



STATUTORY INSTRUMENTS.

**S.I. No. 14 of 2011**



EUROPEAN COMMUNITIES (SAFETY OF TOYS) REGULATIONS  
2011

**(Prn. A11/0095)**

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I, BATT O'KEEFFE, Minister for Enterprise, Trade and Innovation, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009<sup>1</sup>, hereby make the following regulations:

*Citation and Commencement*

1. (1) These Regulations may be cited as the European Communities (Safety of Toys) Regulations 2011.

(2) These Regulations come into operation on 20 July 2011.

*Revocation*

2. (1) The European Communities (Safety of Toys) Regulations 1990 (S.I. No. 32 of 1990) ("1990 Regulations"), other than Regulation 4 in so far as that Regulation relates to Article 2(1) and Part 3 of Annex II of Council Directive 88/378/EEC of 3 May 1988<sup>2</sup> ("Directive 88/378/EEC"), are revoked with effect from 20 July 2011.

(2) The said Regulation 4, in so far as it so relates, is revoked with effect from 20 July 2013.

(3) References in any other instrument to the Regulations revoked under *paragraphs (1) and (2)* shall be construed as references to these Regulations, as appropriate.

*Scope*

3. (1) These Regulations apply to toys which are placed on the market on or after 20 July 2011.

(2) These Regulations do not apply to the following toys:

(a) playground equipment intended for public use;

(b) automatic playing machines, whether coin-operated or not, intended for public use;

(c) toy vehicles equipped with combustion engines;

(d) toy steam engines; and

<sup>1</sup>OJ No. L 170, 30.6.2009, p. 1.

<sup>2</sup>OJ No. L 187, 16.7.1988, p. 1.

*Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 21st January, 2011.*

(e) slings and catapults.

(3) Nothing in these Regulations shall impede the making available on the market of toys which are in accordance with the 1990 Regulations and which were placed on the market before 20 July 2011.

(4) In addition to the requirement of *paragraph 3*, nothing in these Regulations shall impede the making available on the market of toys which are in accordance with the requirements of these Regulations, except those set out in Part III of Annex II, provided that such toys meet the requirements set out in Part 3 of Section 2 of Annex II to Directive 88/378/EEC and were placed on the market before 20 July 2013.

#### *Definitions*

4. (1) In these Regulations, save where the context otherwise requires—

“accreditation” has the meaning assigned to it by Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008<sup>3</sup> (“Regulation (EC) No. 765/2008”);

“Agency” means the National Consumer Agency;

“Annex” means an Annex to the Toy Safety Directive;

“Article” means an Article of Regulation (EC) No. 765/2008;

“applicable requirements” means the requirements of these Regulations;

“approved model” means a model of a toy in respect of which an EC type-examination certificate is in force;

“authorised officer” means a person appointed and holding office under *Regulation 38*;

“Commission” means the European Commission;

“Community” means the European Communities;

“competent authority” means the body referred to in *Regulation 6*;

“compliant” means compliant with the requirements of these Regulations;

“conformity” means conformity with the relevant Community harmonisation legislation;

“EC declaration of conformity” means the declaration referred to in *Regulation 17*;

“EC-type examination” means the examination referred to in *Regulation 20*;

<sup>3</sup>OJ No. L 218, 13.8.2008, p. 30.

“essential safety requirements” mean the general safety requirements specified in *Regulation 13(1)* and the Particular Safety Requirements set out in Annex II;

“market” means the Community market;

“market surveillance authority” means the body referred to in Regulation 6;

“Minister” means the Minister for Enterprise, Trade and Innovation;

“notified body” means a conformity assessment body that has been notified under these Regulations;

“prescribed” means prescribed by regulations made by the Minister;

“required” means required by these Regulations;

“toy” means a product designed or intended, whether or not exclusively, for use in play by children under 14 years of age, but does not include a product listed in Annex I;

“Toy Safety Directive” means Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009<sup>1</sup>.

(2) A word or expression which is used in these Regulations and is also used in the Toy Safety Directive has, unless the contrary intention appears, the same meaning in these Regulations as it has in that Directive.

*These Regulations “relevant statutory provisions” within meaning of Consumer Protection Act 2007*

5. The definition of “relevant statutory provisions” in section 2 of the Consumer Protection Act 2007 (as amended by Regulation 18(3) of the European Communities (Names and Labelling of Textile Products) Regulations 2010 (S.I. No. 485 of 2010)) is amended by substituting for paragraphs (e) and (f) the following:

“(e) this Act and any instrument made under this Act for the time being in force,

(f) the European Communities (Names and Labelling of Textile Products) Regulations 2010 (S.I. No. 485 of 2010), and

(g) the European Communities (Safety of Toys) Regulations 2011;”.

*Agency to be market surveillance authority and competent authority*

6. The Agency, for the purposes of these Regulations, is both the market surveillance authority and the competent authority in the State.

*Obligations of manufacturers*

7. (1) A manufacturer shall, before placing a toy on the market, comply with *Regulation 21*.

<sup>1</sup>OJ No. L 170, 30.6.2009, p. 1

(2) When placing a toy on the market, a manufacturer shall—

- (a) ensure that it has been designed and manufactured in accordance with the requirements set out in the essential safety requirements,
- (b) draw up the required technical documentation in accordance with *Regulation 24* and carry out or have carried out the applicable conformity assessment procedure in accordance with *Regulation 20*,
- (c) where compliance of a toy with the applicable requirements has been demonstrated by that procedure, draw up an EC declaration of conformity, and affix the CE marking as provided for in these Regulations,
- (d) keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market,
- (e) ensure that procedures are in place for series production to remain in conformity; changes in toy design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is declared shall be adequately taken into account,
- (f) when deemed appropriate with regard to the risks presented by a toy, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and keep distributors informed of any such monitoring,
- (g) ensure that his, her or its toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy,
- (h) indicate his, her or its name, registered trade name or registered trade mark and the address at which he, she or it can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy; the address shall indicate a single point at which the manufacturer can be contacted, and
- (i) ensure that the toy is accompanied by instructions and safety information in English.

(3) A manufacturer who considers or has reason to believe that a toy which he, she or it has placed on the market is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, the manufacturer shall immediately inform the competent authorities of the Member States in

which he, she or it made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(4) A manufacturer shall, further to a reasoned request from the competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy, in English. He, she or it shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by a toy which he, she or it has placed on the market.

