SCHEDULE 20

Regulation 23

Amendment of the Electromagnetic Compatibility Regulations 2016

General

1. The Electromagnetic Compatibility Regulations 2016 are amended in accordance with paragraphs 2 to 40.

Commencement Information

I1 Sch. 20 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

- **2.**—(1) Regulation 2 (interpretation) is amended as follows.
- (2) In paragraph (1)—
 - (a) omit the definition of "accreditation";
 - (b) omit the definition of "accreditation certificate";
 - (c) after the definition of "the "2006 Regulations" insert—
 "approved body" has the meaning given in regulation 43 (approved bodies);";
- - (e) omit the definition of "CE marking";
 - (f) omit the definition of "competent national authority";
 - (g) after the definition of "conformity assessment body" insert—
 - ""conformity assessment procedure" means a procedure referred to in regulation 40;
 - "declaration of conformity" means a declaration of conformity required to be drawn up in accordance with regulation 10(1)(a) (declaration of conformity and UK marking);
 - "designated standard" has the meaning given to it in regulation 2A;";
 - (h) in the definition of "the Directive" at the end insert " (as it has effect immediately before [F2 IP completion day])";
 - (i) omit the definition of "EU declaration of conformity";
 - (j) omit the definition of "EU harmonisation legislation";
 - (k) omit the definition of "harmonised standard";
 - (1) for the definition of "importer" substitute—
 - [F3....importer" means a person who—
 - (a) is established in the United Kingdom and places apparatus from a country outside of the United Kingdom on the market; or
 - (b) is established in Northern Ireland and places apparatus on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;"];
- $I^{F4}(m)$ in the definition of "make available on the market" for "EU market" substitute "market" of Great Britain";]

- (n) omit the definition of "national accreditation body";
- (o) omit the definition of "notified body requirements";
- (p) omit the definition of "Official Journal";
- $[^{F5}(q)]$ in the definition of "place on the market" for "EU market" substitute "market of Great Britain";]
 - (r) in the definition of "put into service", for "EU" substitute "United Kingdom market"; and
 - (s) after the definition of "technical specification" insert—
 - ""UK marking" means the marking in the form set out in Annex 2 of RAMS;
 - "UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;".
- (3) In paragraph (3) for "aspects of public interest protection" to the end substitute " the protections against electromagnetic disturbance referred to in these Regulations".
 - (4) Omit paragraphs (4) and (5).
 - F1 Sch. 20 para. 2(2)(d) 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. 3(d)
 - F2 Words in Sch. 20 para. 2(2)(h) 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(i)(ii)
 - F3 Words in Sch. 20 para. 2(2)(l) substituted (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. 12(2)
 - F4 Sch. 20 para. 2(2)(m) substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), 4(8)(a)
 - F5 Sch. 20 para. 2(2)(q) substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), 4(8)(b)

Sch. 20 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

Insertion of regulation 2A

3. After regulation 2 insert—

"Designated standard

- **2A.**—(1) Subject to paragraphs (6) and (7), in these Regulations a "designated standard" means a technical specification which is—
 - (a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and
 - (b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

- (2) For the purposes of paragraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—
 - (a) the characteristics required of a product, including—
 - (i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and
 - (ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
 - (b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.
- (3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—
 - (a) the European Committee for Standardisation (CEN);
 - (b) the European Committee for Electrotechnical Standardisation (Cenelec);
 - (c) the European Telecommunications Standards Institute (ETSI);
 - (d) the British Standards Institution (BSI).
- (4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.
- (5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.
- (6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).
- (7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.
- (8) In this regulation, a reference to a "product" is a reference to apparatus to which these Regulations apply.
- (9) The Secretary of State may by regulation amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.
 - (10) Regulations made under paragraph (9) are to be made by statutory instrument.
- (11) A statutory instrument containing regulations made under paragraph (9) is subject to annulment in pursuance of a resolution of either House of Parliament.".

