#### SCHEDULE 21

Regulation 24

Amendment of the Simple Pressure Vessels (Safety) Regulations 2016

#### Introduction

**1.** The Simple Pressure Vessels (Safety) Regulations 2016 are amended in accordance with paragraphs 2 to 42.

#### **Commencement Information**

I1 Sch. 21 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 (4)—
  - (a) omit the definition of "accreditation";
  - (b) omit the definition of "accreditation certificate";
  - (c) after the definition of "the 1987 Act" insert—
    - ""approved body" has the meaning given to it in regulation 45 (approved bodies);";
- $^{\text{F1}}(d)$  .....
  - (e) omit the definition of "CE marking";
  - (f) omit the definition of "competent national authority";
  - (g) after the definition of "conformity assessment procedure" insert-
    - ""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 "harmonised standard";
  - (j) for the definition of "importer" substitute—
    - [F3....importer" means a person who—
      - (a) is established in the United Kingdom and places a vessel from a country outside of the United Kingdom on the market; or
      - (b) is established in Northern Ireland and places a vessel 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;"];
- $[^{F4}(k)]$  in the definition of "make available on the market" for "EU market" substitute "market of Great Britain";]
  - (1) omit the definition of "national accreditation body";
  - (m) omit the definition of "notified body requirements";
  - (n) omit the definition of "Official Journal";
- $[^{F5}(0)]$  in the definition of "place on the market" for "EU market" substitute "market of Great Britain";]

- (p) 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) Omit paragraphs (6) and (7).

#### **Textual Amendments**

- F1 Sch. 21 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(e)
- F2 Words in Sch. 21 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(j)(ii)
- F3 Words in Sch. 21 para. 2(2)(j) 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. 13(2)
- F4 Sch. 21 para. 2(2)(k) 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(9)(a)
- F5 Sch. 21 para. 2(2)(o) 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(9)(b)

### **Commencement Information**

Sch. 21 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 a vessel to which these Regulations apply.
- (9) The Secretary of State may by regulations 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.".

Sch. 21 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 4

**4.** In regulation 4, in paragraph (2) (design and manufacture in accordance with essential safety requirements and sound engineering practice), for "the sound engineering practice of a Member State" substitute "sound engineering practice".

#### **Commencement Information**

Sch. 21 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 6

- **5.**—(1) Regulation 6 (EU declaration of conformity, CE marking and inscriptions for category A vessels) is amended as follows.
  - (2) In the heading to that regulation—
    - (a) for "EU declaration" substitute "Declaration"; and
    - (b) for "CE" substitute " UK ".
  - (3) In paragraph (1)(a)—
    - (a) for "an EU" substitute "a"; and
    - (b) omit "(EU declaration of conformity)".
  - [<sup>F6</sup>(4) For paragraph (1)(b) substitute—
    - "(b) affix the information set out in paragraph (1B) to—
      - (i) the vessel;
      - (ii) its data plate; or
      - (iii) where paragraph (1A) applies—
        - (aa) to a label affixed to the vessel; or
        - (bb) in a document accompanying the vessel;"]
  - [F7(4A) After paragraph (1) insert—
    - "(1A) This paragraph applies to a vessel that is placed on the market within a period of 24 months beginning with IP completion day.
      - (1B) The information referred to in paragraph (1)(b) is—
        - (a) the UK marking;
        - (b) the last two digits of the year in which the UK marking is affixed;
        - (c) the inscriptions."]
  - (5) In paragraph (4), omit "EU".
  - (6) For paragraph (5) substitute—
    - "(5) Where a category A vessel 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 by its title."

#### **Textual Amendments**

- F6 Sch. 21 para. 5(4) 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. 13(3)
- F7 Sch. 21 para. 5(4A) 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. 13(4)

### **Commencement Information**

I5 Sch. 21 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

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 21. (See end of Document for details)

### Amendment to regulation 8

**6.** In regulation 8 (retention by manufacturers of technical documentation and EU declaration of conformity) and in the heading to that regulation omit "EU".

#### **Commencement Information**

Sch. 21 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

### Amendment to regulation 9

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

#### **Commencement Information**

Sch. 21 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 (labelling of vessels) omit paragraph (3).

