

THE SAFETY OF TOYS

Consultation on the Toys
(Safety) Regulations 2011

FEBRUARY 2011

CONSULTATION ON LEGISLATION TO IMPLEMENT THE DIRECTIVE ON THE SAFETY OF TOYS

Explanation of the wider context for the consultation and what it seeks to achieve

This consultation sets out the Government's legislative approach for the transposition of the European Directive on the safety of toys, 2009/48/EC (the Directive). The proposed UK legislation, which should have been in place by 20 January 2011 is intended to implement the Directive. The Regulations themselves have to be in force for 20 July 2011.

The objective of the Directive is to enhance the level of safety of toys while maintaining the smooth functioning of the Internal Market for toys. To achieve this overall objective three specific objectives were identified.

- Strengthen and modernise the essential safety requirements for toys.
- Improve the understanding and enforcement of the Directive within Member States.
- Improve clarity of the scope and definitions of the Directive.

The shortened consultation period of 8 weeks is necessary in order to ensure that the Regulations can be laid prior to the end of June. Although the closing date for the consultation is 1 April 2011 BIS would welcome any early responses.

The Regulations will be made using, among other powers, the power to make safety regulations under section 11 of the Consumer Protection Act 1987. That section requires the Secretary of State to consult with various concerned interests. This consultation document, which will be made available to stakeholders, together with other formal and informal contacts, satisfies that consultation requirement.

Issued: 4 February 2011

Respond by: 1 April 2011

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This consultation is relevant to: the toy manufacturing and importing and distribution industries, regulatory bodies and local authorities, conformity assessment bodies and consumer organisations.

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1. *Executive Summary*

The European Commission described the Directive as aiming to address three issues:

- Strengthening, clarifying, modernising and completing the essential safety requirements for toys, in response to market developments, scientific progress and to deal with an increased awareness of health and safety issues by consumers and enforcers.
- Improving the understanding, implementation and enforcement of the Directive within Member States.
- Providing clarity in and updating of the scope, concepts and definitions of the Directive, ensuring that it is in line with the general framework for marketing products within the EU.

Scope

1.1 The Directive addresses the three objectives above in reference to toys which are defined as “products designed or intended (whether or not exclusively) for use in play by children under 14 years old. It excludes certain toys and certain categories of object which might otherwise be considered to be toys. It covers the standards for these articles, both physical and chemical, along with requirements for a risk assessment and any warnings to be applied.

1.2 The draft Regulations follow the wording of the Directive as closely as possible although it will be necessary to refer to the underlying Directive in certain cases.

1.3 We are consulting people involved in the industries and public sector organisations affected by the proposals primarily to avoid the Regulations resulting in unintended consequences, although of course much of the wording used in the draft mirrors that used in the Directive. We are therefore seeking the views of manufacturers, importers, and distributors of toys along with those of enforcement agencies and safety services, and safety organisations.

1.4 We are seeking views on:

- a. how we intend to implement the Directive (but not views on the Directive itself which was agreed in the European Parliament and Council and published in June 2009) and
- b. the draft Impact Assessment.

2. Responses and timetable

How to respond

2.1 When responding please state whether you are responding as an individual or whether you are representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

2.2 The closing date for all responses is 1 April 2011

A response can be submitted by letter but preferably by email to:

Email: tony.edenbrown@bis.gsi.gov.uk

Tony Eden-Brown
Department for Business, Innovation and Skills
Environment and Technical Regulation Directorate
1 Victoria Street
London SW1H 0ET
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2.3 A list of specific consultation questions can be found at **Annex A**

2.4 Help with queries

Questions about the policy issues raised in the document can also be addressed to Tony Eden-Brown at the above address.

2.6 Additional copies

You may make copies of this document without seeking permission. Printed copies of the consultation document can be obtained from:

BIS Publications Orderline
ADMAIL 528
London SW1W 8YT
Tel: 0845-015 0010
Fax: 0845-015 0020
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www.bis.gov.uk/publications

An electronic version can be found at <http://www.bis.gov.uk/Consultations>

2.7 Confidentiality & Data Protection

Information provided in response to this consultation, including personal information, may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want information, including personal data that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

2.8 Issues relating to the consultation process

If you have comments or complaints about the way this consultation has been conducted, these should be sent to:

Tunde Idowu, Consultation Co-ordinator
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More information on the Code of Practice on Consultation is in **Annex E**.

3. The Proposal

3.1 Directive 2009/48 replaces the existing Directive 88/378, revising and enhancing it. The existing Directive relies almost fully on the new approach of covering the essential safety requirements on the face of the Directive and delineating the specifics to standards. The revision specifies far more on the face of the Directive although much of the detail will still have to be clarified within European standards groups especially in relation to the chemical restrictions, which will only come into force in July 2013.

3.2 In regard to the use of chemicals in toys, certain allergenic fragrances are banned and the labelling of 26 other fragrance allergens is required in certain circumstances. The revision also bans substances categorised as Carcinogens, Mutagens and substances toxic to Reproduction (CMRs) in accessible parts of toys unless authorised by comitology procedure under the Directive, or within certain derogation limits which although listed on the face of the Directive will have to be refined within standards.

3.3 New measures are designed to improve the effectiveness of warnings in preventing accidents. They provide for the mandatory display of minimum/maximum age for users at point of sale and specific warnings will be required on age or ability, as well as the user weight and the need for the relevant toys to be used under adult supervision.

3.4 The Directive extends the safety requirement relating to the risk of inhalation of small parts from toys so that it covers intended for children under 36 months but also any toys intended to be put in the mouth, regardless of age. The Directive also extends the safety requirements so they cover not only the risk of *external* airway obstruction of the mouth and nose but also *internal* airway obstruction. The Directive also bans 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.

3.5 The revision reinforces the Directive's relationship with the General Product Safety Directive, particularly in relation to specific powers for market surveillance authorities and enforcement cooperation between member States and aligns it to the Regulation on Accreditation and Market Surveillance, and the decision on the marketing of goods.

