

## STATUTORY INSTRUMENTS

# 2011 No. 1881

## CONSUMER PROTECTION

### The Toys (Safety) Regulations 2011

*Made* - - - - 24th July 2011  
*Laid before Parliament* 29th July 2011  
*Coming into force* - - 19th August 2011

<sup>M1M2</sup>The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to consumer protection.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of an EU instrument to be construed as a reference to those provisions as amended from time to time.

<sup>M3</sup>In accordance with section 11(5) of the Consumer Protection Act 1987 the Secretary of State has consulted such organisations as appear to him to be representative of interests substantially affected by the proposal to make these Regulations and such other persons as he considers appropriate.

The Secretary of State makes regulations 1 to 39 in exercise of his powers conferred by section 11 of the Consumer Protection Act 1987 <sup>M4</sup>, and paragraph 1A of Schedule 2 to the European Communities Act 1972<sup>M5</sup>, and all other regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972.

#### **Modifications etc. (not altering text)**

- C1** Regulations modified (19.6.2021) by [The Conformity Assessment \(Mutual Recognition Agreements\) and Weights and Measures \(Intoxicating Liquor\) \(Amendment\) Regulations 2021 \(S.I. 2021/730\)](#), regs. 1, 4, [Sch. 1 para. 4](#)

#### **Marginal Citations**

- M1** [S.I. 1993/2661](#).  
**M2** 1972 c.68. Section 2(2) was amended by the [Legislative and Regulatory Reform Act 2006 \(c.51\)](#), [section 27\(1\)\(a\)](#) and by the [European Union \(Amendment\) Act 2008 \(c.7\)](#), [section 3\(3\)](#) and Schedule, Part 1.  
**M3** 1987 c.43.  
**M4** Section 11(1) was amended by [S.I. 2005/1803](#).

**M5** 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the [Legislative and Regulatory Reform Act 2006 \(c.51\)](#) and was amended by the [European Union \(Amendment\) Act 2008 \(c.7\)](#), [section 3\(3\)](#) and Schedule, Part 1.

## PART 1

### Preliminary

#### Citation and commencement

- 1.—(1) These Regulations may be cited as the Toys (Safety) Regulations 2011.
- (2) These Regulations come into force on 19th August 2011.

#### Revocation, saving and amendment

2.—(1) The Toys (Safety) Regulations 1995 <sup>M6</sup> (“the 1995 Regulations”) and the Toys (Safety) (Amendment) Regulations 2010 <sup>M7</sup> are revoked.

(2) The 1995 Regulations, as amended, continue to apply, [<sup>F1</sup>subject to the modifications in paragraph (2A)] as if they had not been revoked, to a toy placed on the market before these Regulations come into force.

[<sup>F2</sup>(2A) The modifications referred to in paragraph (2) are—

- (a) that references to “the Community” are to be read as including the United Kingdom; and
  - (b) paragraph (5) of regulation 9 is to be read as if “, the Commission of the Communities, the other member States and other approved bodies” were omitted.]
- (3) The Pencils and Graphic Instruments (Safety) Regulations 1998 <sup>M8</sup> are amended as follows.
- (4) In regulation 1, insert after paragraph (2)—

“(3) These Regulations do not apply to any article to which the Toys (Safety) Regulations 2011 apply.”

- F1** Words in [reg. 2\(2\)](#) 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. 15 para. 2\(1\)\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F2** [Reg. 2\(2A\)](#) 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. 15 para. 2\(1\)\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Marginal Citations

- M6** [S.I. 1995/204](#), amended by [S.I. 2004/1769](#), [S.I. 2005/1082](#) and [S.I. 2010/1928](#).
- M7** [S.I. 2010/1928](#)
- M8** [S.I. 1998/2406](#). ([S.I. 1998/2406](#) does not apply, by virtue of regulation 2(3) of [S.I. 1995/204](#), to articles which are toys to which [S.I. 1995/204](#) applies.)

#### [<sup>F3</sup>Transitional provision in relation to EU Exit

2A.—(1) In this regulation—

“pre-exit period” means the period beginning with 19th August 2011 and ending immediately before IP completion day;

“product” means a toy to which these Regulations apply.

(2) Subject to paragraphs (3) and (4), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 15 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, any obligation or prohibition to which a person was subject under these Regulations as they had effect immediately before IP completion day, continues to have effect as it did immediately before IP completion day, in relation to that product.

(3) Paragraph (2) does not apply to—

- (a) any obligation of any enforcement 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 an EC-type examination was issued in relation to a product to which paragraph (2) applies references to “Type examination” in regulations 22 and 45 are to be read as referring to an EC-type examination referred to in regulation 44 as it had effect immediately before IP completion day.

(5) 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 11 to 13 as they had effect immediately before IP completion day in relation to that product,

that action has effect as if it had been done under regulations 11 to 13 as they have effect on and after IP completion day.

<sup>F4</sup>(6) Subject to paragraph (7), where before 11pm on 31st December 2024—

- (a) a product has not been placed on the market; and
- (b) a manufacturer has taken any action under the conformity assessment procedure that applies to that product in accordance with Article 19 of the Directive

that action has effect as if it had been done under the applicable conformity assessment procedure referred to in regulation 13.

(7) Paragraph (6) does not apply—

- (a) after the expiry of the validity of any certificate issued pursuant to the applicable conformity assessment procedure; and
- (b) in any event, after 31st December 2027.]]

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| <p><b>F3</b> <a href="#">Reg. 2A</a> inserted (E.W.S.) (31.12.2020) by <a href="#">The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019</a> (S.I. 2019/696), reg. 1, <b>Sch. 15 para. 3</b> (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/852, regs. 2(2), 4(2), <b>Sch. 1 para. 1(e)(i)</b>); 2020 c. 1, Sch. 5 para. 1(1)</p> <p><b>F4</b> <a href="#">Reg. 2A(6)(7)</a> inserted (31.12.2022) by <a href="#">The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022</a> (S.I. 2022/1393), regs. 1(1), <b>9(2)</b></p> |
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## Interpretation **E+W+S**

3. In these Regulations—

“the 1987 Act” means the Consumer Protection Act 1987;

<sup>F5</sup>“the Directive” means [Directive 2009/48/EC](#) of the European Parliament and of the Council of 18th June 2009 on the safety of toys;]

“the GPSR” means the General Product Safety Regulations 2005 <sup>M9</sup>;

[<sup>F6</sup>“ approved body requirements ” has the meaning given to it in regulation 40A;]

“authorised representative” means a person who has been appointed in accordance with regulation 25(1);

<sup>F7</sup> ...

“conformity assessment” means the process demonstrating whether specified requirements relating to a toy have been fulfilled;

“conformity assessment activities” means activities relating to conformity assessment, including calibration, testing, certification and inspection;

[<sup>F8</sup>“ designated standard ” has the meaning given to it in regulation 3A;]

“distributor” means any person who—

- (a) is in the supply chain for a toy, other than the manufacturer or the importer; and
- (b) makes the toy available on the market;

“economic operator” means a manufacturer, an authorised representative, an importer or a distributor;

“enforcement authority” has the same meaning as in section 45(1) of the 1987 Act;

“essential safety requirements” has the meaning given in regulation 5;

“harm” means physical injury or any other damage to health, including long-term health effects;

<sup>F9</sup> ...

“hazard” means a potential source of harm;

[<sup>F10</sup>“ importer” means a person who—

- (a) is established in the United Kingdom and places a toy from a country outside of the United Kingdom on the market; or
- (b) is established in Northern Ireland and places a toy 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;]

“intended for use by” means that a parent or supervisor shall reasonably be able to assume by virtue of the functions, dimensions and characteristics of a toy that it is intended for use by children of the stated age group;

“make available on the market” means supply in the course of a commercial activity (whether in return for payment or free of charge) for distribution, consumption or use on the EU market, and related expressions shall be construed accordingly;

“manufacturer” means a person who—

- (a) manufactures a toy or has a toy designed or manufactured; and
- (b) markets that toy under that person's name or trademark;

[<sup>F11</sup>“ Module ” means a Module set out in Schedule 6 and Module A, B or C is to be construed accordingly;]

“notified body designation” has the meaning given in regulation 40;

“place on the market” means make a toy available on the EU market for the first time, and related expressions shall be construed accordingly;

“recall” means take any measure aimed at achieving the return of a toy that has already been made available to the end user;

“risk” means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply;

“toy” has the meaning given in regulation 4;

“UK notified body” has the meaning given in regulation 40;

“withdraw” means take any measure aimed at preventing a toy in the supply chain from being made available on the market.

#### 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
- F5** Words in [reg. 3](#) substituted (E.W.S.) (15.10.2022) by [The Toys and Cosmetic Products \(Restriction of Chemical Substances\) Regulations 2022 \(S.I. 2022/659\)](#), regs. 1(2), **2(2)**
- F6** Words in [reg. 3](#) 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. 15 para. 4(b)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2, 4(2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))
- F7** Words in [reg. 3](#) 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. 15 para. 4(d)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))
- F8** Words in [reg. 3](#) 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. 15 para. 4(e)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))
- F9** Words in [reg. 3](#) 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. 15 para. 4(f)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))
- F10** Words in [reg. 3](#) 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. 15 para. 4(g)** (as substituted 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. 9(2)**; 2020 c. 1, **Sch. 5 para. 1(1)**)
- F11** Words in [reg. 3](#) 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. 15 para. 4(i)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

#### Marginal Citations

- M9** [S.I. 2005/1803](#).

#### Interpretation **N.I.**

##### 3. In these Regulations—

“the 1987 Act” means the Consumer Protection Act 1987;

“the Directive” means Directive [2009/48/EC](#) of the European Parliament and of the Council of 18th June 2009 on the safety of toys ;

“the GPSR” means the General Product Safety Regulations 2005 ;

“authorised representative” means a person who has been appointed in accordance with regulation 25(1);

“CE marking” means a marking—

- (a) by which a manufacturer indicates that a toy will comply with the essential safety requirements during its foreseeable and normal period of use; and
- (b) which takes the form set out in Annex II of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ;

“conformity assessment” means the process demonstrating whether specified requirements relating to a toy have been fulfilled;

“conformity assessment activities” means activities relating to conformity assessment, including calibration, testing, certification and inspection;

“distributor” means any person who—

- (a) is in the supply chain for a toy, other than the manufacturer or the importer; and
- (b) makes the toy available on the market;

“economic operator” means a manufacturer, an authorised representative, an importer or a distributor;

“enforcement authority” has the same meaning as in section 45(1) of the 1987 Act;

“essential safety requirements” has the meaning given in regulation 5;

“harm” means physical injury or any other damage to health, including long-term health effects;

“harmonised standard” means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations on the basis of a request made by the European Commission in accordance with Article 6 of that Directive, the reference of which standard has been published in the Official Journal of the European Union;

“hazard” means a potential source of harm;

“importer” means any person who—

- (a) is established within the [<sup>F144</sup>relevant market]; and
- (b) places a toy from a [<sup>F145</sup>market outside the relevant market on the relevant] market;

“intended for use by” means that a parent or supervisor shall reasonably be able to assume by virtue of the functions, dimensions and characteristics of a toy that it is intended for use by children of the stated age group;

“make available on the market” means supply in the course of a commercial activity (whether in return for payment or free of charge) for distribution, consumption or use on the [<sup>F146</sup>relevant] market, and related expressions shall be construed accordingly;

“manufacturer” means a person who—

- (a) manufactures a toy or has a toy designed or manufactured; and
- (b) markets that toy under that person's name or trademark;

“Module” means a Module of Annex II to Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC and Module A, B or C shall be construed accordingly;

“notified body designation” has the meaning given in regulation 40;

“place on the market” means make a toy available on the [<sup>F147</sup>relevant] market for the first time, and related expressions shall be construed accordingly;

“recall” means take any measure aimed at achieving the return of a toy that has already been made available to the end user;

[<sup>F148</sup>“ relevant market ” means -

- (a) the market in Northern Ireland; and
- (b) the market of the EEA states;

“relevant state ”-

- (a) Northern Ireland; or
- (b) any EEA state;]

“risk” means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply;

“toy” has the meaning given in regulation 4;

[<sup>F149</sup>“ UK(NI) indication” means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020;]

“UK notified body” has the meaning given in regulation 40;

“withdraw” means take any measure aimed at preventing a toy in the supply chain from being made available on the market.

- F144** Words in reg. 3 substituted (N.I.) 31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 5 para. 2(1)(a)(i)**
- F145** Words in reg. 3 substituted (N.I.) 31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 5 para. 2(1)(a)(ii)**
- F146** Word in reg. 3 substituted (N.I.) 31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 5 para. 2(1)(b)(i)**
- F147** Word in reg. 3 substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 5 para. 2(1)(b)(ii)**
- F148** Words in reg. 3 inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 5 para. 2(1)(c)**
- F149** Words in reg. 3 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. 5(2)**

### [<sup>F12</sup>Designated standard

**3A.—**(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 [<sup>F13</sup>or an international standardising 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 subparagraph (a), 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; or
- (b) production methods and processes relating to the products, where these have an effect on their characteristics;
- (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);
- [
- <sup>F14</sup>(3A) In this regulation “international standardising body” has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).]
- (4) When considering whether the manner of publication of a reference 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 [<sup>F15</sup>such] technical specifications adopted by the other recognised standardisation organisations; [<sup>F16</sup>or by international standardising bodies as the Secretary of State considers to be relevant.]
- (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 toy 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.

**F12** Regs. 3A, 3B 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. 15 para. 5** (with Sch. 15 para. 3) (as amended 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), **2**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F13** Words in reg. 3A(1)(a) inserted (31.12.2020) by *European Union (Future Relationship) Act 2020* (c. 29), s. 40(7), **Sch. 4 para. 5(a)**; S.I. 2020/1662, reg. 2(ee)

**F14** Reg. 3A(3A) inserted (31.12.2020) by *European Union (Future Relationship) Act 2020* (c. 29), s. 40(7), **Sch. 4 para. 5(b)**; S.I. 2020/1662, reg. 2(ee)

**F15** Word in reg. 3A(5) inserted (31.12.2020) by *European Union (Future Relationship) Act 2020* (c. 29), s. 40(7), **Sch. 4 para. 5(c)(i)**; S.I. 2020/1662, reg. 2(ee)



**F16** Words in [reg. 3A\(5\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), [Sch. 4 para. 5\(c\)\(ii\)](#); S.I. 2020/1662, [reg. 2\(ee\)](#)

### Annexes to EU legislation as Schedules

**3B.**—(1) Schedules 1, 2, 4 and 5 reproduce provisions of the Annexes I, II, IV and V (respectively) to the Directive with amendments to correct deficiencies in retained EU law.

(2) A reference to a provision of Schedules 1, 2, 4, 5 is a reference to the equivalent provision of the relevant Annex to the Directive as set out in the relevant Schedule.

(3) Schedule 6 reproduces provisions of Annex II to Decision No [768/2008/EC](#) of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision [93/465/EEC](#) (“Decision No [768/2008/EC](#)”) which are relevant to these Regulations, as it has effect immediately before IP completion day, with amendments to correct deficiencies in retained EU law.

(4) A reference to a provision of Schedule 6 is a reference to the equivalent provision of Annex II of Decision No [768/2008/EC](#) as set out in that Schedule.]

**F12** [Regs. 3A, 3B](#) 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. 15 para. 5](#) (with [Sch. 15 para. 3](#)) (as amended by [The Product Safety and Metrology etc. \(Amendment to Extent and Meaning of Market\) \(EU Exit\) Regulations 2020 \(S.I. 2020/676\)](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

### Toys to which these Regulations apply **E+W+S**

**4.**—(1) These Regulations apply to toys placed on the market on or after 19th August 2011.

(2) Toys are products designed or intended (whether or not exclusively) for use in play by children under 14 years old.

(3) These Regulations do not apply to—

- (a) playground equipment intended for public use;
- (b) automatic playing machines intended for public use, whether coin operated or not;
- (c) toy vehicles equipped with combustion engines;
- (d) toy steam engines;
- (e) slings and catapults;
- (f) products listed in [<sup>F17</sup>Schedule 1], as amended from time to time.

#### 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

**F17** Words in [reg. 4\(3\)\(f\)](#) 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. 15 para. 6](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

### Toys to which these Regulations apply **N.I.**

**4.**—(1) These Regulations apply to toys placed on the market on or after 19th August 2011.

(2) Toys are products designed or intended (whether or not exclusively) for use in play by children under 14 years old.

(3) These Regulations do not apply to—

- (a) playground equipment intended for public use;
- (b) automatic playing machines intended for public use, whether coin operated or not;
- (c) toy vehicles equipped with combustion engines;
- (d) toy steam engines;
- (e) slings and catapults;
- (f) products listed in Annex I to the Directive, as amended from time to time.

### Essential safety requirements **E+W+S**

5.—(1) The essential safety requirements in respect of a toy are—

- (a) the general safety requirement set out in paragraphs (2) to (5); and
- (b) the particular safety requirements set out in <sup>F18</sup>Schedule 2], so far as relevant.

(2) Toys, including the chemicals they contain, must not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

(3) The ability of the users and, where appropriate, their supervisors must be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.

(4) Information as to the matters mentioned in paragraph (5), aimed at users of the toy or their supervisors, must be preceded by the word “Warning” or “Warnings” and must be marked in English in a clearly visible, easily legible, understandable and accurate manner on—

- (a) the toy, a label affixed to the toy, or the toy's packaging; and
- (b) any instructions for use which accompany the toy.

(5) The matters are—

- (a) the inherent hazards and risks of harm involved in using the toy; and
- (b) the ways of avoiding such hazards and risks.