#### *Authorised representatives*

8. (1) A manufacturer may, by a written mandate, appoint an authorised representative.

(2) The obligations laid down in *Regulation 7(2)* and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

(3) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of 10 years from the date when the toy was placed on the market;
- (b) further to a reasoned request from a competent authority in a Member State, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy;
- (c) cooperate with each such competent authority, at its request, on any action taken to eliminate the risks posed by a toy covered by the mandate.

#### *Obligations of importers*

9. (1) An importer shall place only a toy which is compliant on the market.

(2) Before placing a toy on the market, an importer shall ensure that—

- (a) the appropriate conformity assessment procedure has been carried out by the manufacturer,
- (b) the manufacturer has drawn up the technical documentation, that the toy bears the required conformity marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in *Regulation 7(2)(g)* and *(h)*,
- (c) the toy is accompanied by instructions and safety information in English, and

- (d) while the toy is under his, her or its responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in the essential safety requirements.

(3) Where an importer considers or has reason to believe that a toy is not in conformity with the requirements set out in the essential safety requirements, he, she or it shall not place the toy on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the importer shall inform the manufacturer and the competent authority to that effect.

(4) An importer shall indicate his, her or its name, registered trade name or registered trade mark, and the address at which he, she or it can be contacted, on the toy or, where that is not possible, on its packaging or in a document accompanying the toy.

(5) When deemed appropriate with regard to the risks presented by a toy placed on the market by him, her or it, an importer shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring.

(6) An importer who considers or has reason to believe that a toy placed on the market by him, her or it is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, the importer shall immediately inform the competent authority, giving details, in particular, of the non-compliance and of any corrective measures taken.

(7) An importer shall, for a period of 10 years after a toy has been placed on the market by him, her or it, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

(8) An importer shall, further to a reasoned request from the competent authority—

- (a) provide, in English, that authority with all the information and documentation necessary to demonstrate the conformity of the toy, and
- (b) cooperate with that authority, at its request, on any action taken to eliminate the risks posed by toys which he, she or it has placed on the market.

#### *Obligations of distributors*

10. (1) When making a toy available on the market, a distributor shall act with due care in relation to the applicable requirements.

(2) Before making a toy available on the market, a distributor shall verify that the toy bears the required conformity marking, that it is accompanied by

the required documents and by instructions and safety information in a language or languages easily understood by consumers in each Member State in which the toy is to be made available on the market (and in the case of the State, in English), and that the manufacturer and the importer have complied with the requirements set out in *Regulation 7(2)(g) and (h)* and *Regulation 9(4)*.

(3) Where a distributor considers or has reason to believe that a toy is not in conformity with the requirements set out in the essential safety requirements, he, she or it shall not make the toy available on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the distributor shall inform the manufacturer or the importer, as well as the competent authority, to that effect.

(4) A distributor shall ensure that, while a toy is under his, her or its responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in the essential safety requirements.

(5) A distributor who considers or has reason to believe that a toy which he, she or it has made available on the market is not in conformity with the relevant Community harmonisation legislation shall make sure that the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the toy presents a risk, the distributor shall immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(6) A distributor shall, further to a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy. He, she or it shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by a toy which he, she or it has made available on the market.

*Cases in which obligations of manufacturers apply to importers and distributors*

11. (1) An importer or distributor shall be considered a manufacturer for the purposes of these Regulations, and be subject to the obligations of the manufacturer under *Regulation 7*, where he, she or it places a toy on the market under his, her or its name or trademark or modifies a toy already placed on the market in such a way that compliance with the applicable requirements may be affected.

*Identification of economic operators*

12. (1) An economic operator shall, on request, identify the following to the market surveillance authorities:

- (a) each economic operator who has supplied him, her or it with a toy;
- (b) each economic operator to whom he, she or it has supplied a toy.

(2) An economic operator shall ensure that he, she or it is able to present the information referred to in *paragraph (1)* for a period of—

- (a) 10 years after the toy has been placed on the market, in the case of the manufacturer, and
- (b) 10 years after he, she or it has been supplied with the toy, in the case of other economic operators.

*General safety requirements*

13. (1) Toys, including the chemicals they contain, shall 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. The ability of the users and, where appropriate, their supervisors shall 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. Labels affixed in accordance with *Regulation 14(4), (5) and (6)* and instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks.

(2) Toys placed on the market in the State shall comply with the essential safety requirements during their foreseeable and normal period of use.

*Warnings*

14. (1) Where appropriate for safe use, warnings made for the purposes of *Regulation 13(1)* shall specify appropriate user limitations in accordance with Part A of Annex V.

(2) As regards the categories of toy listed in Part B of Annex V, the warnings set out therein shall be used. The warnings set out in points 2 to 10 of Part B of Annex V shall be used as worded therein.

(3) Toys shall not bear one or more of the specific warnings set out in Part B of Annex V where that warning conflicts with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

(4) A manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging shall have appropriate warnings affixed to them.

(5) The warnings shall be in English and shall be preceded by the words “Warning” or “Warnings”, as the case may be.

(6) Warnings which determine the decision to purchase the toy, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, shall appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, including in cases where the purchase is made on-line.

*Free movement*

15. Nothing in these Regulations shall impede the making available on the market in the State of a toy which complies with the Toy Safety Directive.

*Presumption of conformity*

16. A toy which is in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in the essential safety requirements.

*EC declaration of conformity*

17. (1) An EC declaration of conformity shall state that the fulfilment of the requirements set out in the essential safety requirements has been demonstrated.

(2) An EC declaration of conformity shall contain the elements specified in Annex III and the relevant modules set out in Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008<sup>4</sup> (“Decision No 768/2008/EC”) and shall be continuously updated. It shall be structured as set out in Annex III. It shall be translated into English when being placed on the market in the State.

(3) By drawing up an EC declaration of conformity, a manufacturer assumes responsibility for the compliance of the toy to which it relates.

*General principles of the CE marking*

18. All toys made available on the market shall bear the CE marking, as subject to the general principles set out in Article 30. Toys bearing the CE marking shall be presumed to comply with the Toy Safety Directive. Toys not bearing a CE marking or which do not otherwise comply with these Regulations may be shown and used at trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that they do not comply with these Regulations and that they will not be made available on the market unless they are brought into conformity.