3.6 Manufacturers, or importers where they take on the responsibility of manufacturer, will be required to perform a more detailed analysis of the risks that a toy presents along with including more chemical information in the technical file.

Further detail on the drafting of the draft Regulations

3.7 As noted above the approach has been to follow the wording of the Directive as much as possible. The draft Regulations have been split into five parts:

- those generally applicable and the essential safety requirements;
- obligations on economic operators – manufacturers, importers distributors and authorised representatives;
- designation of notified bodies;
- functions of notified bodies; and
- enforcement measures.

3.8 It should be noted that we intend bringing into force the provisions for the designation of Notified Bodies as soon as possible. This will mean that these regulations are commenced before the rest of the provisions of the Regulations. Do you foresee any difficulties arising for industry as a result of this?

3.9 As in some cases, the Annexes to the Directive can and certainly will be changed by comitology procedures, the UK Regulations will refer to those Annexes of the Directive as amended from time to time.

The procedure is intended to be that when such Annexes are amended the UK will publish those amendments on a publicly available web-site in order to give all interested parties the maximum possible notice by avoiding the need to draft new legislation.

3.10 The definitions used in the draft Regulations are predominantly those used in the Directive. Some of the language has been tailored (though as little as possible).

Background

3.11 The Directive requires us to bring into force the provisions relating to the physical aspects of toys on 20 July 2011, and those relating to chemicals on 20 July 2013, to allow time for the detail to be assessed and industry to adapt. Provisions to allow the authorisation and notification of Notified Bodies, and the carrying out by such bodies of their authorised functions, will be brought into effect as soon as possible.

4. What happens next?

4.1 The Government will consider all responses to this consultation, to see if any adjustments to the draft Regulations are necessary in order to prepare for the draft Regulations to be made as soon as possible and those provisions which the Directive requires to enter into force on 20 July 2011 to do so.

Annexes

Annex A – Summary of questions

Questions

Question 1: Can you provide any evidence to help inform the Impact Assessment?
In particular:

- any observations on the potential immediate benefits from clearer labelling and warnings
- any observations on the potential long term benefits from the additional chemical restrictions
- any clarifications on the costs
 - a) of the immediate new labelling/warning requirements
 - b) of the longer terms chemical restrictions

any views of the observations on costs relationships with SMEs?

Question 2: Do you believe the enforcement provisions are effective, proportional and enforceable?

Question 3: Do you agree that we should bring the Notified Body notifications into force as soon as possible?

Question 4: Do you agree with the proposal to deal with some of the Annexes to the Directive, by ambulatory references; i.e. referring to them in the Regulations rather than reproducing the Annexes in the body of the Regulations? The advantage of this is that as and when the Directive is updated, the Regulations do not need to be updated and the information can be made available to interested parties by publication on the BIS web-site and notification through Businesslink.

For example; at regulation 3(f), listing products to which the regulations do not apply, at regulation 5(1)(b) listing essential safety requirements and regulation 6, particular safety requirements, and .

Question 5: Do you have additional observations on the detailed drafting?

Annex B – Draft UK Regulations

2011 No. XXXX

CONSUMER PROTECTION

The Toys (Safety) Regulations 2011

Made - - - - ***

Laid before Parliament ***

Coming into force ***

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

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

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

The Secretary of State makes the provisions in regulations 10 to 13 and 15 to 39 in exercise of his powers conferred by section 11 of the Consumer Protection Act 1987(d), and paragraph 1A of Schedule 2 to the European Communities Act 1972(e), and all other provisions in these Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972.

(a) S.I. 1993/2661.

(b) 1972 c.68. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a) and by the European Union (Amendment) Act 2008 (c.7), section 3(3) and Schedule, Part 1.

(c) 1987 c.43.

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

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

PART 1

Preliminary

Citation and commencement

1.—(1) These Regulations may be cited as the Toys (Safety) Regulations 2011.

(2) These Regulations come into force on 20th July 2011, except for regulations 3 to 7, 14 and 17(4) and Parts 3 and 4 of these Regulations which come into force on *****.

Revocation, saving and amendment

2.—(1) The Toys (Safety) Regulations 1995(a) (“the 1995 Regulations”) are revoked.

(2) The 1995 Regulations continue to apply, as if they had not been revoked, to a toy placed on the market before 20th July 2011.

(3) The Pencils and Graphic Instruments (Safety) Regulations 1998(b) are amended as follows.

(4) In regulation 1, insert after paragraph (2)—

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

Interpretation

3. In these Regulations—

“the 1987 Act” means the Consumer Protection Act 1987(c);

“the GPSR” means the General Product Safety Regulations 2005(d);

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

“CE marking” means a marking—

(a) by which a manufacturer indicates that a toy will comply with the essential safety requirements during its foreseeable and normal period of use; and

(b) which takes the form set out in Annex II of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (e);;

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

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

“conformity assessment body” means a body that performs conformity assessment activities;

“the Decision” means Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (f);

(a) S.I. 1995/204, amended by S.I. 2004/1769, S.I. 2005/1082, S.R. 2006/425, S.I. 2010/1928.

(b) S.I. 1998/2406. (S.I. 1998/2406 does not apply, by virtue of regulation 2(3) of S.I. 1995/204, to articles which are toys to which S.I. 1995/204 applies.)

(c) 1987 c. 43

(d) S.I. 2005/1803.

(e) OJ No L 218, 13.8.2008, p30.

(f) OJ No L 218, 13.8.2008, p82.

“the Directive” means Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (a);

“distributor” means any person who—

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

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

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

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

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

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

“hazard” means a potential source of harm;

“importer” means any person who—

- (a) is established within the EU; and
- (b) places a toy from a third country on the EU market;

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

“manufacturer” means a person who—

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

“Member State” means a Member State of the EU;

“Module” means a Module of Annex II to the Decision and Module A, B or C shall be construed accordingly;

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

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

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

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

“toy” has the meaning given in regulation 4;

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

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

Toys to which these Regulations apply

4.—(1) These Regulations apply to toys placed on the market on or after 20th July 2011.