#### 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

**F18** Words in [reg. 5\(1\)\(b\)](#) 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. 15 para. 7](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Essential safety requirements **N.I.**

5.—(1) The essential safety requirements in respect of a toy are—

- (a) the general safety requirement set out in paragraphs (2) to (5); and
- (b) the particular safety requirements set out in Annex II to the Directive (as amended from time to time), so far as relevant.

(2) Toys, including the chemicals they contain, must not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

(3) The ability of the users and, where appropriate, their supervisors must be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.

(4) Information as to the matters mentioned in paragraph (5), aimed at users of the toy or their supervisors, must be preceded by the word “Warning” or “Warnings” and must be marked in English in a clearly visible, easily legible, understandable and accurate manner on—

- (a) the toy, a label affixed to the toy, or the toy's packaging; and
- (b) any instructions for use which accompany the toy.

(5) The matters are—

- (a) the inherent hazards and risks of harm involved in using the toy; and
- (b) the ways of avoiding such hazards and risks.

### Particular safety requirements for toys placed on the market before 20th July 2013

[<sup>F19</sup>6. Where a toy is placed on the market before 20th July 2013, the particular safety requirements in respect of chemical properties are those in paragraph 3 of Part II of Annex II to Council Directive [88/378/EEC](#) on the approximation of the laws of the Member States concerning the safety of toys <sup>M10</sup>, and not those in Part III of Annex II to the Directive.]

**F19** [Reg. 6](#) 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. 15 para. 8](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

#### Marginal Citations

**M10** OJ No L 187, 16.7.1988, p1, amended by Directive 2008/112/EC of the European Parliament and of the Council in order to adapt Council Directive 88/378/EEC to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ No L 345, 23.12.2008, p68); there are other amending instruments to Council Directive 88/378/EEC but none is relevant.

### Presumption of conformity **E+W+S**

7.—(1) A toy which conforms with [<sup>F20</sup>designated] standards shall be presumed to comply with the essential safety requirements to the extent that those requirements are covered by those standards.

(2) The presumption set out in paragraph (1) is rebuttable.

#### Extent Information

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

**F20** Word in [reg. 7](#) 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. 15 para. 9](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

### Presumption of conformity **N.I.**

7.—(1) A toy which conforms with harmonised standards shall be presumed to comply with the essential safety requirements to the extent that those requirements are covered by those standards.

(2) The presumption set out in paragraph (1) is rebuttable.

### Exception for trade fairs or exhibitions **E+W+S**

8.—(1) A toy which does not bear the [<sup>F21</sup>UK] marking, or in relation to which any other requirement of these Regulations is not complied with, may be shown or used at a trade fair or exhibition.

(2) Such a toy must be accompanied by a sign which indicates clearly that—

- (a) the toy does not comply with [<sup>F22</sup>these Regulations]; and
- (b) the toy will not be made available in the [<sup>F23</sup>United Kingdom] before being brought into conformity with [<sup>F22</sup>these Regulations].

#### Extent Information

- E5** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F21** Word in reg. 8(1) 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. 15 para. 10(a)** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Word in reg. 8(2) 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. 15 para. 10(b)** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in reg. 8(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. 15 para. 10(c)** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Exception for trade fairs or exhibitions **N.I.**

8.—(1) A toy which does not bear the CE marking, or in relation to which any other requirement of these Regulations is not complied with, may be shown or used at a trade fair or exhibition.

(2) Such a toy must be accompanied by a sign which indicates clearly that—

- (a) the toy does not comply with the Directive; and
- (b) the toy will not be made available in the [<sup>F150</sup>relevant market] before being brought into conformity with the Directive.

- F150** Words in reg. 8(2)(b) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 2(2)**

### Parts 1 and 2 are safety regulations within the meaning of the 1987 Act

9. Parts 1 and 2 of these Regulations are for all purposes safety regulations within the meaning of the 1987 Act.

## PART 2

### Prohibitions and Obligations on Economic Operators

#### *Manufacturers and their authorised representatives*

#### Prohibitions on placing toys on the market **E+W+S**

**10.**—(1) A manufacturer must not place a toy on the market unless it will comply with the essential safety requirements during its foreseeable and normal period of use.

- (2) A manufacturer must not place a toy on the market without having complied with—
- (a) regulation 11 (design and manufacture of toys in accordance with essential safety requirements);
  - (b) regulation 12 (safety assessment);
  - (c) regulation 13 (applicable conformity assessment procedures);
  - (d) regulations 15 (<sup>F24</sup>... declaration of conformity and [<sup>F25</sup>UK] marking);
  - (e) regulation 17(1) to (3) (drawing up of technical documentation);
  - (f) regulation 19 (information identifying toy and manufacturer);
  - (g) regulation 20 (instructions for use, safety information and warnings); and
  - (h) regulation 21 (compliance procedures for series production).

#### Extent Information

- E6** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F24** Word in [reg. 10\(2\)\(d\)](#) omitted (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. 15 para. 11\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F25** Word in [reg. 10\(2\)\(d\)](#) substituted (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. 15 para. 11\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Prohibitions on placing toys on the market **N.I.**

**10.**—(1) A manufacturer must not place a toy on the market unless it will comply with the essential safety requirements during its foreseeable and normal period of use.

- (2) A manufacturer must not place a toy on the market without having complied with—
- (a) regulation 11 (design and manufacture of toys in accordance with essential safety requirements);
  - (b) regulation 12 (safety assessment);
  - (c) regulation 13 (applicable conformity assessment procedures);
  - (d) regulations 15 (EC declaration of conformity and CE marking);
  - (e) regulation 17(1) to (3) (drawing up of technical documentation);
  - (f) regulation 19 (information identifying toy and manufacturer);
  - (g) regulation 20 (instructions for use, safety information and warnings); and
  - (h) regulation 21 (compliance procedures for series production).

## Design and manufacture of toys in accordance with essential safety requirements

11. The manufacturer must ensure that the toy has been designed and manufactured to comply with the essential safety requirements during its foreseeable and normal period of use.

### Safety assessment

12. The manufacturer must carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

### Applicable conformity assessment procedures **E+W+S**

13.—(1) The manufacturer must follow the applicable conformity assessment procedure to demonstrate that the toy will comply with the essential safety requirements during the toy's foreseeable and normal period of use.

(2) If the manufacturer has applied [<sup>F26</sup>designated] standards covering all the essential safety requirements, the manufacturer must use the internal production control procedure set out in Module A.

(3) In each of the following cases, the toy must be submitted to [<sup>F27</sup>Type] examination in accordance with the following provisions of these Regulations, together with the conformity to type procedure set out in Module C—

- (a) where [<sup>F28</sup>designated] standards covering all the essential safety requirements for the toy do not exist;
- (b) where the [<sup>F28</sup>designated] standards referred to in sub-paragraph (a) exist but the manufacturer has not applied them or has applied them only in part;
- (c) where one or more of the [<sup>F28</sup>designated] standards referred to in sub-paragraph (a) has been published with a restriction;
- (d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitates third party verification.

#### Extent Information

- E7** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F26** Word in reg. 13(2) 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. 15 para. 12(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Word in reg. 13(3) 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. 15 para. 12(b)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Word in reg. 13(3)(a)-(c) 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. 15 para. 12(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Applicable conformity assessment procedures **N.I.**

13.—(1) The manufacturer must follow the applicable conformity assessment procedure to demonstrate that the toy will comply with the essential safety requirements during the toy's foreseeable and normal period of use.

(2) If the manufacturer has applied harmonised standards covering all the essential safety requirements, the manufacturer must use the internal production control procedure set out in Module A.

(3) In each of the following cases, the toy must be submitted to EC-type examination in accordance with the following provisions of these Regulations, together with the conformity to type procedure set out in Module C—

- (a) where harmonised standards covering all the essential safety requirements for the toy do not exist;
- (b) where the harmonised standards referred to in sub-paragraph (a) exist but the manufacturer has not applied them or has applied them only in part;
- (c) where one or more of the harmonised standards referred to in sub-paragraph (a) has been published with a restriction;
- (d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitates third party verification.

#### Application for [F29Type] examination **E+W+S**

14. An application for [F29Type] examination to be performed in relation to a toy must—
- (a) be made to [F30an approved] body;
  - (b) be made in accordance with Module B;
  - (c) include a description of the toy;
  - (d) indicate the address at which the toy has been or will be manufactured; and
  - (e) <sup>F31</sup>... be accompanied by such fee as may be required by the body in accordance with regulation 50 (charging of fees [<sup>F32</sup>by approved] body).

#### Extent Information

- E8** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F29** Word in [reg. 14](#) 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. 15 para. 13\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F30** Words in [reg. 14\(a\)](#) 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. 15 para. 13\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F31** Words in [reg. 14\(e\)](#) 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. 15 para. 13\(c\)\(i\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F32** Words in [reg. 14\(e\)](#) 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. 15 para. 13\(c\)\(ii\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Application for EC-type examination **N.I.**

14. An application for EC-type examination to be performed in relation to a toy must—
- (a) be made to a notified body;
  - (b) be made in accordance with Module B;

- (c) include a description of the toy;
- (d) indicate the address at which the toy has been or will be manufactured; and
- (e) if the application is made to a UK notified body, be accompanied by such fee as may be required by the body in accordance with regulation 50 (charging of fees by UK notified body).

### **[<sup>F33</sup>Declaration] of conformity and [<sup>F34</sup>UK] marking **E+W+S****

**15.** Where it has been demonstrated by performance of the applicable conformity assessment procedure that a toy will comply with the essential safety requirements during its foreseeable and normal period of use, the manufacturer must—

- (a) draw up [<sup>F35</sup>a] declaration of conformity in accordance with regulation 16(1) to (4); and
- (b) affix a [<sup>F36</sup>UK] marking in relation to the toy in accordance with regulation 18.

#### **Extent Information**

- E9** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F33** Word in [reg. 15 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. 15 para. 14\(a\)\(i\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F34** Word in [reg. 15 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. 15 para. 14\(a\)\(ii\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F35** Word in [reg. 15\(a\)](#) 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. 15 para. 14\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F36** Word in [reg. 15\(b\)](#) 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. 15 para. 14\(c\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### **EC declaration of conformity and CE marking **N.I.****

**15.** Where it has been demonstrated by performance of the applicable conformity assessment procedure that a toy will comply with the essential safety requirements during its foreseeable and normal period of use, the manufacturer must—

- (a) draw up an EC declaration of conformity in accordance with regulation 16(1) to (4); and
- (b) affix a CE marking in relation to the toy in accordance with regulation 18.

### **[<sup>F37</sup>UK(NI) indication**

**15A.—(1)** Where the CE marking is affixed on the basis of an assessment or a certificate issued by a UK notified body, a UK(NI) indication must be affixed in relation to the toy, in accordance with this regulation.

- (2) The UK(NI) indication must be affixed—
  - (a) visibly, legibly and indelibly; and
  - (b) before a toy is placed on the market in Northern Ireland.

(3) The UK(NI) indication must be affixed wherever the CE marking is affixed, in accordance with regulation 18.



- (4) The UK(NI) indication must be affixed by—
  - (a) the manufacturer; or
  - (b) the manufacturer's authorised representative who has been appointed by the manufacturer in accordance with regulation 25(1) to affix the UK(NI) indication on the manufacturer's behalf.
- (5) When placing a toy on the market in Northern Ireland, an importer must ensure that the manufacturer has complied with their obligations under this regulation.

**F37** Regs. 15A, 15B 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. 5(3)**

### Register of UK notified bodies

**15B.**—(1) The Secretary of State must ensure that—

- (a) each UK notified body is assigned an identification number; and
- (b) there is a register of—
  - (i) UK notified bodies;
  - (ii) their notified body identification number;
  - (iii) the activities for which they have been notified;
  - (iv) any restrictions on those activities.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).]

**F37** Regs. 15A, 15B 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. 5(3)**

### E+W+S

**16.**—(1) The <sup>F38</sup>... declaration of conformity must state that it has been demonstrated that the essential safety requirements have been satisfied in relation to the toy.

(2) The <sup>F38</sup>... declaration of conformity must also—

- (a) include the information, and follow the structure, set out in [<sup>F39</sup>Schedule 3]; and
- (b) include any information required to be included by any Module which was followed in relation to the toy.

(3) The <sup>F38</sup>... declaration of conformity may contain further information.

(4) The manufacturer must keep up to date the <sup>F38</sup>... declaration of conformity drawn up in relation to a toy.

<sup>F40</sup>(5) .....

(6) By drawing up the <sup>F38</sup>... declaration of conformity, the manufacturer assumes responsibility for the compliance of the toy.

**Extent Information**

- E10** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F38** Word in [reg. 16](#) 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. 15 para. 15(a)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)
- F39** Words in [reg. 16\(2\)\(a\)](#) 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. 15 para. 15(b)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)
- F40** [Reg. 16\(5\)](#) 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. 15 para. 15(c)** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

**N.I.**

**16.—(1)** The EC declaration of conformity must state that it has been demonstrated that the essential safety requirements have been satisfied in relation to the toy.

(2) The EC declaration of conformity must also—

- (a) include the information, and follow the structure, set out in Annex III to the Directive; and
- (b) include any information required to be included by any Module which was followed in relation to the toy.

(3) The EC declaration of conformity may contain further information.

(4) The manufacturer must keep up to date the EC declaration of conformity drawn up in relation to a toy.

(5) Where the EC declaration of conformity drawn up in relation to a toy which is made available on the market in the United Kingdom was drawn up in a language other than English, the manufacturer must translate the EC declaration of conformity into English.

(6) By drawing up the EC declaration of conformity, the manufacturer assumes responsibility for the compliance of the toy.

**Technical documentation and correspondence relating to <sup>F41</sup>Type examination E+W+S**

**17.—(1)** The manufacturer must draw up technical documentation which contains all relevant information about the means used by the manufacturer to ensure that a toy will comply with the essential safety requirements during its foreseeable and normal period of use.

<sup>F42</sup>(2) The technical documentation must be drawn up in English.]

(3) The technical documentation must include the information and documents listed in <sup>F43</sup>Schedule 4] (technical documentation).

<sup>F44</sup>(4) Any correspondence relating to the Type examination of a toy must be drawn up in English.]

(5) The manufacturer must keep the technical documentation for a toy (including the <sup>F45</sup>... declaration of conformity) for a period of 10 years after the day on which the toy was placed on the market.

<sup>F46</sup>(6) .....

<sup>F46</sup>(7) .....

- F<sup>46</sup>(8) .....
- F<sup>46</sup>(9) .....

(10) If a manufacturer fails to comply with any of the manufacturer's obligations under paragraphs (1), (2) [F<sup>47</sup> or (3)], an enforcement authority may request the manufacturer to ensure that [F<sup>48</sup> an approved] body performs such tests as [F<sup>49</sup> the approved] body identifies, within such period as [F<sup>49</sup> the approved] body may specify, to verify that the toy will comply with the essential safety requirements during its foreseeable and normal period of use, and that the toy complies with any [F<sup>50</sup> designated] standard applicable to the toy.

(11) The manufacturer must comply with the request (at the manufacturer's own expense).

**Extent Information**

- E11** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F41** Word in reg. 17 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. 15 para. 16(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F42** Reg. 17(2) 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. 15 para. 16(b)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F43** Words in reg. 17(3) 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. 15 para. 16(c)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F44** Reg. 17(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. 15 para. 16(d)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F45** Word in reg. 17(5) 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. 15 para. 16(e)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F46** Reg. 17(6)-(9) omitted (1.10.2015) by virtue of The Consumer Rights Act 2015 (Commencement No. 3, Transitional Provisions, Savings and Consequential Amendments) Order 2015 (S.I. 2015/1630), art. 1, **Sch. 2 para. 122(a)**
- F47** Words in reg. 17(10) substituted (1.10.2015) by The Consumer Rights Act 2015 (Commencement No. 3, Transitional Provisions, Savings and Consequential Amendments) Order 2015 (S.I. 2015/1630), art. 1, **Sch. 2 para. 122(b)**
- F48** Words in reg. 17(10) 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. 15 para. 16(f)(i)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F49** Words in reg. 17(10) 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. 15 para. 16(f)(ii)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F50** Word in reg. 17(10) 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. 15 para. 16(f)(iii)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**Technical documentation and correspondence relating to EC-type examination** N.I.

17.—(1) The manufacturer must draw up technical documentation which contains all relevant information about the means used by the manufacturer to ensure that a toy will comply with the essential safety requirements during its foreseeable and normal period of use.

- (2) The technical documentation must be drawn up—
  - (a) in so far as it relates to EC-type examination of the toy, in an official language of the [<sup>F151</sup>relevant] State in which the notified body which performed that examination is established or in a language acceptable to that body;
  - (b) in so far as it does not relate to such examination, in one of the official languages of the EU.
- (3) The technical documentation must include the information and documents listed in Annex IV of the Directive (technical documentation).
- (4) Any correspondence relating to the EC-type examination of a toy must be drawn up in the official language of the [<sup>F152</sup>relevant] State in which the notified body is established or in a language acceptable to that body.
- (5) The manufacturer must keep the technical documentation for a toy (including the EC declaration of conformity) for a period of 10 years after the day on which the toy was placed on the market.
- (6) .....
- (7) .....
- (8) .....
- (9) .....
- (10) If a manufacturer fails to comply with any of the manufacturer's obligations under paragraphs (1), (2) [<sup>F153</sup>or (3)], an enforcement authority may request the manufacturer to ensure that a notified body performs such tests as the notified body identifies, within such period as the notified body may specify, to verify that the toy will comply with the essential safety requirements during its foreseeable and normal period of use, and that the toy complies with any harmonised standard applicable to the toy.
- (11) The manufacturer must comply with the request (at the manufacturer's own expense).