*Rules and conditions for affixing the CE marking*

19. (1) The CE marking shall be affixed visibly, legibly and indelibly to a toy, to an affixed label or to the packaging. In the case of a small toy and a toy consisting of small parts, the CE marking may alternatively be affixed to a label or an accompanying leaflet. Where, in the case of a toy sold in a counter displays, that is not technically possible, and on condition that the counter display was originally used as packaging for the toy, the CE marking may be affixed to the counter display.

(2) Where the CE marking is not visible from outside the packaging, if any, it shall as a minimum be affixed to the packaging.

(3) The CE marking shall be affixed before the toy is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

<sup>4</sup>OJ No. L 218, 13.8.2008, p. 82.

*EC-Type Examination*

20. (1) For the purposes of these Regulations, EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of a toy satisfies the provisions of these Regulations.

(2) Before placing a toy on the market, manufacturers shall use the conformity assessment procedures referred to in *paragraphs 3 and 4* to demonstrate that the toy complies with the essential safety requirements.

(3) If the manufacturer has applied harmonised standards, which have been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, he, she or it shall use the internal production control procedure set out in Module A of Annex II to Decision No. 768/2008/EC.

(4) In the following cases, a toy shall be submitted to EC-type examination together with the conformity to type procedure set out in Module C of Annex II to Decision No. 768/2008/EC:

- (a) where harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy do not exist;
- (b) where the harmonised standards referred to in *subparagraph (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 specified in *subparagraph (a)* has been published with a restriction;
- (d) where the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

*Safety assessments*

21. A manufacturer shall, before placing a toy on the market, 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.

*Application for EC-type examination*

22. (1) An application for EC-type examination, performance of that examination and issue of the EC-type examination certificate shall be carried out in accordance with the procedures set out in Module B of Annex II to Decision No. 768/2008/EC. EC-type examination shall be carried out in the manner specified in the second indent of point 2 of that Module.

(2) An application under *paragraph (1)* shall be made in writing and shall contain such information and be supported by such documents as the notified body may reasonably require, including—

- (a) a description of the toy, and

- (b) the name and address of the manufacturer or his, her or its authorised representative or representatives, and the place of manufacture of the toy.

(3) When a notified body carries out the EC-type examination, it shall evaluate, if necessary together with the manufacturer, an analysis of the hazards the toy may present, in accordance with *Regulation 21*.

*Description of the EC-type examination certificate*

23. (1) The EC-type examination certificate shall include a reference to the Toy Safety Directive, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference to the relevant test report.

(2) The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy. The maximum period between reviews shall be five years.

(3) The EC-type examination certificate shall be withdrawn if the toy fails to comply with the essential safety requirements.

(4) Notified bodies shall withdraw EC-type examination certificates which are no longer valid.

(5) Notified bodies shall not grant an EC-type examination certificate for a toy in respect of which a certificate has been refused or withdrawn.

(6) The technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in English.

*Technical documentation*

24. (1) The technical documentation referred to in *Regulation 7(2)* shall contain all relevant data or details of the means used by a manufacturer to ensure that a toy complies with the essential safety requirements. It shall, in particular, contain the documents listed in Annex IV.

(2) The technical documentation shall be drawn up in English.

(3) Following a reasoned request from the market surveillance authority of a Member State, a manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State within thirty days of receipt of the request. In cases of serious and immediate risk, a shorter deadline may be set.

(4) If a manufacturer does not comply with the requirements of *paragraphs (1), (2) and (3)*, the market surveillance authority may require the manufacturer to have a test performed by a notified body at the manufacturer's own expense within a specified period of time in order to verify compliance with the harmonised standards and essential safety requirements.

*Appointment of notified bodies and their duties*

25. (1) The Minister shall act as a notifying authority in the State, with the authority to designate notified bodies.

(2) The Minister may appoint, in writing, such one or more persons or bodies as satisfy the minimum criteria set out in the Schedule to be a notified body in the State, for a specified period of time, to carry out the assessment of conformity, with the Toy Safety Directive and these Regulations, of a toy for placing on the market. Subject to *paragraph (3)*, the duration of the appointment shall be at the discretion of the Minister who may renew or withdraw the appointment as appropriate.

(3) The appointment may be made subject to such conditions as the Minister may determine, and such conditions may include conditions which apply upon, during or following the termination of the appointment.

(4) (a) Where the Minister has ascertained or has been informed that a notified body no longer meets the requirements laid down in the Schedule, or that it is failing to fulfil its obligations, the Minister shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements of fulfil those obligations. The Minister shall immediately inform the Commission and the other Member States accordingly.

(b) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Minister shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the Minister and the Agency, as the Minister may direct.

(5) Such an appointment shall be withdrawn upon the expiry of 90 days notice in writing given by a notified body to the Minister.

(6) The Minister shall apply the criteria set out in the Schedule in assessing the bodies to be notified and the bodies already notified.

(7) A notified body shall—

(a) conform with the minimum criteria set out in the Schedule, and

(b) undertake the functions and comply with requirements specified in the Schedule relating to EC type examinations.

(8) The Minister shall ensure that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

(9) The Minister shall not offer or provide any activities that conformity assessment bodies perform, nor offer or provide consultancy services on a commercial or competitive basis.

*Provision of information to the Commission, other Member States and the public on notified bodies*

26. (1) The Minister shall, without delay, inform the Commission and other Member States of the name and address of each notified body appointed to carry out the assessment of conformity in accordance with the Toy Safety Directive and these Regulations. The information shall include full details of the conformity assessment procedures, the conformity assessment module or modules, the toy or toys concerned and the relevant attestation of competence.

(2) The Minister shall, without delay, inform the Commission and other Member States of any subsequent amendments to the information provided pursuant to *paragraph (1)*.

(3) The Minister shall publish in *Iris Oifigiúil* the relevant information concerning each notified body appointed by him or her, including information concerning the withdrawal of an appointment.

*Monitoring of notified bodies*

27. (1) A notified body shall be monitored by or on behalf of the Minister as is necessary to ensure—

- (a) compliance with any condition specified in the appointment, and
- (b) that it continues to meet the criteria set out in the Schedule.