### **Commencement Information**

I8 Sch. 21 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. For regulation 12 (provision of instructions and safety information), substitute—

### "Provision of instructions and safety information

12. When placing a vessel on the market, a manufacturer must ensure that a vessel is accompanied by instructions and safety information that are clear, legible and in easily understandable English.".

#### **Commencement Information**

Sch. 21 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 (duty of manufacturers to take action), in paragraph (2) omit "and the competent national authorities of any other Member State in which the manufacturer made the vessel available on the market,".

Sch. 21 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 15

11. In regulation 15 (appointment of authorised representative) after "a person" insert "established in the United Kingdom".

#### **Commencement Information**

III Sch. 21 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 16

12. In regulation 16 (obligations of authorised representative), in paragraph (2)(a) omit "EU".

#### **Commencement Information**

Sch. 21 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

[F813. In regulation 18 for paragraph (c) substitute—

"(c) the UK marking and the inscriptions have been affixed in accordance with regulation 6(1)(b) to (d);"]

#### **Textual Amendments**

F8 Sch. 21 para. 13 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. 13(5)

#### **Commencement Information**

Sch. 21 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

#### Amendment to regulation 20

**14.** In regulation 20 (requirements which must be satisfied before an importer places a category B vessel on the market), in paragraph (a) for "the sound engineering practice in a Member State" substitute "sound engineering practice".

Sch. 21 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 (information identifying importer)—
  - (a) in paragraph (1) omit the words from "or, where" to "vessel";
  - (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) on the vessel, or
        - (ii) the importer has imported the vessel from an EEA state [F9 or Switzerland] and places it on the market within the period of [F1024 months] beginning with [F11IP completion day], and
      - (b) before placing the vessel on the market, the importer sets out the information referred to in paragraph (1) in a document accompanying the vessel.";
  - (c) in paragraph (2) for "competent national authority in the Member State in which it is to be made available to such end-users" substitute "enforcing authority".

### **Textual Amendments**

- F9 Words in Sch. 21 para. 15(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)
- **F10** Words in Sch. 21 para. 15(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)(f)
- F11 Words in Sch. 21 para. 15(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(j)(iii)

### **Commencement Information**

Sch. 21 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 22

**16.** For regulation 22 (instructions and safety information) substitute—

### "Instructions and safety information

**22.** When placing a vessel on the market, an importer must ensure that the vessel is accompanied by instructions and safety information that are clear, legible and in easily understandable English.".

Sch. 21 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 25

17. In regulation 25 (duty of importer to take action in respect of vessels placed on the market which are considered not to be in conformity), in paragraph (2) omit "and the competent national authorities of any other Member State in which the importer made the vessel available on the market,".

#### **Commencement Information**

Sch. 21 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 26

**18.** In regulation 26 (retention by importer of technical documentation and EU declaration of conformity), in the heading to that regulation and in paragraph (a), omit "EU".

#### **Commencement Information**

Sch. 21 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 29

- **19.** Regulation 29 (requirements which must be satisfied before a distributor makes available on the market a category A vessel), paragraph (a) is amended as follows—
  - (a) in subparagraph (i) for "CE" substitute "UK"; and
  - (b) for subparagraph (ii) substitute—
    - "(ii) is accompanied by instructions and safety information that are clear, legible and in easily understandable English;".

#### **Commencement Information**

Sch. 21 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

- **20.** In regulation 31 (requirements which must be satisfied before a distributor makes a category B vessel available on the market)—
  - (a) for paragraph (1)(a)(ii) substitute—
    - "(ii) is accompanied by instructions and safety information that are clear, legible and in easily understandable English;"; and

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 21. (See end of Document for details)

(b) omit paragraph (2).

#### **Commencement Information**

Sch. 21 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 33**

**21.** In regulation 33 (duty for distributor to take action), in paragraph (2) omit "and the competent national authorities of any other Member States in which the distributor made the vessel available on the market".

#### **Commencement Information**

Sch. 21 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

### **Omission of regulation 36**

22. Omit regulation 36 (translation of EU declaration of conformity).

#### **Commencement Information**

I22 Sch. 21 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 (improper use of CE marking) in the heading and in each place in which it occurs, for "CE" substitute " UK ".

#### **Commencement Information**

23 Sch. 21 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 regulations 38A and 38B

**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 2(17);
- (c) "harmonised standard" has the meaning given to it in Article 2(9).

