L.N. 50 of 2011

PRODUCT SAFETY ACT (CAP. 427)

Safety of Toys Regulations, 2011

IN exercise of the powers conferred by article 38 of the Product Safety Act, the Prime Minister, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation, scope and commencement.

1. (1) The title of these regulations is the Safety of Toys Regulations, 2011.

(2) These regulations transpose Directives 88/378/EEC, 2008/112/EC and 2009/48/EC and lay down rules on the safety of toys and on their free movement in the Community.

(3) These regulations shall enter into force on the 20th July 2011.

(4) The Act shall apply to toys in accordance with article 5 thereof.

(5) The making available on the local or Community market of toys which are in accordance with the Safety of Toys Regulations, 2002, and which were placed on the local or Community market before the 20th July 2011, shall not be restricted.

L.N. 373 of 2002.

Scope and applicability.

2. (1) These regulations shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age, hereinafter referred to as "toys".

(2) These regulations shall not apply, in particular, to the following products:

(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;

(e) Slings and Catapults;

(f) Decorative objects for festivities and celebrations;

(g) Products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above. Examples of this category are:

(i) Detailed and faithful scale models,

(ii) Kits for the assembly of detailed scale models,

(iii) Folk dolls and decorative dolls and other similar articles,

(iv) Historical replicas of toys, and

(v) Reproductions of real fire arms;

(h) Sports equipment, including roller skates, inline skates and skateboards, intended for children with a body mass of more than 20kg;

(i) Bicycles with a maximum saddle height of more than 435mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark;

(j) Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads, public highways, or the pavement thereof;

(k) Aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids;

(l) Puzzles with more than 500 pieces;

(m) Guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120cm long;

(n) Fireworks, including percussion caps, which are not specifically designed for toys;

(o) Products and games using sharp-pointed missiles, such as sets of darts with metallic points;

(p) Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision;

(q) Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment;

(r) Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for an targeted at children and have a play value on their own, such as specially designed personal computers, keyboards, joy sticks or steering wheels;

(s) Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs;

(t) Babies' soothers;

(u) Child-appealing luminaries;

(v) Electrical transformers for toys;

(w) Fashion accessories for children which are not for use in play.

Definitions.

3. For the purposes of these regulations, the following definitions shall apply:

"accreditation" shall have the meaning assigned to it by Regulation (EC) No 765/2008;

"the Act" means the Product Safety Act;

"activity toy" means a toy for domestic use in which the support structure remains stationary while the activity is taking place and which is intended for the performance by a child of any of the following activities: climbing, jumping, swinging, sliding, rocking, spinning, crawling and creeping, or any combination thereof;

"aquatic toy" means a toy intended for use in shallow water which is capable of carrying or supporting a child on the water;

"authorised representative" means any natural or legal person established in Malta or within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

"CE marking" means the marking by which the manufacturer indicates that the toy is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;

"chemical toy" means a toy intended for the direct handling of chemical substances and mixtures and which is used in a manner appropriate to a given age-group and under the supervision of an adult;

"the Community" means the European Community;

"Community harmonisation legislation" means any Community legislation harmonising the conditions for marketing of products;

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

"conformity assessment body" means a body designated in accordance with the Method for Designating Conformity Assessment Bodies Regulations, 2003, that performs

L.N. 136 of 2003.

conformity assessment activities, including calibration, testing, certification and inspection;

"cosmetic kit" means a toy the purpose of which is to assist a child to learn to make products such as fragrances, soaps, creams, shampoos, bath foams, glosses, lipsticks, other make-up, tooth-paste and conditioners;

"design speed" means representative potential operating speed that is determined by the design of the toy;

"distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a toy available on the market;

"economic operators" means the manufacturer, the authorised representative, the importer and the distributor;

"functional product" means a product which performs and is used in the same way as a product, appliance or installation intended for use by adults and which may be a scale model of such product, appliance or installation;

"functional toy" means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, and which may be a scale model of such product, appliance or installation;

"gustative game" means a toy the purpose of which is to allow children to make sweets or dishes which involve the use of food ingredients such as sweets, liquids, powders and aromas;

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

"harmonised standard" means a standard adopted by the Malta Standards Authority or one of the European Standardisation bodies listed in Schedule I to the Notification Procedure Regulations, 2003, on the basis of a request made by the Commission in accordance with Article 6 of Directive 98/34/EC; L.N. 373 of 2003.

"hazard" means a potential source of harm;

"importer" means any natural or legal person established in Malta or within the Community who places a toy from a third country on the local or Community market;

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

"making available on the market" means any supply of a toy for distribution, consumption or use on the local or Community market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means any natural or legal person who manufactures a toy or has a toy designed or manufactured, and markets that toy under his name or trademark;

"Market Surveillance Directorate" means the Market Surveillance Directorate of the Malta Standards Authority as described in the Establishment of Directorates of the Malta Standards Authority Order, 2008;

L.N. 39 of 2008.

"market surveillance" means the activities carried out and measures taken by the Market Surveillance Directorate to ensure that toys comply with the applicable requirements set out in Community harmonisation legislation and do not endanger health or any other aspect of public interest protection;

"National Accreditation Board (Malta)" means the National Accreditation Board (Malta) established in terms of regulation 3 of the National Accreditation Board (Malta) (Establishment) Regulations, 2007;

L.N. 306 of 2007.