(2) Such monitoring may include the examination of premises, equipment and documents.

(3) The notified body shall provide to the person carrying out the monitoring such assistance, including documents, as is necessary for the proper conduct of the inspection.

(4) The Minister shall furnish a written report on the findings of such monitoring to the notified body which has been investigated.

*Suspension, withdrawal or restriction of certificates or approvals by notified bodies*

28. (1) If a notified body finds that relevant requirements of the Directive 2009/48/EC have not been met or are no longer being met by a manufacturer, or that an EC type-examination certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued, or place restrictions on it.

(2) A notified body shall give detailed reasons in writing for any action taken by it pursuant to *paragraph (1)*.

(3) A notified body may choose not to use the sanctions available to it under *paragraph (1)* if compliance with its requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.

*Provision of information by notified bodies to notifying authority*

29. (1) A notified body shall inform the Minister of the following:

- (a) any refusal, restriction, suspension or withdrawal of an EC-type examination certificate;
- (b) any circumstances affecting the scope of and conditions for notification;
- (c) any request for information which it has received from a market surveillance authority in a Member State regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of its notification, and any other activity performed, including cross-border activities and subcontracting.

(2) When the Minister receives information pursuant to paragraph (1), he or she shall inform the Commission and other Member States.

(3) Notified bodies shall provide the other bodies notified under the Toy Safety Directive 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.

(4) A manufacturer aggrieved by a decision of a notified body under *Regulation 28(1)* may appeal the decision to the Minister.

*Application for notification*

30. (1) A conformity assessment body shall submit an application for notification under the Toy Safety Directive to the Minister.

(2) The Minister may only notify a conformity assessment body which has satisfied the requirements laid down in the Schedule.

(3) The application referred to in *paragraph (1)* shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the toy or toys for which the body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in the Schedule.

(4) Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the Minister with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in the Schedule.

(5) Where a notification is not based on an accreditation certificate, the Minister shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's

competence and the arrangements in place to ensure the body will be monitored regularly and will continue to satisfy the requirements laid down in the Schedule.

(6) The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or another Member State within two weeks of a notification where an accreditation certificate is used, or within two months of a notification where accreditation is not used. Only once the relevant period has passed without objection, can such a body be considered a notified body for the purposes of these Regulations.

#### *Operational obligations of notified bodies*

31. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in *Regulation 20*.

(2) A conformity assessment shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. A notified body shall perform its activities taking 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. In so doing, it shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the toy with the Toy Safety Directive.

(3) Where a notified body finds that the requirements set out in the essential safety requirements or in corresponding harmonised standards have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue the EC-type examination certificate.

(4) Where, in the course of the monitoring of conformity following the issue of an EC-type examination certificate, a notified body finds that a toy is no longer in compliance, it shall require the manufacturer to take appropriate corrective measures, and shall suspend or withdraw the EC-type examination certificate if necessary.

(5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EC-type examination certificate, as appropriate.

#### *Obligations and Powers of the Agency*

32. (1) When the Agency takes measures as provided for in these Regulations, in particular that referred to in *paragraph (2)*, it shall take due account of the precautionary principle.

(2) The Agency shall organise and perform surveillance of toys placed on the market in accordance with Articles 15 to 29. In addition, *paragraphs (3) to (5)* shall apply.

(3) The Agency may request a notified body to provide information relating to any EC-type examination certificate which that body has issued or withdrawn, or which relates to any refusal to issue such a certificate, including the test reports and technical documentation.

(4) If the Agency finds that a toy is not in conformity with the requirements set out in the essential safety requirements, it shall, where appropriate, instruct the notified body to withdraw the EC-type examination certificate in respect of that toy.

(5) Where necessary, and in particular in the cases specified in *Regulation 23(2)*, the Agency shall instruct the notified body to review the EC-type examination certificate.

*Procedure for dealing with toys presenting a risk at national level*

33. (1) Where the Agency has taken action pursuant to Article 20, or where it has sufficient reason to believe that a toy covered by these Regulations presents a risk to the health or safety of persons, it shall carry out an evaluation in relation to the toy concerned covering all the requirements laid down in these Regulations. The relevant economic operators shall cooperate as necessary with the Agency.

(2) Where, in the course of that evaluation, the Agency finds that the toy does not comply with the requirements laid down in these Regulations, it shall without delay require each relevant economic operator to take appropriate corrective action to bring the toy into compliance with those requirements, to withdraw the toy from the market, or to recall it within a reasonable period, commensurate with the nature of the risk. Article 21 shall apply to those measures. The Agency shall inform the relevant notified body accordingly.

(3) Where the Agency considers that non-compliance is not restricted to the territory of the State, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the relevant economic operators to take.

(4) Each relevant economic operator shall ensure that appropriate corrective action is taken in respect of a toy which that operator has made available on the market.

(5) Where a relevant economic operator does not take adequate corrective action within a reasonable period as referred to in *paragraph 2*, the Agency shall take appropriate provisional measures to prohibit or restrict the toy being made available on the market in the State, to withdraw the toy from that market or to recall it. The Agency shall inform the Commission and the other Member States, without delay, of those measures.

(6) The information shall include all available details, in particular the data necessary for the identification of the non-compliant toy, the origin of the toy, the nature of the alleged non-compliance and the risk involved, the nature and duration of the measures taken in the State, and the arguments put forward by the relevant economic operator. In particular, the Agency shall indicate whether the non-compliance is due to either—

- (a) failure of the toy to meet requirements relating to the health or safety of persons, or

(b) shortcomings in the harmonised standards.

(7) The Agency shall ensure that appropriate restrictive measures are taken in respect of a toy which has been subject to restrictive measures by the market surveillance authorities of another Member State, such as withdrawal of the toy from the market in the State, without delay.

(8) Where, within three months of receipt of the information referred to in *paragraph 6*, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by the Agency, that measure shall be deemed to be justified.

*Exchange of information — Community Rapid Information Exchange System*

34. If a measure referred to in *Regulation 33(5)* is a type of measure which is required under Article 22 to be notified through the Community Rapid Information Exchange System, it shall not be necessary to make a separate notification under *Regulation 33(5)*, provided that the following conditions are met:

- (a) the Community Rapid Information Exchange notification indicates that the notification of the measure is also required by the Toy Safety Directive;
- (b) the supporting evidence referred to in *Regulation 33(6)* is enclosed with the Community Rapid Information Exchange notification.

