

STATUTORY INSTRUMENTS

2008 No. 1597

The Supply of Machinery (Safety) Regulations 2008

PART 3

General prohibitions and obligations

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 [^{F1}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 [^{F2}designated] standards; and
 - (ii) that the [^{F3}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 [^{F4}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).

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. 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)**
- F2** 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)**

- F3** 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)**
- F4** 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).

Extent Information

- E3** 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 [^{F5}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 [^{F6}designated] standards which relate to it; or
 - (ii) that the machinery is only partly manufactured in accordance with the [^{F6}designated] standards which relate to it; or
 - (iii) that the [^{F6}designated] standards in accordance with which the machinery is manufactured do not cover all the applicable essential health and safety requirements; or
 - (iv) that no [^{F7}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 [F8Type-] 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

- E2** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F5** 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)
- F6** 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)
- F7** 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)
- F8** 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).

Extent Information

- E4** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F9}Obligations 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(1), 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.

F9 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 [^{F10}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.

F9 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)**

F10 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.]

F9 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, Conformity assessment procedures.