(a) OJ No L 170, 30.6.2009, p1.

(b) OJ No L 24, 21.7.1998, p37, to which there are amendments not relevant to these Regulations.

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

(3) These Regulations do not apply to—

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

Essential safety requirements

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

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

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

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

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

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

(5) The matters are—

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

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

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

Presumption of conformity

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

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

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

Exception for trade fairs or exhibitions

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

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

- (a) the toy does not comply with the Directive; and
- (b) the toy will not be made available in the EU before being brought into conformity with the Directive.

Regulations to be treated as safety regulations within the meaning of the 1987 Act

9. These Regulations, except for Parts 3, 4 and 5, shall be treated for all purposes as if they were safety regulations within the meaning of the 1987 Act.

PART 2

Prohibitions and Obligations on Economic Operators

Manufacturers and their authorised representatives

Prohibitions on placing toys on the market

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

(2) A manufacturer must not place a toy on the market without having complied with—

- (a) regulation 11 (design and manufacture of toy in accordance with essential safety requirements);
- (b) regulation 12 (safety assessment);
- (c) regulation 13 (applicable conformity assessment procedure);
- (d) regulations 15, (obligations in relations to toys complying with essential safety requirements, drawing up of EC declaration of conformity and affixing of CE marking);
- (e) regulation 17(1) to (3) (drawing up of technical documentation);
- (f) regulation 19 (information identifying toy and manufacturer to accompany toys);
- (g) regulation 20 (instructions for use, safety information and warnings to accompany toys); and
- (h) regulation 21 (maintenance of conformity of series production with essential safety requirements).

Design and manufacture of toys in accordance with essential safety requirements

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

Safety assessment

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

Applicable conformity assessment procedures

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

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

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

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

Application for EC-type examination

14. An application for EC-type examination to be performed in relation to a toy must—

- (a) be made to a notified body;
- (b) be made in accordance with Module B;
- (c) include a description of the toy;
- (d) indicate the address at which the toy has been or will be manufactured; and
- (e) if it is made to a UK notified body, be accompanied by such fee as may be required by the body in accordance with regulation 48 (charging of fees by UK notified body).

Obligations in relation to toys complying with essential safety requirements

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

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

EC declaration of conformity

16.—(1) The EC declaration of conformity must state that it has been demonstrated that the requirements set out in Article 10 of, and Annex II to, the Directive have been satisfied in relation to the toy.

(2) Where the toy is placed on the market before 20th July 2013, paragraph (1) does not apply and paragraph (3) applies instead.

(3) The EC declaration of conformity must state that it has been demonstrated that the following have been satisfied in relation to the toy—

- (a) the requirements set out in Article 10 of the Directive;
- (b) the requirements set out in Annex II to the Directive other than those set out in Part III of that Annex; and

- (c) the requirements set out in paragraph 3 of Part II of Annex II to Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys.
- (4) The EC declaration of conformity must also—
 - (a) include the information, and follow the structure, set out in Annex III to the Directive; and
 - (b) include any information required to be included by any Module which was followed in relation to the toy.
- (5) The EC declaration of conformity may contain further information.
- (6) The manufacturer must keep the EC declaration of conformity drawn up in relation to a toy up to date.
- (7) Where the EC declaration of conformity drawn up in relation to a toy which is made available on the market in the territory of the United Kingdom was drawn up in a language other than English, the manufacturer must translate the EC declaration of conformity into English.
- (8) By drawing up the EC declaration of conformity, the manufacturer assumes responsibility for the compliance of the toy

Technical documentation and correspondence relating to EC-type examination

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

- (2) The technical documentation must be drawn up—
 - (a) in so far as it relates to EC-type examination of the toy, in an official language of the Member State in which the notified body who performed that examination is established or in a language acceptable to that body;
 - (b) in so far as it does not relate to such examination, in one of the official languages of the EU.
- (3) The technical documentation must include the information and documents listed in Annex IV of the Directive (technical documentation).
- (4) Any correspondence relating to the EC-type examination of a toy must be drawn up in the official language of the Member State in which the notified body is established or in a language acceptable to that body.
- (5) The manufacturer must keep the technical documentation for a toy (including the EC declaration of conformity) for a period of 10 years after the day on which the toy was placed on the market.
- (6) An enforcement authority may, during the 10 year period, request a manufacturer to provide to it, within a specified period—
 - (a) a copy of all or part of the technical documentation drawn up in relation to a toy; and
 - (b) a translation into English of all or part of the technical documentation.
- (7) A request must be accompanied by the reasons for making the request.
- (8) The specified period must be 30 days beginning with the day on which the request was received by the manufacturer, unless a shorter period is justified in the case of serious and immediate risk.
- (9) The manufacturer must comply with the request.
- (10) If a manufacturer fails to comply in with any of the manufacturer's obligations under paragraphs (1), (2), (3) or (9), an enforcement authority may request the manufacturer to ensure that a notified body performs within such period as the body may specify such tests as may be necessary in order to verify that the toy will comply with the essential safety requirements during its foreseeable and normal period of use, or that the toy complies with any harmonised standard specified by the body.

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

Toys to bear CE marking

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

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

(3) The CE marking must be affixed to—

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

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

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

(5) Where—

- (a) the toy is sold in a counter display;
- (b) it is not possible to affix the CE marking in accordance with paragraph (3) or (4); and
- (c) the counter display was originally used as packaging for the toy,

the manufacturer may (in place of affixing the CE marking in accordance with paragraphs (3) or (4)) affix the CE marking to the counter display.

(6) Where the toy is inside packaging the CE marking must—

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

(7) The CE marking may be followed by a pictogram or by any other mark indicating a special risk or use.