- (2) Subject to paragraphs (6) and (7), paragraph (3) applies where, before placing a category A vessel on the market, the manufacturer—
  - (a) ensures that the vessel has been designed and manufactured in accordance with the essential safety requirements set out in Annex I;
  - (b) ensures that the relevant conformity assessment procedures that apply to that vessel in accordance with Article 13(1) and (2) have been carried out;
  - (c) draws up the technical documentation referred to in Annex II;
  - (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 and the inscriptions, in accordance with Articles 15 and 16(1) to (4);
  - (f) draws up an EU declaration of conformity, in accordance with Article 14; 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 4(1), 5, 6(1) to (3) and (5) are to be treated as being satisfied;
    - (b) regulations 2(5)(a), 6(4), 8, 9(2), 16(2) and 38 apply subject to the modifications in paragraph (10);
    - (c) Part 3 does not apply; and
    - (d) regulation 62 does not apply.
- (4) Subject to paragraphs (6) and (7), paragraph (5) applies where, before placing a category A vessel on the market, the importer ensures that—
  - (a) the relevant conformity assessment procedures that apply to that vessel in accordance with Article 13(1) and (2) have been carried out;
  - (b) the manufacturer has drawn up the technical documentation referred to in Annex II; and
  - (c) the vessel bears the CE marking and inscriptions referred to in point 1 of Annex III
  - (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(5)(a), 19(1), 23 and 26 apply subject to the modifications in paragraph (10).
- (6) This paragraph applies where there is no designated standard or part of a designated standard which corresponds exactly to a harmonised standard or part of a harmonised standard referred to in Article 12.
- (7) Where paragraph (6) applies, paragraphs (2)(b) and (4)(a) are to be treated as requiring the manufacturer to have carried out—
  - (a) the conformity assessment procedure set out in Article 13(1)(b); and
  - (b) the relevant conformity assessment procedure that applies to that product in accordance with Article 13(2).
- (8) Paragraph (9) applies where, before making a category A vessel available on the market, a distributor ensures that the vessel bears the CE marking and inscriptions referred to in point 1 of Annex III.

- (9) Where this paragraph applies—
  - (a) regulation 29(a)(i) is to be treated as being satisfied; and
  - (b) regulations 2(5)(a), 30(1) and 32 apply subject to the modifications in paragraph (10).
- (10) The modifications referred to in 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 safety 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 conformity assessment procedures that apply to the vessel in accordance with Article 13(1) and (2);
  - (f) any reference to "technical documentation" is a reference to the technical documentation referred to in Annex II.

# Conformity assessment procedure obligation which is met by complying with the Directive

- **38B.**—(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) "harmonised standard" has the meaning given to it in Article 2(9).
- (2) Subject to paragraphs (4) and (5), paragraph (3) applies where, prior to the manufacture of a category A vessel, the manufacturer ensures that the conformity assessment procedure that applies to that vessel in accordance with Article 13(1) has been carried out.
  - (3) Where this paragraph applies—
    - (a) regulation 40 is to be treated as being satisfied;
    - (b) any reference to "relevant conformity assessment procedure" in regulations 5(b), 6(1), 18(a), 38(b) and 43(c) is to be read as including the conformity assessment procedure referred to in Article 13(1); and
    - (c) any reference to "technical documentation" in regulations 5(a), 8, 18(b) and 26(b) is to be read as including the technical documentation relating to the design of the vessel referred to in Annex II.
- (4) This paragraph applies where there is no designated standard or part of a designated standard which corresponds exactly to a harmonised standard or part of a harmonised standard referred to in Article 12.
- (5) Where paragraph (4) applies, paragraph (2) is to be treated as requiring the manufacturer to have carried out the conformity assessment procedure set out in Article 13(1)(b).

### [F12Expiry of regulations 38A and 38B

- **38C.**—(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 vessel which was placed on the market pursuant to regulation 38A may continue to be made available on the market after the expiry of regulation 38A;
    - (b) any obligation to which a person was subject under regulation 38A in respect of a vessel placed on the market pursuant to regulation 38A continues to have effect after the expiry of regulation 38A, in respect of that vessel.
- (3) Subject to paragraph (4), regulation 38B 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 38B in relation to a vessel prior to the expiry of regulation 38B, regulation 38B continues to apply in respect of that vessel where—
  - (a) the manufacturer arranges for the EU-Type examination certificate and any annexes 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 an EU-Type examination has been carried out in accordance with a conformity assessment procedure set out in point 1 of Annex II of the Directive.