I3 Sch. 20 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 3

4. Regulation 3 (application) is amended as follows—

- (a) in paragraph (2)(a) for the words from "Directive" to "applies" substitute " the Radio Equipment Regulations 2017 apply ";
- (b) in paragraph (4) for the words from "Directive" to the end substitute " the Measuring Instruments Regulations 2016";
- (c) for "EU law" in the third place in which it occurs, substitute "that enactment"; and
 - (i) omit "rules of" in both places which it occurs;
 - (ii) for "EU law" in the first two places in which it occurs substitute "any enactment";
 - (iii) for "EU law" in the third place in which it occurs, substitute "that enactment"; and
 - (iv) for "the Directive" substitute "these Regulations" in both places in which it occurs.

Sch. 20 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 4

5. In regulation 4 (application of safety legislation) for "EU or national legislation" substitute "any enactment".

Commencement Information

I5 Sch. 20 para. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 9

6. In regulation 9 (technical documentation and conformity assessment) in paragraph (b)(i) omit "EU-".

Commencement Information

Sch. 20 para. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

- 7. In regulation 10 (EU declaration of conformity and CE marking)—
 - (a) in the heading to that regulation—
 - (i) for "EU declaration" substitute "Declaration"; and
 - (ii) for "CE" substitute " UK ";
 - (b) in paragraph (1)(a)—
 - (i) for "an EU" substitute " a "; and
 - (ii) omit "(EU declaration of conformity)";
 - (c) in paragraph (1)(b) for "CE" substitute "UK" in both places in which it occurs;
 - (d) in paragraph (2), omit "EU";

Changes to legislation: There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 20. (See end of Document for details)

- (e) for paragraph (3) substitute—
 - "(3) Where apparatus is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment concerned by its title."

Commencement Information

I7 Sch. 20 para. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 11

8. In regulation 11 (retention of technical documentation and EU declaration of conformity), and in the heading to that regulation, omit "EU".

Commencement Information

Sch. 20 para. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 12

- 9. In regulation 12 (compliance procedures for series production), in paragraph (2)(b)—
 - (a) for "harmonised" substitute "designated"; and
 - (b) omit "EU".

Commencement Information

Sch. 20 para. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 13

10. In regulation 13 (information identifying manufacturer), in paragraph (4) for "in a language which can be easily understood by end-users and the competent national authority in the member State in which it is to be made available to such end-users" substitute "clear, legible and in easily understandable English".

Commencement Information

Sch. 20 para. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 14

11. For regulation 14 (instructions and information) substitute—

"Instructions and information

14. When placing apparatus on the market, a manufacturer must ensure that the apparatus is accompanied by instructions and the information referred to in regulation 36 (information concerning the use of apparatus) which are clear, legible and in clearly understandable English.".

Commencement Information

Sch. 20 para. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 15

12. In regulation 15 (manufacturer's duty to take action in respect of apparatus placed on the market which is considered not to be in conformity), in paragraph (2) omit "and the competent national authorities of any other member State in which the manufacturer has made the apparatus available on the market,".

Commencement Information

Sch. 20 para. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 18

13. In regulation 18 (requirements that must be satisfied before an importer places apparatus on the market), at paragraph (1)(c)(i) for "CE" substitute "UK".

Commencement Information

I13 Sch. 20 para. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

- **14.** Regulation 20 (information identifying importer) is amended as follows—
 - (a) in paragraph (1) omit the words from "or, where" to "accompanying the apparatus";
 - (b) after paragraph (1) insert—
 - "(1A) Paragraph (1) does not apply where—
 - (a) either—
 - (i) it is not possible to set out the information referred to in paragraph (1) I^{F6} on the packaging of the apparatus or] on the apparatus, or
 - (ii) the importer has imported the apparatus from an EEA state [F7 or Switzerland] and places it on the market within the period of [F824 months] beginning with [F9IP completion day], and
 - (b) before placing the apparatus on the market, the importer sets out the information referred to in paragraph (1) in a document accompanying the apparatus.";

- (c) in paragraph (2) for "competent national authority in the member State in which it is to be made available" substitute "enforcing authority".
- F6 Words in Sch. 20 para. 14(b) inserted (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), 6(2); 2020 c. 1, Sch. 5 para. 1(1)
- Words in Sch. 20 para. 14(b) inserted (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), 5; 2020 c. 1, Sch. 5 para. 1(1)
- F8 Words in Sch. 20 para. 14(b) substituted (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. 2(1)(e)
- F9 Words in Sch. 20 para. 14(b) 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(i)(iii)

Sch. 20 para. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 21

- 15. In regulation 21 (instructions and information)—
 - (a) in paragraph (1) for "is in a language which can be easily understood by consumers and other end users in the member State in which the apparatus is to be made available" substitute "are clear, legible and in easily understandable English"; and
 - (b) omit paragraph (2).