"olfactory board game" means a toy the purpose of which is to assist a child to learn to recognise different odours or flavours;

"placing on the market" means the first making available of a toy on the local or Community market;

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

"Regulatory Affairs Directorate" means the Regulatory Affairs Directorate of the Malta Standards Authority as described in the Establishment of Directorates of the Malta Standards Authority Order, 2008;

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

"withdrawal" means any measure aimed at preventing a toy in the supply chain from being made available on the market;

Responsibilities of manufacturers.

4. (1) When placing their toys on the market, manufacturers shall ensure that the toys have been designed and manufactured in accordance with the requirements set out in regulation 9 and Schedule I.

(2) (a) Manufacturers shall draw up the required technical documentation in accordance with regulation 14 and carry out or have carried out the applicable conformity assessment procedure in accordance with regulation 13.

(b) Where compliance of a toy with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity, as referred to in regulation 12, and affix the CE marking, as set out in regulation 11.

(3) Manufacturers shall keep the technical documentation and the EC declaration of conformity at the disposal of the Market Surveillance Directorate for a period of ten years after the toy has been placed on the market.

(4) Manufacturers shall 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.

(5) When deemed appropriate with regard to the risks presented by a toy, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate and keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of any

such monitoring. They shall keep such register at the disposal of the Market Surveillance Directorate.

(6) Manufacturers shall ensure that their 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.

(7) Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they 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.

(8) Manufacturers shall ensure that the toy is accompanied by instructions and safety information. All information accompanying the toy and on the toy itself must be in, at least, the English or Maltese language.

(9) Manufacturers who consider or have reason to believe that a toy which they have 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, manufacturers shall immediately inform the Market Surveillance Directorate giving details, in particular, of the non-compliance and of any corrective measures taken.

(10) Manufacturers shall, further to a reasoned request from the Market Surveillance Directorate, provide that Directorate with all the information and documentation necessary to demonstrate the conformity of the toy, in the English or Maltese language. They shall cooperate with that Directorate, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.

Authorised representatives.

5. (1) A manufacturer established outside the Community may, by a written mandate, appoint an authorised representative established in Malta or within the Community.

(2) The obligations laid down in regulation 4(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

(3) The 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 the Market Surveillance Directorate for a period of 10 years after the toy has been placed on the market;

(b) Further to a reasoned request from the Market Surveillance Directorate, provide that Directorate with all the information and documentation necessary to demonstrate the conformity of the toy, in the English or Maltese language;

(c) Cooperate with the Market Surveillance Directorate, at its request, as regards any action taken to eliminate the risks posed by toys covered by the mandate.

Obligations of importers.

6. (1) Importers shall only place toys that comply to these regulations on the local or Community market.

(2) Before placing a toy on the market, importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that 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 4.

(3) Where an importer considers or has reason to believe that a toy is not in conformity with the requirements set out in regulation 9 and Schedule I, 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 Market Surveillance Directorate to that effect.

(4) Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy itself or, where that is not possible, on its packaging or in a document accompanying the toy.

(5) Importers shall ensure that the toy is accompanied by instructions and safety information. All information

accompanying the toy and on the toy itself must be in, at least, the English or Maltese language.

(6) Importers shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in regulation 9 and Schedule I.

(7) When deemed appropriate with regard to the risks presented by a toy, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate and keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of any such monitoring. They shall keep such register at the disposal of the Market Surveillance Directorate.

(8) Importers who consider or have reason to believe that a toy which they have 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, manufacturers shall immediately inform the Market Surveillance Directorate giving details, in particular, of the non-compliance and of any corrective measures taken.

(9) Importers shall, for a period of ten years after the toy has been placed on the market, keep a copy of the EC declaration of conformity at the disposal of the Market Surveillance Directorate and ensure that the technical documentation can be made available to the Directorate upon request.

(10) Importers shall, further to a reasoned request from the Market Surveillance Directorate, provide that Directorate with all the information and documentation necessary to demonstrate the conformity of the toy, in the English or Maltese language. They shall cooperate with that Directorate, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.

(11) An importer shall be considered as a manufacturer for the purposes of these regulations and be subject to the obligations of the manufacturer under regulation 4 when it places a toy on the market under 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.

Obligations of distributors.

7. (1) When making a toy available on the local or Community market, distributors shall act with due care in relation to the applicable requirements.

(2) Before making a toy available on the market, distributors 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, at least, the English or Maltese language, and that the manufacturer and the importer have complied with requirements set out in regulation 4 and regulation 6(4).

(3) Where a distributor considers or has reason to believe that a toy is not in conformity with the requirements set out in regulation 9 and Schedule I, 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 Market Surveillance Directorate, to that effect.

(4) Distributors shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in regulation 9 and Schedule I.

(5) Distributors who consider or have reason to believe that a toy which they have 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, distributors shall immediately inform the Market Surveillance Directorate giving details, in particular, of the non-compliance and of any corrective measures taken.

(6) Distributors shall, further to a reasoned request from the Market Surveillance Directorate, provide that Directorate with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with that Directorate, at its request, as regards any action taken to eliminate the risks posed by toys which they have made available on the market.

(7) A distributor shall be considered as a manufacturer for the purposes of these regulations and be subject to the obligations of the manufacturer under regulations 4(1) to (10) when it places a toy on the market under 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.

Other responsibilities.

8. (1) In addition to the preceding regulations, the economic operator shall, on request from the Market Surveillance Directorate, identify:

(a) any economic operator who has supplied them with a toy;

(b) any economic operator to whom they have supplied a toy.