### **Qualifying Northern Ireland Goods**

- **38D.**—(1) Where paragraph (2) applies, a vessel is to be treated as being in conformity with Part 2.
  - (2) This paragraph applies where—
    - (a) a vessel—
      - (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 vessel on the market, the importer—
  - (a) complies with regulation 21;
  - (b) ensures that—
    - (i) the relevant conformity assessment procedure has been carried out in relation to the vessel, in accordance with Part 3, as that Part applies in Northern Ireland;
    - (ii) the manufacturer has drawn up the technical documentation; and
    - (iii) the vessel bears the CE marking.
  - (4) In this regulation—

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 21. (See end of Document for details)

- "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;
- "technical documentation" means the documentation referred to in paragraph 2(2)(c) of Part 1 of Schedule 2 to these Regulations, as that Schedule applies in Northern Ireland. "].

#### **Textual Amendments**

F12 Words in Sch. 21 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. 13(6)

#### **Commencement Information**

Sch. 21 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 of category A vessels), in paragraph (1)—
  - (a) for "harmonised" substitute "designated";
  - (b) omit "the reference to which has been published in the Official Journal".

### **Commencement Information**

I25 Sch. 21 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 40

- **26.** In regulation 40 (conformity assessment procedures prior to manufacturer)—
  - (a) in paragraphs (1) and (4) for "an EU-type", substitute "a Type";
  - (b) in paragraphs (2) and (3) for "harmonised" substitute "designated".

#### **Commencement Information**

Sch. 21 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

- 27. In regulation 42 (records and correspondence language requirements)—
  - (a) for "an official language of the Member State in which the notified body is established" substitute "English";
  - (b) for "that body" substitute "the approved body".

Sch. 21 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 regulation 43

- 28. In regulation 43 (EU declaration of conformity)—
  - (a) in the heading for "EU declaration" substitute "Declaration";
  - (b) omit "EU".

#### **Commencement Information**

Sch. 21 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

#### Amendment to regulation 44

- 29. In regulation 44 (identification number)—
- [F13(a) for paragraph (1) substitute—
  - "(1) The UK marking must be followed by the identification number of the approved body involved in the relevant conformity assessment procedure pursuant to regulation 41."]
  - (b) in paragraph (2) for "notified" in each place it in which it occurs, substitute "approved".

#### **Textual Amendments**

F13 Sch. 21 para. 29(a) 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. 13(7)

### **Commencement Information**

Sch. 21 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 Part 4**

**30.** For Part 4, substitute—

### "PART 4

Approval of Conformity Assessment Bodies

#### **Approved bodies**

**45.**—(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 46 (approval of conformity assessment bodies); or
- (b) immediately before [F14IP completion day] was a notified body in respect of which the Secretary of State had taken no action under regulation 51(1) or (2) as they had effect immediately before [F14IP completion day] to suspend or withdraw the body's status as a notified body.
- (2) Paragraph (1) has effect subject to regulation 49 (restriction, suspension or withdrawal of approval).
  - (3) In this Part—
    - "notified body" means a body—
    - which the Secretary of State had before [F14IP completion day] notified to the European Commission and the member States of the European Union in accordance with Article 17 of the Directive; and
    - (b) in respect of which no objections had been raised, as referred to in regulation 45(1)(b), as it had effect immediately before [F14IP completion day];
    - "approved body requirements" means the requirements set out in Part 1 of Schedule 4.

### Approval of conformity assessment bodies

- **46.**—(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;
    - (iii) the category of vessels 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

- **47.**—(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**

- **48.** 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 46(6)(b); or
    - (ii) in the case of an approved body which was a notified body immediately before [F15IP completion day], in accordance with regulation 46(6)(b), as it applied immediately before [F15IP completion day]; and
  - (c) carries out its functions in accordance with these Regulations.

## Restriction, suspension or withdrawal of approval

- **49.**—(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 48(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 45 (approved bodies).