Commencement Information

Sch. 20 para. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 23

16. In regulation 23 (importer's duty to take action in respect of apparatus placed on the market which is considered not to be in conformity), in paragraph (2) omit "and the competent authorities of any member State in which the importer has made the apparatus available on the market".

Commencement Information

Sch. 20 para. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 24

]17. In regulation 24 (retention of technical documentation and EU declaration of conformity) and in the heading to that regulation, omit "EU".

Sch. 20 para. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 27

- **18.** In paragraph (1) of regulation 27 (making available on the market)—
 - (a) in sub-paragraph (a)(i) for "CE" substitute "UK"; and
 - (b) in sub-paragraph (a)(iii) for "is in a language which can be easily understood by consumers and other end-users in the member State in which the apparatus is to be made available on the market" substitute " are clear, legible and in easily understandable English".

Commencement Information

Sch. 20 para. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 30

19. In regulation 30 (duty to take action in respect of apparatus placed on the market or made available on the market which is considered not to be in conformity) in paragraph (2) omit "and the competent authorities of any other member State in which the distributor has made the apparatus available on the market".

Commencement Information

Sch. 20 para. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 31

20. In regulation 31 (provision of information and co-operation) in paragraph (3)(b) for "in a language that can be easily understood by the enforcing authority" substitute "clear, legible and in easily understandable English".

Commencement Information

20 Sch. 20 para. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 34

21. Omit regulation 34 (translation of EU declaration of conformity).

Sch. 20 para. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 35

22. In regulation 35 (prohibition on improper use of CE marking), and in the heading to that regulation, for "CE" in each place in which it occurs, substitute "UK".

Commencement Information

Sch. 20 para. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 38

- 23. In regulation 38 (appointment of an authorised representative)—
 - (a) in paragraph (1) after "a person" insert "established in the United Kingdom";
 - (b) in paragraph (2)(a) omit "EU".

Commencement Information

123 Sch. 20 para. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Insertion of regulation 38A

24. After regulation 38 insert—

"Obligations which are met by complying with obligations in the Directive

38A.—(1) In this regulation—

- (a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;
- (b) "CE marking" has the meaning given to it in Article 3(25);
- (c) "harmonised standard" has the meaning given to it in Article 3(17).
- (2) Paragraph (3) applies where, before placing apparatus on the market, the manufacturer—
 - (a) ensures that the apparatus has been designed and manufactured in accordance with the essential requirements set out in Annex I;
 - (b) draws up the technical documentation relating to such apparatus referred to in Annex III;
 - (c) ensures that the relevant conformity assessment procedure relating to such apparatus referred to in Article 14 has been carried out;

