (4A),"";

(ii) for paragraph (b) substitute—

"(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".";

(iii) for paragraph (c) substitute—

"(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";";

(iv) omit paragraph (d);

(v) in paragraph (e) for "5A" substitute "5";

(c) omit sub-paragraphs (8) and (9).

Miscellaneous amendments

10. In Schedule 8—

(a) in paragraph 2(b)(i) after the inserted definition of "approved body" insert—

""authorised representative" means—

(a) a person who—

(i) immediately before exit day was established in the United Kingdom or an EEA state and was appointed by a manufacturer to perform specified tasks for that manufacturer; and

(ii) on or after exit day continues to be so established and appointed by the manufacturer to perform those tasks; or

(b) a person who on or after exit day is established in the United Kingdom and appointed by the manufacturer by written mandate to perform specified tasks for that manufacturer;";

(b) for paragraph 2(b)(v) substitute—

"(v) in the definition of "responsible person"—

(aa) in sub-paragraph (b), omit "established in the European Union";

(bb) for sub-paragraph (c) substitute—

"(c) where the manufacturer is not established in the United Kingdom and does not have an authorised representative, the person placing the equipment on the market or putting it into service in the United Kingdom;""

(c) in the following provisions, for "for "European Union" substitute "United Kingdom"", substitute "omit "established in the European Union""—

(i) paragraph 18(b);

(ii) paragraph 21(a)(ii), (b)(i) and (c)(ii);

(iii) paragraph 22(a)(ii), (b)(i), (c)(ii), (e)(iii) and (f)(ii);

(iv) paragraph 23(a)(iii), (b)(i) and (e);

(v) paragraph 24(a)(iii) and (b)(ii);

(d) in paragraph 13(b) for "for "European Union" substitute "United Kingdom"", substitute "omit "established within the European Union"";

(e) in paragraph 19(a)(iv) for "for "European Union" substitute "United Kingdom"", substitute "omit "in the European Union"";

(f) after paragraph 21(a)(i) insert—

"(ia) omit "established within the European Union";";

(g) in paragraph 21(a)(ii) omit "in each place it occurs";

(h) after paragraph 22(e)(iii) insert—

"(iiia) omit "established within the European Union";";

(i) after paragraph 22(f)(ii) insert—

"(iia) omit "established within the European Union";";

(j) for paragraph 24(e)(i) substitute—

"(i) omit "established within the European Union";".

11. In Schedule 12—

(a) for paragraph 24(2)(d) substitute—

"(d) in point 5—

(i) for "notified" substitute "approved";

(ii) for "EC type-" substitute "Type-" in both places in which it occurs;";

(b) after paragraph 24(2)(d) insert—

"(da) in point 6 for "notified" substitute "approved";";

(c) after paragraph 29(3)(a) insert—

"(aa) for "a notified" substitute "an approved";";

(d) in paragraph 29(13)—

(i) omit "point 9.1 and in";

(ii) for "point 9.3" substitute "points 9.1 and 9.3";

(e) in paragraph 30—

(i) in paragraph (b)(iii) before "third" insert "second paragraph and the";

(ii) in paragraph (b)(vii) for "and" substitute "in both places in which it occurs and in";

(f) after paragraph 31(a) insert—

"(aa) in point 3 for "notified" substitute "approved";".

12. In Schedule 16, in paragraph 33(b) after "paragraph 8" insert "and paragraph 9(b)".

13. In Schedule 21, after paragraph 29(a)(ii) insert—

"(iii) for "notified" substitute "approved";".

14. In Schedule 24—

(a) after paragraph 7(c) insert—

"(ca) in paragraph (1)(c), for "notified" substitute "approved";";

(b) after paragraph 40(a) insert—

"(aa) in paragraph (1)(b)—

(i) for "a notified" substitute "an approved";

(ii) for "the notified" substitute "the approved";";

(c) in paragraph 45—

(i) in sub-paragraph (b), at the end, omit "and";

(ii) in sub-paragraph (c), omit "and (8)";

(iii) at the end of sub-paragraph (c), insert—

"(d) in paragraph 31(8) for "within the Union" substitute "in the United Kingdom"".

15. In Schedule 27—

(a) for paragraph 39(d) substitute—

"(d) omit paragraph (9);";

(b) for paragraph 39(e) substitute—

"(e) omit paragraph (10).".

16. In Schedule 28—

(a) after paragraph 35(b), insert—

"(ba) in paragraph (4) for "notified" substitute "approved";";

(b) in paragraph 64, at the end of paragraph 2 of the inserted Article 9A insert—

"**3.** Where during the pre-exit period the national body of the United Kingdom has assigned the unique code for a manufacturer, in accordance with Article 4 as it had effect immediately before exit day, that unique code is to be treated as if it were issued by the UK national body (or, if none is designated, the Secretary of State) in accordance with Article 4 as it has effect on and after exit day.".

17. In Schedule 33, in paragraph 11 in the inserted Article 10, for paragraph 1(a) substitute—

"(a) ensure that it is evaluated in accordance with the requirements of this Article by a body which is approved by the Secretary of State;".

Amendment to the Conformity Assessment (Mutual Recognition Agreements) Regulations 2019

18. In the Conformity Assessment (Mutual Recognition Agreements) Regulations 2019, omit regulation 6.