*Formal non-compliance*

35. (1) Without prejudice to *Regulation 33*, where the Agency makes one of the following findings, it shall require each relevant economic operator to put an end to the non-compliance concerned:

- (a) that the CE marking has been affixed in violation of *Regulation 18* or *19*;
- (b) that the CE marking has not been affixed;
- (c) that the EC declaration of conformity has not been drawn up;
- (d) that the EC declaration of conformity has not been drawn up correctly;
- (e) that technical documentation is either not available or not complete.

(2) Where the non-compliance referred to in paragraph 1 persists, the Agency shall take appropriate measures to restrict or prohibit the toy being made available on the market, or shall ensure that it is recalled or withdrawn from the market.

*Transparency and confidentiality*

36. When the Agency adopts measures under these Regulations, the requirements of transparency and confidentiality provided for in Article 16 of Directive 2001/95/EC shall apply.

*Motivation of measures*

37. Any measure taken pursuant to these Regulations to prohibit or restrict the placing on the market of a toy, to withdraw a toy or to recall a toy from the market shall state the exact grounds on which it is based. Such a measure shall be notified without delay to the party concerned, which shall at the same time be informed of the remedies available to him, her or it under the laws in force in the State and of the time limits applicable to them.

*Appointment of authorised officers*

38. The Agency may appoint such and so many persons as it thinks fit to be authorised officers for the purposes of these Regulations and any function conferred on the Agency by these Regulations may be performed by an authorised officer.

*Warrants or certificates of appointment*

39. A person appointed under *Regulation 38* shall, on his or her appointment, be furnished by the Agency with a warrant or certificate of his or her appointment, and when exercising a power conferred by these Regulations shall, if requested by any person thereby affected, produce a copy of such warrant or certificate to that person for inspection, together with a form of personal identification.

*Powers of authorised officers*

40. (1) An authorised officer shall, for the purposes of these Regulations, have power to do any one or more of the following:

- (a) subject to *paragraph (4)*, at any time enter, inspect, examine and search any place;
- (b) inquire into, search, examine and inspect—
  - (i) any place referred to in *subparagraph (a)*,
  - (ii) any activity, installation, process, procedure, matter or thing at or in that place, and
  - (iii) any toy or any record relating to such toy or to a component of such toy,

to ascertain whether these Regulations have been or are being complied with and, for that purpose, take with him or her and use any equipment or materials he or she consider necessary;

- (c) require that that place and anything at or in it be left undisturbed for so long as is reasonably necessary for the purposes of any search,

examination, investigation, inspection or inquiry under these Regulations;

- (d) require the person in charge to produce to the authorised officer—
  - (i) any toy which is in the possession or under the control of such person, and
  - (ii) any records, and in the case of such information in a non-legible form, to reproduce it in a legible form, and to give to the authorised officer such information as the authorised officer may reasonably require in relation to any entries in those records;
- (e) inspect and take copies of or extracts from any such records or any electronic information system at that place, including in the case of information in a non-legible form, copies of or extracts from such information in a permanent legible form or require that such copies be provided;
- (f) require a person at or in that place by whom or on whose behalf a computer is or has been used to produce or store records or any person having control of, or otherwise concerned with the operation of the computer, to afford the authorised officer access thereto and all reasonable assistance as the authorised officer may require;
- (g) remove from that place and retain the records (including documents stored in a non-legible form) and copies taken and detain the records for such period as the authorised officer reasonably considers to be necessary for further examination or until the conclusion of any legal proceedings;
- (h) require that records at or in that place be maintained for such period as may be reasonable;
- (i) require the person in charge to give the authorised officer such information as the authorised officer may reasonably require for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;
- (j) require the person in charge to give the authorised officer such assistance and facilities within the person's power or control as are reasonably necessary to enable the authorised officer to exercise any of his or her powers under these Regulations;
- (k) require by notice, at a time and place specified in the notice, any person (including the person in charge) to give the authorised officer any information that the authorised officer may reasonably require in relation to any toy at or in the place, and to produce to the authorised officer any records that are under that person's power or control;

- (l) examine any person whom the authorised officer reasonably believes to be able to give to the authorised officer information relevant to any search, examination, investigation, inspection or inquiry under these Regulations and require the person to answer such questions as the authorised officer may ask relative to the search, examination, investigation, inspection or inquiry and to sign a declaration of the truth of the answers;
- (m) require that any procedure be followed for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;
- (n) take any measurements or photographs or make any tape, electrical or other recordings that the authorised officer considers necessary for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;
- (o) take samples of air, soil, water or waste at or near that place;
- (p) where appropriate, install, use and maintain at that place monitoring instruments, systems and seals for the purposes of these Regulations;
- (q) at that place, or at any other location, carry out, or have carried out, such testing, examination or analysis of any toy found at that place, as he or she reasonably considers to be necessary, and for that purpose—
  - (i) require the person in charge to supply to the authorised officer without charge any toy, or a sample thereof, or
  - (ii) remove, or have removed, to another location, any toy, or a sample thereof;
- (r) cause any toy found at that place in respect of which there has been or there appears to the authorised officer to have been a contravention of these Regulations, to be subjected to any testing, examination or analysis in accordance with subparagraph (q) (but not so as to damage or destroy it unless necessary for the purposes of these Regulations) and where an authorised officer proposes to exercise the power conferred by this subparagraph in the case of any such toy found at any place, he or she shall, if so requested by the person in charge, cause anything that is to be done by virtue of that power to be done in the presence of that person;
- (s) remove and retain for such period as is necessary any toy found at that place for all or any of the following purposes:
  - (i) to examine or arrange for the examination, testing or analysis of the toy;
  - (ii) to ensure that it is not tampered with before the examination of it under *subparagraph (i)* is completed;

(iii) to ensure that it is available for use as evidence in any proceedings;

(t) where necessary—

(i) require the disposal of any toy in respect of which there has been or there appears to the authorised officer to have been a contravention of these Regulations at the expense of the person in charge, or remove that toy and arrange for it to be disposed of at the expense of the person in charge, and

(ii) require that such disposal shall be—

(I) such as will prevent the toy from being used or placed on the market, and

(II) in compliance with requirements under the Waste Management Acts 1996 to 2003;

(u) require the removal from the market of a toy by the person who has placed that toy on the market, where it appears to the authorised officer that, in relation to that toy, these Regulations have been contravened.

