#### STATUTORY INSTRUMENTS

### 2008 No. 1597

### The Supply of Machinery (Safety) Regulations 2008

#### PART 3

### General prohibitions and obligations

#### Supply of machinery: general obligations and prohibition E+W+S

- 7.—(1) No responsible person shall place machinery on the market or put it into service unless it is safe.
  - (2) Before machinery is placed on the market or put into service, the responsible person must—
    - (a) ensure that the applicable essential health and safety requirements are satisfied in respect of it;
    - (b) ensure that the technical file is compiled and made available in accordance with the requirements of Annex VII (Part 7 of Schedule 2), part A;
    - (c) provide, in particular, the information necessary to operate it safely, such as instructions;
    - (d) follow, as appropriate—
      - (i) the conformity assessment procedure prescribed by regulation 10;
      - (ii) one of the conformity assessment procedures prescribed by regulation 11; or
      - (iii) one of the conformity assessment procedures prescribed by regulation 12;
    - (e) draw up the F1... declaration of conformity in accordance with the requirements of Annex II (Part 2 of Schedule 2), section A, part 1, and ensure that—
      - (i) a copy of it accompanies the machinery; and
      - (ii) the original is retained in accordance with the requirements of Annex II, part 2, first paragraph; and
    - (f) affix the [F2UK] marking to the machinery [F3 or where paragraph (2A) applies, or on a label affixed to, or document accompanying, the machinery]—
      - (i) visibly, legibly and indelibly; and
      - (ii) as prescribed in Annex III (Part 3 of Schedule 2).
- [<sup>F4</sup>(2A) For a period of [<sup>F5</sup>seven years] beginning with IP completion day, the UK marking may be affixed to—
  - (a) a label affixed to the machinery; or
  - (b) a document accompanying the machinery.]
- (3) In order to comply with the requirements of paragraphs (1) and (2), a responsible person must carry out, or procure the carrying out of, all the necessary research and tests on components, fittings or the completed machinery to determine whether, by its design and construction, it is capable of being assembled and put into service safely.

- (4) For the purposes of paragraph (2)(a), machinery which is manufactured in conformity with a [F6 designated] standard, F7... shall be presumed to comply with the essential health and safety requirements covered by that standard.
  - (5) Where—
    - (a) the conformity assessment procedure specified in regulations 11(2)(b) and 12(2)(a) has been followed; and
    - (b) a type-examination certificate has been issued,

in respect of machinery, the manufacturer must comply with the ongoing obligations of manufacturers prescribed in Annex IX (Part 9 of Schedule 2), point 9, in respect of that machinery.

- (6) Where—
  - (a) the conformity assessment procedure specified in regulations 11(2)(c) and 12(2)(b) has been followed; and
  - (b) a quality system has been approved,

in respect of machinery, the manufacturer must comply with the ongoing obligations of manufacturers prescribed in Annex X (Part 10 of Schedule 2) in respect of that machinery.

#### **Extent Information**

- E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F1 Word in reg. 7(2)(e) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 6(a) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F2 Word in reg. 7(2)(f) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 6(b)(i) (as substituted by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 7(4)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F3 Words in reg. 7(2)(f) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 6(b)(ii) (as substituted by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 7(4)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F4 Reg. 7(2A) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 6(ba) (as inserted by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 7(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)
- Words in reg. 7(2A) substituted (E.W.S.) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 3, Sch. 2 para. (c)
- **F6** Word in reg. 7(4) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 12 para. 6(c)(i)** (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F7 Words in reg. 7(4) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 6(c)(ii) (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Supply of machinery: general obligations and prohibition N.I.

- 7.—(1) No responsible person shall place machinery on the market or put it into service unless it is safe.
  - (2) Before machinery is placed on the market or put into service, the responsible person must—
    - (a) ensure that the applicable essential health and safety requirements are satisfied in respect of it;