**F151** Word in reg. 17(2) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 3(1)**

**F152** Word in reg. 17(4) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 3(1)**

**F153** Words in reg. 17(10) substituted (1.10.2015) by [The Consumer Rights Act 2015 \(Commencement No. 3, Transitional Provisions, Savings and Consequential Amendments\) Order 2015 \(S.I. 2015/1630\)](#), art. 1, **Sch. 2 para. 122(b)**

**Toys to bear [<sup>F51</sup>UK] marking E+W+S**

- 18.—(1) The manufacturer must affix a [<sup>F51</sup>UK] marking in relation to a toy.
- (2) The [<sup>F51</sup>UK] marking must be affixed visibly, legibly and indelibly.
- (3) The [<sup>F51</sup>UK] marking must be affixed to—
  - (a) the toy;
  - (b) a label affixed to the toy; or
  - (c) the toy's packaging.

[<sup>F52</sup>(3A) For a period of [<sup>F53</sup>seven years] beginning with IP completion day, the manufacturer may, in place of affixing the UK marking in accordance with paragraph (3) affix the UK marking to a document accompanying the toy.]

(4) Where the toy is small or consists of small parts, the manufacturer may, in place of affixing the [<sup>F51</sup>UK] marking in accordance with paragraph (3), affix the [<sup>F51</sup>UK] marking to—

- (a) a label which is not affixed to the toy; or
- (b) a leaflet which accompanies the toy.

(5) The manufacturer may (in place of affixing the [<sup>F51</sup>UK] marking in accordance with paragraphs (3) or (4)) affix the CE marking to a counter display where —

- (a) the toy is sold in the counter display;
- (b) it is not possible to affix the [<sup>F51</sup>UK] marking in accordance with paragraph (3) or (4); and
- (c) the counter display was originally used as packaging for the toy.

(6) Where the toy is inside packaging the [<sup>F51</sup>UK] marking must—

- (a) be affixed to the packaging (whether or not it is also affixed elsewhere); or
- (b) be otherwise visible from outside the packaging.

(7) The [<sup>F51</sup>UK] marking may be followed by a pictogram or by any other mark indicating a special risk or use.

(8) Any toy which bears the [<sup>F51</sup>UK] marking shall be presumed to comply with all the provisions of these Regulations.

(9) The presumption set out in paragraph (8) is rebuttable.

#### **Extent Information**

**E12** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F51** Word in [reg. 18](#) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 15 para. 17(a) (as substituted 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. 9\(3\)](#))

**F52** [Reg. 18\(3A\)](#) inserted (E.W.S.) (31.12.2020) by S.I. 2019/696, [Sch. 15 para. 17\(b\)](#) (as substituted 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. 9\(3\)](#))

**F53** Words in [reg. 18\(3A\)](#) 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. \(e\)](#)

#### **Toys to bear CE marking** **N.I.**

**18.**—(1) The manufacturer must affix a CE marking in relation to a toy.

(2) The CE marking must be affixed visibly, legibly and indelibly.

(3) The CE marking must be affixed to—

- (a) the toy;
- (b) a label affixed to the toy; or
- (c) the toy's packaging.

(4) Where the toy is small or consists of small parts, the manufacturer may, in place of affixing the CE marking in accordance with paragraph (3), affix the CE marking to—

- (a) a label which is not affixed to the toy; or
  - (b) a leaflet which accompanies the toy.
- (5) The manufacturer may (in place of affixing the CE marking in accordance with paragraphs (3) or (4)) affix the CE marking to a counter display where —
- (a) the toy is sold in the counter display;
  - (b) it is not possible to affix the CE marking in accordance with paragraph (3) or (4); and
  - (c) the counter display was originally used as packaging for the toy.
- (6) Where the toy is inside packaging the CE marking must—
- (a) be affixed to the packaging (whether or not it is also affixed elsewhere); or
  - (b) be otherwise visible from outside the packaging.
- (7) The CE marking may be followed by a pictogram or by any other mark indicating a special risk or use.
- (8) Any toy which bears the CE marking shall be presumed to comply with all the provisions of these Regulations.
- (9) The presumption set out in paragraph (8) is rebuttable.

#### **Information identifying toy and manufacturer**

- 19.**—(1) The manufacturer must ensure that the required information is marked—
- (a) on the toy; or
  - (b) where the size or nature of the toy precludes the information from being marked on the toy—
    - (i) on the toy's packaging; or
    - (ii) in a document accompanying the toy.
- (2) The required information is—
- (a) a type, batch, serial or model number or other information enabling the toy to be identified;
  - (b) the manufacturer's name, registered trade name or registered trademark; and
  - (c) a single address at which the manufacturer can be contacted.

#### **Instructions for use, safety information and warnings** E+W+S

- 20.**—(1) The manufacturer must ensure that a toy is accompanied by such instructions for use and safety information as is appropriate.
- (2) In particular, the manufacturer must ensure that the following provisions of this regulation are complied with.
- (3) Where it is appropriate in order to ensure the safe use of a toy, any information provided as to hazards and risks and avoiding them required by regulation 5(5) must include the specification of appropriate user limitations in accordance with Part A of [<sup>F54</sup>Schedule 5] (general warnings).
- (4) Where a toy falls within a category listed in Part B of [<sup>F54</sup>Schedule 5], the toy must be accompanied by any warning and other information which is required to accompany that category of toy.
- (5) But a toy must not be accompanied by a warning set out in Part B where that warning would conflict with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

(6) The wording of a warning which is required by any of points 2 to 10 of Part B to accompany a category of toy must be replicated without alteration.

(7) A warning, instructions or other information required to accompany a toy must be marked in English in a clearly visible, easily legible, understandable and accurate manner on—

- (a) the toy;
- (b) a label affixed to the toy; or
- (c) the toy's packaging and, if appropriate, on any instructions for use which accompany the toy.

(8) Any warning or warnings accompanying a toy in accordance with this regulation must be preceded by the word “Warning” or “Warnings”.

(9) A warning which determines the decision to purchase a toy (such as a warning specifying the minimum or maximum age for users) must also be clearly visible to the consumer before the purchase (whether by appearing on the consumer packaging for the toy or elsewhere), including in cases where the purchase is made on-line.

<sup>F55</sup>(10) .....

**Extent Information**

- E13** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F54** Words in [reg. 20](#) 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. 15 para. 18\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F55** [Reg. 20\(10\)](#) 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. 15 para. 18\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Instructions for use, safety information and warnings** **N.I.**

**20.—(1)** The manufacturer must ensure that a toy is accompanied by such instructions for use and safety information as is appropriate.

(2) In particular, the manufacturer must ensure that the following provisions of this regulation are complied with.

(3) Where it is appropriate in order to ensure the safe use of a toy, any information provided as to hazards and risks and avoiding them required by regulation 5(5) must include the specification of appropriate user limitations in accordance with Part A of Annex V to the Directive (general warnings).

(4) Where a toy falls within a category listed in Part B of Annex V to the Directive, the toy must be accompanied by any warning and other information which is required to accompany that category of toy.

(5) But a toy must not be accompanied by a warning set out in Part B where that warning would conflict with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

(6) The wording of a warning which is required by any of points 2 to 10 of Part B to accompany a category of toy must be replicated without alteration.

(7) A warning, instructions or other information required to accompany a toy must be marked in English in a clearly visible, easily legible, understandable and accurate manner on—

- (a) the toy;
- (b) a label affixed to the toy; or
- (c) the toy's packaging and, if appropriate, on any instructions for use which accompany the toy.

(8) Any warning or warnings accompanying a toy in accordance with this regulation must be preceded by the word “Warning” or “Warnings”.

(9) A warning which determines the decision to purchase a toy (such as a warning specifying the minimum or maximum age for users) must also be clearly visible to the consumer before the purchase (whether by appearing on the consumer packaging for the toy or elsewhere), including in cases where the purchase is made on-line.

(10) In this regulation a reference to Part A or Part B of Annex V to the Directive, or to any provision of either of those Parts, is a reference to that Part or to that provision as amended from time to time.

#### Compliance procedures for series production **E+W+S**

**21.—(1)** A manufacturer of toys which are manufactured by means of series production must ensure that procedures are in place to ensure that any toy so manufactured will comply with the essential safety requirements during its foreseeable and normal period of use.

- (2) In doing so, the manufacturer must take into account—
  - (a) any change in the design or characteristics of the toy; and
  - (b) any change which has been made to any of the [<sup>F56</sup>designated] standards referred to in the <sup>F57</sup>... declaration of conformity drawn up in relation to the toy.

#### Extent Information

- E14** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F56** Word in [reg. 21\(2\)\(b\)](#) 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. 15 para. 19\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))
- F57** Word in [reg. 21\(2\)\(b\)](#) 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. 15 para. 19\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

#### Compliance procedures for series production **N.I.**

**21.—(1)** A manufacturer of toys which are manufactured by means of series production must ensure that procedures are in place to ensure that any toy so manufactured will comply with the essential safety requirements during its foreseeable and normal period of use.

- (2) In doing so, the manufacturer must take into account—
  - (a) any change in the design or characteristics of the toy; and
  - (b) any change which has been made to any of the harmonised standards referred to in the EC declaration of conformity drawn up in relation to the toy.



### Submission of [<sup>F58</sup>Type] examination certificate for review **E+W+S**

22. [<sup>F59</sup>A Type] examination certificate issued in relation to a toy must be submitted by the manufacturer to [<sup>F60</sup>an approved] body for review if—

- (a) any change is made to—
  - (i) the manufacturing process for the toy;
  - (ii) any raw material used in the toy; or
  - (iii) any component of the toy;
- (b) 5 years have elapsed since the certificate was issued without it having being reviewed by [<sup>F60</sup>an approved] body;
- (c) 5 years have elapsed since the certificate was last reviewed by [<sup>F60</sup>an approved] body without it having being reviewed again by [<sup>F60</sup>an approved] body; or
- (d) the manufacturer is of the view that a review of the certificate is necessary for any other reason.

#### Extent Information

- E15** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F58** Word in [reg. 22 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. 15 para. 20\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F59** Words in [reg. 22](#) 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. 15 para. 20\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F60** Words in [reg. 22](#) 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. 15 para. 20\(c\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Submission of EC-type examination certificate for review **N.I.**

22. An EC-type examination certificate issued in relation to a toy must be submitted by the manufacturer to a notified body for review if—

- (a) any change is made to—
  - (i) the manufacturing process for the toy;
  - (ii) any raw material used in the toy; or
  - (iii) any component of the toy;
- (b) 5 years have elapsed since the certificate was issued without it having being reviewed by a notified body;
- (c) 5 years have elapsed since the certificate was last reviewed by a notified body without it having being reviewed again by a notified body; or
- (d) the manufacturer is of the view that a review of the certificate is necessary for any other reason.

### Monitoring of toys

**23.**—(1) The manufacturer must take such of the following actions in relation to a toy as the manufacturer considers appropriate for the purpose of protecting the health and safety of consumers, taking into account any risk presented by the toy.

(2) The actions are—

- (a) carrying out sample testing of marketed toys;
- (b) investigating any complaint made in relation to the toy;
- (c) keeping a register of—
  - (i) any such complaints;
  - (ii) any toy in relation to which any provision of these Regulations has not been complied with; and
  - (iii) any toy which has been recalled; and
- (d) keeping distributors informed of any action taken by the manufacturer in accordance with sub-paragraph (a), (b) or (c).

### Non-compliant toys and toys presenting a risk

**24.**—(1) Where a manufacturer has placed a toy on the market and has reason to believe that any provision of these Regulations has not in fact been complied with by the manufacturer in relation to the toy, the manufacturer must immediately—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the toy, or withdraw or recall the toy, if appropriate; and
- (b) where the toy presents a risk, provide the relevant enforcement authority with information about the following matters.

(2) The matters are—

- (a) the risk presented by the toy;
- (b) the non-compliance in question; and
- (c) any corrective measures taken in accordance with paragraph (1)(a).

(3) An enforcement authority may request a manufacturer who has placed a toy on the market to cooperate with it in relation to any action taken or to be taken to eliminate any risk posed by the toy.

- (4) The request must be accompanied by the reasons for making the request
- (5) The manufacturer must comply with the request.

### Manufacturer's authorised representative **E+W+S**

**25.**—(1) A manufacturer may, by a written mandate, appoint a person established [<sup>F61</sup>in the United Kingdom] as the manufacturer's authorised representative to act on the manufacturer's behalf in relation to specified tasks in relation to a toy.

(2) The mandate must allow the authorised representative to do at least the following—

- (a) perform the manufacturer's obligations under regulations 17(5) and (9) (duties to keep technical documentation and comply with a request by an enforcement authority for a copy <sup>F62</sup>... of technical documentation); and
- (b) perform the manufacturer's obligations under regulation 24(5) (duty to comply with a request in relation to action taken to eliminate risks posed by a toy).

(3) An authorised representative may not be appointed to perform the manufacturer's obligations under regulation 11 (duty to design and manufacture toy in accordance with essential safety requirements) or regulation 17(1) (duty to draw up technical documentation).

(4) An authorised representative must perform each obligation under these Regulations that the representative is appointed by the mandate to perform.

(5) A manufacturer who has appointed an authorised representative to perform on the manufacturer's behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

#### Extent Information

- E16** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F61** Words in [reg. 25\(1\)](#) 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. 15 para. 21\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F62** Words in [reg. 25\(2\)\(a\)](#) 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. 15 para. 21\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Manufacturer's authorised representative **N.I.**

**25.**—(1) A manufacturer may, by a written mandate, appoint a person established within the [<sup>F154</sup>relevant market] as the manufacturer's authorised representative to act on the manufacturer's behalf in relation to specified tasks in relation to a toy.

- (2) The mandate must allow the authorised representative to do at least the following—
- (a) perform the manufacturer's obligations under regulations 17(5) and (9) (duties to keep technical documentation and comply with a request by an enforcement authority for a copy or translation of technical documentation); and
  - (b) perform the manufacturer's obligations under regulation 24(5) (duty to comply with a request in relation to action taken to eliminate risks posed by a toy).

(3) An authorised representative may not be appointed to perform the manufacturer's obligations under regulation 11 (duty to design and manufacture toy in accordance with essential safety requirements) or regulation 17(1) (duty to draw up technical documentation).

(4) An authorised representative must perform each obligation under these Regulations that the representative is appointed by the mandate to perform.

(5) A manufacturer who has appointed an authorised representative to perform on the manufacturer's behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

- F154** Words in [reg. 25](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 5 para. 3\(2\)](#)

### *Importers*

#### **Prohibitions on placing toys on the market** **E+W+S**

**26.**—(1) An importer must not place a toy on the market unless it will comply with the essential safety requirements during its foreseeable and normal period of use.

- (2) An importer must not place a toy on the market unless—
- (a) the importer has ensured that the manufacturer has done all of the following in relation to the toy—
- (i) followed the applicable conformity assessment procedure in accordance with regulation 13;
  - (ii) drawn up the technical documentation in accordance with regulation 17;
  - (iii) affixed the [<sup>F63</sup>UK] marking in accordance with regulation 18;
  - (iv) complied with regulation 19 (information identifying toy and manufacturer);
  - (v) complied with regulation 20 (instructions for use, safety information and warnings);
- and
- (b) the importer has complied with both of the following—
- (i) regulation 27 (information identifying importer);
  - (ii) regulation 28 (storage or transport of toys).

#### **Extent Information**

**E17** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F63** Word in [reg. 26\(2\)\(a\)\(iii\)](#) 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. 15 para. 22](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

#### **Prohibitions on placing toys on the market** **N.I.**

**26.**—(1) An importer must not place a toy on the market unless it will comply with the essential safety requirements during its foreseeable and normal period of use.

- (2) An importer must not place a toy on the market unless—
- (a) the importer has ensured that the manufacturer has done all of the following in relation to the toy—
- (i) followed the applicable conformity assessment procedure in accordance with regulation 13;
  - (ii) drawn up the technical documentation in accordance with regulation 17;
  - (iii) affixed the CE marking in accordance with regulation 18;
  - (iv) complied with regulation 19 (information identifying toy and manufacturer);
  - (v) complied with regulation 20 (instructions for use, safety information and warnings);
- and
- (b) the importer has complied with both of the following—
- (i) regulation 27 (information identifying importer);
  - (ii) regulation 28 (storage or transport of toys).

### Information identifying importer **E+W+S**

- 27.—(1) An importer must ensure that the following information is marked on the toy—
- (a) the importer's name, registered trade name or registered trade mark; and
  - (b) the address at which the importer can be contacted.
- [<sup>F64</sup>(2) Paragraph (1) does not apply where—
- (a) either—
    - (i) the size or nature of the toy precludes the information from being marked on the toy;
    - (ii) the importer would have to open the toy's packaging in order to mark the information on the toy; or
    - (iii) the importer imported the toy from an EEA state or Switzerland and places it on the market within the period of [<sup>F65</sup>seven years] beginning with IP completion day; and
  - (b) the importer ensures that the information referred to in paragraph (1) is set out on the toy's packaging or in a document accompanying the toy.]

#### Extent Information

**E18** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F64** Reg. 27(2) 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. 15 para. 23** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), **2**; and S.I. 2019/1246, regs. 1(3), **5**, **6(1)**; and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 2(1)(c)**; and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(e)(v)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F65** Words in reg. 27(2)(a)(iii) 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), 4, **Sch. 3 (c)**

#### Modifications etc. (not altering text)

**C2** Reg. 27 modified (temp.) (10.9.2019) by S.I. 2019/392, **reg. 6** (as inserted by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(2)(4), **2(3)** (with reg. 18))

### Information identifying importer **N.I.**

- 27.—(1) An importer must ensure that the following information is marked on the toy—
- (a) the importer's name, registered trade name or registered trade mark; and
  - (b) the address at which the importer can be contacted.
- (2) The information may instead be marked on the toy's packaging or on a document accompanying the toy where—
- (a) the size or nature of the toy precludes the information from being marked on the toy; or
  - (b) the importer would have to open the toy's packaging in order to mark the information on the toy.