(2) Where a toy is found at a place, and an inquiry is made by an authorised officer in the course of a search, examination, investigation or inspection as to the identity of the person who supplied that toy, the person in charge shall give the authorised officer the name and address of the supplier from whom the toy was purchased or otherwise obtained.

(3) Before exercising any of the powers conferred by *subparagraphs (q) to (t)* of *paragraph (1)*, an authorised officer shall, in so far as it is practicable, consult such persons as appear to him or her to be appropriate for the purpose of ascertaining what dangers, if any, there may be in doing what he or she proposes to do under those subparagraphs.

(4) An authorised officer shall not enter a dwelling other than—

(a) with the consent of the occupier, or

(b) in accordance with a warrant of the District Court issued under *paragraph (7)* authorising such entry.

(5) The Agency may authorise such and so many other persons as it considers appropriate to accompany an authorised officer in the performance of his or her functions.

(6) Where an authorised officer in the exercise of his or her powers under this Regulation is prevented from entering any place, an application may be made to the District Court for a warrant under *paragraph (7)* authorising such entry.

(7) Without prejudice to the powers conferred on an authorised officer by or under any other provision of this Regulation, if a judge of the District Court is satisfied by information on oath of an authorised officer that there are reasonable grounds for believing that—

- (a) there is any toy at any place or any records (including documents stored in a non-legible form) or information, relating to a place or to a toy, that the authorised officer requires to inspect for the purposes of these Regulations, held at any place, or
- (b) there is, or such an inspection is likely to disclose, evidence of a contravention of these Regulations, the judge may issue a warrant authorising an authorised officer, accompanied by such other authorised officers or such other competent persons as may be appropriate or members of the Garda Síochána as may be necessary, at any time or times, within one month from the date of issue of the warrant, on production of the warrant if requested, to enter the place, if necessary by the use of reasonable force, and perform the functions conferred on an authorised officer by or under these Regulations.

(8) Where an authorised officer has reasonable grounds for apprehending any serious obstruction in the performance of his or her functions or otherwise considers it necessary, he or she may be accompanied by a member or members of the Garda Síochána and by any other person or persons authorised by the Agency, when performing any functions conferred on him or her by or under these Regulations.

(9) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations he or she may require that person to provide him or her with the person's name and the address at which the person ordinarily resides.

(10) A statement or admission made by a person pursuant to a requirement under *subparagraph (i), (k) or (l) of paragraph (1)* shall not be admissible in proceedings brought against that person for an offence (other than an offence under *Regulation 48(4)* relating to a breach of, or failure to comply with, an obligation in the said *subparagraph (i), (k) or (l)*).

(11) In this Regulation and in Regulations 41 and 42—

“person in charge” means, in relation to a place—

- (a) the person under whose direction and control the activities at that place are being conducted, or
- (b) the person whom the authorised officer has reasonable grounds for believing is in control of that place;

“place” means a place at or in which the authorised officer concerned believes there is or may be toy connected to a matter to which these Regulations apply, or may apply.

*Contravention notice*

41. (1) An authorised officer who is of the opinion that a person is contravening or has contravened any of the provisions of these Regulations may serve a notice (in these Regulations referred to as a “contravention notice”) on the person in charge.

(2) A contravention notice shall—

- (a) state that the authorised officer is of the opinion referred to in *paragraph (1)*,
- (b) state the reason for that opinion,
- (c) identify the relevant provision, in respect of which that opinion is held,
- (d) direct the person to—
  - (i) remedy, by a date specified in the notice, the contravention or the matters occasioning that notice, or
  - (ii) remove a toy from the market, by a date specified in the notice that shall not be earlier than the end of the period within which an appeal may be made under *paragraph (6)*,
- (e) include information regarding the making of an appeal under *paragraph (6)* and the provisions of *paragraph (7)*,
- (f) include any other requirement that the authorised officer considers appropriate, and
- (g) be signed and dated by the authorised officer.

(3) A contravention notice may include directions—

- (a) as to the measures to be taken to remedy any contravention or matter to which the notice relates, or to otherwise comply with the notice, and
- (b) to bring the notice to the attention of any person who may be affected by it or the public generally.

(4) A person on whom a contravention notice has been served who is of the opinion that the contravention notice has been complied with shall confirm in writing to the authorised officer concerned that the matters referred to in the notice have been so remedied.

(5) Where a person on whom a contravention notice has been served so confirms in writing in accordance with *paragraph (4)* that the matters referred to in the contravention notice have been remedied, the authorised officer concerned shall, on being satisfied that the matters have been so remedied, within one month of receipt of such confirmation, give notice to the person concerned of compliance with the contravention notice.

(6) A person aggrieved by a contravention notice may, within 14 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the district court district in which the notice was served and, in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(7) A person who appeals under *paragraph (6)* shall at the same time notify the Agency of the appeal and the grounds for the appeal and the Agency shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal.

(8) Where an appeal under *paragraph (6)* is taken, and the contravention notice is not cancelled, the notice shall take effect on the later of—

- (a) the day next following the day on which the notice is confirmed on appeal or the appeal is withdrawn, or
- (b) the day specified in the notice.

(9) Where there is no appeal under *paragraph (6)*, the contravention notice shall take effect on the later of—

- (a) the end of the period for making an appeal, or
- (b) the day specified in the notice.

(10) An authorised officer may—

- (a) withdraw a contravention notice at any time, or
- (b) where no appeal is made or pending under *paragraph (6)*, extend the period specified under *paragraph (2)(d)*.

#### *Prohibition notice*

42. (1) Where an authorised officer is of the opinion that at any place there is occurring or is likely to occur any situation or activity relating to a toy that involves or is likely to involve a serious risk to safety or health, or in relation to which toy the CE marking is not affixed in circumstances in which it should have been affixed, or is affixed in circumstances in which it should not have been affixed, the authorised officer may serve a notice (in these Regulations referred to as a “prohibition notice”) on the person in charge.