(2) Manufacturers must be able to present the information referred to in the preceding sub-regulation for a period of ten years after the toy has been placed on the market. In the case of other economic operators, they must be able to present this information for a period of ten years after they have been supplied with the toy.

Placing on the market and essential safety requirements.

9. (1) Only toys complying with the essential safety requirements set out, as far as the general safety requirement is concerned, in regulation 9(5) and, as far as the particular safety requirements are concerned, in Schedule I and bearing the CE marking shall be placed on the local or Community market.

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

(3) The making available on the market of toys complying with these regulations shall not be restricted. Toys bearing the CE marking shall be presumed to comply with these regulations.

(4) Toys not bearing the CE marking or which do not otherwise comply with these regulations may be displayed 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 local or Community market before being brought into conformity.

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

(6) The ability of 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.

(7) Labels affixed in accordance with regulations 10(4) to (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.

Warnings.

10. (1) Where appropriate for safe use, warnings made for the purposes of regulations 9(5) to (7) shall specify appropriate user limitations in accordance with Part A of Schedule VI.

(2) As regards the categories of toys listed in Part B of Schedule VI to these regulations, the warnings set out therein shall be used. The warnings set out in points 2 to 10 of Part B of Schedule VI shall be used as worded therein.

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

(4) The 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 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 Schedule VI, 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.

(7) In accordance with regulation 4(8), all warnings and safety instructions shall be in, at least, the English or Maltese language.

CE marking.

11. (1) The CE marking shall be affixed only by the manufacturer or his authorised representative.

(2) The CE marking as presented in Schedule X shall be affixed only to products that fall within the scope of these regulations.

(3) By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the toy with all applicable requirements set out in these regulations and, where applicable, other relevant Community harmonisation legislation providing for its affixing.

(4) The CE marking shall be the only marking which attests the conformity of the toy with the applicable requirements of these regulations.

(5) The affixing to a toy of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the toy provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

(6) The CE marking shall be affixed visibly, legible and indelibly to the toy, to an affixed label or to the packaging. In case of small toys and toys consisting of small parts, the CE marking may alternatively be affixed to a label or an accompanying leaflet.

(7) In the case of toys sold in counter displays, the CE marking may be affixed to counter displays only when it is not technically possible to affix the CE marking on the toy itself or on a label or accompanying leaflet, and on condition that the counter display was originally used as packaging for the toy.

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

(9) 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.

EC declaration of conformity.

12. (1) The EC declaration of conformity shall state that the fulfilment of the requirements set out in regulation 9 and Schedule I has been demonstrated.

(2) The EC declaration of conformity shall as a minimum contain the elements specified in Schedule IV and the relevant modules set out in Schedules VIII to IX and shall be continuously updated. It shall have the model structure set out in Schedule IV and shall be in, at least the English or Maltese language.

(3) By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the toy.

Conformity assessment.

13. (1) Toys which are 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 regulation 9 and Schedule I.

(2) Manufacturers shall, before placing a toy on the local or Community 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.

(3) Before placing a toy on the local or Community market, manufacturers shall use the conformity assessment procedures referred to in sub-regulations (4) and (5) to demonstrate that the toy complies with the requirements set out in regulation 9 and Schedule I.

(4) If the manufacturer has applied 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, it shall use the internal production control procedure set out in Schedule VII.

(5) In the following cases, the toy shall be submitted to EC-type examination, as referred to in sub-regulations (6) to (15), together with the conformity to type procedure set out in Schedule IX:

(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 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 paragraph (a) has been published with a restriction;

(d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

(6) 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 Schedule VIII.

(7) EC-type examination shall be carried out in the manner specified in the second indent of point 2 of Schedule VIII.

(8) In addition to those provisions, the requirements laid down in sub-regulations (9) to (15) shall apply.

(9) The application for an EC-type examination shall include a description of the toy and an indication of the place of manufacture, including the address.

(10) When a conformity assessment body notified under regulation 15 (hereinafter referred to as "notified body") carries out the EC-type examination, it shall evaluate, if necessary together with the manufacturer, the analysis of the hazards that toy may present carried out by the manufacturer in accordance with sub-regulation (2).

(11) The EC-type examination certificate shall include a reference to these regulations, 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.

(12) 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, and, in any case, every five years.

(13) The EC-type examination certificate shall be withdrawn if the toy fails to comply with the requirements set out in regulation 9 and Schedule I.

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

(15) When the notified body is established in Malta, the technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in at least, the English or Maltese language.

Technical documentation.

14. (1) The technical documentation referred to in regulation 4(2) shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements set out in regulation 9 and Schedule I. It shall, in particular, contain the documents listed in Schedule V.

(2) The technical documentation shall be drawn up in one of the official languages of the Community, subject to the requirement set out in regulation 13(15).

(3) Following a reasoned request from the Market Surveillance Directorate, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the English or Maltese language. When making such a request, the Market Surveillance Directorate may fix a deadline for receipt of such file or translation, which shall be 30 calendar days, unless a shorter deadline is justified in the case of serious and immediate risk.

(4) If the manufacturer does not comply with the requirements of sub-regulations (1) to (3), the Market Surveillance Directorate may require it to have a test performed by a notified

body at the manufacturer's own expense within a specified period in order to verify compliance with the harmonised standards and essential safety requirements.

Notification of notified bodies.