- (b) ensure that the technical file is compiled and made available in accordance with the requirements of Annex VII (Part 7 of Schedule 2), part A;
- (c) provide, in particular, the information necessary to operate it safely, such as instructions;
- (d) follow, as appropriate—
  - (i) the conformity assessment procedure prescribed by regulation 10;
  - (ii) one of the conformity assessment procedures prescribed by regulation 11; or
  - (iii) one of the conformity assessment procedures prescribed by regulation 12;
- (e) draw up the EC declaration of conformity in accordance with the requirements of Annex II (Part 2 of Schedule 2), section A, part 1, and ensure that—
  - (i) a copy of it accompanies the machinery; and
  - (ii) the original is retained in accordance with the requirements of Annex II, part 2, first paragraph; and
- (f) affix the UK marking to the machinery—
  - (i) visibly, legibly and indelibly; and
  - (ii) as prescribed in Annex III (Part 3 of Schedule 2).
- [F19(2A) Where a UK notified body carries out the functions of notified bodies specified in Annexes IX and X the CE marking must be accompanied by the UK(NI) indication affixed in accordance with paragraph (2B).
  - (2B) The UK(NI) indication must be affixed—
    - (a) in a visible, legible and indelible form to the machinery; and
    - (b) before the machinery is placed on the market in Northern Ireland.
- (2C) Where paragraph (2A) applies, the reference to the identification number of the notified body in Schedule 2, Part 3 Annex III, is a reference to the identification number assigned to the UK notified body by the Secretary of State pursuant to regulation 19A.
- (3) In order to comply with the requirements of paragraphs (1) and (2), a responsible person must carry out, or procure the carrying out of, all the necessary research and tests on components, fittings or the completed machinery to determine whether, by its design and construction, it is capable of being assembled and put into service safely.
- (4) For the purposes of paragraph (2)(a), machinery which is manufactured in conformity with a harmonised standard, the references to which have been published in the *Official Journal of the European Union* (a "published harmonised standard") shall be presumed to comply with the essential health and safety requirements covered by that standard.
  - (5) Where—
    - (a) the conformity assessment procedure specified in regulations 11(2)(b) and 12(2)(a) has been followed; and
    - (b) a type-examination certificate has been issued,

in respect of machinery, the manufacturer must comply with the ongoing obligations of manufacturers prescribed in Annex IX (Part 9 of Schedule 2), point 9, in respect of that machinery.

- (6) Where—
  - (a) the conformity assessment procedure specified in regulations 11(2)(c) and 12(2)(b) has been followed; and
  - (b) a quality system has been approved,

in respect of machinery, the manufacturer must comply with the ongoing obligations of manufacturers prescribed in Annex X (Part 10 of Schedule 2) in respect of that machinery.

- **E4** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only
- F19 Reg. 7(2A)-(2C) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), Sch. 2 para. 3(3)

#### Supply of partly completed machinery: general obligations and prohibition

- **8.**—(1) Before partly completed machinery is placed on the market, the responsible person must ensure that—
  - (a) the relevant technical documentation is prepared and made available in accordance with the requirements of Annex VII (Part 7 of Schedule 2), part B;
  - (b) assembly instructions are prepared in accordance with Annex VI (Part 6 of Schedule 2);
  - (c) a declaration of incorporation has been drawn up in accordance with Annex II (Part 2 of Schedule 2), part 1, section B, and that—
    - (i) a copy of it accompanies the machinery; and
    - (ii) the original is retained in accordance with Annex II, part 2, second paragraph.
- (2) The assembly instructions and the declaration of incorporation shall accompany partly completed machinery until it is incorporated into machinery.
- (3) After partly completed machinery is incorporated into machinery its assembly instructions and declaration of incorporation shall form part of the technical file for that machinery.
- (4) In order to comply with the requirements of paragraph (1), a responsible person must carry out, or procure the carrying out of, all the necessary research and tests on components, fittings or the partly completed machinery to determine whether, by its design and construction, it is capable of being assembled and used safely.

#### **Putting machinery into service**

F8	Reg. 9 revoked (15.12.2011) by The Supply of Machinery (Safety) (Amendment) Regulations 2011
	(S.I. 2011/2157), regs. 1, 4

Conformity assessment procedures

#### Machinery not referred to in Annex IV

10. If machinery falls within a category which is not referred to in Annex IV (Part 4 of Schedule 2), the responsible person shall follow the conformity assessment procedure with internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2) in respect of it.