- (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedure are prepared in or translated into English;
- (e) affixes a CE marking, in accordance with Articles 16 and 17(1) to (2);
- (f) draws up an EU declaration of conformity, in accordance with Article 15; 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 regulations 8, 9, 10(1)(a) and (b) and (3) and 42(1) are to be treated as being satisfied;
 - (b) regulations 2(2)(a), 10(2), 11, 12, 38(2) and 35 apply subject to the modifications in paragraph (8);
 - (c) Part 4 does not apply; and
 - (d) regulation 59 does not apply.
- (4) Paragraph (5) applies where, before placing a category apparatus on the market, the importer ensures that—
 - (a) the relevant conformity assessment procedure referred to in Article 14 has been carried out;
 - (b) the manufacturer has drawn up the technical documentation referred to in Annex III; and
 - (c) the apparatus bears the CE marking.
 - (5) Where this paragraph applies—
 - (a) the requirements of regulation 18(a) to (c) are to be treated as being satisfied; and
 - (b) regulations 2(2)(a), 17, 19(1), 22 and 24 apply subject to the modifications in paragraph (8).
- (6) Paragraph (7) applies where, before making apparatus available on the market, a distributor ensures that the apparatus bears the CE marking.
 - (7) Where this paragraph applies—
 - (a) regulation 27(1)(a) is to be treated as being satisfied; and
 - (b) regulations 2(2)(a), 28(1) and 29 apply subject to the modifications in paragraph (10).
 - (8) The modifications referred to in sub-paragraphs (3)(b), (5)(b) and (9)(b) are that—
 - (a) any reference to "declaration of conformity" is to be read as a reference to the EU declaration of conformity;
 - (b) any reference to "UK marking" is to be read as a reference to the CE marking;
 - (c) any reference to "essential requirements" is to be read as a reference to the essential safety requirements referred to in Annex I;
 - (d) any reference to "designated standard" is to be read as a reference to a harmonised standard;
 - (e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures referred to in Article 14:
 - (f) any reference to "technical documentation" is a reference to the technical documentation referred to in Annex III.

[F10 Expiry of regulation 38A

- **38B.**—(1) Subject to paragraph (2), regulation 38A ceases to have effect at the end of the period of 12 months beginning with IP completion day.
 - (2) Notwithstanding the expiry of regulation 38A—
 - (a) any apparatus which was placed on the market pursuant to regulation 38A may continue to be made available on the market on or after the expiry of regulation 38A;
 - (b) any obligation to which a person was subject under regulation 38A in respect of apparatus placed on the market pursuant to regulation 38A continues to have effect after the expiry of regulation 38A, in respect of that apparatus.

Qualifying Northern Ireland Goods

- **38C.**—(1) Where paragraph (2) applies, apparatus is to be treated as being in conformity with Part 2.
 - (2) This paragraph applies where—
 - (a) apparatus—
 - (i) is in conformity with Part 2, as that Part applies in Northern Ireland; and
 - (ii) is qualifying Northern Ireland goods; and
 - (b) an importer has complied with the obligations set out in paragraph (3).
- (3) The obligations referred to in paragraph (2)(b) are that, before placing the apparatus on the market, the importer—
 - (a) complies with regulation 20;
 - (b) ensures that—
 - (i) the relevant conformity assessment procedure has been carried out in relation to the apparatus;
 - (ii) the manufacturer has drawn up the technical documentation; and
 - (iii) the apparatus bears the CE marking.
 - (4) In this regulation—
 - "CE marking" has the meaning given to it in regulation 2(1), as it applies in 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;
 - "relevant conformity assessment procedure" has the meaning given to it in regulation 2(1), as it applies in Northern Ireland;
 - "technical documentation" means the documentation a manufacturer must draw up, in accordance with regulation 9(b), as it applies in Northern Ireland."].
- **F10** Words in Sch. 20 para. 24 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. 12(3)**

Commencement Information

Sch. 20 para. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 39

- 25. In regulation 39 (presumption of conformity), paragraph (1) is amended as follows—
 - (a) for "harmonised" substitute "designated"; and
 - (b) omit "the reference to which has been published in the Official Journal".

Commencement Information

Sch. 20 para. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 41

- **26.** Regulation 41 (EU declaration of conformity) is amended as follows—
 - (a) in the heading to that regulation, for "EU declaration", substitute "Declaration"; and
 - (b) in that regulation, omit "EU".

