# 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

The Secretary of State is a Minister designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) 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.

In accordance with section 11(5) of the Consumer Protection Act 1987(c) 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(d), and paragraph 1A of Schedule 2 to the European Communities Act 1972(e), 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.

# 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.

<sup>(</sup>a) S.I. 1993/2661.

<sup>(</sup>b) 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.

<sup>(</sup>c) 1987 c.43

<sup>(</sup>d) Section 11(1) was amended by S.I. 2005/1803.

<sup>(</sup>e) 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.

#### Revocation, saving and amendment

- 2.—(1) The Toys (Safety) Regulations 1995(a) ("the 1995 Regulations") and the Toys (Safety) (Amendment) Regulations 2010 (b) are revoked.
- (2) The 1995 Regulations, as amended, continue to apply, as if they had not been revoked, to a toy placed on the market before these Regulations come into force.
  - (3) The Pencils and Graphic Instruments (Safety) Regulations 1998(c) 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."

#### Interpretation

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(d);

"the GPSR" means the General Product Safety Regulations 2005(e);

"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(f);

"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

<sup>(</sup>a) S.I. 1995/204, amended by S.I. 2004/1769, S.I. 2005/1082 and S.I. 2010/1928.

**<sup>(</sup>b)** S.I. 2010/1928

<sup>(</sup>c) 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>(</sup>d) OJ No L 170, 30.6.2009, p1.

<sup>(</sup>e) S.I. 2005/1803. (f) OJ No L 218, 13.8.2008, p30.

and regulations(a) 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 EU; and
- (b) places a toy from a third country on the EU 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 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;

"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(**b**) 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 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.

# Toys to which these Regulations apply

- **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;

<sup>(</sup>a) OJ No L 204, 21.7.1998, p37, to which there are amendments not relevant to these Regulations.

**<sup>(</sup>b)** OJ No L 218, 13.8.2008, p82.

(f) products listed in Annex I to the Directive, as amended from time to time.

#### **Essential safety requirements**

- 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

**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(a), and not those in Part III of Annex II to the Directive.

#### Presumption of conformity

- 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

- **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 EU before being brought into conformity with the Directive.

<sup>(</sup>a) 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.

#### 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

- 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

- 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 EC-type examination

- **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).

#### EC declaration of conformity and CE marking

- **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.
- **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 EC-type examination

- 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 Member 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 Member 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) An enforcement authority may, during the 10 year period, request a manufacturer to provide to it, within a specified period—
  - (a) a copy of all or part of the technical documentation drawn up in relation to a toy; and
  - (b) a translation into English of all or part of the technical documentation.
  - (7) A request must be accompanied by the reasons for making the request.
- (8) The specified period must be 30 days beginning with the day on which the request was received by the manufacturer, unless a shorter period is justified in the case of serious and immediate risk.
  - (9) The manufacturer must comply with the request.
- (10) If a manufacturer fails to comply with any of the manufacturer's obligations under paragraphs (1), (2), (3) or (9), 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).

#### Toys to bear CE marking

- **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

- **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

- **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 EC-type examination certificate for review

- **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

- **25.**—(1) A manufacturer may, by a written mandate, appoint a person established within the EU 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.

#### **Importers**

#### Prohibitions on placing toys on the market

- **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

- 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 EC declaration of conformity; and
  - (b) ensure that the technical documentation can be made available to an enforcement authority on request by the authority.
- (2) An enforcement authority may, during the 10 year period, request an importer to provide, within such period as the authority may specify, a copy of all or part of the technical documentation (including the EC declaration of conformity), or a translation of it into English.
  - (3) The request must be accompanied by the reasons for making the request.
  - (4) The importer must comply with the request.

# 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

- 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**

- **36.**—(1) An enforcement authority may request a distributor to provide, within such period as the authority may specify, any information or documents within the distributor's knowledge or possession which demonstrate that the toy will satisfy the essential safety requirements during its foreseeable and normal period of use.
  - (2) A request must be accompanied by the reasons for making the request.
  - (3) The distributor must comply with the request.
- (4) A request for information or documents may not be made more than 10 years after the day on which the toy is placed on the market.

# 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 CE marking**

- **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.
- (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.

#### PART 3

# Designation of Notified Bodies

#### 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 member States,
  - (b) no objections have raised by the Commission or the other member States within the time periods in Article 31 of the Directive.
- (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.

# Duration, variation and termination of designation

- **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 UK Notified Bodies

# **Duty to perform EC-type examinations**

- **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 EC-type examinations

- **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 EC-type examination certificate, and refusal and appeal against refusal to issue certificate

- **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 EC-type examination certificate) where a toy fails to comply with essential safety requirements

**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 subparagraph (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 subparagraph (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 UK notified bodies to other notified bodies

**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 UK notified bodies in relation to EC-type examination certificates

- **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 being reviewed by a notified body;
  - (c) where 5 years have elapsed since the certificate was last reviewed by a notified body without it having being 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.**—(1) A UK notified body must participate in 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.

#### Subcontracting by a UK notified body

- **49.**—(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.

#### Charging of fees by UK notified body

- **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 UK notified bodies to the Secretary of State

- **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

- **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;
  - (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 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.

# Enforcement action in cases of toys presenting a risk

- **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 Member 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).

# Notification of enforcement action taken in cases of toys presenting a risk

- **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 other 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) Where 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.

#### **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(a) 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(b).".

#### PART 6

#### Review

#### Review

- 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.

Edward Davey
Minister for Employment Relations, Consumer and Postal Affairs
Department for Business, Innovation and Skills

24th July 2011

<sup>(</sup>a) S.I. 2005/1803.

**<sup>(</sup>b)** OJ No L218, 13.8.2008, p30.

#### **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).

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). They are also annexed to the Explanatory Memorandum which is available alongside the instrument on www.legislation.gov.uk. Copies have also been placed in the Libraries of both Houses of Parliament.

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# **CONSUMER PROTECTION**

The Toys (Safety) Regulations 2011