15. (1) The Regulatory Affairs Directorate shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment under regulation 13.

(2) The Regulatory Affairs Directorate shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of these regulations, and for the monitoring of notified bodies, including compliance with regulation 16.

(3) The assessment and monitoring referred to in sub-regulation (2) shall be carried out by the National Accreditation Board (Malta).

(4) The Regulatory Affairs Directorate shall inform the Commission of its procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Notified bodies.

16. (1) For the purposes of notification under these regulations, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (15) and the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(2) 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 independent and the absence of any conflict of interest are demonstrated, be considered such a body.

(3) (a) 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.

(b) 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.

(c) 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.

(4) 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.

(5) (a) Conformity assessment bodies shall be capable of carrying out the conformity assessment tasks assigned to them by the provisions of regulation 13 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.

(b) At all times and for each conformity assessment procedure and each kind or category of toy in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(i) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(ii) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(iii) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

(c) A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

(6) 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.

(7) 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.

(8) Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with its national law, or the State itself is directly responsible for the conformity assessment.

(9) The personnel of a conformity assessment body shall observe professional secrecy with regard to all information

obtained in carrying out their tasks under regulation 13 or any provision of national law, except in relation to the Regulatory Affairs in which its activities are carried out. Proprietary rights shall be protected.

(10) Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under regulation 18(8), and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

(11) Where a conformity assessment body demonstrates its conformity with the criteria laid down in the 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 these regulations insofar as the applicable harmonised standards cover those requirements.

(12) 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 these regulations, and shall inform the Regulatory Affairs Directorate accordingly.

(13) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

(14) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(15) Notified bodies shall keep at the disposal of the Regulatory Affairs Directorate the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under regulation 13.

Notification procedure.

17. (1) A conformity assessment body established in Malta shall submit an application for notification under these regulations to the Regulatory Affairs Directorate.

(2) The application referred to in the preceding sub-regulation shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or

modules and the toy or toys for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by the National Accreditation Board (Malta) attesting that the conformity assessment body fulfils the requirements laid down in regulation 16 and the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(3) Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the Regulatory Affairs Directorate with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in regulation 16.

(4) The Regulatory Affairs Directorate may only notify conformity assessment bodies which have satisfied the requirements laid down in regulation 16 and the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(5) The Regulatory Affairs Directorate shall notify conformity assessment bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

(6) The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules, toy or toys concerned and the relevant attestation of competence.

(7) The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification. Only such a body shall be considered a notified body for the purposes of these regulations.

(8) The Regulatory Affairs Directorate shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

(9) Where the Regulatory Affairs Directorate has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulation 16 or the Method for Designating Conformity Assessment Bodies Regulations, 2003, or that it is failing to fulfil its obligations, the Regulatory Affairs Directorate shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet

those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

(10) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Regulatory Affairs Directorate shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying and market surveillance authorities, at their request.

(11) The Regulatory Affairs Directorate shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

Operational obligations of notified bodies.

18. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in regulation 13.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their 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, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the toy with these regulations.

(3) Where a notified body finds that the requirements set out in regulation 9 and Schedule I 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 as referred to in regulation 13.

(4) Where, in the course of the monitoring of conformity following the issue of a 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 certificates, as appropriate.

(6) Notified bodies shall inform the Regulatory Affairs Directorate 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 they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification, and any other activity performed, including cross-border activities and subcontracting.

(7) Notified bodies shall provide the other bodies notified under these regulations or under Directive 2009/48/EC 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.

(8) Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the Commission.

Formal objection to a harmonised standard.

19. (1) Where the Regulatory Affairs Directorate considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in regulation 9 and Schedule I, it shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments.

(2) Where the Regulatory Affairs Directorate has a formal objection to the harmonised standards referred to in regulation 16, sub-regulation (1) shall apply.

Market surveillance.

20. (1) When the Market Surveillance Directorate takes measures as provided for in these regulations, and in particular those referred to in sub-regulation (2), it shall take due account of the precautionary principle.

(2) The Market Surveillance Directorate shall organise and perform surveillance of toys placed on the market in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008. In addition to those Articles, sub-regulations (3) to (5) shall apply.

(3) The Market Surveillance Directorate 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) Where the Market Surveillance Directorate finds that a toy is not in conformity with the requirements set out in regulation 9 and Schedule I, 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 the regulation 13(12), the Market Surveillance Directorate shall instruct the notified body to review the EC-type examination certificate.

(6) Where the Market Surveillance Directorate has taken action pursuant to Article 20 of Regulation (EC) No 765/2008, 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 Market Surveillance Directorate.

(7) (a) Where, in the course of that evaluation, the Market Surveillance Directorate finds that the toy does not comply with the requirements laid down in these regulations, it shall without delay require the 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, as they may prescribe.

(b) The Market Surveillance Directorate shall inform the relevant notified body accordingly.

(c) Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred in the preceding sub-paragraph.

(8) Where the Market Surveillance Directorate considers that non-compliance is not restricted to the local territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the relevant economic operator to take.

(9) The relevant economic operator shall ensure that appropriate corrective action is taken in respect of toys which that operator has made available on the local or Community market.

(10) (a) Where the relevant economic operator does not take adequate corrective action within the period referred to in the second sub-paragraph of regulation 20(7), the Market Surveillance Directorate shall take appropriate provisional measures to prohibit or restrict the toy being made available on the local market, to withdraw the toy from that market or to recall it.