Commencement Information

Sch. 20 para. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para.
 1(1)), see reg. 1

- [F1127. In regulation 42—
 - (a) in the heading and in paragraph (2) in both places in which it occurs for "CE" substitute "UK";
 - (b) for paragraph (1) substitute—
 - "(1) The UK marking must be affixed visibly, legibly and indelibly—
 - (a) to the apparatus;
 - (b) to its data plate; or
 - (c) where paragraph (1A) applies, to—
 - (i) a label affixed to the apparatus or its data plate; or
 - (ii) to a document accompanying the apparatus.";
 - (c) after paragraph (1) insert—
 - "(1A) For a period of 24 months beginning with IP completion day, the UK marking may be affixed to—
 - (a) a label affixed to the apparatus or its data plate; or
 - (b) a document accompanying the apparatus.";
 - (d) in paragraph (2) after "Where" insert "paragraph (1A) does not apply and ".]
- F11 Sch. 20 para. 27 substituted (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. 12(4)

Sch. 20 para. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to Part 4

28. For Part 4, substitute—

"PART 4

Approval of Conformity Assessment Bodies

Approved bodies

- **43.**—(1) An approved body is a conformity assessment body which—
 - (a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 44 (approval of conformity assessment bodies); or
 - (b) immediately before [F12IP completion day] was a notified body in respect of which the Secretary of State had taken no action under regulation 49(1) or (2) as they had effect immediately before [F12IP completion day] to suspend or withdraw the body's status as a notified body.
- (2) Paragraph (1) has effect subject to regulation 47 (restriction, suspension or withdrawal of approval).
 - (3) In this Part—
 - "notified body" means a body—
 - (a) which the Secretary of State had before [F12IP completion day] notified to the European Commission and the member State of the European Union, in accordance with Article 20 of the Directive; and
 - (b) in respect of which no objections had been raised, as referred to in regulation 43(1)(b), as it had effect immediately before [F12IP completion day];

Approval of conformity assessment bodies

- **44.**—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.
- (2) A conformity assessment body qualifies for approval if the first and second conditions below are met.
- (3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—
 - (a) a description of-
 - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
 - (ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

[&]quot;approved body requirements" means the requirements set out in Schedule 5.

- (iii) the category of apparatus in respect of which the conformity assessment body claims to be competent; and
- (b) either—
 - (i) an accreditation certificate; or
 - (ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.
- (4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.
- (5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.
- (6) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—
 - (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
 - (b) set conditions that the conformity assessment body must meet.
- (7) For the purposes of this regulation "accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

Presumption of conformity of approved bodies

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

Monitoring

- **46.** The Secretary of State must monitor each approved body with a view to verifying that the body—
 - (a) continues to meet the approved body requirements;
 - (b) meets any conditions set—
 - (i) in accordance with regulation 44(6)(b); or
 - (ii) in the case of an approved body which was a notified body immediately before [F13IP completion day], in accordance with regulation 44(6)(b) as it applied immediately before [F13IP completion day]; and
 - (c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval

- 47.—(1) Where the Secretary of State determines that an approved body—
 - (a) no longer meets an approved body requirement, or
 - (b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 46(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 43 (approved bodies).

- (2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 46(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 43.
- (3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.
 - (4) Before taking action under paragraph (1) or (2), the Secretary of State must—
 - (a) give notice in writing to the approved body of the proposed action and the reasons for it;
 - (b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and
 - (c) consider any such representations made by the approved body.
- (5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—
 - (a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or
 - (b) keep its files relating to the activities it has undertaken as an approved body available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.
- (6) The activities undertaken as an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.

Operational matters in relation to approved bodies

- **48.**—(1) Subject to the terms of its appointment, an approved body must carry out the conformity assessment activities and procedures—
 - (a) in respect of which the body's approval was given under regulation 44; or
 - (b) in respect of which the body's notification as a notified body was made.
- (2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.
- (3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body to issue a Type-examination certificate referred to in Schedule 3.

Subsidiaries and contractors

- **49.**—(1) An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—
 - (a) the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;
 - (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
 - (c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

- (2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).
- (3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—
 - (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
 - (b) the conformity assessment activity carried out by the subcontractor or subsidiary.
- (4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006^{M1} .

Register of approved bodies

- **50.**—(1) The Secretary of State must—
 - (a) assign an approved body identification number to each approved body; and
 - (b) compile and maintain a register of—
 - (i) approved bodies;
 - (ii) their approved body notification numbers;
 - (iii) the activities for which they have been approved; and
 - (iv) any restrictions on those activities.
- (2) The register referred to in paragraph (1) must be made publicly available.