### Storage or transport of toys

28. An importer must ensure that, while a toy is under the importer's responsibility, the conditions in which it is stored or transported will not jeopardise the toy's compliance with the essential safety requirements during its foreseeable and normal period of use.

### **Monitoring of toys**

**29.**—(1) An importer must take such of the following actions in relation to a toy as the importer considers appropriate for the purpose of protecting the health and safety of consumers, taking into account any risk presented by the toy.

(2) The actions are—

- (a) carrying out sample testing of marketed toys;
- (b) investigating any complaint made in relation to the toy;
- (c) keeping a register of—
  - (i) any such complaints;
  - (ii) any toy in relation to which any provision of these Regulations has not been complied with; and
  - (iii) any toy which has been recalled; and
- (d) keeping distributors informed of any action taken by the importer in accordance with subparagraph (a), (b) or (c).

### **Non-compliant toys and toys presenting a risk**

**30.**—(1) Paragraph (2) applies if an importer has reason to believe that a toy which the importer was intending to place on the market—

- (a) will not comply with the essential safety requirements during its foreseeable and normal period of use; and
- (b) presents a risk.

(2) The importer must inform the manufacturer and the relevant enforcement authority of the risk presented by the toy.

(3) An importer who has placed a toy on the market and has reason to believe that any provision of these Regulations has not been complied with in relation to the toy must immediately—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the toy, or withdraw or recall the toy, if appropriate; and
- (b) where the toy presents a risk, provide the relevant enforcement authority with information about the following matters.

(4) The matters are—

- (a) the risk presented by the toy;
- (b) the non-compliance in question; and
- (c) any corrective measures taken in accordance with paragraph (1)(a).

(5) An enforcement authority may request an importer who has placed a toy on the market to cooperate with it in relation to any action taken or to be taken to eliminate any risk posed by the toy.

(6) The importer must comply with the request.

### **Duties to retain and provide information**

**31.**—(1) An importer must, for a period of 10 years after the day on which the toy is placed on the market—

- (a) keep a copy of the [F<sup>66</sup>EC] declaration of conformity; and
- (b) ensure that the technical documentation can be made available to an enforcement authority on request by the authority.

- F67(2) .....
- F67(3) .....
- F67(4) .....

<p><b>F66</b> Word in <a href="#">reg. 31</a> omitted (E.W.S.) (31.12.2020) by virtue of <a href="#">The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019</a> (S.I. 2019/696), <a href="#">reg. 1</a>, <b>Sch. 15 para. 24</b> (with <a href="#">Sch. 15 para. 3</a>) (as amended by <a href="#">S.I. 2020/676</a>, <a href="#">regs. 1(1), 2</a>); 2020 c. 1, <a href="#">Sch. 5 para. 1(1)</a></p> <p><b>F67</b> <a href="#">Reg. 31(2)-(4)</a> omitted (1.10.2015) by virtue of <a href="#">The Consumer Rights Act 2015 (Commencement No. 3, Transitional Provisions, Savings and Consequential Amendments) Order 2015</a> (S.I. 2015/1630), <a href="#">art. 1</a>, <b>Sch. 2 para. 123</b> (with <a href="#">art. 8</a>)</p>
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**Duty in certain circumstances to comply with manufacturers' duties in place of importers' duties**

- 32.**—(1) This regulation applies where an importer—
- (a) places a toy on the market under the importer's name or trademark; or
  - (b) modifies a toy already placed on the market in such a way that compliance with the essential safety requirements may be affected.
- (2) The importer must comply with all of the duties imposed by these Regulations on a manufacturer and in such a case, a reference to the manufacturer in these Regulations is to be taken as being a reference to the importer.
- (3) Such an importer is not required to comply with the duties imposed by these Regulations on importers.

*Distributors*

**Duty to act with due care and prohibitions on making toys available on the market** **E+W**  
**+S**

- 33.**—(1) A distributor must act with due care in relation to the compliance of a toy which the distributor intends to make available on the market with the provisions of these Regulations.
- (2) A distributor must not make a toy available on the market if the distributor has reason to believe that the toy will not comply with the essential safety requirements during its foreseeable and normal period of use.
- (3) A distributor must not make a toy available on the market unless the distributor has—
- (a) verified that the manufacturer has done all of the following things in relation to the toy—
    - (i) affixed the [<sup>F68</sup>UK] marking in accordance with regulation 18;
    - (ii) complied with regulation 19 (information identifying toy and manufacturer); and
    - (iii) complied with regulation 20 (instructions for use, safety information and warnings);
  - (b) verified that any importer has complied with regulation 27 (information identifying importer) in relation to the toy; and
  - (c) complied with regulation 34 (storage or transport of toys) in relation to the toy.

#### Extent Information

- E19** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F68** Word in [reg. 33\(3\)\(a\)\(i\)](#) 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. 15 para. 25](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

#### Duty to act with due care and prohibitions on making toys available on the market **N.I.**

**33.**—(1) A distributor must act with due care in relation to the compliance of a toy which the distributor intends to make available on the market with the provisions of these Regulations.

(2) A distributor must not make a toy available on the market if the distributor has reason to believe that the toy will not comply with the essential safety requirements during its foreseeable and normal period of use.

- (3) A distributor must not make a toy available on the market unless the distributor has—
- (a) verified that the manufacturer has done all of the following things in relation to the toy—
    - (i) affixed the CE marking in accordance with regulation 18;
    - (ii) complied with regulation 19 (information identifying toy and manufacturer); and
    - (iii) complied with regulation 20 (instructions for use, safety information and warnings);
  - (b) verified that any importer has complied with regulation 27 (information identifying importer) in relation to the toy; and
  - (c) complied with regulation 34 (storage or transport of toys) in relation to the toy.

#### Storage or transport of toys under distributor's responsibility

**34.** A distributor must ensure that, while a toy is under the distributor's responsibility, the conditions in which it is stored or transported will not jeopardise the toy's compliance with the essential safety requirements during its foreseeable and normal period of use.

#### Non-compliant toys and toys presenting a risk

**35.**—(1) Paragraph (2) applies if a distributor has reason to believe that a toy which the distributor was intending to make available on the market—

- (a) will not comply with the essential safety requirements during its foreseeable and normal period of use; and
  - (b) presents a risk.
- (2) The distributor must inform the following of the risk presented by the toy—
- (a) the importer (if there is one);
  - (b) the manufacturer (if there is no importer); and
  - (c) the relevant enforcement authority.
- (3) A distributor who has made a toy available on the market and has reason to believe that any provision of these Regulations has not been complied with in relation to the toy must immediately—
- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the toy, or withdraw or recall the toy, if appropriate; and



- (b) where the toy presents a risk, provide the relevant enforcement authority with information about the following matters.
- (4) The matters are—
  - (a) the risk presented by the toy;
  - (b) the non-compliance in question; and
  - (c) any corrective measures taken in relation to the toy in accordance with paragraph (3)(a).
- (5) An enforcement authority may request a distributor who has made a toy available on the market to cooperate with it in relation to any action taken or to be taken to eliminate any risk posed by the toy.
- (6) The request must be accompanied by the reasons for making the request.
- (7) The distributor must comply with the request.

### **Duty to provide information**

<sup>F69</sup>**36.** . . . . .

**F69** Reg. 36 revoked (1.10.2015) by [The Consumer Rights Act 2015 \(Commencement No. 3, Transitional Provisions, Savings and Consequential Amendments\) Order 2015 \(S.I. 2015/1630\)](#), art. 1, [Sch. 2 para. 124](#) (with art. 8)

### **Duty in certain circumstances to comply with manufacturers' duties in place of distributors' duties**

- 37.**—(1) This regulation applies where a distributor—
- (a) places a toy on the market under the distributor's name or trademark; or
  - (b) modifies a toy already placed on the market in such a way that compliance with the essential safety requirements may be affected.
- (2) The distributor must comply with all of the duties imposed by these Regulations on a manufacturer, and in such a case, a reference to the manufacturer in these Regulations is to be taken as being a reference to the distributor.
- (3) Such a distributor is not required to comply with the duties imposed by these Regulations on distributors.

*All economic operators*

### **Identification of economic operators to enforcement authorities**

- 38.**—(1) An enforcement authority may, before the end of the period specified in paragraph (3), request an economic operator to identify to the authority, within such period as the authority may specify—
- (a) any other economic operator who has supplied it with a toy; and
  - (b) any other economic operator to whom it has supplied a toy.
- (2) The economic operator must comply with the request.
- (3) The period is—
- (a) where the request is made to a manufacturer, 10 years after the day on which the toy was placed on the market;

- (b) where the request is made to any other economic operator, 10 years after the day on which the economic operator was supplied with the toy.

### Protection of [F70UK] marking **E+W+S**

**39.**—(1) A person must not affix a [F70UK] marking in relation to a toy unless—

- (a) the person is—
- (i) the manufacturer; or
  - (ii) an authorised representative of the manufacturer who has been appointed by the manufacturer <sup>F71</sup>... to affix the [F70UK] marking on the manufacturer's behalf; and
- (b) it has been demonstrated by performance of the applicable conformity assessment procedure that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) A person must not affix any marking in relation to a toy which—

- (a) is not a [F70UK] marking; but
- (b) purports to attest that the toy satisfies the essential safety requirements.

(3) A person must not affix in relation to a toy any marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the [F70UK] marking affixed in relation to the toy.

(4) Any other marking may be affixed in relation to a toy provided that the visibility, legibility and meaning of the [F70UK] marking is not thereby impaired.

#### Extent Information

**E20** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F70** Word in [reg. 39](#) 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. 15 para. 26\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

**F71** Words in [reg. 39\(1\)\(a\)\(ii\)](#) 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. 15 para. 26\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

### Protection of CE marking **N.I.**

**39.**—(1) A person must not affix a CE marking in relation to a toy unless—

- (a) the person is—
- (i) the manufacturer; or
  - (ii) an authorised representative of the manufacturer who has been appointed by the manufacturer in accordance with regulation 25(1) to affix the CE marking on the manufacturer's behalf; and
- (b) it has been demonstrated by performance of the applicable conformity assessment procedure that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) A person must not affix any marking in relation to a toy which—

- (a) is not a CE marking; but

(b) purports to attest that the toy satisfies the essential safety requirements.

[<sup>F155</sup>(2A) Paragraph (2) does not apply to the UK(NI) indication.]

(3) A person must not affix in relation to a toy any marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking affixed in relation to the toy.

(4) Any other marking may be affixed in relation to a toy provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

**F155** Reg. 39(2A) 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. 5(4)**

### [<sup>F72</sup>Obligations which are met by complying with obligations in the Directive

**39A.**—(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” has the meaning given to it in Article 3(16);
- (c) “harmonised standard” has the meaning given to it in Article 3(8);

(2) Subject to paragraphs (6) and (7) paragraph (3) applies where, before placing a toy on the UK market, a manufacturer—

- (a) ensures that the toy has been designed and manufactured in accordance with the requirements set out in—
  - (i) in Article 10 (essential safety requirements); and
  - (ii) Annex II (particular safety requirements);
- (b) carries out the safety assessment in accordance with Article 18;
- (c) ensures that the relevant conformity assessment procedure has been carried out in accordance with Article 19;
- (d) in cases where the manufacturer considers that Article 19(3) applies, ensures that the provisions of Article 20 are complied with;
- (e) draws up the technical documentation in accordance with Article 21(1);
- (f) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;
- (g) affixes the CE marking in accordance with Articles 16 and 17;
- (h) draws up an EC declaration of conformity, in accordance with Article 15; and
- (i) ensures that the EC declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

- (a) the requirements of regulations 10 to 15, 16(1) to (2), 17(1) to (4) and 18, are to be treated as being satisfied;
- (b) regulations 16(4) to (5), 17(5) and (10), 21, 22, 39 and 44 are to be read subject to the modifications in paragraph (10);
- (c) regulations 42 to 44 do not apply; and
- (d) regulation 52 does not apply.

(4) Subject to paragraphs (6) and (7), paragraph (5) applies, where before placing a toy on the market, the importer ensures that—

- (a) the relevant conformity assessment procedure that applies to that toy has been carried out in accordance with Article 19;
  - (b) the manufacturer has drawn up the technical documentation in accordance with Article 21(1); and
  - (c) the toy bears the CE marking affixed in accordance with Articles 16 and 17.
- (5) Where this paragraph applies—
- (a) the requirements in regulation 26(a)(i) to (iii) are to be treated as being satisfied; and
  - (b) regulations 26(1), 28 and 30 to 32 are to be read 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.
- (7) Where paragraph (6) applies paragraphs (2)(c) and (4)(a) are to be treated as requiring the manufacturer to carry out the conformity assessment procedure referred to in Article 19(3).
- (8) Paragraph (9) applies where before making a toy available on the market, a distributor ensures that the manufacturer has affixed the CE marking in accordance with Articles 16 and 17.
- (9) Where this paragraph applies—
- (a) regulation 33(3)(a)(i) is to be treated as being satisfied;
  - (b) regulation 33(2), 34, 35 and 37 are to be read 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 EC 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 requirements set out in—
    - (i) in Article 10 (essential safety requirements); and
    - (ii) Annex II (particular safety requirements);
  - (d) any reference to “designated standard” is to be read as a reference to a harmonised standard;
  - (e) any reference to “applicable conformity assessment procedure” is to be read as a reference to the applicable conformity assessment procedures referred to in Article 19;
  - (f) any reference to “technical documentation” is a reference to the technical documentation referred to in Article 21(1);
  - (g) any reference to “authorised representative” is a reference to a person appointed in accordance with Article 5; and
  - (h) any reference to “Type examination” is a reference to “EC-type examination”.

**F72** Regs. 39A-39AB and Pt. 2A (regs. 39B-39E) 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. 15 para. 27** (with **Sch. 15 para. 3**) (as amended by [S.I. 2020/676](#), regs. 1(1), 2; and [S.I. 2020/852](#), regs. 2(2), 4(2), **Sch. 1 para. 1(e)(vi)**); and [S.I. 2020/1460](#), reg. 1(4), **Sch. 3 para. 9(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

## Expiry of regulation 39A

**39AA.**—(1) Subject to paragraph (2), regulation 39A ceases to have effect at the end of the period of [<sup>F73</sup>four years] beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 39A—

- (a) any toy which was placed on the market pursuant to regulation 39A may continue to be made available on the market on or after the expiry of regulation 39A;
- (b) any obligation to which a person was subject under regulation 39A in respect of a toy placed on the market pursuant to regulation 39A continues to have effect after the expiry of regulation 39A, in respect of that toy.

**F72** Regs. 39A-39AB and Pt. 2A (regs. 39B-39E) 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. 15 para. 27** (with **Sch. 15 para. 3**) (as amended by S.I. 2020/676, regs. 1(1), 2; and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(e)(vi)**; and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 9(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F73** Words in [reg. 39AA\(1\)](#) 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. (f)**

## Qualifying Northern Ireland Goods

**39AB.**—(1) Where paragraph (2) applies—

- (a) a toy is to be treated as being in conformity with the essential safety requirements; and
- (b) each relevant economic operator is to be treated as having complied or as complying with the obligations imposed on them under Part 2.

(2) This paragraph applies where—

- (a) a toy is—
  - (i) in conformity with the essential safety requirements, within the meaning of regulation 3 as it applies in Northern Ireland; and
  - (ii) qualifying Northern Ireland goods;
- (b) each relevant economic operator has complied or is complying with the obligations imposed on them under Part 2, as that Part applies in Northern Ireland; and
- (c) an importer has complied with the obligations set out in paragraph (3).

(3) The obligations referred to in paragraph (2)(c) are that, before placing the toy on the market, the importer—

- (a) complies with regulation 27;
- (b) ensures that—
  - (i) the applicable conformity assessment procedure has been carried out;
  - (ii) the manufacturer has drawn up the technical documentation; and
  - (iii) the toy bears the CE marking.

(4) In this regulation—

“applicable conformity assessment procedure” means the conformity assessment procedure applicable to the toy under regulation 15, as it applies in Northern Ireland;

“CE marking” has the meaning given to it in regulation 3, 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 technical documentation that a manufacturer has to draw up in accordance with regulation 17, as it applies in Northern Ireland.

**F72** Regs. 39A-39AB and Pt. 2A (regs. 39B-39E) 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. 15 para. 27](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2; and [S.I. 2020/852](#), regs. 2(2), 4(2), [Sch. 1 para. 1\(e\)\(vi\)](#); and [S.I. 2020/1460](#), reg. 1(4), [Sch. 3 para. 9\(4\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

## PART 2A

### Powers and duties of the Secretary of State in relation to toys

#### Power to amend Schedules 1, 2 and 5

**39B.**—(1) The Secretary of State may by regulations amend the provision of the Schedules referred to in paragraph (2) where the Secretary of State considers it necessary to do so in order to take technical progress and scientific developments into account.

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

- (a) any provision in Schedule 1;
- (b) points 11 and 13 of Part 3 of Schedule 2; and
- (c) any provision of Schedule 5.

(3) The power to make regulations made under paragraph (1) includes power—

- (a) to make different provisions for different cases; and
- (b) to make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(4) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

#### Power to amend Appendix C to Schedule 2

**39C.**—(1) The Secretary of State may by regulations amend Appendix C to Schedule 2 to add specific values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.

(2) Regulations made under paragraph (1) may—

- (a) make different provisions for different cases; and
- (b) make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(3) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

#### Powers to amend Appendix A to Schedule 2

**39D.**—(1) Where the conditions set out in paragraph (3)(a) and (b) are met, the Secretary of State may by regulations amend Appendix A to Schedule 2 to allow substances or mixtures classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 4 of

Appendix B of Schedule 2 to be used in toys, in components of toys or micro-structurally distinct parts of toys.