# Annex IV machinery manufactured fully in accordance with [F9 designated] standards and fully covered by such standards E+W+S

- 11.—(1) This regulation applies to machinery—
  - (a) which falls within a category which is referred to in Annex IV (Part 4 of Schedule 2); and

- (b) in respect of which both of the following conditions are satisfied—
  - (i) that the machinery is manufactured in accordance with [F10 designated] standards; and
  - (ii) that the [FII designated] standards in accordance with which it is manufactured cover all the applicable essential health and safety requirements.
- (2) Where this regulation applies, the responsible person shall follow one of the following conformity assessment procedures—
  - (a) the conformity assessment procedure with internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2); or
  - (b) the [F12 Type-] examination procedure prescribed in Annex IX (Part 9 of Schedule 2) and the internal checks on the manufacture of machinery prescribed in Annex VIII, point 3; or
  - (c) the full quality assurance procedure prescribed in Annex X (Part 10 of Schedule 2).

- **E2** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- Word in reg. 11 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 7(a) (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F10** Word in reg. 11(1)(b)(i) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 7(a) (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F11 Word in reg. 11(1)(b)(ii) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 7(a) (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F12** Word in reg. 11(2)(b) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 12 para. 7(b)** (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

# Annex IV machinery manufactured fully in accordance with published harmonised standards and fully covered by such standards N.I.

- 11.—(1) This regulation applies to machinery—
  - (a) which falls within a category which is referred to in Annex IV (Part 4 of Schedule 2); and
  - (b) in respect of which both of the following conditions are satisfied—
    - (i) that the machinery is manufactured in accordance with published harmonised standards; and
    - (ii) that the published harmonised standards in accordance with which it is manufactured cover all the applicable essential health and safety requirements.
- (2) Where this regulation applies, the responsible person shall follow one of the following conformity assessment procedures—
  - (a) the conformity assessment procedure with internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2); or
  - (b) the EC type-examination procedure prescribed in Annex IX (Part 9 of Schedule 2) and the internal checks on the manufacture of machinery prescribed in Annex VIII, point 3; or
  - (c) the full quality assurance procedure prescribed in Annex X (Part 10 of Schedule 2).

E5 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

# Annex IV machinery not manufactured fully in accordance with [F13 designated] standards or not fully covered by such standards E+W+S

- 12.—(1) This regulation applies to machinery—
  - (a) which falls within a category which is referred to in Annex IV (Part 4 of Schedule 2); and
  - (b) in respect of which any of the following conditions is satisfied—
    - (i) that the machinery is not manufactured in accordance with the [F14designated] standards which relate to it; or
    - (ii) that the machinery is only partly manufactured in accordance with the [F14designated] standards which relate to it; or
    - (iii) that the [F14designated] standards in accordance with which the machinery is manufactured do not cover all the applicable essential health and safety requirements; or
    - (iv) that no [F15] designated] standards exist for the machinery.
- (2) Where this regulation applies, the responsible person shall follow one of the following conformity assessment procedures—
  - (a) the [F16Type-] examination procedure prescribed in Annex IX (Part 9 of Schedule 2) and the internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2), point 3; or
  - (b) the full quality assurance procedure prescribed in Annex X (Part 10 of Schedule 2).

#### **Extent Information**

- E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F13 Word in reg. 12 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 8(a) (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F14** Word in reg. 12(1)(b)(i)-(iii) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 12 para. 8(a)** (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F15 Word in reg. 12(1)(b)(iv) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 8(b) (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F16 Word in reg. 12(2)(a) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 8(c) (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Annex IV machinery not manufactured fully in accordance with published harmonised standards or not fully covered by such standards N.I.

12.—(1) This regulation applies to machinery—

- (a) which falls within a category which is referred to in Annex IV (Part 4 of Schedule 2); and
- (b) in respect of which any of the following conditions is satisfied—
  - (i) that the machinery is not manufactured in accordance with the published harmonised standards which relate to it; or
  - (ii) that the machinery is only partly manufactured in accordance with the published harmonised standards which relate to it; or
  - (iii) that the published harmonised standards in accordance with which the machinery is manufactured do not cover all the applicable essential health and safety requirements; or
  - (iv) that no harmonised standards exist for the machinery.
- (2) Where this regulation applies, the responsible person shall follow one of the following conformity assessment procedures—
  - (a) the EC type-examination procedure prescribed in Annex IX (Part 9 of Schedule 2) and the internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2), point 3; or
  - (b) the full quality assurance procedure prescribed in Annex X (Part 10 of Schedule 2).