UK national accreditation body

- **51.** The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—
 - (a) assessing whether a conformity assessment body meets the approved body requirements;
 - (b) monitoring approved bodies in accordance with regulation 46; and
 - (c) compiling and maintaining the register of approved bodies, in accordance with regulation 50.".
- F12 Words in Sch. 20 para. 28 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(i)(iv)
- F13 Words in Sch. 20 para. 28 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(i)(v)

Commencement Information

Sch. 20 para. 28 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 2006 c.46.

Changes to legislation: There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 20. (See end of Document for details)

Amendment to regulation 55

29. In regulation 55 (exercise of enforcement powers) omit paragraph (c).

Commencement Information

Sch. 20 para. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para.
 1(1)), see reg. 1

Amendment to regulation 57

- **30.** Regulation 57 (enforcement action in respect of apparatus that is not in conformity and which present a risk) is amended as follows—
 - (a) in paragraph (2) for "notified" substitute "approved";
 - (b) omit paragraphs (4) and (7);
 - (c) in paragraph (8) for "notices in paragraphs (6) and (7)", substitute "notice in paragraph (6) "; and
 - (d) in paragraph (8)(f)(ii) for "harmonised" substitute "designated".

Commencement Information

I30 Sch. 20 para. 30 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 58

31. Omit regulation 58 (EU safeguard procedure).

Commencement Information

I31 Sch. 20 para. 31 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to regulation 59

- **32.** Regulation 59 (enforcement action in respect of formal non-compliance) is amended as follows—
 - (a) in paragraph (1)(a) for "CE" substitute "UK" in each place in which it occurs;
 - (b) in paragraph (1)(b)—
 - (i) omit "EU" in each place in which it occurs;
 - (ii) for "CE" substitute " UK ".

Commencement Information

I32 Sch. 20 para. 32 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para.
 1(1)), see reg. 1

Transitional provision in relation to EU Exit

33. After regulation 74 (transitional provision) insert—

"Transitional provision in relation to EU Exit

- **74.**—(1) In this regulation—
 - "pre-exit period" means the period beginning with 8th December 2016 and ending immediately before [F14IP completion day];
 - "product" means electromagnetic equipment to which these Regulations apply.
- (2) Subject to paragraph (3) where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 20 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 M2, any obligation to which a person was subject under these Regulations as they had effect immediately before [F14IP completion day], continues to have effect as it did immediately before [F14IP completion day], in relation to that product.
 - (3) Paragraph (2) does not apply to—
 - (a) any obligation to any enforcing authority to inform the European Commission or the member States of any matter; or
 - (b) any obligation to take action outside of the United Kingdom in respect of that product.
 - (4) Where during the pre-exit period—
 - (a) a product has not been placed on the market; and
 - (b) a manufacturer has taken any action under regulation 40 as it had effect immediately before [F14IP completion day];

that action has effect as if it had been done under regulation 40 as it has effect on and after I^{F14}IP completion dayl.".

F14 Words in Sch. 20 para. 33 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(i)(vi)

Commencement Information

I33 Sch. 20 para. 33 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

M2 S.I. 2019/696.

- **34.**—(1) Regulation 75 (revocation and savings) is amended as follows—
- (2) In paragraph (2) before "as if" insert "subject to the modifications in paragraph (2A),"
- (3) After paragraph (2), insert—
 - "(2A) The modifications referred to in paragraph (2) are that in the Electromagnetic Compatibility Regulations 2006—
 - (a) any reference to "the Community" is to be read as including the United Kingdom;

(b) any reference to a "member State" is to be read as including the United Kingdom.".

Commencement Information

Sch. 20 para. 34 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para.
 1(1)), see reg. 1

Amendment to Schedule 2

- **35.** Schedule 2 (Module A internal production control) is amended as follows—
 - (a) in paragraph 5(d)
 - (i) for "harmonised" substitute "designated" in each place in which it occurs;
 - (ii) omit "the references of which have been published in the Official Journal";
 - (b) in the heading to paragraph 7—
 - (i) for "CE" substitute " UK ";
 - (ii) omit "EU";
 - (c) in paragraph 7, for "CE" substitute "UK"; and
 - (d) in paragraph 8, omit "EU" in both places in which it occurs.