(2) Where the conditions set out in paragraphs (3)(a), (b) and (c) are met, the Secretary of State may by regulations amend Appendix A to Schedule 2 to allow substances or mixtures classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down Section 3 of Appendix B of Schedule 2 to be used in toys, in components of toys or micro-structurally distinct parts of toys.

(3) The conditions referred to in paragraphs (1) and (2) are—

- (a) the Secretary of State considers that there is sufficient scientific evidence to demonstrate that the use of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 5 of Appendix B to Schedule 2 are safe for use in toys, particularly in view of exposure;
- (b) the substance or mixture is not prohibited for use in consumer articles by Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC.
- (c) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and

(4) Regulations made under paragraph (1) or (2) may—

- (a) make different provisions for different cases; and
- (b) make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(5) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

(6) The Secretary of State must—

- (a) carry out a review of regulations made under paragraph (1) or (2);
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(7) A review to which paragraph (6) refers must be made—

- (a) as soon as any safety concerns arise; and
- (b) at intervals not exceeding five years beginning with the date regulations made under paragraph (1) or (2) come into force.

### **Duty of the Secretary of State to evaluate use of hazardous substances**

**39E.**—(1) The Secretary of State must—

- (a) evaluate the occurrence of hazardous substances of materials in toys;
- (b) set out the conclusions of the evaluation in a report; and
- (c) publish the report.

(2) During the evaluation the Secretary of State must consult—

- (a) any enforcement authority which is not the Secretary of State; and
- (b) any person that the Secretary of State considers appropriate.

(3) The first report must be published before the end of the period of five years beginning on IP completion day.

(4) Subsequent reports are to be published at intervals not exceeding five years.]

### PART 3

[<sup>F74</sup>Designation of Notified Bodies][<sup>F74</sup>Approval of Conformity Assessment Bodies]

#### Extent Information

**E21** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F74** Pt. 3 (regs. 40A-41) substituted for Pt. 3 (regs. 40, 41) (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. 15 para. 28** (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), regs. 1(1), 2; by [S.I. 2020/1460](#), reg. 1(4), **Sch. 3 para. 9(5)**) and by [S.I. 2020/852](#), regs. 2(2), 4(2), **Sch. 1 para. 1(e)(vii)**; 2020 c. 1, **Sch. 5 para. 1(1)**

#### [<sup>F74</sup>Designation of UK notified bodies

**40.**—(1) The Secretary of State may designate a person to carry out conformity assessment (a “notified body designation”).

(2) A person in respect of whom a notified body designation has been made is a UK notified body to the extent that the designation remains in effect provided that—

- (a) the designation has been notified by the Secretary of State to the European Commission and the other [<sup>F75</sup>relevant states],
- (b) no objections [<sup>F76</sup>, other than an immaterial objection,] have [<sup>F77</sup>been] raised by the Commission or the other [<sup>F75</sup>relevant states] within the time periods in Article 31 of the [<sup>F78</sup>Directive;]

[<sup>F79</sup>(c) in sub-paragraph (b), an “immaterial objection” is an objection on the grounds that—

- (i) the person designated is established in the United Kingdom; or
- (ii) an accreditation certificate attesting that the person meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive was issued by the United Kingdom Accreditation Service, in respect of that person.]

(3) A person wishing to be a UK notified body must apply to the Secretary of State for designation.

(4) A notified body designation must not be made unless the Secretary of State is satisfied that the person meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive (the “notified body criteria”).

(5) A person who meets the relevant assessment criteria laid down in a harmonised standard shall be presumed to meet that part of the notified body criteria which corresponds to the criteria in that standard.

(6) The presumption of compliance in paragraph (5) is rebuttable.

(7) A notified body designation—

- (a) must be in writing;



- (b) must specify the conformity assessment procedures that the person designated may carry out;
  - (c) may designate a person for a specified period; and
  - (d) may be made subject to such other conditions as are specified in the designation, including conditions which are to apply upon or following termination of the designation.
- (8) In making a notified body designation the Secretary of State may have regard (in addition to the notified body criteria) to any other matter which appears to the Secretary of State to be relevant.
- (9) A UK notified body must comply with any request of the Secretary of State to provide information relevant to determining its compliance with the notified body criteria, these Regulations, or any condition to which its designation is subject. ]

- F75** Words in reg. 40(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 4(a)**
- F76** Words in reg. 40(2)(b) inserted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 4(b)(i)**
- F77** Word in reg. 40(2)(b) inserted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 4(b)(ii)**
- F78** Word in reg. 40(2)(b) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 4(b)(iii)**
- F79** Reg. 40(2)(c) inserted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 4(c)**

#### [<sup>F74</sup>Approved bodies

- 40A.**—(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 40B (approval of conformity assessment bodies); or
  - (b) immediately before IP completion day was a UK notified body in respect of which the Secretary of State has taken no action under regulation 41(4) as it had effect immediately before IP completion day to suspend or withdraw the body's status as a UK notified body.
- (2) Paragraph (1) has effect subject to regulation 40E (restriction, suspension or withdrawal of approval).
- (3) In this Part—
- “UK notified body” means a body—
- (a) which the Secretary of State had before IP completion day notified to the European Commission and the member States of the European Union, in accordance with Article 31 of the Directive; and
  - (b) in respect of which no objections had been raised, as referred to in regulation 40(2), as it had effect immediately before IP completion day;
- “approved body requirements” means the requirements set out in Schedule 7.]

#### [<sup>F74</sup>Approval of conformity assessment bodies

- 40B.**—(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 module in respect of which the conformity assessment body claims to be competent;
  - (iii) the category of toys 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.]

#### **[<sup>F74</sup>Presumption of conformity of approved bodies**

**40C.**—(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.]

#### **[<sup>F74</sup>Monitoring**

**40D.** 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 40B(6)(b); or
  - (ii) by the Secretary of State before IP completion day in that body's capacity as a UK notified body; and
- (c) carries out its functions in accordance with these Regulations.]

**[<sup>F74</sup>Restriction, suspension or withdrawal of approval**

**40E.**—(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 40D(b), the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 40A (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 40D(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 40A.

(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 other enforcement 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 UK notified body.]

**[<sup>F74</sup>Operational matters in relation to approved bodies**

**40F.**—(1) Subject to the terms of its appointment and to regulation 44, an approved body must carry out the conformity assessment activities and modules—

- (a) in respect of which the body's approval was given under regulation 40B; or
- (b) in respect of which 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.]

**[<sup>F74</sup>Subsidiaries and contractors**

**40G.**—(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.]

#### [<sup>F74</sup>Register of approved bodies

**40H.**—(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.]

#### [<sup>F74</sup>UK national accreditation body **E+W**

**41.** 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 40D; and
- (c) compiling and maintaining the register of approved bodies, in accordance with regulation 40H.]

#### **Extent Information**

**E22** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### **UK national accreditation body **N.I.****

**41.**—(1) A notified body designation other than one which designates a person as a UK notified body for a specified period has effect unless it is suspended, restricted or withdrawn under paragraph (4).

(2) A notified body designation which designates a person as a UK notified body for a specified period expires in accordance with its terms unless the period so specified is extended or shortened under paragraph (3) before the date on which it had been due to expire.

(3) The Secretary of State may vary any aspect of a notified body designation if—

- (a) the UK notified body so requests;
  - (b) it appears to the Secretary of State necessary or expedient to do so; or
  - (c) upon a request of the European Commission.
- (4) The Secretary of State may suspend, restrict or withdraw a notified body designation—
- (a) on the expiry of 90 days' notice in writing at the request of the UK notified body;
  - (b) if it appears to the Secretary of State that any condition of the designation is not complied with;
  - (c) if the Secretary of State considers that the UK notified body no longer satisfies the notified body criteria; or
  - (d) upon a request of the European Commission.
- (5) Where the Secretary of State is minded to vary a designation in accordance with paragraph (3) (b), or to suspend, restrict or withdraw a notified body designation under paragraph (4)(b) or (c), the Secretary of State must—
- (a) give notice in writing to the UK notified body of the proposed variation or suspension, restriction or withdrawal and the reasons for it, stating that the body has 21 days from the date of the notice in which to make representations to the Secretary of State in respect of the proposed variation, suspension, restriction or withdrawal; and
  - (b) consider any representations received in accordance with the notice.
- (6) If a designation is suspended, restricted or withdrawn under paragraph (4), the Secretary of State may, by notice in writing—
- (a) authorise another UK notified body to take over the functions of the UK notified body whose designation has been suspended, restricted or withdrawn in respect of such cases as are specified in the notice; and
  - (b) give such directions as the Secretary of State considers appropriate (either to the UK notified body whose designation has been suspended, restricted or withdrawn or to another UK notified body) in respect of the UK notified body's files or any other matter which the Secretary of State considers expedient for the purposes of ensuring that another notified body carries out the functions of a notified body for the existing customers of the body whose designation has been suspended, restricted or withdrawn.

## PART 4

### Functions of <sup>F80</sup>UK Notified]<sup>F80</sup>Approved] Bodies

**F80** Word in Pt. 4 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. 15 para. 29** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

#### Duty to perform <sup>F81</sup>Type] examinations **E+W+S**

42.—(1) <sup>F82</sup>An approved] body to whom an application for <sup>F83</sup>Type] examination is made in accordance with regulation 14 must carry out the functions specified in Module B (<sup>F83</sup>Type] examination) in relation to that application.

(2) But <sup>F84</sup>an approved] body is not obliged to carry out such functions where—

- (a) the documents submitted to it in relation to the carrying out of the functions are not in English or another language acceptable to the body;
- (b) the manufacturer has not submitted with its application the fee which the body requires (in accordance with regulation 50);
- (c) the body reasonably believes that, having regard to the number of outstanding applications made to it in relation to its designation, it will be unable to carry out the required work within 6 months of receiving the application; or
- (d) the terms of the body's [<sup>F85</sup>approval] do not entitle the body to carry out the functions of [<sup>F86</sup>approved] bodies specified in Module B in relation to the application.

#### Extent Information

- E23** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F81** Word in reg. 42 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. 15 para. 30(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F82** Words in reg. 42(1) 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. 15 para. 30(b)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F83** Word in reg. 42(1) 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. 15 para. 30(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F84** Words in reg. 42(2) 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. 15 para. 30(c)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F85** Word in reg. 42(2)(d) 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. 15 para. 30(d)(i)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F86** Word in reg. 42(2)(d) 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. 15 para. 30(d)(ii)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Duty to perform EC-type examinations **N.I.**

**42.**—(1) A UK notified body to whom an application for EC-type examination is made in accordance with regulation 14 must carry out the functions specified in Module B (EC-type examination) in relation to that application.

- (2) But a UK notified body is not obliged to carry out such functions where—
- (a) the documents submitted to it in relation to the carrying out of the functions are not in English or another language acceptable to the body;
  - (b) the manufacturer has not submitted with its application the fee which the body requires (in accordance with regulation 50);
  - (c) the body reasonably believes that, having regard to the number of outstanding applications made to it in relation to its designation, it will be unable to carry out the required work within 6 months of receiving the application; or
  - (d) the terms of the body's designation do not entitle the body to carry out the functions of notified bodies specified in Module B in relation to the application.

### Performance of [F87Type] examinations **E+W+S**

- 43.—(1) [F88An approved] body performing [F89a Type] examination in relation to a toy must—
- (a) perform that examination in accordance with the provisions of Module B;
  - (b) evaluate (if necessary together with the manufacturer) the analysis carried out by the manufacturer in accordance with regulation 12 (safety assessment); and
  - (c) while respecting the need for the requirements that are imposed by these Regulations in relation to the toy to be complied with, perform the examination—
    - (i) in a proportionate manner, avoiding unnecessary burdens for economic operators; and
    - (ii) taking due account of—
      - (aa) the size of the relevant economic operator;
      - (bb) the sector in which the economic operator operates;
      - (cc) the structure of the economic operator;
      - (dd) the degree of complexity of the technology of the toy; and
      - (ee) the mass or serial nature of the production process for the toy.
- (2) Point 2 of Module B shall be treated as requiring [F90Type] examination to be performed in the manner specified in the second indent of point 2 (combination of product type and design type).

#### Extent Information

- E24** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F87** Word in reg. 43 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. 15 para. 31(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F88** Words in reg. 43(1) 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. 15 para. 31(b)(i)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F89** Words in reg. 43(1) 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. 15 para. 31(b)(ii)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F90** Word in reg. 43(2) 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. 15 para. 31(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Performance of EC-type examinations **N.I.**

- 43.—(1) A UK notified body performing an EC-type examination in relation to a toy must—
- (a) perform that examination in accordance with the provisions of Module B;
  - (b) evaluate (if necessary together with the manufacturer) the analysis carried out by the manufacturer in accordance with regulation 12 (safety assessment); and
  - (c) while respecting the need for the requirements that are imposed by these Regulations in relation to the toy to be complied with, perform the examination—
    - (i) in a proportionate manner, avoiding unnecessary burdens for economic operators; and
    - (ii) taking due account of—

- (aa) the size of the relevant economic operator;
- (bb) the sector in which the economic operator operates;
- (cc) the structure of the economic operator;
- (dd) the degree of complexity of the technology of the toy; and
- (ee) the mass or serial nature of the production process for the toy.

(2) Point 2 of Module B shall be treated as requiring EC-type examination to be performed in the manner specified in the second indent of point 2 (combination of product type and design type).

**Issue and content of [F91-Type] examination certificate, and refusal and appeal against refusal to issue certificate E+W+S**

44.—(1) [F92 An approved] body who has performed [F93 a Type] examination in relation to a toy must comply with the provisions of Module B relating to the issue of (or refusal to issue) [F93 a Type] examination certificate.

(2) [F93 A Type] examination certificate must include—

- (a) a reference to [F94 these Regulations];
- (b) a colour image of the toy;
- (c) a clear description of the toy, including its dimensions;
- (d) a list of the tests performed during the [F95 Type] examination of the toy; and
- (e) a reference to the test report for each listed test.

(3) [F96 An approved] body must refuse to issue [F93 a Type] examination certificate if—

- (a) in the body's opinion the toy will not comply with the essential safety requirements during its foreseeable and normal period of use;
- (b) the body is aware that [F93 a Type] examination certificate that was previously issued in relation to the toy has been withdrawn by any [F97 approved] body; or
- (c) the body is aware that [F98 an approved] body has previously refused to issue [F93 a Type] examination certificate in relation to the toy.

(4) But sub-paragraphs (b) and (c) of paragraph (3) do not preclude [F99 an approved body] from issuing [F93 a Type] examination certificate if, following the withdrawal of, or refusal to issue, [F93 a Type] examination certificate, the manufacturer has taken corrective measures in relation to the toy which have the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(5) If [F100 an approved body] has refused to issue [F93 a Type] examination certificate under paragraph (3)(a), the body must inform the manufacturer of the corrective measures which in the body's view the manufacturer needs to take in relation to the toy.

(6) [F101 an approved body] must make provision for a manufacturer to appeal against a refusal by the body to issue [F93 a Type] examination certificate in relation to a toy.

**Extent Information**

**E25** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only



- F91** Word in reg. 44 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. 15 para. 32(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F92** Words in reg. 44(1) 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. 15 para. 32(c)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F93** Words in reg. 44 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. 15 para. 32(b)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F94** Words in reg. 44(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. 15 para. 32(d)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F95** Word in reg. 44(2)(d) 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. 15 para. 32(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F96** Words in reg. 44(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 15 para. 32(c)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F97** Words in reg. 44(3)(c) 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. 15 para. 32(e)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F98** Words in reg. 44(3)(c) 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. 15 para. 32(f)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F99** Words in reg. 44(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. 15 para. 32(g)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F100** Words in reg. 44(5) 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. 15 para. 32(g)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F101** Words in reg. 44(6) 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. 15 para. 32(g)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Issue and content of EC-type examination certificate, and refusal and appeal against refusal to issue certificate **N.I.**

44.—(1) A UK notified body who has performed an EC-type examination in relation to a toy must comply with the provisions of Module B relating to the issue of (or refusal to issue) an EC-type examination certificate.

(2) An EC-type examination certificate must include—

- (a) a reference to the Directive;
- (b) a colour image of the toy;
- (c) a clear description of the toy, including its dimensions;
- (d) a list of the tests performed during the EC-type examination of the toy; and
- (e) a reference to the test report for each listed test.

(3) A UK notified body must refuse to issue an EC-type examination certificate if—

- (a) in the body's opinion the toy will not comply with the essential safety requirements during its foreseeable and normal period of use;

- (b) the body is aware that an EC-type examination certificate that was previously issued in relation to the toy has been withdrawn by any notified body; or
- (c) the body is aware that a notified body has previously refused to issue an EC-type examination certificate in relation to the toy.

(4) But sub-paragraphs (b) and (c) of paragraph (3) do not preclude a UK notified body from issuing an EC-type examination certificate if, following the withdrawal of, or refusal to issue, an EC-type examination certificate, the manufacturer has taken corrective measures in relation to the toy which have the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(5) If a UK notified body has refused to issue an EC-type examination certificate under paragraph (3)(a), the body must inform the manufacturer of the corrective measures which in the body's view the manufacturer needs to take in relation to the toy.

(6) A UK notified body must make provision for a manufacturer to appeal against a refusal by the body to issue an EC-type examination certificate in relation to a toy.

**Action (after issue of [F102]Type examination certificate) where a toy fails to comply with essential safety requirements E+W+S**

**45.**—(1) This regulation applies where—

- (a) [F103]a Type] examination certificate has been issued in relation to a toy; and
- (b) [F104]an approved] body finds that the toy will not comply with the essential safety requirements during its foreseeable and normal period of use—
  - (i) following the review by the body of the certificate on its submission to the body for review by the manufacturer; or
  - (ii) in the course of any other monitoring by the body of whether the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) [F105]The approved] body must—

- (a) consider—
  - (i) what corrective measures the manufacturer needs to take in relation to the toy in the light of the body's findings; and
  - (ii) whether it is necessary to suspend or withdraw the [F106]Type] examination certificate;
- (b) send the manufacturer a notice in writing—
  - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
  - (ii) setting out the reasons for those conclusions; and
  - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;
- (c) make a decision on the matters specified in sub-paragraph (2)(a), taking into account any response received from the manufacturer within the period specified in the notice; and
- (d) inform the manufacturer of the decision and the reasons for it.