E6 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### [F17Obligations which are met by complying with obligations in the Directive

- **12A.**—(1) In this regulation—
  - (a) any reference to an Article or an Annex is a reference to an Article of or an Annex to the Directive;
  - (b) "CE marking" means the marking referred to in Article 16(1);
  - (c) "harmonised standard" means a harmonised standard within the meaning of Article 2(l), the reference to which has been published in the Official Journal of the European Union.
- (2) Subject to paragraphs (6) and (7), paragraph (3) applies where, before placing machinery on the market or putting machinery into service, the responsible person—
  - (a) ensures that the machinery satisfies the essential health and safety requirements set out in Annex I;
  - (b) ensures that the technical file referred to in Annex VII, part A is available to the enforcement authorities on request;
  - (c) provides the necessary information, referred to in Article 5(1)(c);
  - (d) carries out the appropriate procedures for assessing conformity in accordance with Article 12;
  - (e) ensures that the technical file, necessary information and records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;
  - (f) draws up the EC declaration of conformity in accordance with Annex II, part I, Section A and ensure that it accompanies the machinery;
  - (h) ensures that the EC declaration of conformity is prepared in or translated into English; and
  - (i) affixes the CE marking in accordance with Article 16.

- (3) Where this paragraph applies—
  - (a) the requirements of regulation 7(2)(a), (b), (c), (e)(i) and (f) are to be treated as being satisfied;
  - (b) regulations 7(2)(e)(ii), 15 and 21 apply subject to the modifications in paragraph (8);
  - (c) Part 8 of Schedule 2 does not apply.
- (4) Subject to paragraphs (6) and (7) paragraph (5) applies where, before placing partly completed machinery on the market, the responsible person ensures that—
  - (a) the relevant technical documentation referred to in Annex VII part B is prepared in or translated into English;
  - (b) the assembly instructions referred to in Annex VI are prepared in or translated into English; and
  - (c) a declaration of incorporation referred to in Annex II part 1, Section B has been drawn up in or translated into English.
- (5) Where this paragraph applies the requirements of regulation 8(1) are to be treated as being satisfied.
- (6) This paragraph applies to machinery listed in Annex IV 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 7(2).
- (7) Where paragraph (6) applies, paragraph (2)(d) is to be read as requiring the responsible person to have carried out the conformity assessment procedure in Article 12(4).
  - (8) The modifications referred to in paragraph (3)(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.
  - F17 Regs. 12A-12C inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 9 (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, regs. 1(4), Sch. 3 para. 7(5)); 2020 c. 1, Sch. 5 para. 1(1)

#### Expiry of regulation 12A

- **12B.**—(1) Subject to paragraph (2), regulation 12A ceases to have effect at the end of the period of [F18 four years] beginning with IP completion day.
  - (2) Notwithstanding the expiry of regulation 12A—
    - (a) any machinery or partly completed machinery which was placed on the market or put into service pursuant to regulation 12A may continue to be made available on the market on or after the expiry of regulation 12A;
    - (b) any obligation to which a person was subject under regulation 12A(2) in respect of machinery or partly completed machinery placed on the market or put into service pursuant to regulation 12A continues to have effect after the expiry of regulation 12A, in respect of that machinery or partly completed machinery.
  - F17 Regs. 12A-12C inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 9 (with Sch. 12 para. 22) (as

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amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, regs. 1(4), Sch. 3 para. 7(5)); 2020 c. 1, Sch. 5 para. 1(1)
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**F18** Words in reg. 12B(1) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1** para. (c)

#### **Qualifying Northern Ireland Goods**

- **12C.**—(1) Where paragraph (2) applies the requirements of Part 3, other than those in regulations 12A, 12B and this regulation, are treated as being satisfied.
  - (2) This paragraph applies where—
    - (a) the responsible person has complied with the requirements of Part 3, as that Part applies in Northern Ireland; and
    - (b) the machinery or partly completed machinery is qualifying Northern Ireland goods.
- (3) In this regulation "qualifying Northern Ireland goods has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018.]
  - F17 Regs. 12A-12C inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 12 para. 9 (with Sch. 12 para. 22) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, regs. 1(4), Sch. 3 para. 7(5)); 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:**There are currently no known outstanding effects for the The Supply of Machinery (Safety) Regulations 2008, PART 3.