(b) The Market Surveillance Directorate shall inform the Commission and the other Member States, without delay, of those measures.

(11) The information referred to in sub-regulation (10) 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 national measures taken and the arguments put forward by the relevant economic operator. In particular, the Market Surveillance Directorate 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 referred to in regulation 13(1) conferring a presumption of conformity.

(12) Where market surveillance procedures are initiated in another Member State other than Malta, the Market Surveillance Directorate shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the toy concerned, and, in the event of disagreement with the notified national measure, of their objections.

(13) Where, within three months of receipt of the information referred to in sub-regulation (10), no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by the Market Surveillance Directorate, that measure shall be deemed to be justified.

(14) The Market Surveillance Directorate shall take appropriate restrictive measures in respect of the toy concerned, such as withdrawal of the toy from their market, without delay.

(15) Where, on completion of the procedure set out in sub-regulations (9) and (10), the national measure is considered justified, irrespective of whether the national measure was initiated in Malta or in another Member State, the Market Surveillance Directorate shall take the measures necessary to ensure that the non-compliant toy is withdrawn from their market, and shall inform the Commission accordingly.

(16) Where the national measure is considered unjustified by the Commission, the Market Surveillance Directorate shall withdraw it.

(17) If a measure referred to in sub-regulation (10) is a type of measure which is required under Article 22 of Regulation (EC) No 765/2008 to be notified through the Community Rapid Information Exchange System, it shall not be necessary to make a separate notification under sub-regulation (10), 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 these regulations;

(b) the supporting evidence referred to in sub-regulation (11) is enclosed with the Community Rapid Information Exchange notification.

(18) Without prejudice to sub-regulations (6) to (14), where the Market Surveillance Directorate makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) that the CE marking has been affixed in violation of regulations 9 or 11;

(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.

(19) Where the non-compliance referred to in sub-regulation (18) persists, the Market Surveillance Directorate 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.

(20) By the 20th July 2014 and every five years thereafter, the Market Surveillance Directorate shall send the Commission a report on the application of these regulations. That report shall contain an evaluation of the situation concerning the safety of toys and of the effectiveness of these regulations, as well as a presentation of the market surveillance activities performed by the Market Surveillance Directorate.

(21) When the Market Surveillance Directorate adopts measures under these regulations, the requirements of transparency and confidentiality provided for in Article 22 of the Act shall apply.

Act V of 2001.

(22) (a) 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.

(b) 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 it under local laws and of the time limits applicable to them.

Penalties.

21. The penalties applicable for the infringement of any of the provisions above shall be those provided for in Part IV of the Act.

Revokes L.N. 373 of 2002.

22. The Safety of Toys Regulations, 2002, are being revoked.

Saving.

23. References to the revoked regulations shall be construed as references to these regulations.

Schedule I
PARTICULAR SAFETY REQUIREMENTS
(Regulation 9)

I. Physical and Mechanical Properties

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

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

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

(4) (a) Toys and their parts must not present a risk of strangulation.

(b) Toys and their parts must not present a risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.

(c) Toys and their parts must be of such dimensions as to not present a risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

(d) Toys, which are clearly intended for use by children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.

(e) The packaging in which toys are contained for retail sale must not present a risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.

(f) Toys contained within food or co-mingled with food must have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent its being swallowed or inhaled.

(g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

(h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, shall be prohibited. Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in points (c) and (d).

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

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

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

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

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

(9) Toys must be manufactured so as to ensure that:

(a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched; and

(b) liquids and gases contained within the toy do not reach temperatures or pressures which are such that their escape from the toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.

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

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

II. Flammability

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

(a) they do not burn if directly exposed to a flame or spark or other potential source of fire;

(b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);

(c) if they do ignite, they burn slowly and present a low rate of spread of the flame;

(d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

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

(2) Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down below, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.

As a result of the timing of the application of Regulation (EC) No 1272/2008, there are equivalent ways of referring to a given classification that should be used at different points in time, as shown below:

(a) Criteria for classifying substances and mixtures for the purposes above applicable as from the 20th July 2011 until the 31st May 2015:

Substances

The substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

(i) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(ii) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(iii) hazard class 4.1;

(iv) hazard class 5.1.

Mixtures

The mixture is dangerous within the meaning of the Classification, Labelling and Packaging of Substances and Mixtures (CLP) (Implementation) Regulations, 2009.

(b) Criteria to be applied as from the 1st June 2015:

The substance or mixture fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

(i) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(ii) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(iii) hazard class 4.1;

(iv) hazard class 5.1.

(3) Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in regulation 9(5).

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

(a) which, when mixed together, may explode through chemical reaction or through heating;

(b) which may explode when mixed with oxidizing substances; or

(c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

III. Chemical Properties applicable as from the 20th July 2011 until the 19th July 2013

(1) Toys must be so designed and constructed that, when used as specified in regulation 9(5), they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes. They must in all cases comply with the relevant local or Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and mixtures.

(2) In particular, for the protection of children's health, bioavailability resulting from

the use of toys must not, as an objective, exceed the following levels per day:

(a) 0.2 µg for antimony,

(b) 0.1 µg for arsenic,

(c) 25.0 µg for barium,

(d) 0.6 µg for cadmium,

(e) 0.3 µg for chromium,

(f) 0.7 µg for lead,

(g) 0.5 µg for mercury,

(h) 5.0 µg for selenium,

or such other values as may be laid down for these or other substances in Community legislation based on scientific evidence. The bioavailability of these substances means the soluble extract having toxicological significance.