(8) Any toy which bears the CE marking shall be presumed to comply with all the provisions of these Regulations.

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

Information identifying toy and manufacturer to accompany toys

19.—(1) The manufacturer must ensure that the information required is marked—

- (a) on the toy; or
- (b) where the size or nature of the toy precludes the information from being marked on the toy—
 - (i) on the toy's packaging; or
 - (ii) in a document accompanying the toy.

(2) The required information is—

- (a) a type, batch, serial or model number or other information enabling the toy to be identified;
- (b) the manufacturer's name, registered trade name or registered trademark; and
- (c) an address (but not more than one) at which the manufacturer can be contacted.

Instructions for use, safety information and warnings to accompany toys

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

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

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

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

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

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

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

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

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

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

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

Maintenance of conformity of series production with essential safety requirements

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

(2) In doing so, the manufacturer must take into account—

- (a) any change in the design or characteristics of the toy; and
- (b) any change which has been made to any of the harmonised standards referred to in the EC declaration of conformity drawn up in relation to the toy.

Submission of EC-type examination certificate for review

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

- (a) any change is made to—
 - (i) the manufacturing process for the toy;
 - (ii) any raw material used in the toy; or
 - (iii) any component of the toy;
- (b) 5 years have elapsed since the certificate was issued without it having being reviewed by a notified body;

- (c) 5 years have elapsed since the certificate was last reviewed by a notified body without it having been reviewed again by a notified body; or
- (d) the manufacturer is of the view that a review of the certificate is necessary for any other reason.

Monitoring of toys

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

(2) The actions are—

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

Non-compliant toys and toys presenting a risk

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

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

(2) The matters are—

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

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

(4) The manufacturer must comply with the request.

Manufacturer's authorised representative

25.—(1) A manufacturer may, by a written mandate, appoint a person established within the EU as the manufacturer's authorised representative to act on the manufacturer's behalf in relation to specified tasks in relation to a toy.

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

- (a) perform the manufacturer's obligations under regulations 17(5) and (9) (duties to keep technical documentation and provide to the relevant enforcement authority a copy or translation of technical documentation); and
- (b) perform the manufacturer's obligations under regulation 24(4) (duty to cooperate with the relevant enforcement authority in relation to action taken to eliminate risks posed by a toy).

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

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

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

Importers

Prohibitions on placing toys on the market

26.—(1) An importer must not place a toy on the market unless—

- (a) the importer has ensured that the manufacturer has done all of the following things in relation to the toy—
 - (i) followed the applicable conformity assessment procedure in accordance with regulation 13;
 - (ii) drawn up the technical documentation in accordance with regulation 17;
 - (iii) affixed the CE marking in accordance with regulation 18;
 - (iv) complied with regulation 19 (information identifying toy and manufacturer to accompany toys);
 - (v) complied with regulation 20 (instructions for use, safety information and warnings to accompany toys); and
- (b) the importer has complied with both of the following—
 - (i) regulation 27 (information identifying importer to accompany toys);
 - (ii) regulation 28 (storage or transport of toys under importer's responsibility).

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

Information identifying importer to accompany toys

27.—(1) An importer must ensure that the following information is marked on the toy—

- (a) the importer's name, registered trade name or registered trade mark; and
- (b) the address at which the importer can be contacted.

(2) The information may instead be marked on the toy's packaging or on a document accompanying the toy where—

- (a) the size or nature of the toy precludes the information from being marked on the toy; or
- (b) the importer would have to open the toy's packaging in order to mark the information on the toy.

Storage or transport of toys under importer's responsibility

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

Monitoring of toys

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

(2) The actions are—

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

Non-compliant toys and toys presenting a risk

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

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

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

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

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

(4) The matters are—

- (a) the risk presented by the toy;
- (b) the non-compliance in question; and
- (c) any action taken in relation to the toy in accordance with paragraph (3)(a).

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

(6) The importer must comply with the request.

Duties to retain and provide information

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

- (a) keep a copy of the EC declaration of conformity; and
- (b) ensure that the technical documentation can be made available to an enforcement authority on request by the authority.

(2) An enforcement authority, during the 10 year period, request an importer to provide, within such period as the authority may specify, a copy of all or part of the technical documentation (including the EC declaration of conformity), or a translation of it into English.

- (3) A request must be accompanied by the reasons for making the request.
- (4) The importer must comply with the request.

Duty in certain circumstances to comply with manufacturers' duties in place of importers' duties

32.—(1) An importer who places a toy on the market under the importer's name or trademark must comply with all of the duties imposed by these Regulations on manufacturers, and a reference to the manufacturer in these Regulations is to be taken as being a reference to the importer.

(2) Such an importer is not required to comply with the duties imposed by these Regulations on importers.

Distributors

Duty to act with due care and prohibitions on making toys available on the market

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

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

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

Storage or transport of toys under distributor's responsibility

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

Non-compliant toys and toys presenting a risk

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

- (a) will not comply with the essential safety requirements during its foreseeable and normal period of use; and
 - (b) presents a risk,
- (2) The distributor must inform the following of the risk presented by the toy-
- (a) the importer (if there is one);
 - (b) the manufacturer (if there is no importer); and
 - (c) the relevant enforcement authority.

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

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

(4) The matters are—

- (a) the risk presented by the toy;
- (b) the non-compliance in question; and
- (c) any corrective measures taken in relation to the toy in accordance with paragraph (3)(a).

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

(6) The distributor must comply with the request.

Duty to provide information

36.—(1) An enforcement authority may request a distributor to provide, within such period as the authority may specify, any information or documents within the distributor’s knowledge or possession which demonstrate that the toy will satisfy the essential safety requirements during its foreseeable and normal period of use.

(2) A request must be accompanied by the reasons for making the request.

(3) A distributor must comply with a request.

(4) A request for information or documents may not be made more than 10 years after the day on which the toy is placed on the market.