- (2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 48(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 45.
- (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

- **50.**—(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 46; 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 Part 2 of Schedule 4.
- (3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—
  - (a) to issue a Type examination certificate referred to in Schedule 2; or
  - (b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 44 (identification number).

### Subsidiaries and contractors

- **51.**—(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

- **52.**—(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 identification 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

- **53.** 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 48; and
  - (c) compiling and maintaining the register of approved bodies, in accordance with regulation 52.".

#### **Textual Amendments**

- F14 Words in Sch. 21 para. 30 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(j)(iv)
- F15 Words in Sch. 21 para. 30 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(j)(v)

### **Commencement Information**

I30 Sch. 21 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

### **Marginal Citations**

M1 2006 c.46.

### Amendment to regulation 57

**31.** In regulation 57 omit paragraph (c).

### **Commencement Information**

I31 Sch. 21 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 vessels which are not in conformity) 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) ":
  - (d) in paragraph (8)(f)(ii) for "harmonised" substitute "designated"; and
  - (e) in paragraph (10) omit "throughout the EU".

#### **Commencement Information**

I32 Sch. 21 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

### Omission of regulation 60

**33.** Omit regulation 60 (EU safeguard procedure).

### **Commencement Information**

Sch. 21 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

### Amendment to regulation 61

- **34.** In regulation 61 (enforcement action in respect of vessels which are in conformity, but which present a risk)—
  - (a) omit paragraph (3); and
  - (b) in paragraph (4) for "notices referred to in paragraphs (2) and (3)" substitute " notice referred to in paragraph (2)".

### **Commencement Information**

I34 Sch. 21 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

- **35.** Regulation 62 (enforcement action in respect of formal non-compliance) is amended as follows—
  - (a) in paragraphs (1)(a)(i), (1)(a)(ii), (1)(a)(iv) and (1)(b)(i) for "CE" substitute "UK" in each place in which it occurs;
  - (b) in paragraphs (1)(a)(ii), (1)(a)(iv), (1)(b)(i) omit "EU" in each place in which it occurs;
  - (c) in paragraph (1)(a)(iii) for "a notified" substitute "an approved";
  - (d) in paragraphs (1)(a)(iii)(aa) and (bb) for "notified" substitute "approved";

(e) in paragraph (4) omit "or 60(3) (the EU safeguard procedure)".

#### **Commencement Information**

Sch. 21 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 regulation 76

**36.** In regulation 76 (transitional provisions) in paragraph (1) for "another" substitute "a".

#### **Commencement Information**

I36 Sch. 21 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

### Transitional provision in relation to EU Exit

**37.** After regulation 76 insert—

### "Transitional provision in relation to EU Exit

**76A.**—(1) In this regulation—

"pre-exit period" means the period beginning with the commencement date and ending immediately before [F16IP completion day];

"product" means a vessel 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 21 to 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 [F16IP completion day], continues to have effect as it did immediately before [F16IP completion day], in relation to that product.
  - (3) Paragraph (2) does not apply to—
    - (a) any obligation of 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 regulations 40 or 41 as they had effect immediately before [F16IP completion day] in relation to that product

that action has effect as if it had been done under regulations 40 or 41 as they have effect on and after [F16IP completion day].".

#### **Textual Amendments**

F16 Words in Sch. 21 para. 37 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(j)(vi)

#### **Commencement Information**

Sch. 21 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

### **Marginal Citations**

M2 S.I. 2019/696.

- **38.**—(1) Regulation 77 (revocations 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 as follows—
    - (a) in the 1991 Regulations—
      - (i) any reference to "the Community" is to be read as including the United Kingdom;
      - (ii) any reference to "member State" is to be read as including the United Kingdom;
      - (iii) in regulation 11 (EC type-examination certificate)—
        - (aa) in paragraph (6)(a), for "the Commission, any other approved body or any other member State" substitute " or any other United Kingdom approved body ";
        - (bb) in paragraph (8), omit ", with a view to this information being passed by him to the Commission and the other member States";
      - (iv) in regulation 17 (Functions of approved bodies in course of EC Surveillance)—
        - (aa) paragraph (2) is to be read as if "or elsewhere" were omitted;
        - (bb) paragraph (3) is to be read as if ", the Commission, any other approved body or any other member State" were omitted;
      - (v) paragraph 6 of Schedule 5 (enforcement), is to be read as if ", with a view to this information being passed by him to the Commission" were omitted;
    - (b) in the Simple Pressure Vessels (Safety) (Amendment) Regulations 1994, in regulation 5 (transitional provisions in respect of marking arrangements)—
      - (i) any reference to "the Community" is to be read as including the United Kingdom; and
      - (ii) paragraph (3) is to be read as if the following paragraph were substituted—
        - "(3) In the event of such election, to demonstrate compliance with the marking arrangements in force on 31 December 1994, the manufacturer or his authorised representative established in the Community, shall apply the principal Regulations (as amended by these Regulations)—