(3) [F105]The approved] body must restrict, suspend or withdraw, as appropriate, the [F107]Type] examination certificate issued in relation to the toy, where the manufacturer has been informed in accordance with paragraph (2)(d) of the corrective measures that the manufacturer needs to take in relation to the toy and where—

- (a) the [<sup>F108</sup>Type] examination certificate issued in relation to the toy has not already been withdrawn under paragraph (2)(c); and either
  - (b) the manufacturer fails within such period as is reasonable in the circumstances to take those measures; or
  - (c) the manufacturer takes those measures, but [<sup>F105</sup>the approved] body forms the view that those measures have not in fact had the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.
- (4) Before restricting, suspending or withdrawing [<sup>F109</sup>a Type] examination certificate under paragraph (3) [<sup>F105</sup>the approved] body must—
- (a) consider which of those actions it is appropriate to take in the circumstances; and
  - (b) send the manufacturer a notice in writing—
    - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
    - (ii) setting out the reasons for those conclusions; and
    - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;
  - (c) make a decision on the matter specified in sub-paragraph (a), taking into account any response received from the manufacturer within the period specified in the notice; and
  - (d) inform the manufacturer of the decision and the reasons for it.

#### **Extent Information**

- E26** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F102** Word in [reg. 45 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. 15 para. 33\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F103** Words in [reg. 45\(1\)\(a\)](#) 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. 15 para. 33\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F104** Words in [reg. 45\(1\)\(b\)](#) 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. 15 para. 33\(c\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F105** Words in [reg. 45](#) 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. 15 para. 33\(d\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F106** Word in [reg. 45\(2\)\(a\)\(ii\)](#) 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. 15 para. 33\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F107** Word in [reg. 45\(3\)](#) 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. 15 para. 33\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F108** Word in [reg. 45\(3\)\(a\)](#) 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. 15 para. 33\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F109** Words in [reg. 45\(4\)](#) 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. 15 para. 33\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Action (after issue of EC-type examination certificate) where a toy fails to comply with essential safety requirements N.I.**

- 45.**—(1) This regulation applies where—
- (a) an EC-type examination certificate has been issued in relation to a toy; and
  - (b) a UK notified body finds that the toy will not comply with the essential safety requirements during its foreseeable and normal period of use—
    - (i) following the review by the body of the certificate on its submission to the body for review by the manufacturer; or
    - (ii) in the course of any other monitoring by the body of whether the toy will comply with the essential safety requirements during its foreseeable and normal period of use.
- (2) The UK notified body must—
- (a) consider—
    - (i) what corrective measures the manufacturer needs to take in relation to the toy in the light of the body's findings; and
    - (ii) whether it is necessary to suspend or withdraw the EC-type examination certificate;
  - (b) send the manufacturer a notice in writing—
    - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
    - (ii) setting out the reasons for those conclusions; and
    - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;
  - (c) make a decision on the matters specified in sub-paragraph (2)(a), taking into account any response received from the manufacturer within the period specified in the notice; and
  - (d) inform the manufacturer of the decision and the reasons for it.
- (3) The UK notified body must restrict, suspend or withdraw, as appropriate, the EC-type examination certificate issued in relation to the toy, where the manufacturer has been informed in accordance with paragraph (2)(d) of the corrective measures that the manufacturer needs to take in relation to the toy and where—
- (a) the EC-type examination certificate issued in relation to the toy has not already been withdrawn under paragraph (2)(c); and either
  - (b) the manufacturer fails within such period as is reasonable in the circumstances to take those measures; or
  - (c) the manufacturer takes those measures, but the UK notified body forms the view that those measures have not in fact had the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.
- (4) Before restricting, suspending or withdrawing an EC-type examination certificate under paragraph (3) the UK notified body must—
- (a) consider which of those actions it is appropriate to take in the circumstances; and
  - (b) send the manufacturer a notice in writing—
    - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
    - (ii) setting out the reasons for those conclusions; and
    - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;

- (c) make a decision on the matter specified in sub-paragraph (a), taking into account any response received from the manufacturer within the period specified in the notice; and
- (d) inform the manufacturer of the decision and the reasons for it.

**Provision of information by [F110 approved] bodies to [F111 other approved] bodies** **E+W+S**

46. [F112 An approved] body must provide [F113 other approved] bodies which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

**Extent Information**

- E27** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F110** Word in reg. 46 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. 15 para. 34(a)(i)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F111** Words in reg. 46 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. 15 para. 34(a)(ii)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F112** Words in reg. 46 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. 15 para. 34(b)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F113** Words in reg. 46 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. 15 para. 34(c)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**Provision of information by UK notified bodies to other notified bodies** **N.I.**

46. A UK notified body must provide other notified bodies which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

**Instructions to [F114 approved] bodies in relation to [F115 Type] examination certificates** **E+W+S**

47.—(1) An enforcement authority may request [F116 an approved] body to provide to it, within such period as the body may specify, information relating to—

- (a) [F117 a Type] examination certificate which that body has issued or withdrawn in relation to a toy; or
- (b) a refusal by that body to issue [F117 a Type] examination certificate in relation to a toy.

(2) The information which may be requested under paragraph (1) includes test reports and the technical documentation which relate to the toy.

(3) The [F118 approved] body must comply with the request.

(4) If an enforcement authority forms the opinion that a toy will not comply with the essential safety requirements during its foreseeable and normal period of use, it must, where appropriate, require [F116 an approved] body who issued [F117 a Type] examination certificate in relation to the toy to withdraw it.

(5) An enforcement authority must, where it considers it to be necessary, require [<sup>F116</sup>an approved] body to review [<sup>F117</sup>a Type] examination certificate issued by that body in relation to a toy.

(6) The following are examples of when an enforcement authority may consider it to be necessary to impose a requirement under paragraph (5)—

- (a) where any change has been made to the following without the certificate having been reviewed by [<sup>F119</sup>an approved] body—
  - (i) the manufacturing process for the toy;
  - (ii) any raw material used in the toy; or
  - (iii) any component of the toy;
- (b) where 5 years have elapsed since the certificate was issued without it having being reviewed by [<sup>F119</sup>an approved] body;
- (c) where 5 years have elapsed since the certificate was last reviewed by [<sup>F119</sup>an approved] body without it having being reviewed again by [<sup>F119</sup>an approved] body.

(7) The [<sup>F120</sup>approved] body must comply with a requirement imposed under paragraph (5).

#### Extent Information

- E28** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F114** Word in reg. 47 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. 15 para. 35(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F115** Word in reg. 47 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. 15 para. 35(b)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F116** Words in reg. 47 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. 15 para. 35(d)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F117** Words in reg. 47 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. 15 para. 35(e)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F118** Word in reg. 47(3) 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. 15 para. 35(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F119** Words in reg. 47 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. 15 para. 35(c)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F120** Word in reg. 47(7) 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. 15 para. 35(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Instructions to UK notified bodies in relation to EC-type examination certificates **N.I.**

**47.**—(1) An enforcement authority may request a UK notified body to provide to it, within such period as the body may specify, information relating to—

- (a) an EC-type examination certificate which that body has issued or withdrawn in relation to a toy; or
- (b) a refusal by that body to issue an EC-type examination certificate in relation to a toy.

(2) The information which may be requested under paragraph (1) includes test reports and the technical documentation which relate to the toy.

(3) The UK notified body must comply with the request.

(4) If an enforcement authority forms the opinion that a toy will not comply with the essential safety requirements during its foreseeable and normal period of use, it must, where appropriate, require a UK notified body who issued an EC-type examination certificate in relation to the toy to withdraw it.

(5) An enforcement authority must, where it considers it to be necessary, require a UK notified body to review an EC-type examination certificate issued by that body in relation to a toy.

(6) The following are examples of when an enforcement authority may consider it to be necessary to impose a requirement under paragraph (5)—

(a) where any change has been made to the following without the certificate having been reviewed by a notified body—

(i) the manufacturing process for the toy;

(ii) any raw material used in the toy; or

(iii) any component of the toy;

(b) where 5 years have elapsed since the certificate was issued without it having been reviewed by a notified body;

(c) where 5 years have elapsed since the certificate was last reviewed by a notified body without it having been reviewed again by a notified body.

(7) The UK notified body must comply with a requirement imposed under paragraph (5).

### **Participation by UK notified bodies in sectoral groups of notified bodies**

**48.**—<sup>F121</sup>(1) A UK notified body must participate in <sup>F122</sup>, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the work of each relevant sectoral group of notified bodies put in place by the European Commission in accordance with Article 38 of the Directive (coordination of notified bodies).

(2) A UK notified body may participate by means of a representative designated by it to participate on its behalf.]

**F121** Reg. 48 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. 15 para. 36** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F122** Words in reg. 48 inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 5**

### **Subcontracting by a UK notified body**

**49.**—<sup>F123</sup>(1) A UK notified body may subcontract a specific task or activity connected with conformity assessment or have recourse to a subsidiary to carry out a task or activity if—

(a) the body is satisfied that the subcontractor or subsidiary meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive (requirements relating to notified bodies); and

(b) the economic operator for whom the task or activity is to be carried out has consented to the task or activity being performed by that person.

(2) A UK notified body which subcontracts a specific task or activity connected with conformity assessment or has recourse to a subsidiary to carry out a task or activity—

- (a) must inform the Secretary of State that the body is satisfied that the subcontractor or subsidiary meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive; and
- (b) remains responsible for the proper performance of the task or activity (irrespective of where the subcontractor or subsidiary is established).

(3) The Secretary of State may request a UK notified body to provide to the Secretary of State, within a specified period, any relevant documents concerning the assessment of the qualifications of the subcontractor or subsidiary and the tasks or activities carried out by the subcontractor or subsidiary.

(4) The UK notified body must comply with the request.]

**F123** Reg. 49 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. 15 para. 36** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Charging of fees by [<sup>F124</sup>approved] body **E+W+S**

**50.**—(1) [<sup>F125</sup>An approved] body may charge such fees in connection with, or incidental to, the carrying out of its functions under regulations 42 to 45 as it may determine

(2) But any such fee shall not exceed the sum of—

- (a) the costs incurred or to be incurred by the body in performing the relevant functions; and
- (b) an amount on account of profit which is reasonable in the circumstances having regard to—
  - (i) the character and extent of the work done or to be done by the body for the manufacturer, and
  - (ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) [<sup>F125</sup>An approved] body may require the payment of fees or a reasonable estimate of fees in advance of carrying out the work for the manufacturer.

#### Extent Information

**E29** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F124** Word in [reg. 50](#) 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. 15 para. 37(a)** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F125** Words in [reg. 50](#) 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. 15 para. 37(b)** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Charging of fees by UK notified body **N.I.**

**50.**—(1) A UK notified body may charge such fees in connection with, or incidental to, the carrying out of its functions under regulations 42 to 45 as it may determine



- (2) But any such fee shall not exceed the sum of—
- (a) the costs incurred or to be incurred by the body in performing the relevant functions; and
  - (b) an amount on account of profit which is reasonable in the circumstances having regard to—
    - (i) the character and extent of the work done or to be done by the body for the manufacturer, and
    - (ii) the commercial rate normally charged on account of profit for that work or similar work.
- (3) A UK notified body may require the payment of fees or a reasonable estimate of fees in advance of carrying out the work for the manufacturer.

### Provision of information by <sup>F126</sup>approved] bodies to the Secretary of State **E+W+S**

- 51.**—(1) <sup>F127</sup>An approved] notified body must notify the Secretary of State of—
- (a) any refusal by the body to issue <sup>F128</sup>a Type] examination certificate in relation to a toy;
  - (b) any restriction, suspension or withdrawal by the body of <sup>F128</sup>a Type] examination certificate issued in relation to a toy;
  - (c) any circumstances affecting the scope of the body's designation or any conditions to which its <sup>F129</sup>approval] is subject; and
  - (d) any request which the body has received from an enforcement body for information about conformity assessment activities.
- (2) The Secretary of State may request <sup>F127</sup>an approved] body to provide to the Secretary of State, within such period as the Secretary of State may specify—
- (a) information about any conformity assessment activity carried out by the body within the scope of the body's <sup>F129</sup>approval] ;
  - (b) information about any other activity carried out by the body, including cross-border activities and sub-contracting; and
  - (c) information relevant to determining the body's compliance with any of the requirements laid down in <sup>F130</sup>the approved body requirements] , any provision of these Regulations or any condition to which the body's <sup>F129</sup>approval] is subject.
- (3) The <sup>F131</sup>approved] body must comply with the request.

#### Extent Information

**E30** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F126** Word in [reg. 51](#) 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. 15 para. 38\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F127** Words in [reg. 51](#) 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. 15 para. 38\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F128** Words in [reg. 51](#) 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. 15 para. 38\(c\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

- F129** Words in reg. 51 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. 15 para. 38(d)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F130** Words in reg. 51(2)(c) 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. 15 para. 38(e)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F131** Word in reg. 51(3) 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. 15 para. 38(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Provision of information by UK notified bodies to the Secretary of State **N.I.**

- 51.**—(1) A UK notified body must notify the Secretary of State of—
- (a) any refusal by the body to issue an EC-type examination certificate in relation to a toy;
  - (b) any restriction, suspension or withdrawal by the body of an EC-type examination certificate issued in relation to a toy;
  - (c) any circumstances affecting the scope of the body's designation or any conditions to which its designation is subject; and
  - (d) any request which the body has received from an enforcement body for information about conformity assessment activities.
- (2) The Secretary of State may request a UK notified body to provide to the Secretary of State, within such period as the Secretary of State may specify—
- (a) information about any conformity assessment activity carried out by the body within the scope of the body's designation;
  - (b) information about any other activity carried out by the body, including cross-border activities and sub-contracting; and
  - (c) information relevant to determining the body's compliance with any of the requirements laid down in paragraphs (2) to (11) of Article 26 of the Directive (requirements relating to notified bodies), any provision of these Regulations or any condition to which the body's designation is subject.
- (3) The UK notified body must comply with the request.

## PART 5

### Enforcement

#### Enforcement action in cases of formal non-compliance **E+W+S**

- 52.**—(1) An enforcement authority may serve a compliance notice on an economic operator if it finds that a non-compliance of any of the following types has occurred in relation to a toy—
- (a) no <sup>F132</sup>[UK] marking has been affixed;
  - (b) a <sup>F132</sup>[UK] marking has been affixed but any provision of regulation 18 or regulation 39 has not been complied with or has been contravened;
  - (c) the manufacturer has not drawn up <sup>F133</sup>[a] declaration of conformity;
  - (d) the manufacturer has drawn up <sup>F133</sup>[a] declaration of conformity but the declaration does not comply with any provision of regulation 16(1) to (4); or

- (e) the technical documentation is unavailable or incomplete.
- (2) A compliance notice must—
  - (a) require the economic operator—
    - (i) to put an end to the non-compliance within such period as may be specified in the notice; or
    - (ii) to provide evidence within that period to the satisfaction of the enforcement authority that the non-compliance has not in fact occurred; and
  - (b) warn the economic operator that, if the non-compliance continues, or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken by an enforcement authority in respect of that toy or any toy of the same type supplied by that person.
- (3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.
- (4) A compliance notice has effect throughout the United Kingdom.
- (5) Where an economic operator fails to comply with the requirements of a compliance notice, the enforcement authority may—
  - (a) serve a withdrawal notice under regulation 14(1) GPSR;
  - (b) serve a recall notice under regulation 15(1) GPSR;.
- (6) For the purposes of taking an action referred to in paragraph (5), regulations 14, 15, 16, and 17 of the GPSR are applicable
- (7) Where a notice is served under paragraph (5), the grounds for serving the notice that would otherwise apply under the GPSR are satisfied by complying with this regulation.

#### Extent Information

- E31** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F132** Word in [reg. 52](#) 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. 15 para. 39\(a\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))
- F133** Word in [reg. 52](#) 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. 15 para. 39\(b\)](#) (with [Sch. 15 para. 3](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#))

#### Enforcement action in cases of formal non-compliance **N.I.**

**52.**—(1) An enforcement authority may serve a compliance notice on an economic operator if it finds that a non-compliance of any of the following types has occurred in relation to a toy—

- (a) no CE marking has been affixed;
- (b) a CE marking has been affixed but any provision of regulation 18 or regulation 39 has not been complied with or has been contravened;
- [<sup>F156</sup>(ba) a UK(NI) indication—
  - (i) has not been affixed, in contravention of regulation 15A(1); or
  - (ii) has been affixed but any provision of regulation 15A has not been complied with or has been contravened.]
- (c) the manufacturer has not drawn up an EC declaration of conformity;

- (d) the manufacturer has drawn up an EC declaration of conformity but the declaration does not comply with any provision of regulation 16(1) to (4); or
  - (e) the technical documentation is unavailable or incomplete.
- (2) A compliance notice must—
- (a) require the economic operator—
    - (i) to put an end to the non-compliance within such period as may be specified in the notice; or
    - (ii) to provide evidence within that period to the satisfaction of the enforcement authority that the non-compliance has not in fact occurred; and
  - (b) warn the economic operator that, if the non-compliance continues, or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken by an enforcement authority in respect of that toy or any toy of the same type supplied by that person.
- (3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.
- (4) A compliance notice has effect throughout [<sup>F157</sup>Northern Ireland].
- (5) Where an economic operator fails to comply with the requirements of a compliance notice, the enforcement authority may—
- (a) serve a withdrawal notice under regulation 14(1) GPSR;
  - (b) serve a recall notice under regulation 15(1) GPSR;.
- (6) For the purposes of taking an action referred to in paragraph (5), regulations 14, 15, 16, and 17 of the GPSR are applicable
- (7) Where a notice is served under paragraph (5), the grounds for serving the notice that would otherwise apply under the GPSR are satisfied by complying with this regulation.