Duty in certain circumstances to comply with manufacturers’ duties in place of distributors’ duties

37.—(1) A distributor who modifies a toy already placed on the market in such a way that compliance with the essential safety requirements may be affected must comply with all of the duties imposed by these Regulations on manufacturers, and in such a case, a reference to the manufacturer in these Regulations is to be taken as being a reference to the distributor.

(2) Such a distributor is not required to comply with the duties imposed by these Regulations on distributors.

All economic operators

Identification of economic operators to enforcement authorities

38.—(1) An enforcement authority may, within the period specified in paragraph (3), request an economic operator (“A”) to identify to the authority, within such period as the authority may specify—

- (a) any economic operator who has supplied A with a toy; and
- (b) any economic operator to whom A has supplied a toy.

(2) The economic operator must comply with the request.

(3) The period is—

- (a) where the request is made to a manufacturer, 10 years after the day on which the toy was placed on the market;

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

Protection of CE marking

- 39.**—(1) A person must not affix a CE marking in relation to a toy unless—
- (a) the person is—
 - (i) the manufacturer; or
 - (ii) an authorised representative of the manufacturer who has been appointed by the manufacturer in accordance with regulation 25(1) to affix the CE marking on the manufacturer’s behalf; and
 - (b) it has been demonstrated by performance of the applicable conformity assessment procedure that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.
- (2) A person must not affix any marking in relation to a toy which—
- (a) is not a CE marking; but
 - (b) purports to attest that the toy satisfies the essential safety requirements.
- (3) A person must not affix in relation to a toy any marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking affixed in relation to the toy.
- (4) Any other marking may be affixed in relation to a toy provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

PART 3

Designation of Notified Bodies

Designation of UK notified bodies

- 40.**—(1) The Secretary of State may designate a person to carry out conformity assessment.
- (2) Such a designation (a “notified body designation”) must be made in accordance with paragraphs (4) to (8).
- (3) A person in respect of whom a notified body designation has been made is a UK notified body to the extent that the designation remains in effect provided that—
- (a) designation has been notified by the Secretary of State to the European Commission and the other member states,
 - (b) no objections have raised by the Commission or the other Member States within the time periods in Article 31 of the Directive.
- (4) A person wishing to be a UK notified body must apply to the Secretary of State for designation under this regulation.
- (5) A notified body designation must not be made unless the Secretary of State is satisfied that the person meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive (the “notified body criteria”).
- (6) A person who meets the assessment criteria laid down in a published harmonised standard shall be presumed to meet that part of the notified body criteria which corresponds to the criteria in that standard.
- (7) The presumption of compliance in paragraph (6) is rebuttable.
- (8) A notified body designation—
- (a) must be in writing;

- (b) must specify the conformity assessment procedures that the person designated may carry out;
- (c) may designate a person for a specified period; and
- (d) may be made subject to such other conditions as are specified in the designation, including conditions which are to apply upon or following termination of the designation.

(9) In making a notified body designation the Secretary of State may have regard (in addition to the notified body criteria) to any other matter which appears to the Secretary of State to be relevant.

(10) A UK notified body must comply with any request of the Secretary of state to provide information relevant to determining its compliance with the notified body criteria, these Regulations, or any condition to which its designation is subject.

Duration, variation and termination of designation

41.—(1) A notified body designation which does not designate a person as a UK notified body for a specified period has effect until it is terminated under paragraph (4).

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

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

- (a) the UK notified body so requests;
- (b) it appears to the Secretary of State necessary or expedient to do so; or
- (c) upon a request of the European Commission.

(4) The Secretary of State may suspend, restrict or withdraw a notified body designation—

- (a) on the expiry of 90 days' notice in writing at the request of the UK notified body;
- (b) if it appears to the Secretary of State that any condition of the designation is not complied with;
- (c) if the Secretary of State considers that the UK notified body no longer satisfies the notified body criteria; or
- (d) upon a request of the European Commission.

(5) Where the Secretary of State is minded to vary a designation in accordance with paragraph (3)(b), or to terminate a notified body designation under paragraph (4)(b) to (d), the Secretary of State must—

- (a) give notice in writing to the UK notified body of the proposed variation or termination and the reasons for it, stating that the body has 21 days from the date of the notice in which to make representations to the Secretary of State in respect of the proposed variation or termination; and
- (b) consider any representations received in accordance with the notice.

(6) If a designation is terminated under paragraph (4), the Secretary of State may, by notice in writing—

- (a) authorise another UK notified body to take over the functions of the UK notified body whose designation has been terminated in respect of such cases as are specified in the notice; and
- (b) give such directions as the Secretary of State considers appropriate (either to the UK notified body whose designation has been terminated or to another UK notified body) in respect of a UK notified body's files or any other matter which the Secretary of State considers expedient for the purposes of ensuring that another notified body carries out the functions of a notified body for the existing customers of the body whose designation has been terminated.

PART 4

UK Notified Bodies: Functions

Duty to perform EC-type examinations

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

(2) But a UK notified body is not obliged to carry out such functions where—

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

Performance of EC-type examinations

43.—(1) A UK notified body performing an EC-type examination in relation to a toy must—

- (a) perform that examination in accordance with the provisions of Module B;
- (b) evaluate (if necessary together with the manufacturer) the analysis carried out by the manufacturer in accordance with regulation 12(safety assessment); and
- (c) while respecting the need for the requirements that are imposed by these Regulations in relation to the toy to be complied with, perform the examination—
 - (i) in a proportionate manner, avoiding unnecessary burdens for economic operators; and
 - (ii) taking due account of—
 - (aa) the size of the relevant economic operator;
 - (bb) the sector in which the economic operator operates;
 - (cc) the structure of the economic operator;
 - (dd) the degree of complexity of the technology of the toy; and
 - (ee) the mass or serial nature of the production process for the toy.