- (a) as if the amendments made by regulation 4(f) and (k) had not come into force; and
- (b) read subject to the modifications made by regulation 77(2A)(a) of the Simple Pressure Vessels (Safety) Regulations 2016 M3.""

I38 Sch. 21 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

#### **Marginal Citations**

**M3** S.I. 2016/1092.

#### **Amendment to Schedule 1**

**39.** In Schedule 1, in paragraph 21(2) for "a notified" in each place in which it occurs substitute "an approved".

#### **Commencement Information**

Sch. 21 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 2

- **40.** Schedule 2 (conformity assessment procedures) is amended as follows—
  - (a) in the heading, omit "EU-";
  - (b) in paragraphs 1, 7(1), 8(3) to (5), 11(2) and 15(2) for "a notified" substitute "an approved";
  - (c) in all places in which it occurs (other than those referred to in sub-paragraph (b)) for "notified" substitute "approved";
  - (d) in paragraph 6(1) and (3) for "an EU-Type" substitute "a Type";
  - (e) in all places in which it occurs (other than the paragraphs referred to in sub-paragraph (d)) for "EU-Type" substitute "Type";
  - (f) in paragraphs 2(2)(e)(i), 3(1)(c)(iv) and (v) and 16(2) for "harmonised" substitute "designated";
  - (g) in paragraph 3(c)(iv) omit ", the references to which have been published in the Official Journal";
  - (h) in paragraph 8(3) for "Commission, the member States" substitute "Secretary of State";
  - (i) in paragraph 8(4), for "Commission and the member States" substitute "Secretary of State
  - (j) in paragraph 12(3) for "Member State in which the test is performed" substitute "Secretary of State";
  - (k) in paragraphs 12(9) and 16(6) omit "other Member States and the Commission,";
  - (l) for the headings to paragraphs 13, 17 and 20 substitute— "UK marking and declaration of conformity";
  - (m) in paragraphs 13, 17 and 20—

- (i) for "CE" substitute "UK"; and
- (ii) for "EU declaration" substitute "declaration" in each place in which it occurs; and
- (n) in paragraph 18 for "the Directive" substitute "these Regulations".

I40 Sch. 21 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

### Amendment to Schedule 3

- 41. Schedule 3 (EU Declaration of conformity) is amended as follows—
  - (a) omit "EU" in each place in which it occurs;
  - (b) for "declaration" in the first place in which it occurs substitute "Declaration";
  - (c) in paragraph 5, for "Union harmonisation legislation" substitute "statutory requirements";
  - (d) in paragraph 6, for "harmonised" substitute "designated"; and
  - (e) in paragraph 7 for "notified" substitute "approved".

#### **Commencement Information**

Sch. 21 para. 41 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

#### Amendments to Schedule 4

- **42.** Schedule 4 (notified bodies) is amended as follows—
  - (a) in paragraphs 8(b), 17, 18, 19, 20, 21, 24, 26, 27, 28 and 29 for "a notified" substitute "an approved";
  - (b) in all places in which it occurs (other than the paragraphs referred to in subparagraph (a)) for "notified" substitute "approved";
  - (c) in paragraph 10(c)—
    - (i) for "harmonised" substitute "designated"; and
    - (ii) omit "the relevant Directives and of";
  - (d) in paragraphs 16 and 29 for "under the Directive" substitute "by the Secretary of State";
  - (e) in paragraph 21 for "harmonised" substitute "designated"; and
  - (f) in paragraph 26(b) omit "(notification)".

#### **Commencement Information**

Sch. 21 para. 42 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 21.