(2) A prohibition notice shall—

- (a) state that the authorised officer is of the opinion referred to in paragraph (1),
- (b) state the reason for that opinion,
- (c) specify the situation or activity in respect of which that opinion is held,

- (d) where in the opinion of the authorised officer the activity involves a contravention, or likely contravention of any of these Regulations, specify the provision concerned,
  - (e) prohibit the carrying on of the activity concerned until the matters that give rise or are likely to give rise to the risk are remedied, and
  - (f) be signed and dated by the authorised officer.
- (3) A prohibition notice may include directions—
  - (a) as to the measures to be taken to remedy any contravention or matter to which the notice relates, or to otherwise comply with the notice, and
  - (b) to bring the notice to the attention of any person who may be affected by it or the public generally.
- (4) A prohibition notice shall take effect—
  - (a) when the notice is received by the person on whom it is served, or
  - (b) where an appeal is brought against the prohibition notice, on the day immediately following—
    - (i) the day on which the notice is confirmed on appeal or the appeal is withdrawn, or
    - (ii) the day specified in the notice,whichever occurs later.
- (5) The bringing of an appeal against a prohibition notice shall not have the effect of suspending the operation of the notice but the appellant may apply to the court to have the operation of the notice suspended until the appeal is disposed of and, on such application, the court may, if it thinks proper to do so, direct that the operation of the notice be suspended until the appeal is disposed of.
- (6) A person on whom a prohibition notice is served may, within 7 days beginning on the day on which the notice is served on him, her or it, appeal against the notice to a judge of the District Court in the district court district in which the notice was served and in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.
- (7) Where, on the hearing of an appeal under this Regulation, a prohibition notice is confirmed, notwithstanding paragraph (4), the judge by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition notice for such period as in the circumstances of the case the judge considers appropriate.

(8) A person who—

- (a) brings an appeal under paragraph (6), or
- (b) applies for the suspension of the operation of a prohibition notice under paragraph (7),

shall at the same time notify the Agency of the appeal or the application, and the grounds for the appeal or application.

(9) A person on whom a prohibition notice has been served who is of the opinion that the matters referred to in the prohibition notice have been remedied by the date specified in the notice shall confirm in writing to the authorised officer that those matters have been so remedied.

(10) Where a person on whom a prohibition notice has been served confirms in writing to the authorised officer in accordance with paragraph (9) that the matters referred to in the prohibition notice have been remedied, the authorised officer shall, on being satisfied that the matters have been so remedied, within one month of receipt of such confirmation, give notice to the person concerned of such compliance with the prohibition notice.

(11) An authorised officer may at any time withdraw a prohibition notice if—

- (a) the authorised officer is satisfied that the situation or activity to which the notice relates no longer involves a serious risk to health or the environment, or
- (b) the authorised officer is satisfied that the notice was issued in error or is incorrect in some material respect.

*Contravention of prohibition notice — application to High Court*

43. (1) Where a person contravenes a prohibition notice, an authorised officer may apply ex parte to the High Court for an order prohibiting the continued contravention of the notice.

(2) The High Court may, upon an application under this Regulation, order the person on whom the prohibition notice concerned was served to cease doing such acts as the High Court directs.

*Publication of information relating to contravention notices and prohibition notices*

44. The Agency may, in the interest of the protection of safety or health and in consultation, where appropriate, with another competent authority, take such measures as it considers appropriate to bring to the attention of the public matters giving rise to any contravention notice or prohibition notice served under these Regulations.

*Immunity*

45. None of the following persons, that is to say, the Agency, an authorised officer, or a member or a member of staff of the Agency shall be liable in

damages in respect of any act done or omitted to be done by it or him or her in the performance, or purported performance, of that person's functions under these Regulations, unless the act or omission concerned was done in bad faith.

*Indemnification*

46. The Agency shall, subject to the provisions of any enactment or rule of law, indemnify an authorised officer appointed by it, or a member or member of staff of the Agency, in respect of any act done or omitted to be done by him or her in the performance, or purported performance, of his or her functions under these Regulations as such authorised officer, member or member of staff, unless the act or omission concerned was done in bad faith.

*Restrictions on the disclosure of information*

47. A person in receipt of information as a result of the application of these Regulations shall treat same as confidential. In particular, business, professional and trade secrets shall be treated as confidential unless the divulging of such information is—

- (a) for the purpose of the discharge of functions under these Regulations,
- (b) made with the consent of the person to whom the information applies, or
- (c) for the purposes of—
  - (i) any legal proceedings (including by means of a report to a coroner holding an inquest under the Coroners Acts 1962 and 2005 on the body of a person whose death may have been caused through personal injury), or
  - (ii) any investigation or special report under section 70 of the Safety, Health and Welfare at Work Act 2005,
- (d) necessary in order to protect the health and safety of persons,
- (e) required by the provisions of these Regulations or the Toy Safety Directive, or
- (f) ordered by a court of law.

*Offences*

48. (1) A person who contravenes a provision or requirement of Regulation 7, 8, 9, 10, 11, 12, 13, 14, 18, 19, 20 or 21 commits an offence.

(2) A person who contravenes a requirement in a contravention notice or a prohibition notice commits an offence.

(3) A person who, in relation to the CE marking or any document required for the purposes of these Regulations—

- (a) forges or counterfeits any such document,

- (b) gives or signs a document or makes a marking knowing it to be false in any material particular,
- (c) knowingly utters or uses a marking or document so forged or counterfeited, or which is false as aforesaid,
- (d) knowingly utters or uses as applying to any person or toy a marking or document which does not so apply,
- (e) knowingly connives at any such forging, counterfeiting, giving, signing, uttering or using,
- (f) knowingly makes a false entry in any such document which is so required to be kept, served or sent,
- (g) knowingly uses any such false entry, or
- (h) knowingly has, without lawful authority, a forged marking or document or an altered marking or document in his, her or its possession,

commits an offence.

(4) A person who obstructs or interferes with an authorised officer or a member of the Garda Síochána in the course of exercising a power conferred on him or her by these Regulations or impedes the exercise by the officer or member, as the case may be, of such power, or fails or refuses to comply with a request or requirement of, or to answer a question asked by, such officer or member pursuant to a power conferred by these Regulations, or in purported compliance with such request or requirement, or who in answer to such question gives information to the officer or member that he, she or it knows to be false or misleading in any material respect, commits an offence.