Commencement Information

I35 Sch. 20 para. 35 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to Schedule 3

- **36.** Part 1 of Schedule 3 (applicable conformity assessment procedures Module B: EU-type Examination) is amended as follows—
 - (a) in the heading, for "EU-Type" substitute "Type";
 - (b) in paragraphs 1, 2, 3, 8, 9, 10, 12, 13, 14, 15 and 16 for "EU-type" substitute "Type" in each place in which it occurs;
 - (c) in paragraphs 1 and 14 for "a notified" substitute "an approved";
 - (d) in paragraphs 3, 5, 6, 7, 10, 11, 12,13, 14 and 15 for "notified" substitute "approved" in each place in which it occurs;
 - (e) in paragraph 4(d)—
 - (i) for "harmonised" substitute "designated" in each place in which it occurs;
 - (ii) omit "the references of which have been published in the Official Journal";
 - (f) in paragraph 7 for "an EU-type", substitute "a Type";
 - (g) in paragraph 15 for "The Commission, the Member States" substitute "The Secretary of State";
 - (h) in the heading to paragraph 20—
 - (i) for "CE" substitute " UK ";
 - (ii) omit "EU";

- (i) in paragraph 20(1) for "CE" substitute "UK"; and
- (j) in paragraphs 20(2) and (3) omit "EU" in each place in which it occurs.

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Sch. 20 para. 36 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1
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- **37.** Part 2 of Schedule 3 (applicable conformity assessment procedures) Module C (conformity to type based on internal production control) is amended as follows—
 - (a) in paragraphs 18 and 19 for "EU-type" substitute "Type";
 - (b) in the heading to paragraph 20—
 - (i) for "CE" substitute " UK ";
 - (ii) omit "EU";
 - (c) in paragraph 20(1)—
 - (i) for "CE" substitute " UK ";
 - (ii) for "EU-type" substitute " Type ";
 - (d) in paragraphs 20(2) and (3) omit "EU" in each place in which it occurs.

Commencement Information

I37 Sch. 20 para. 37 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

Amendment to Schedule 4

- 38. Schedule 4 (EU declaration of conformity) is amended as follows—
 - (a) in the heading, for "EU declaration" substitute "Declaration";
 - (b) in the sub-heading, for "EU declaration" substitute "Declaration";
 - (c) in paragraph 5, for "EU harmonisation legislation" substitute " statutory requirements ";
 - (d) in paragraph 6, for "harmonised" substitute "designated"; and
 - (e) in paragraph 7, for "notified" substitute "approved".

Commencement Information

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I38 Sch. 20 para. 38 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1
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Amendment to Schedule 5

- **39.** Schedule 5 (requirements for notified bodies) is amended as follows—
 - (a) in the heading, and in paragraphs 6, 9, 12 and 18, for "notified" substitute "approved";
 - (b) in paragraph 10(c) for "a notified" substitute "an approved";
 - (c) in paragraph 12(c)—
 - (i) for "harmonised" substitute "designated";

Changes to legislation: There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 20. (See end of Document for details)

- (ii) omit "of the Directive and";
- (d) in paragraph 18 for "under the Directive" substitute "by the Secretary of State".

Commencement Information

I39 Sch. 20 para. 39 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para.
 1(1)), see reg. 1

Amendment to Schedule 6

- **40.** Schedule 6 (operational obligations of notified bodies) is amended as follows—
 - (a) in the heading, and in paragraphs 7 and 9 for "notified" substitute "approved";
 - (b) in paragraphs 1, 2, 5, 6, 8, 10, 11, 12 and 13 for "a notified" substitute "an approved";
 - (c) in paragraph 5, for "harmonised" substitute "designated";
 - (d) in paragraph 12, for "notified under the Directive" substitute "approved under these Regulations";
 - (e) in paragraph 13—
 - (i) for "under the Directive" substitute "by the Secretary of State"; and
 - (ii) for "any notified" substitute " any approved ".

Commencement Information

Sch. 20 para. 40 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 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, SCHEDULE 20.