**F156** Reg. 52(1)(ba) 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. 5\(5\)](#)

**F157** Words in reg. 52(4) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), [Sch. 5 para. 6\(1\)](#)

### Enforcement action in cases of toys presenting a risk **E+W+S**

- 53.**—(1) This regulation applies where—
- (a) an enforcement authority or other person has taken any action under the 1987 Act or the GPSR to ensure that a toy which presents a serious risk requiring rapid intervention is recalled, withdrawn or prohibited from being made available on the market; or
  - (b) an enforcement authority has sufficient reason to believe that a toy presents a risk to the health or safety of persons.
- (2) An enforcement authority—
- (a) must carry out an evaluation in relation to the toy covering all the requirements of these Regulations;
  - (b) may require the relevant economic operator to take appropriate corrective action to bring the toy into compliance with these Regulations;
  - (c) may serve a withdrawal notice under regulation 14(1) GPSR;

(d) may serve a recall notice under regulation 15(1) GPSR.

(3) For the purposes of taking an action referred to in paragraph (2)(c) or (d), regulations 14, 15, 16 and 17 of the GPSR are applicable.

(4) Where a notice is served under paragraph 2(c) or (d) the grounds for serving the notice that would otherwise apply under the GPSR are satisfied by complying with this regulation.

<sup>F134</sup>(5) .....

#### Extent Information

**E32** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**F134** Reg. 53(5) 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. 15 para. 40** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Enforcement action in cases of toys presenting a risk **N.I.**

**53.**—(1) This regulation applies where—

- (a) an enforcement authority or other person has taken any action under the 1987 Act or the GPSR to ensure that a toy which presents a serious risk requiring rapid intervention is recalled, withdrawn or prohibited from being made available on the market; or
- (b) an enforcement authority has sufficient reason to believe that a toy presents a risk to the health or safety of persons.

(2) An enforcement authority—

- (a) must carry out an evaluation in relation to the toy covering all the requirements of these Regulations;
- (b) may require the relevant economic operator to take appropriate corrective action to bring the toy into compliance with these Regulations;
- (c) may serve a withdrawal notice under regulation 14(1) GPSR;
- (d) may serve a recall notice under regulation 15(1) GPSR.

(3) For the purposes of taking an action referred to in paragraph (2)(c) or (d), regulations 14, 15, 16 and 17 of the GPSR are applicable.

(4) Where a notice is served under paragraph 2(c) or (d) the grounds for serving the notice that would otherwise apply under the GPSR are satisfied by complying with this regulation.

(5) This regulation does not apply where any provisional measure taken by another [<sup>F158</sup>relevant state] in relation to a toy pursuant to Article 42(4) of the Directive is deemed under Article 42(7) of the Directive to be justified or is decided by the European Commission to be justified pursuant to Article 43(1) of the Directive (and that decision is communicated to the United Kingdom).

**F158** Words in reg. 53(5) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 5 para. 6(2)**

#### Notification of enforcement action taken in cases of toys presenting a risk **E+W+S**

**54.**—[<sup>F135</sup>(1) Where a person or an enforcing authority is not the Secretary of State and it has taken action under regulation 53, it must notify the Secretary of State of—

- (a) the results of the evaluation; and
  - (b) the corrective actions which it requires the relevant economic operator to take.]
- (2) An enforcement authority which has taken action under regulation 53 must inform the relevant [F136approved] body accordingly.

#### Extent Information

- E33** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only
- F135** Reg. 54(1) 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. 15 para. 41(a)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F136** Word in reg. 54(2) 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. 15 para. 41(b)** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Notification of enforcement action taken in cases of toys presenting a risk **N.I.**

**54.**—(1) An enforcement authority, or other person who has taken action under the 1987 Act or the GPSR, must give immediate notice to the Secretary of State of any action taken by it, finding made or other opinion formed by it, or other matter within its knowledge, which is required to be notified to the European Commission or the ... Member States under Articles 42, 43 or 44 of the Directive.

(2) An enforcement authority which has taken action under regulation 53 must inform the relevant notified body accordingly.

#### Requirements relating to certain measures taken by enforcement authorities or other persons

**55.**—(1) Paragraph (2) applies in relation to a measure taken by an enforcement authority or other person to—

- (a) prohibit or restrict a toy from being made available on the market;
  - (b) withdraw a toy; or
  - (c) recall a toy.
- (2) The following requirements must be complied with in relation to the measure—
- (a) the measure must state the exact grounds on which it is based;
  - (b) the measure must be notified without delay to the party concerned; and
  - (c) at the same time as the measure is notified to the party concerned that party must also be informed of—
    - (i) any remedy available to that party in relation to the measure; and
    - (ii) any time limit to which that remedy is subject.

(3) Where an enforcement authority takes a measure in relation to a toy, the authority must take due account of the precautionary principle.

(4) [F137Where an enforcement authority takes a measure in relation to a toy which is considered unjustified in accordance with Article 43(2) of the Directive (Community safeguard procedure), the enforcement authority must withdraw the measure or apply to the court to withdraw the measure as may be required.]

**F137** Reg. 55(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. 15 para. 42** (with Sch. 15 para. 3) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### [<sup>F138</sup> **Offence in respect of UK(NI) indication**

**55A.**—(1) Regulation 15A is to be treated as if it were a safety regulation made under section 11 of the Consumer Protection Act 1987.

(2) Notwithstanding section 12(5) of the Consumer Protection Act 1987, any person guilty of an offence under that section of contravening regulation 15A is liable on summary conviction to a fine not exceeding level 5 on the standard scale.]

**F138** Reg. 55A 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. 5(6)**

### **Commencement of proceedings**

**56.**—(1) In England and Wales a magistrates' court may try an information, and in Northern Ireland a magistrates' court may try a complaint, in respect of an offence committed under section 12 of the 1987 Act in relation to a contravention of or a failure to comply with these Regulations if the information is laid or the complaint is made within twelve months from the discovery of the offence by the prosecutor.

(2) In Scotland summary proceedings in relation to an offence committed under section 12 of the 1987 Act in relation to a contravention of or a failure to comply with these Regulations may be begun at any time within twelve months from the discovery of the offence by the prosecutor.

(3) No such proceedings shall be brought more than three years after the commission of the offence.

### **Amendment to the General Product Safety Regulations 2005**

**57.** The General Product Safety Regulations 2005<sup>M11</sup> are amended as follows—

(a) In regulation 2 (Interpretation) insert the following at the end of the definition of “Community law” –  
“and does not include Regulation (EC) No 765/2008 of the European Parliament and the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>M12</sup>.”.

#### **Marginal Citations**

**M11** [S.I. 2005/1803](#).

**M12** [OJ No L218, 13.8.2008, p30](#).

## PART 6

### Review

#### Review **E+W+S**

**58.**—(1) Before the end of each review period, the Secretary of State must—

- (a) carry out a review of these Regulations
- (b) set out the conclusions of the review in a report, and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how Directive [2009/48/EC](#) of the European Parliament and of the Council on the safety of toys (which is implemented by means of these Regulations) is implemented in other member States.

(3) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved, and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) “Review period” means—

- (a) the period of five years beginning with the day on which these Regulations come into force, and
- (b) subject to paragraph (5), each successive period of five years.

(5) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

#### **Extent Information**

**E34** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Review **N.I.**

**58.**—(1) Before the end of each review period, the Secretary of State must—

- (a) carry out a review of these Regulations
- (b) set out the conclusions of the review in a report, and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how Directive [2009/48/EC](#) of the European Parliament and of the Council on the safety of toys (which is implemented by means of these Regulations) is implemented in other [<sup>F159</sup>relevant states].

(3) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved, and



- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (4) “Review period” means—
  - (a) the period of five years beginning with the day on which these Regulations come into force, and
  - (b) subject to paragraph (5), each successive period of five years.
- (5) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

**F159** Words in [reg. 58\(2\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 5 para. 7](#)

Department for Business, Innovation and Skills

*Edward Davey*  
Minister for Employment Relations, Consumer  
and Postal Affairs

[<sup>F139</sup>SCHEDULE 1

Regulations 3B and 4(3)

## PRODUCTS THAT ARE NOT TOYS (Annex I to the Directive)

**F139** Schs. 1-7 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. 15 para. 43** (with Sch. 15 para. 3) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 9(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

1. Products listed in paragraphs 2 to 20 are not to be considered as toys.
2. Decorative objects for festivities and celebrations.
3. Products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above. Examples of this category are—
  - (a) detailed and faithful scale models;
  - (b) kits for the assembly of detailed scale models;
  - (c) folk dolls and decorative dolls and other similar articles;
  - (d) historical replicas of toys; and
  - (e) reproductions of real fire arms.
4. Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg.
5. Bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark.
6. Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways.
7. Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof.
8. Aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids.
9. Puzzles with more than 500 pieces.
10. Guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long.
11. Fireworks, including percussion caps which are not specifically designed for toys.
12. Products and games using sharp-pointed missiles, such as sets of darts with metallic points.
13. Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision.
14. Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment.
15. Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels.

16. Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as compact disks.

17. Babies' soothers.

18. Child-appealing luminaires.

19. Electrical transformers for toys.

20. Fashion accessories for children which are not for use in play.

## SCHEDULE 2

Regulations 3B and 5(1)

### PARTICULAR SAFETY REQUIREMENTS (Annex II to the Directive)

#### Part 1

##### Physical and Mechanical Properties

1. Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.

2. Accessible edges, protrusions, cords, cables and fastenings on toys must be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as far as possible.

3. Toys must be designed and manufactured in such a way as not to present any risk or only the minimum risk inherent to their use which could be caused by the movement of their parts.

- (a) (a) Toys and their parts must not present a risk of strangulation.
- (b) Toys and their parts must not present a risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.
- (c) Toys and their parts must be of such dimensions as to not present a risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
- (d) Toys, which are clearly intended for use by children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.
- (e) The packaging in which toys are contained for retail sale must not present a risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.
- (f) Toys contained within food or co-mingled with food must have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent its being swallowed and/or inhaled.
- (g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
- (h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, are

**Changes to legislation:** There are currently no known outstanding effects for the Toys (Safety) Regulations 2011. (See end of Document for details)

prohibited. Parts of toys otherwise directly attached to a food product must fulfil the requirements set out in points (c) and (d).

5. Aquatic toys must be designed and manufactured so as to reduce as far as possible, taking into account the recommended use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.

6. Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants must have a means of exit which the intended user can open easily from the inside.

7. Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy generated by it. Such a system must be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

The maximum design speed of electrically driven ride-on toys must be limited so as to minimise the risk of injury.

8. The form and composition of projectiles and the kinetic energy they may generate when fired from a toy designed for that purpose must be such that, taking into account the nature of the toy, there is no risk of physical injury to the user or to third parties.

9. Toys must be manufactured so as to ensure that:

- (a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched; and
- (b) liquids and gases contained within the toy do not reach temperatures or pressures which are such that their escape from the toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.

10. Toys which are designed to emit a sound must be designed and manufactured in such a way in terms of the maximum values for impulse noise and continuous noise that the sound from them is not able to impair children's hearing.

11. Activity toys must be manufactured so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and of falls, impacts and drowning as far as possible. In particular, any surface of such a toy accessible for one or more children to play on must be designed to bear their load.

## Part 2

### Flammability

1. Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:

- (a) they do not burn if directly exposed to a flame or spark or other potential source of fire;
- (b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);
- (c) if they do ignite, they burn slowly and present a low rate of spread of the flame;
- (d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

2. Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down in Section 1 of Appendix B, in particular materials and equipment

for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.

3. Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

4. Toys and, in particular, chemical games and toys, must not contain as such substances or mixtures:

- (a) which, when mixed together, may explode through chemical reaction or through heating;
- (b) which may explode when mixed with oxidizing substances; or
- (c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

## Part 3

### Chemical Properties

1. Toys must be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

2. Toys that are themselves substances or mixtures must comply also with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures (“Regulation 1272/2008”).

3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation 1272/2008 must not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

- (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
- (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as intended or in a foreseeable way, bearing in mind the behaviour of children;
- (c) regulations have been made under regulation 39D.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:

- (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;

**Changes to legislation:** There are currently no known outstanding effects for the *The Toys (Safety) Regulations 2011*. (See end of Document for details)

- (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as intended or in a foreseeable way, bearing in mind the behaviour of children; or
- (c) regulations have been made under regulation 39D.
6. Points 3, 4 and 5 do not apply to nickel in stainless steel.
7. Points 3, 4 and 5 do not apply to materials that comply with the specific limit values set out in Appendix C.
8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances are prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.
9. Not applicable.
10. Cosmetic toys, such as play cosmetics for dolls, must comply with the compositional and labelling requirements laid down in Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
11. Toys must not contain the following allergenic fragrances:

<i>No</i>	<i>Name of the allergenic fragrance</i>	<i>CAS number</i>
(1)	Alanroot oil (Inula helenium)	97676-35-2
(2)	Allylthiocyanate	57-06-7
(3)	Benzyl cyanide	140-29-4
(4)	4 tert-Butylphenol	98-54-4
(5)	Chenopodium oil	8006-99-3
(6)	Cyclamen alcohol	4756-19-8
(7)	Diethyl maleate	141-05-9
(8)	Dihydrocoumarin	119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4,6,10-dodecatrien-3-one	26651-96-7
(14)	6,10-Dimethyl-3,5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2-Hexenal diethyl acetal	67746-30-9
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6

(22)	4-Ethoxy-phenol	622-62-8
(23)	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenoate	623-43-8
(29)	6-Methylcoumarin	92-48-8
(30)	7-Methylcoumarin	2445-83-2
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke)	8023-88-9
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1
(37)	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil (Lippia citriodora Kunth)	8024-12-2
(39)	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
(40)	4-Phenyl-3-buten-2-one	122-57-6
(41)	Amyl cinnamal	122-40-7
(42)	Amylcinnamyl alcohol	101-85-9
(43)	Benzyl alcohol	100-51-6
(44)	Benzyl salicylate	118-58-1
(45)	Cinnamyl alcohol	104-54-1
(46)	Cinnamal	104-55-2
(47)	Citral	5392-40-5
(48)	Coumarin	91-64-5
(49)	Eugenol	97-53-0
(50)	Geraniol	106-24-1
(51)	Hydroxy-citronellal	107-75-5
(52)	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
(53)	Isoeugenol	97-54-1
(54)	Oakmoss extracts	90028-68-5
(55)	Treemoss extracts	90028-67-4

**Changes to legislation:** There are currently no known outstanding effects for the *The Toys (Safety) Regulations 2011*. (See end of Document for details)

[ <sup>F140</sup> (56)Atranol (2,6-Dihydroxy-4-methyl-benzaldehyde)	526-37-4
(57) Chloroatranol (3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde)	57074-21-2
(58) Methyl heptine carbonate	111-12-6]

However, the presence of traces of these fragrances is allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances must be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof:

<i>No</i>	<i>Name of the allergenic fragrance</i>	<i>CAS number</i>
(1)	Anisyl alcohol	105-13-5
(2)	Benzyl benzoate	120-51-4
(3)	Benzyl cinnamate	103-41-3
(4)	Citronellol	106-22-9
(5)	Farnesol	4602-84-0
(6)	Hexyl cinnamaldehyde	101-86-0
(7)	Lilial	80-54-6
(8)	d-Limonene	5989-27-5
(9)	Linalool	78-70-6
F141	F141	F141
...	...	...
(11)	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

**F140** Words in Sch. 2 Pt. 3 table inserted (15.10.2022) by [The Toys and Cosmetic Products \(Restriction of Chemical Substances\) Regulations 2022 \(S.I. 2022/659\)](#), regs. 1(2), **2(3)(a)** (with reg. 4(1))

**F141** Words in Sch. 2 Pt. 3 table omitted (15.10.2022) by virtue of [The Toys and Cosmetic Products \(Restriction of Chemical Substances\) Regulations 2022 \(S.I. 2022/659\)](#), regs. 1(2), **2(3)(b)** (with reg. 4(1))

**12.** The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point are allowed in olfactory board games, cosmetic kits and gustative games, provided that

- (i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- (ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products; and
- (iii) if applicable, those fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games must not be used by children under 36 months and must comply with point 1 of Part B of Schedule 5.



**Changes to legislation:** There are currently no known outstanding effects for the The Toys (Safety) Regulations 2011. (See end of Document for details)

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, must not be exceeded:

<i>Element</i>	<i>mg/kg in dry, brittle, powder-like or pliable toy material</i>	<i>mg/kg in liquid or sticky toy material</i>	<i>mg/kg in scraped-off toy material</i>
[ <sup>F142</sup> Aluminium]	2 250	560	28 130]
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	1 500	375	18 570
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,053
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	2,0	0,5	23
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values do not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

**F142** Words in Sch. 2 Pt. 3 table substituted (15.12.2022) by The Toys and Cosmetic Products (Restriction of Chemical Substances) Regulations 2022 (S.I. 2022/659), regs. 1(3), 2(3)(c) (with reg. 4(2))

## Part 4

### Electrical Properties

1. Toys must not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and their accessible parts must not exceed 24 volts DC or the equivalent AC voltage.

**Changes to legislation:** There are currently no known outstanding effects for the Toys (Safety) Regulations 2011. (See end of Document for details)

Internal voltages must not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk or harmful electric shock, even when the toy is broken.

2. Parts of toys which are connected to, or liable to come into contact with, a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock.

3. Electric toys must be designed and manufactured in such a way as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.