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

Issue and content of EC-type examination certificate, and refusal and appeal against refusal to issue certificate

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

(2) An EC-type examination must include—

- (a) a reference to the Directive;
- (b) a colour image of the toy;
- (c) a clear description of the toy, including its dimensions;

- (d) a list of each test performed during the EC-type examination of the toy; and
 - (e) a reference to the test report for each listed test).
- (3) A UK notified body must refuse to issue an EC-type examination certificate if—
- (a) in the body’s opinion the toy will not comply with the essential safety requirements during its foreseeable and normal period of use;
 - (b) the body is aware that an EC-type examination certificate that was previously issued in relation to the toy has been withdrawn by any notified body; or
 - (c) the body is aware that a notified body has previously refused to issue an EC-type examination certificate in relation to the toy.

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

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

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

Action following issue of EC-type examination certificate where toy fails to comply with essential safety requirements

45.—(1) This regulation applies where—

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

(2) The UK notified body must—

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

(3) The UK notified body must restrict, suspend or withdraw the EC-type examination certificate issued in relation to the toy, as appropriate, where—

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

Provision of information by UK notified bodies to other notified bodies

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

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

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

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

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

(3) A notified body must comply with a request.

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

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

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

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

- (i) the manufacturing process for the toy;
 - (ii) any raw material used in the toy; or
 - (iii) any component of the toy;
 - (b) where 5 years have elapsed since the certificate was issued without it having being reviewed by a notified body;
 - (c) where 5 years have elapsed since the certificate was last reviewed by a notified body without it having being reviewed again by a notified body.
- (7) A UK notified body must comply with a requirement imposed under paragraph (5).

Participation by UK notified bodies in sectoral groups of notified bodies

48.—(1) A UK notified body must participate in the work of each relevant sectoral group of notified bodies put in place by the European Commission in accordance with Article 38 of the Directive (coordination of notified bodies).

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

Subcontractors by UK notified body of third party to carry out conformity assessment tasks

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

- (a) the body is satisfied that the subcontractor or subsidiary meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive (requirements relating to notified bodies); and
- (b) the economic operator for whom the task or activity is to be carried out has consented to the task or activity being performed by that person.

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

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

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

(4) A UK notified body must comply with a request.

Charging of fees by UK notified body

50.—(1) A UK notified body may charge such fees in connection with, or incidental to, the carrying out of its functions under regulations 40, 41, 42 and 43, as it may determine.

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

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

- (ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) A UK notified body may require the payment of fees or a reasonable estimate of fees in advance of carrying out the work for the manufacturer.

Provision of information by UK notified bodies to the Secretary of State

51.—(1) A notified body must notify the Secretary of State of—

- (a) any refusal by the body to issue an EC-type examination certificate in relation to a toy;
- (b) any restriction, suspension or withdrawal by the body of an EC-type examination certificate issued in relation to a toy;
- (c) any circumstances affecting the scope of the body’s designation or any conditions to which its designation is subject; and
- (d) any request which the body has received from an enforcement body for information about conformity assessment activities.

(2) The Secretary of State may request a notified body to provide to the Secretary of State, within such period as the Secretary of State may specify—

- (a) information about any conformity assessment activity carried out by the body within the scope of the body’s designation;
- (b) information about any other activity carried out by the body, including cross-border activities and sub-contracting; and
- (c) information relevant to determining the body’s compliance with any of the requirements laid down in paragraphs (2) to (11) of Article 26 of the Directive (requirements relating to notified bodies), any provision of these Regulations or any condition to which the body’s designation is subject.

(3) A notified body must comply with the request.

PART 5

Enforcement

Enforcement action in cases of formal non-compliance

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

- (a) no CE marking has been affixed;
- (b) a CE marking has been affixed but any provision of regulation 18 or regulation 39 has not been complied with or has been contravened;
- (c) the manufacturer has not drawn up an EC declaration of conformity;
- (d) the manufacturer has drawn up an EC declaration of conformity but the declaration does not comply with any provision of regulation 16(1) to (4); or
- (e) the technical documentation is unavailable or incomplete.

(2) A compliance notice must—

- (a) specify the description of the toy to which the notice relates;
- (b) specify which type of non-compliance listed in paragraph (1) the enforcement authority has found has occurred in relation to the toy and the reasons for its finding;
- (c) require the economic operator—
 - (i) to put an end to the non-compliance concerned within such period as may be specified in the notice; or

- (ii) to provide evidence within that period to the satisfaction of the enforcement authority that the non-compliance concerned has not in fact occurred; and
 - (d) warn the economic operator that, if the non-compliance concerned continues, or if satisfactory evidence has not been produced under sub-paragraph (c) (ii) within the period specified in the notice, further action may be taken by an enforcement authority in respect of that toy or any toy of the same type supplied by that person.
- (3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.
- (4) A compliance notice has effect throughout the United Kingdom.
- (5) Where an enforcement authority has power to serve a compliance notice in relation to a toy, no action may be taken under sections 14, 16 or 17 of the 1987 Act in relation to the toy until a compliance notice has been served and the economic operator has failed to comply with its requirements.
- (6) Where an enforcement authority has served a compliance notice in relation to a toy and the economic operator has failed to comply with its requirements, paragraphs (7) and (8) apply in relation to the toy.
- (7) An enforcement authority may (on the grounds that an economic operator has failed to comply with a compliance notice) serve a withdrawal notice under regulation 14(1) of the GPSR, and—
- (a) regulations 14(3) and 16(5) of the GPSR do not apply in relation to such a notice;
 - (b) regulation 17(2) of the GPSR shall be treated as conferring power on the court or the sheriff (as the case may be) to make an order setting aside such a notice only if satisfied that it was inappropriate in all the circumstances for the enforcement authority to serve the notice.
- (8) An enforcement authority may (on the grounds that an economic operator has failed to comply with a compliance notice) serve a recall notice under regulation 15(1) of the GPSR, and—
- (a) regulations 15(4) and 16(6) of the GPSR do not apply in relation to such a notice;
 - (b) regulation 17(2)(d) of the GPSR shall be treated as conferring power on the court or the sheriff (as the case may be) to make an order setting aside such a notice only if satisfied that it was inappropriate in all the circumstances for the enforcement authority to serve the notice;
 - (c) for the purposes of regulation 15(9) of the GPSR (power of enforcement authority to take such action itself as could have been required by a recall notice), the condition in regulation 15(1) of the GPSR that an enforcement authority has reasonable grounds for believing that the toy is a dangerous product is deemed to be satisfied.
- (9) This regulation does not apply where the enforcement authority in question has sufficient reason to believe that the toy presents a risk to the health or safety of persons, and in such a case regulation 53 applies instead.

