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STATUTORY INSTRUMENTS

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**2011 No. 1881**

**The Toys (Safety) Regulations 2011**

**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.