(3) (a) Toys must not contain mixtures which are dangerous within the meaning of the Dangerous Substances and Preparations Regulations, 2007, or substances fulfilling the criteria for any of the following hazard classes or categories set out in the Classification, Labelling and Packaging of Substances and Mixtures (CLP) (Implementation) Regulations, 2009, and Annex I to Regulation (EC) No 1272/2008:

L.N. 10 of 2007

L.N. 214 of 2009

(i) Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(ii) Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(iii) Hazard class 4.1;

(iv) Hazard class 5.1,

in amounts which may harm the health of children using them. In any event it is strictly forbidden to include, in a toy, such substances or mixtures if they are intended to be used as such while the toy is being used.

(b) However, where a limited number of substances or mixtures are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a

maximum concentration level as may be defined for each substance or mixture by the European Committee for Standardisation (CEN), provided the permitted substances and mixtures comply with the local or Community classification rules in respect of labelling, without prejudice to Schedule VI, part B, section 4.

IV. Chemical Properties applicable as from the 20th July 2013

(1) (a) Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in regulation 9(5).

(b) Toys shall comply with the relevant local or Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.

(2) Toys that are themselves substances or mixtures must comply also with the Classification, Labelling and Packaging of Substances and Mixtures (CLP) (Implementation) Regulations, 2009, the Dangerous Substances and Preparations Regulations, 2007, and Regulation (EC) No 1272/2008 as applicable, relating to the classification, packaging and labelling of certain substances and mixtures.

(3) Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

(4) By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in point 7 below may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the local or Community legal acts referred to in point 6 below for the classification of mixtures containing these substances;

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the regulation 9(5);

(c) a decision in accordance with Article 46(3) of Directive 2009/48/EC has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Schedule II.

That decision may be taken if the following conditions are met:

(i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;

(ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and

(iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

(5) By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in point 8 below may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the local or Community legal acts referred to in point 6 below for the classification of mixtures containing these substances;

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in regulation 9(5); or

(c) a decision in accordance with Article 46(3) of Directive 2009/48/EC has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Schedule II.

That decision may be taken if the following conditions are met:

(i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;

(ii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

(6) local and Community legal acts governing the use of certain substances for the purposes of points 4(a) and 5(a) above:

(a) As from the 20th July 2011 until the 31st May 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with the Dangerous Substances and Preparations Regulations, 2007.

(b) As from the 1st June 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Regulation (EC) No 1272/2008.

(7) Categories of substances and mixtures classified as carcinogenic, mutagenic or

toxic for reproduction (CMR) for the purposes of point 4 above:

(a) *Substances*

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

(b) *Mixtures*

As from the 20st July 2011 until the 31st May 2015, point 4 concerns mixtures classified as CMR category 1 and 2 under the Classification, Labelling and Packaging of Substances and Mixtures (CLP) (Implementation) Regulations, 2009, and the Dangerous Substances and Preparations Regulations, 2007, as applicable.

As from the 1st June 2015, point 4 concerns mixtures classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

(8) Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5:

(a) *Substances*

Point 5 concerns substances classified as CMR category 2 under Regulation (EC) No 1272/2008.

(b) *Mixtures*

As from the 20th July 2011 until the 31st May 2015, point 5 concerns mixtures classified as CMR category 3 under the Classification, Labelling and Packaging of Substances and Mixtures (CLP) (Implementation) Regulations, 2009, and the Dangerous Substances and Preparations Regulations, 2007, as applicable.

As from the 1st June 2015, point 5 concerns mixtures classified as CMR category 2 under Regulation (EC) No 1272/2008.

(9) Points 3, 4 and 5 shall not apply to nickel in stainless steel.

(10) Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Schedule III, or, until such provisions have been laid down, but not later than the 20th July 2017, to materials covered by and complying with the provisions for food contact materials set out in Regulation (EC) No 1935/2004 and the related specific measures for particular materials.

(11) Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0.05 mg/kg for

nitrosamines and 1 mg/kg for nitrosable substances.

(12) Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in the Cosmetic Products Regulations, 2004.

L.N. 424 of 2004

(13) Toys shall not contain the following allergenic fragrances:

No:	Name of the allergenic fragrance:	CAS Number:
1	Alanroot oil (Inula helenium)	97676-35-2
2	Allylisothiocyanate	57-06-7
3	Benzyl Cyanide	140-29-4
4	4 tert-Butylphenol	98-54-4
5	Chenopodium oil	8006-99-3
6	Cyclamen alcohol	4756-19-8
7	Diethyl maleate	141-05-9
8	Dihydrocoumarin	119-84-6
9	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
10	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
11	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
12	Dimethyl citraconate	617-54-9
13	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
14	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
15	Diphenylamine	122-39-4
16	Ethyl acrylate	140-88-5
17	Fig leaf, fresh and preparations	68916-52-9
18	trans-2-Heptenal	18829-55-5
19	trans-2-Hexenal diethyl acetal	67746-30-9
20	trans-2-Hexenal dimethyl acetal	18318-83-7
21	Hydroabietyl alcohol	13393-93-6
22	4-Ethoxy-phenol	622-62-8
23	6-lsopropyl-2-decahydronaphthalenol	34131-99-2
24	7-Methoxycoumarin	531-59-9
25	4-Methoxyphenol	150-76-5
26	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
27	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
28	Methyl trans-2-butenoate	623-43-8
29	6-Methylcoumarin	92-48-8
30	7-Methylcoumarin	2445-83-2
31	5-Methyl-2,3-hexanedione	13706-86-0
32	Costus root oil (Saussurea lappa Clarke)	8023-88-9
33	7-Ethoxy-4-methylcoumarin	87-05-8
34	Hexahydrocoumarin	700-82-3
35	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
36	2-Pentylidene-cyclohexanone	25677-40-1
37	3.6,10-Trimethyl-3.5,9-undecatrien-2-one	1117-41-5