Enforcement action in cases of toys presenting a risk

53.—(1) This regulation applies where—

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

and an enforcement authority carries out an evaluation as to whether the toy complies with all the requirements of these Regulations.

(2) Where the enforcement authority carrying out the evaluation finds that the toy does not comply with any requirement of these Regulations, paragraphs (4) to (7) apply in relation to the toy.

(3) Where the body carrying out the evaluation—

- (a) as a result of carrying out the evaluation no longer has sufficient reason to believe that the toy presents a risk to the health or safety of persons; and
 - (b) finds that only a non-compliance (or non-compliances) of any of the types listed in regulation 52(1) has (or have) occurred in relation to the toy,
- paragraphs (4) to (7) shall not apply and regulation 52 shall apply instead.

(4) An enforcement authority may serve a withdrawal notice under regulation 14(1) of the GPSR in relation to the toy, and—

- (a) regulations 14(3) and 16(5) of the GPSR do not apply in relation to such a notice;
- (b) regulation 17(2) of the GPSR shall be treated as conferring power on the court or the sheriff (as the case may be) to make an order setting aside such a notice only if satisfied that it was inappropriate in all the circumstances for the enforcement authority to serve the notice.

(5) An enforcement authority may (on the grounds that the enforcement authority carrying out the evaluation has found that the toy does not comply with any requirement of these Regulations) serve a recall notice under regulation 15(1) of the GPSR in relation to the toy, and—

- (a) regulations 15(4) and 16(6) of the GPSR do not apply in relation to such a notice;
- (b) regulation 17(2)(d) of the GPSR shall be treated as conferring power on the court or the sheriff (as the case may be) to make an order setting aside such a notice only if satisfied that it was inappropriate in all the circumstances for the enforcement authority to serve the notice; and
- (c) for the purposes of regulation 15(9) of the GPSR (power of enforcement authority to take such action itself as could have been required by a recall notice), the condition in regulation 15(1) of the GPSR that an enforcement authority has reasonable grounds for believing that the toy is a dangerous product is deemed to be satisfied.

(6) Where any measure taken by an enforcement authority is considered unjustified in accordance with Article 43(2) of the Directive, the enforcement authority must withdraw the measure or apply to the court to withdraw the measure as necessary.

(7) This Regulation does not prevent an enforcement authority or other person from taking such action as it considers appropriate under the 1987 Act or the GPSR in relation to a toy which presents a serious risk requiring rapid intervention.

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

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

(2) An enforcement authority which, following an evaluation finds that the toy does not comply with any requirement of these Regulations, has served any of the following notices in relation to a toy must inform the relevant notified body that it has done so—

- (a) a withdrawal notice under regulation 14(1) of the GPSR;
- (b) a recall notice under regulation 15(1) of the GPSR;
- (c) a prohibition notice under section 13(1)(a) of the 1987 Act;
- (d) a suspension notice under section 14(1) of the 1987 Act.

Action to be taken where Article 42 procedure for toys presenting a risk is initiated by another Member State

55.—(1) Where any provisional measure taken by another Member State in relation to a toy pursuant to Article 42(4) of the Directive is deemed under Article 42(7) of the Directive to be justified or is decided by the European Commission to be justified pursuant to Article 43(1) of the Directive (and that decision is communicated to the United Kingdom), the following provisions of this regulation apply, and regulation 53 does not apply, in relation to the toy.

(2) An enforcement authority may (on the grounds that a provisional measure taken by another Member State pursuant to Article 42(4) in relation to the toy is deemed under Article 42(7) to be justified or has been decided by the European Commission to be justified pursuant to Article 43(1) of the Directive) serve a withdrawal notice under regulation 14(1) of the GPSR, and—

- (a) regulations 14(3) and 16(5) of the GPSR do not apply in relation to such a notice;
- (b) regulation 17(2) of the GPSR shall be treated as conferring power on the court or the sheriff (as the case may be) to make an order setting aside such a notice only if satisfied that it was inappropriate in all the circumstances for the enforcement authority to serve the notice.

(3) An enforcement authority may (on the grounds that a provisional measure taken by another Member State pursuant to Article 42(4) in relation to the toy is deemed under Article 42(7) to be justified or has been decided by the European Commission to be justified pursuant to Article 43(1) of the Directive) serve a recall notice under regulation 15(1) of the GPSR, and—

- (a) regulations 15(4) and 16(6) of the GPSR do not apply in relation to such a notice;
- (b) regulation 17(2)(d) of the GPSR shall be treated as conferring power on the court or the sheriff (as the case may be) to make an order setting aside such a notice only if satisfied that it was inappropriate in all the circumstances for the enforcement authority to serve the notice;
- (c) for the purposes of regulation 15(9) of the GPSR (power of enforcement authority to take such action itself as could have been required by a recall notice), the condition in regulation 15(1) of the GPSR that an enforcement authority has reasonable grounds for believing that the toy is a dangerous product is deemed to be satisfied.