(5) A person who falsely represents himself or herself to be an authorised officer commits an offence.

(6) A person who, at any time during the period of 3 months immediately following the affixing of a notice in accordance with *Regulation 53(1)(d)*, removes, alters, damages or defaces the notice without lawful authority commits an offence.

(7) A person who states to the Agency that another person has committed an offence under this Regulation or has failed to comply with a provision of these Regulations, knowing the statement to be false, commits an offence.

(8) A person who, in purported compliance with a requirement in an information notice, furnishes information to the Agency that he, she or it knows to be false or misleading in a material respect commits an offence.

(9) A person who contravenes *Regulation 36* commits an offence.

*Penalties*

49. (1) A person guilty of an offence under *Regulation 48* shall be liable—
- (a) on summary conviction, to a class A fine or imprisonment for a term not exceeding 6 months or both, or
  - (b) on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.
- (2) (a) Where a person is convicted of an offence under these Regulations in proceedings brought by the Agency, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Agency the costs and expenses, measured by the court, incurred by the Agency in relation to the investigation, detection and prosecution of the offence, including the costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of authorised officers, employees, consultants and advisers engaged by the Agency.
- (b) An order for costs and expenses under *subparagraph (a)* is in addition to and not instead of any fine or penalty the court may impose.

*Offences by bodies corporate*

50. Where an offence under these Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a person being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she had committed the first-mentioned offence.

*Defence in proceedings*

51. In any proceedings for an offence for a contravention of any of the provisions of these Regulations it shall be a defence for the person charged to prove that—

- (a) the commission of the offence was due to the act or default of another person, not being one of his, her or its employees, or
- (b) he, she or it took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

*Prosecution of offences*

52. (1) Subject to paragraph (2), summary proceedings in relation to an offence under these Regulations may be brought and prosecuted by the Agency.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under *Regulation 48* or *Regulation 50* may be instituted at any time within 12 months from the date on which the offence was committed or alleged to have been committed.

*Service of notices etc.*

53. (1) A notice or other document required or authorised to be served on, sent or given to a person under these Regulations shall, subject to paragraph (2), be addressed to the person concerned by name, and may be served on, sent or given to the person in one of the following ways:

- (a) by delivering it to the person;
- (b) by leaving it at the address at which the person ordinarily resides or, in a case where an address for service has been furnished, at that address;
- (c) by sending it by post in a prepaid registered letter to the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, to that address;
- (d) where the address at which the person ordinarily resides cannot be ascertained by reasonable inquiry and the notice or other document relates to any place of business, by delivering it to a person over the age of 16 years resident or employed at the place of business or by affixing it in a conspicuous position at or near the place of business;
- (e) if the person concerned has agreed to service of notices by means of an electronic communication (within the meaning assigned by section 2 of the Electronic Commerce Act 2000), service by such means, provided that there is a facility for confirming receipt of electronic communication and that such receipt has been confirmed;
- (f) where there is a facility for receiving a facsimile of the notice by electronic means at the address at which the person ordinarily resides or carries on business, by transmitting a facsimile of the notice by such means to that address, or
- (g) by any other means that may be prescribed.

(2) Where a notice or other document required or authorised under these Regulations is to be served on, sent or given to a person who is the owner or occupier of a place of business and the name of the person cannot be ascertained by reasonable inquiry, it may be addressed to the person by using the words, “the owner” or, as the case may require, “the occupier”.

(3) or the purposes of these Regulations, a company within the meaning of the Companies Acts shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

## SCHEDULE

## MINIMUM CRITERIA FOR A NOTIFIED BODY IN THE STATE.

1. A conformity assessment body shall be a third-party body independent of the organisation or the toy it assesses. 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.
2. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the toys which they assess, nor the authorised representative of any of those parties. This shall 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.
3. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design or manufacture, the marketing, installation, use or maintenance of those toys, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.
4. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.
5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall 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.
6. Conformity assessment bodies shall be capable of carrying out the conformity assessment tasks assigned to them by the provisions of Regulation 20 and in relation to which they have been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.
7. Conformity assessment bodies shall be established under the law of the State and shall have legal personality.

8. The personnel responsible for carrying out the conformity assessment activities shall have:
- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
  - (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 requirements, of the applicable harmonised standards and of the relevant Community harmonisation legislation and of its implementing regulations;
  - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
9. The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
10. The body shall take out liability insurance in an amount acceptable to the Minister.
11. The staff of the body shall be bound to observe professional secrecy (except as regards information provided to the Agency) with regard to all information obtained in carrying out its tasks under these Regulations. Proprietary rights shall be protected.
12. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the Commission coordination group or groups established under the Toy Safety Directive and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group or groups.
13. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in this Schedule, and shall inform the Minister accordingly.
14. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.
15. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

16. Notified bodies shall keep at the disposal of the Minister the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Regulation 20.

17. Where a conformity assessment body demonstrates its conformity with the criteria laid down in relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in this Schedule insofar as the applicable harmonised standards cover those requirements.



GIVEN under my Official Seal,  
20 January 2011.

BATT O'KEEFFE,  
Minister for Enterprise, Trade and Innovation.

## EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

These Regulations transpose Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys and replaces S.I. No. 32 of 1990. They prohibit the placing of toys on the market unless they are safe.

These Regulations set down updated safety requirements for placing toys on the market, conformity assessment and CE marking, and also set down a requirement to ensure risk assessment is carried out for toys. The Regulations make provision for the appointment and monitoring of Notified Bodies and for the appointment and functions of the National Consumer Agency as the Competent Authority responsible for enforcing the Regulations and the carrying out of market surveillance.

Toys must carry (i) a CE mark indicating that they conform to the relevant harmonised EC standards and/or that they have been approved by an Approved Body and (ii) on the toys or on the packaging, the name and address of the manufacturer or his authorised representative established within the Community or the importer of the toys into the Community.

The person first putting toys on the market must keep available for inspection a dossier giving detailed information about the manufacturer/storage of the toys and a description of the means whereby conformity with the legal requirements was established.

The penalties applicable to breach of these Regulations have been updated and increased.

Toys placed on the market prior to the making of these Regulations are covered by S.I. No. 32 of 1990 which sets out the safety requirements applicable.

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