4. Under foreseeable fault conditions, toys must provide protection against electrical hazards arising from an electrical power source.

5. Electric toys must provide adequate protection against fire hazards.

6. Electric toys must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the equipment are limited to the extent necessary for the operation of the toy and must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Community measures.

7. Toys which have an electronic control system must be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to failure of the system itself or an outside factor.

8. Toys must be designed and manufactured in such a way that they do not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation.

9. The electrical transformer of a toy must not be an integral part of the toy.

## Part 5

### Hygiene

1. Toys must be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination.

2. A toy intended for use by children under 36 months must be designed and manufactured in such a way that it can be cleaned. A textile toy must, to this end, be washable, except if it contains a mechanism that may be damaged if soaked. The toy must fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

## Part 6

### Radioactivity

Toys must comply with all retained EU law that was adopted for the purposes of implementing Chapter 3 of Euratom.

**Changes to legislation:** There are currently no known outstanding effects for the The Toys (Safety) Regulations 2011. (See end of Document for details)

## Appendix A

*List of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III*

<b><i>Substance</i></b>	<b><i>Classification</i></b>	<b><i>Permitted use</i></b>
Nickel	CMR 2	In toys and toy components made of stainless steel. In toy components which are intended to conduct an electric current

## Appendix B

### *Classification of Substances and Mixtures*

**A1.** In this Appendix—  
 “Regulation (EC) No 1272/2008” means Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classifications, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) 1907/2006.

**1.** Criteria for classifying substances and mixtures for the purposes of point 2 of Part 2

The substance or mixture fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) 1272/2008:

- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- (c) hazard class 4.1;
- (d) hazard class 5.1.

**2.** Enactments governing the use of certain substances for the purposes of points 4(a) and 5(a) of Part 3

The relevant concentrations for the classification of mixtures containing the substances are those established in accordance with Regulation (EC) No 1272/2008.

**3.** Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 4 of Part 3.

**Substances** Point 4 of Part 3 concerns substances classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

**Mixtures** Point 4 of Part 3 concerns mixtures classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

**4.** Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5 of Part III

**Substances** Point 5 of Part 3 concerns substances classified as CMR category 2 under Regulation (EC) No 1272/2008.

**Mixtures** Point 5 of Part 3 concerns mixtures classified as CMR category 2 under Regulation (EC) No 1272/2008.

**5.** Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of regulation 39D(3)(a).

**Substances** Regulation 39D(3)(a) concerns substances classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

**Mixtures** Regulation 39D(3)(a) concerns mixtures classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

## Appendix C

Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted by the Secretary of State.

<b>Substance</b>	<b>CAS No</b>	<b>Limit value</b>
TCEP	115-96-8	5 mg/kg (content limit)
TCCP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Bisphenol A	80-05-7	0,04 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.
Formamide	75-12-7	20µg/m <sup>3</sup> (emission limit) after a maximum of 28 days from commencement of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content)
1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit) in aqueous toy materials, in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no. 247-500-7) and 2-methyl-2H -isothiazol-3-one (EC no. 220-239-6) (3:1)	55965-84-9	1 mg/kg (content limit) in aqueous toy materials
5-Chloro-2-methyl-isothiazolin-3(2H)-one	26172-55-4	0,75 mg/kg (content limit) in aqueous toy materials
2-methylisothiazolin-3(2H)-one	2682-20-4	0,25 mg/kg (content limit) in aqueous toy materials
Phenol	108-95-2	5mg/l (migration limit) in polymeric materials in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005 10mg/kg (content limit) as a preservative in accordance with the methods laid down in EN 71-10: 2005 and EN 71-11:2005.

**Changes to legislation:** There are currently no known outstanding effects for the The Toys (Safety) Regulations 2011. (See end of Document for details)

[ <sup>F143</sup> Aniline	62-53-3	30 mg/kg after reductive cleavage in textile and leather materials 30 mg/kg after reductive cleavage in finger paints 10 mg/kg as free aniline in finger paints
Formaldehyde	50-00-0	Polymeric 1.5 mg/l (migration limit) Resin-bonded wood 0.1 ml/m <sup>3</sup> (emission limit) Textile 30 mg/kg Leather 30 mg/kg Paper 30 mg/kg Water-based 10 mg/kg]

**F143** Words in Sch. 2 Appendix C table inserted (15.12.2022) by The Toys and Cosmetic Products (Restriction of Chemical Substances) Regulations 2022 (S.I. 2022/659), regs. 1(3), 2(4) (with reg. 4(2))

### SCHEDULE 3

Regulation 16(2)

#### DECLARATION OF CONFORMITY

1. No (unique identification of the toy(s))
  2. Name and address of the manufacturer or the manufacturer's authorised representative:
  3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
  4. Object of the declaration (identification of toy allowing traceability). It must include a colour image of sufficient clarity to enable the identification of the toy.
  5. The object of the declaration described in point 4 is in conformity with the following enactments:
  6. References to the relevant designated standards used, or references to the specifications in relation to which conformity is declared:
  7. Where applicable: the approved body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate:
  8. Additional information:
- Signed for and on behalf of: (place and date of issue) (name, function) (signature)

## SCHEDULE 4

Regulations 3B and 17(3)

### TECHNICAL DOCUMENTATION (Annex IV to the Directive)

The technical documentation referred to in regulation 17(3) must contain so far as relevant for assessment:

- (a) a detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;
- (b) the safety assessment(s) carried out in accordance with regulation 12.
- (c) a description of the conformity assessment procedure followed;
- (d) a copy of the declaration of conformity;
- (e) the addresses of the places of manufacture and storage;
- (f) copies of documents that the manufacturer has submitted to an approved body, if involved;
- (g) test reports and description of the means whereby the manufacturer ensured conformity of production with designated standards, if the manufacturer followed the internal production control procedure set out in Module A; and
- (h) a copy of the Type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the Type examination certificate, and copies of the documents that the manufacturer submitted to the approved body, if the manufacturer submitted the toy to Type examination and followed the conformity to type procedure set out in Module C.

## SCHEDULE 5

Regulations 3B and 20(3)

### WARNINGS (Annex V to the Directive)

#### **PART A**

#### **GENERAL WARNINGS**

The user limitations referred to in regulation 20(3) must include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

#### **PART B**

#### **SPECIFIC WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING CERTAIN CATEGORIES OF TOYS**

##### **1. Toys not intended for use by children under 36 months**

Toys which might be dangerous for children under 36 months of age must bear a warning such as 'Not suitable for children under 36 months' or 'Not suitable for children under three years' or a warning in the form of the following graphic:



These warnings must be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution.

This point does not apply to toys which, on account of their function, dimensions, characteristics or properties, or on other cogent grounds, are manifestly unsuitable for children under 36 months.

## 2. Activity toys

Activity toys must bear the following warning: ‘Only for domestic use’.

Activity toys attached to a crossbeam as well as other activity toys, where appropriate, must be accompanied by instructions drawing attention to the need to carry out checks and maintenance of the main parts (suspensions, fixings, anchorages, etc.) at intervals, and pointing out that, if these checks are not carried out, the toy may cause a fall or overturn.

Instructions must also be given as to the correct assembly of the toy, indicating those parts which can present a danger if incorrectly assembled. Specific information regarding a suitable surface on which to place the toy must be given.

## 3. Functional toys

Functional toys must bear the following warning: ‘To be used under the direct supervision of an adult’.

In addition, these toys must be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to take these precautions will expose the user to the hazards – to be specified – normally associated with the appliance or product of which the toy is a scale model or imitation. It must also be indicated that the toy must be kept out of the reach of children under a certain age, which must be specified by the manufacturer.

## 4. Chemical toys

Without prejudice to the application of the provisions laid down in applicable enactments on the classification, packaging and labelling of certain substances or mixtures, the instructions for use of toys containing inherently dangerous substances or mixtures must bear a warning of the dangerous nature of these substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which must be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy must also be set out. It must also be stated that the toy must be kept out of reach of children under a certain age, which must be specified by the manufacturer.

In addition to the instructions provided for in the first subparagraph, chemical toys must bear the following warning on their packaging: ‘Not suitable for children under (insert appropriate age) years. For use under adult supervision’.

In particular, the following are regarded as chemical toys: chemistry sets, plastic embedding sets, miniature workshops for ceramics, enamelling or photography and similar toys which lead to a chemical reaction or similar substance alteration during use.

## 5. Skates, roller skates, inline skates, skateboards, scooters and toy bicycles for children

Where these toys are offered for sale as toys, they must bear the following warning: ‘Protective equipment should be worn. Not to be used in traffic’.



Moreover, the instructions for use must contain a reminder that the toy must be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user or third parties. Some indication must also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

**6. Aquatic toys**

Aquatic toys must bear the following warning: 'Only to be used in water in which the child is within its depth and under adult supervision'.

**7. Toys in food**

Toys contained in food or co-mingled with food must bear the following warning: 'Toy inside. Adult supervision recommended'.

**8. Imitations of protective masks and helmets**

Imitations of protective masks and helmets must bear the following warning: 'This toy does not provide protection'.

**9. Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps**

Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps must carry the following warning on the packaging, which must also be permanently marked on the toy: 'To prevent possible injury by entanglement, remove this toy when the child starts trying to get up on its hands and knees in a crawling position'.

**10. Packaging for fragrances in olfactory board games, cosmetic kits and gustative games**

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part 3 of Schedule 2 and of the fragrances set out in points 1 to 11 of the list set out in third paragraph of that point must contain the following warning: 'Contains fragrances that may cause allergies'.

SCHEDULE 6

Regulations 3 and 3B

CONFORMITY ASSESSMENT PROCEDURES (Annex II to Decision No [768/2008/EC](#))

MODULE A

*Internal production control*

**1.** Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on the manufacturer's sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

**Technical documentation**

**2.** The manufacturer must establish the technical documentation. The documentation must make it possible to assess the product's conformity to the relevant requirements, and must include an adequate analysis and assessment of the risk(s). The technical documentation must specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture

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and operation of the product. The technical documentation must, wherever applicable, contain at least the following elements:

- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the designated standards and/or other relevant technical specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the enactments where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation must specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

### **Manufacturing**

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

### **UK marking and declaration of conformity**

4.1. The manufacturer must affix the UK marking to each individual product in accordance with regulation 18.

4.2. The manufacturer must draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity must identify the product for which it has been drawn up.

A copy of the declaration of conformity must be made available to the relevant authorities upon request.

### **Authorised representative**

5. The manufacturer's obligations set out in point 4 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

## **MODULE B**

### *Type examination*

1. Type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of these Regulations.

2. Type examination may be carried out in either of the following manners:

- examination of a specimen, representative of the production envisaged, of the complete product (production type),

- assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type),
- assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

**3.** The manufacturer must lodge an application for Type examination with a single approved body of the manufacturer's choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative as well,
- a written declaration that the same application has not been lodged with any other approved body,
- the technical documentation. The technical documentation must make it possible to assess the product's conformity with the applicable requirements of these Regulations and must include an adequate analysis and assessment of the risk(s). The technical documentation must specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation must contain, wherever applicable, at least the following elements:
  - a general description of the product,
  - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
  - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
  - a list of the designated standards and/or other relevant technical specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation must specify the parts which have been applied,
  - results of design calculations made, examinations carried out, etc., and
  - test reports,
- the specimens representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme,
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence must mention any documents that have been used, in particular where the relevant designated standards and/or technical specifications have not been applied in full. The supporting evidence must include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

**4.** The approved body must:

For the product:

**4.1.** examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

For the specimen(s):

**4.2.** verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

**4.3.** carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards and/or technical specifications, these have been applied correctly;

**4.4.** carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

**4.5.** agree with the manufacturer on a location where the examinations and tests will be carried out.

**5.** The approved body must draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations set out in paragraph 8, the approved body must release the content of that report, in full or in part, only with the agreement of the manufacturer.

**6.** Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the approved body must issue a Type examination certificate to the manufacturer. The certificate must contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes must contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body must refuse to issue a Type examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

**7.** The approved body must keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and must determine whether such changes require further investigation. If so, the approved body must inform the manufacturer accordingly.

The manufacturer must inform the approved body that holds the technical documentation relating to the Type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential safety requirements or the conditions for validity of the certificate. Such modifications must require additional approval in the form of an addition to the original Type examination certificate.

**8.** Each approved body must inform the Secretary of State concerning the Type examination certificates and/or any additions thereto which it has issued or withdrawn, and must, periodically or upon request, make available to the Secretary of State the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body must inform the other approved bodies concerning the Type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The authorised body must keep a copy of the Type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer must keep a copy of the Type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

## MODULE C

### *Conformity to type based on internal production control*

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

#### **Manufacturing**

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the Type examination certificate and with the requirements of these Regulations.

#### **Conformity marking and declaration of conformity**

3.1. The manufacturer must affix the UK marking to each individual product that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

3.2. The manufacturer must draw up a written declaration of conformity for a product model and keep it at the disposal of the enforcement authorities for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

A copy of the declaration of conformity must be made available to the enforcement authorities upon request.

#### **Authorised representative**

4. The manufacturer's obligations set out in point 3 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

## SCHEDULE 7

Regulation 3 and 40A

### Approved body requirements

1. A conformity assessment body must be established in the United Kingdom and must have legal personality.

2.—(1) A conformity assessment body must be a third-party body independent of the organisation or the toy it assesses.

(2) A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of toys which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

**3.—(1)** A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the toys which they assess, not the authorised representative of any of those parties.

(2) Sub-paragraph (1) does not preclude the use of assessed toys that are necessary for the operations of the conformity assessment body or the use of such toys for personal purposes.

**4.** A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be directly involved in the design or manufacture, the marketing, installation, use or maintenance of toys it assesses, or represent parties involved in those activities.

**5.** A conformity assessment body must not engage in any activity, including consultancy services, that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are approved.

**6.** Conformity assessment bodies must ensure that the activities of their subsidiaries and subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

**7.** Conformity assessment bodies and their personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

**8.** Conformity assessment bodies must be capable of carrying out the conformity assessment tasks assigned to them by the provisions of regulation 14 or by their approval whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

**9.** At all times and for each conformity assessment procedure and each kind or category of toy in relation to which it has been approved, a conformity assessment body must have at its disposal—

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures. It must have appropriate policies and procedures in place that distinguish between tasks it carries out as an approved body and other activities.
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

**10.** A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment or facilities.

**11.** The personnel responsible for carrying out the conformity assessment activities must have—

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been approved;

- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

**12.** A conformity assessment body must be able to demonstrate the impartiality of their top level management and personnel responsible for assessment.

**13.** The remuneration of the top level management and personnel responsible for assessment of a conformity assessment body must not depend on the number of assessments carried out or on the results of those assessments.

**14.** A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.

**15.** A conformity assessment body must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.

**16.** Paragraph 15 does not prevent the personnel from providing information to the Secretary of State or an enforcement authority.

**17.** A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any approved body coordination group established by the Secretary of State and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.]

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations implement Directive [2009/48/EC](#) of the European Parliament and of the Council of 18th June 2009 on the safety of toys (OJ No L 170, 30.06.2009, p1). The Directive sets harmonised safety requirements for toys and minimum requirements for market surveillance, in order to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market.

The Directive repeals and replaces Council Directive [88/378/EEC](#) of 3rd May 1988 on the approximation of the laws of the Member States concerning the safety of toys (OJ No L 187, 16.7.88, p1) (as amended), which was implemented in the United Kingdom by the Toys (Safety) Regulations 1995 (S.I. 1995/204) (as amended). These Regulations revoke and replace S.I. 1995/204, subject to the continuing application of S.I. 1995/204 to toys placed on the market before these Regulations come into force. (regulation 2).

Regulation 4 sets out the toys to which the Regulations apply. In particular, they apply only to toys placed on the market on or after these Regulations come into force. Regulation 5 defines the essential safety requirements which apply to toys, and is subject to a transitional provision in respect of the requirements concerning the chemical properties of toys placed on the market before 20th July 2013 (regulation 6).

**Changes to legislation:** There are currently no known outstanding effects for the Toys (Safety) Regulations 2011. (See end of Document for details)

Part 2 of the Regulations sets out the prohibitions and obligations on economic operators. These are divided into prohibitions and obligations on manufacturers and their authorised representatives (regulations 10 to 25), on importers (regulations 26 to 32), on distributors (regulations 33 to 37), and on all economic operators (regulations 38 and 39). The various categories of economic operator are defined in regulation 3. In certain circumstances, importers and distributors are required to comply with the duties on manufacturers in place of the duties on importers or distributors (regulations 32 and 37).

Parts 1 and 2 are safety regulations and are enforceable under the Consumer Protection Act 1987. Section 12 of the Act contains offences for breaching safety regulations and other enforcement provisions.

Part 3 of the Regulations sets out the process for the appointment of conformity assessment bodies as UK notified bodies. Conformity assessment is the process of demonstrating whether specified requirements relating to a toy have been fulfilled. Part 4 sets out the functions of UK notified bodies.

Part 5 of the Regulations deals with enforcement of the Regulations, both in cases of formal non-compliance and toys presenting a risk. Regulation 57 addresses the relationship between the General Product Safety Regulations 2005 (SI 2005/1803) and Regulation (EC) No 765/2008 on accreditation and market surveillance (OJ L 218, 13.8.2008, p30) so that the powers in the General Product Safety Regulations 2005 are available to supplement the enforcement provisions in these Regulations.

Part 6 of the Regulations requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

A transposition note and a full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector are available from the BIS website ([www.bis.gov.uk](http://www.bis.gov.uk)).

They are also annexed to the Explanatory Memorandum which is available alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk). Copies have also been placed in the Libraries of both Houses of Parliament.



**Changes to legislation:**

There are currently no known outstanding effects for the The Toys (Safety) Regulations 2011.