38	Verbena oil (Lippia citriodora Kunth)	8024-12-2
39	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
40	4-Phenyl-3-buten-2-one	122-57-6
41	Amyl cinnamal	122-40-7
42	Amylcinnamyl alcohol	101-85-9
43	Benzyl alcohol	100-51-6
44	Benzyl salicylate	118-58-1
45	Cinnamyl alcohol	104-54-1
46	Cinnamal	104-55-2
47	Citral	5392-40-5
48	Coumarin	91-64-5
49	Eugenol	97-53-0
50	Geraniol	106-24-1
51	Hydroxy-citronellal	107-75-5
52	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
53	Isoeugenol	97-54-1
54	Oakmoss extracts	90028-68-5
55	Treemoss extracts	90028-67-4

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

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

No:	**Name of the allergenic fragrance:**	**CAS Number:**
1	Anisyl alcohol	105-13-5
2	Benzyl benzoate	120-51-4
3	Benzyl cinnamate	103-41-3
4	Citronellol	106-22-9
5	Farnesol	4602-84-0
6	Hexyl cinnamaldehyde	101-86-0
7	Lilial	80-54-6
8	d-Limonene	5989-27-5
9	Linalool	78-70-6
10	Methyl heptine carbonate	111-12-6
11	3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

(14) The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 13 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games,

cosmetic kits and gustative games, provided that:

(i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Schedule VI;

(ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of the Cosmetic Products Regulations, 2004; and

(iii) if applicable, those fragrances comply with the relevant legislation on food.

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

(15) Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

Element:	**mg/kg in dry, brittle, powder-like or pliable toy material:**	**mg/kg in liquid or sticky toy material:**	**mg/kg in scraped-off toy material:**
Aluminium	5625	1406	70000
Antimony	45	11.3	560
Arsenic	3.8	0.9	47
Barium	4500	1125	56000
Boron	1200	300	15000
Cadmium	1.9	0.5	23
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.2
Cobalt	10.5	2.6	130
Copper	622.5	156	7700
Lead	13.5	3.4	160
Manganese	1200	300	15000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4500	1125	56000
Tin	15000	3750	180000
Organic tin	0.9	0.2	12
Zinc	3750	938	46000

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in regulation 9(5).

V. Electrical Properties

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

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

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

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

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

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

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

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

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

(9) The electrical transformer of a toy shall not be an integral part of the toy.

VI. Hygiene

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

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

VII. Radioactivity

Toys shall comply with all relevant measures adopted under Chapter III of the Treaty establishing the European Atomic Community.

Schedule II
LIST OF CMR SUBSTANCES AND THEIR PERMITTED USES IN ACCORDANCE WITH
(Points 4, 5 and 9 of Part IV of Schedule I)

Substance:	Classification:	Permitted use:
Nickel	CMR 2	In stainless steel

Schedule III
SPECIFIC LIMIT VALUES FOR CHEMICALS USED IN TOYS INTENDED FOR USE BY CHILDREN UNDER 36 MONTHS OR IN TOYS INTENDED TO BE PLACED IN THE MOUTH
(Article 46(2) of Directive 2009/48/EC)

Schedule IV
EC DECLARATION OF CONFORMITY
(Regulation 12)

1. Unique identification of the toy;

2. Name and address of the manufacturer or his authorised representative;

3. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;

4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy;

5. A statement that the object of the declaration described in point 4 is in conformity with the relevant local or Community harmonisation legislation;

6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared;

7. Where applicable, the notified body's name and number, together with a description of its intervention with respect to the conformity assessment of the toy, including the reference of the certificate issued;

8. Signature of person acting for and on behalf of the manufacturer or the authorised representative. This shall include the name and function of such person;

9. Place and date of issue.

Schedule V
TECHNICAL DOCUMENTATION
(Regulation 14)

The technical documentation referred to in regulations 14(1) to (4) shall contain, in particular, so far as relevant for assessment:

(a) a detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;

(b) the safety assessment carried out in accordance with regulation 13(2);

(c) a description of the conformity assessment procedure followed;

(d) a copy of the EC declaration of conformity;

(e) the addresses of the places of manufacture and storage;

(f) copies of documents that the manufacturer has submitted to a notified body, if involved;

(g) test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in regulation 13(4); and

(h) a copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in regulation 13(5).

Schedule VI
WARNINGS
(Regulation 10)

PART A – General warnings

The user limitations referred to in regulation 10(1) shall include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

PART B – Specific warnings and indications of precautions to be taken when using certain categories of toys

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

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



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

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

2. Activity toys:

Activity toys shall bear the following warning: 'Only for domestic use'.

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

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

3. Functional toys:

Functional toys shall bear the following warning: 'To be used under the direct supervision of an adult'.

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

4. Chemical toys:

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

In addition to the instructions provided for in the first subparagraph, chemical toys shall bear the following warning on their packaging:
'Not suitable for children under ([1]) years. For use under adult supervision'.

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

5. Skates, roller skates, online skates, skateboards, scooters and toy bicycles for children:

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

Moreover, the instructions for use shall contain a reminder that the toy must be

[1] Age to be specified by the manufacturer.

used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user or third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

6. Aquatic toys:

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

7. Toys in food:

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

8. Imitations of protective masks and helmets:

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

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

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

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

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 13 of Part IV of Schedule I and of the fragrances set out in points 1 to 11 of the list set out in third paragraph of that point shall contain the following warning: 'Contains fragrances that may cause allergies'.

Schedule VII
INTERNAL PRODUCTION CONTROL
(Regulation 13)

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

(2) **Technical Documentation**

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the toy's conformity to the relevant requirements, and shall include an adequate analysis and assessment of any risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the toy. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the toy,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the toy,
- a list of the harmonised standards or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

(3) **Manufacturing**

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

(4) **Conformity marking and declaration of conformity**

The manufacturer shall affix the required conformity marking set out in the

legislative instrument to each individual toy that satisfies the applicable requirements of the legislative instrument.

The manufacturer shall draw up a written declaration of conformity for a toy model and keep it together with the technical documentation at the disposal of the Market Surveillance Directorate for 10 years after the toy has been placed on the market. The declaration of conformity shall identify the toy for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the Market Surveillance Directorate upon request.

(5) **Authorised representative**

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

Schedule VIII
EC-TYPE EXAMINATION
(Regulation 13)

(1) EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a toy and verifies and attests that the technical design of the toy meets the requirements of the legislative instrument that apply to it.

(2) EC-type examination may be carried out in either of the following manners:

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

- assessment of the adequacy of the technical design of the toy through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the toy (combination of production type and design type),

- assessment of the adequacy of the technical design of the toy through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

(3) The manufacturer shall lodge an application for EC-type examination with a single notified body of his choice. The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

- a written declaration that the same application has not been lodged with any other notified body,

- the technical documentation. The technical documentation shall make it possible to assess the toy's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the toy. The technical documentation shall contain, wherever applicable, at least the following elements:

  i. a general description of the toy,

  ii. conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

  iii. descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the toy,

iv. a list of the harmonised standards or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

v. results of design calculations made, examinations carried out, etc., and

vi. test reports,

– the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,

– the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

(4) The notified body shall:

For the product:

a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the toy;

For the specimen:

a) verify that the specimen has been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

b) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or technical specifications, these have been applied correctly;

c) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or technical specifications have not been applied, the solutions adopted by the

manufacturer meet the corresponding essential requirements of the legislative instrument;

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

(5) The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

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

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

Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

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

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

(8) Each notified body shall inform its notifying authority concerning the EC-type examination certificates or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of certificates or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EC-type examination certificates or any additions thereto which it has refused, withdrawn,

suspended or otherwise restricted, and, upon request, concerning the certificates or additions thereto which it has issued.

The Regulatory Affairs Directorate and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates or additions thereto. On request, the Regulatory Affairs Directorate may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

(9) The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the Market Surveillance Directorate for 10 years after the toy has been placed on the market.

(10) The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Schedule IX
CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL
(Regulation 13)

(1) Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the toys concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

(2) **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured toys with the approved type described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

(3) **Conformity marking and declaration of conformity**

The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual toy that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

The manufacturer shall draw up a written declaration of conformity for a toy model and keep it at the disposal of the Market Surveillance Directorate for 10 years after the toy has been placed on the market. The declaration of conformity shall identify the toy model for which it has been drawn up.

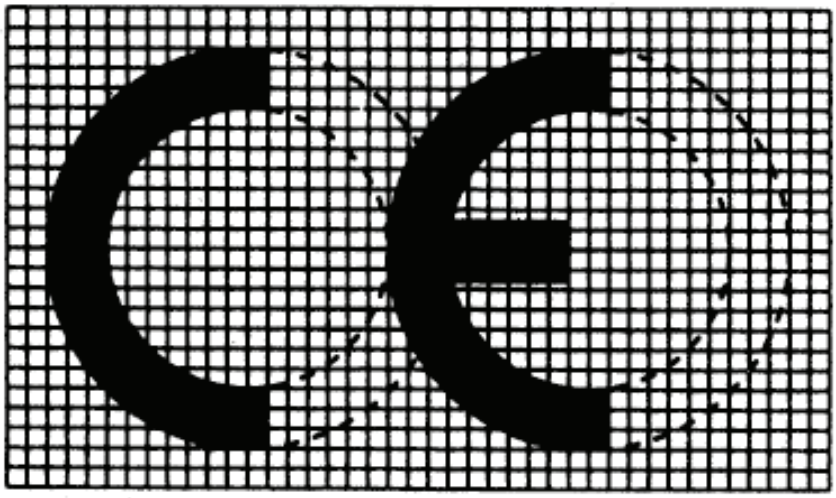
A copy of the declaration of conformity shall be made available to the Market Surveillance Directorate upon request.

(4) **Authorised representative**

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Schedule X
CE-MARKING
(Regulation 11)

1. The CE marking shall consist of the initials ‘CE’ taking the following form:



2. If the CE marking is reduced or enlarged, the proportions given in the graduated drawing in paragraph 1 shall be respected.

3. Where specific legislation does not impose specific dimensions, the CE marking shall be at least 5 mm high.

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