(4) In England and Wales or Northern Ireland an enforcement authority may (on the grounds that a provisional measure taken by another Member State pursuant to Article 42(4) in relation to the toy is deemed under Article 42(7) to be justified or has been decided by the European Commission to be justified pursuant to Article 43(1) of the Directive) apply for an order for the forfeiture of the toy under regulation 18(1) of the GPSR, and regulation 18(6) of the GPSR does not apply in relation to such an order.

(5) In Scotland a sheriff may make an order for forfeiture of the toy under regulation 19(1) of the GPSR (on the grounds that a provisional measure taken by another Member State pursuant to Article 42(4) in relation to the toy is deemed under Article 42(7) to be justified or has been decided by the European Commission to be justified pursuant to Article 43(1) of the Directive), and regulation 19(6) of the GPSR does not apply in relation to such an order.

(6) Where any provisional measure taken by another Member State in relation to a toy pursuant to Article 42(4) of the Directive is decided by the European Commission to be justified pursuant to Article 43(1) of the Directive (and that decision is communicated to the United Kingdom), the Secretary of State must inform the European Commission of any subsequent action taken by an enforcement authority or other person, or any order made, under the 1987 Act, the GPSR or this Part of these Regulations in relation to the toy.

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

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

- (a) prohibit or restrict a toy from being made available on the market;

- (b) withdraw a toy; or
 - (c) recall a toy.
- (2) The following requirements must be complied with in relation to the measure—
- (a) the measure must state the exact grounds on which it is based;
 - (b) the measure must be notified without delay to the party concerned; and
 - (c) at the same time as the measure is notified to the party concerned that party must also be informed of—
 - (i) any remedy available to that party in relation to the measure; and
 - (ii) any time limit to which that remedy is subject.
- (3) Where an enforcement authority takes any measure in relation to a toy, the authority must take due account of the precautionary principle.

Commencement of proceedings

57.—(1) In England and Wales a magistrates’ court may try an information, and in Northern Ireland a magistrates’ court may try a complaint, in respect of an offence committed under—

- (a) these Regulations; or
- (b) section 12 of the 1987 Act in relation to a contravention of or a failure to comply with these Regulations,

if the information is laid or the complaint is made within twelve months from the discovery of the offence by the prosecutor.

(2) In Scotland summary proceedings in relation to an offence committed under—

- (a) these Regulations; or
- (b) section 12 of the 1987 Act in relation to a contravention of or a failure to comply with these Regulations,

may be begun at any time within twelve months from the discovery of the offence by the prosecutor.

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

Duty of review

58. The Secretary of State must review these Regulations after 20th July 2016.

	<i>Name</i>
	Title
Date	Department for Business, Innovation and Skills

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ No L 170, 30.06.2009, p.1). The Directive sets harmonised safety requirements for toys and minimum requirements for market surveillance, in order to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market.

The Directive repeals and replaces Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (OJ No L 187, 16.7.88, p.1) (as amended), which was implemented in the United Kingdom by the Toys (Safety) Regulations 1995 (S.I. 1995/204) (as amended). These Regulations revoke and replace S.I. 1995/204, subject to the continuing application of S.I. 1995/204 to toys placed on the market before 20 July 2011 (regulation 2).

The substantive requirements in the Regulations come into force on 20 July 2011 (regulation 1). However, the provisions enabling conformity assessment bodies to apply to become UK notified bodies, and enabling UK notified bodies to carry out the functions of notified bodies, come into force on ***** (regulation 1).

Regulation 4 sets out the toys to which the Regulations apply. In particular, they apply only to toys placed on the market on or after 20 July 2011. Regulation 5 defines the essential safety requirements which apply to toys, and is subject to a transitional provision in respect of the requirements in respect of the chemical properties of toys placed on the market before 20 July 2013 (regulation 6).

Part 2 of the Regulations sets out the prohibitions and obligations on economic operators. These are divided into prohibitions and obligations on manufacturers and their authorised representatives (regulations 10 to 25), on importers (regulations 26 to 31), on distributors (regulations 33 to 36), and on all economic operators (regulations 38 and 39). The various categories of economic operator are defined in regulation 3. In certain circumstances, importers and distributors are required to comply with the duties on manufacturers in place of the duties on importers or distributors (regulations 32 and 37).

Part 3 of the Regulations sets out the process for the appointment of conformity assessment bodies as UK Notified Bodies.

Part 4 sets out the functions of UK notified bodies.

Part 5 of the Regulations deals with enforcement of the Regulations, both in cases of formal non-compliance and toys presenting a risk.

A transposition note and a full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector are available from the BIS website (www.bis.gov.uk). They are also annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website (www.opsi.gov.uk). Copies have also been placed in the Libraries of both Houses of Parliament.

Annex C – Impact Assessment

Title: Impact Assessment of Proposals to Revise the Toys (Safety) Regulations 1995 Lead department or agency: BIS Other departments or agencies:	Impact Assessment (IA)
	IA No: BIS0016
	Date: January 2011
	Stage: Consultation
	Source of intervention: EU
	Type of measure: Secondary legislation
	Contact for enquiries: Tony Eden-Brown 020 7215 0360

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

The market failure rationale behind the revision of the 1995 Toy Safety Directive (TSD) is asymmetric information:

- (i) children/parents are not necessarily able to accurately judge the toy's appropriateness prior to purchase;
- (ii) there is insufficient provision for manufacturers or importers to display/document the products characteristics and surveillance authorities lack enough information on the toy's safety, and
- (iii) the existing TSD lacks clarity on the scope.

Additionally after 20 years in place, EU Member States considered an update necessary in the light of experience of its operation, developments in scientific knowledge in respect of the long term effects of chemicals. Without government intervention UK manufacturers would be left with considerable uncertainty as exporters would need to comply with two different sets of Regulations (UK Regulations and European law)

What are the policy objectives and the intended effects?

The objectives that the revision of the Directive try to fulfil are to improve the smooth functioning of the internal market for toys, in part by incorporating the New Legislative Framework, while ensuring an improved level of safety, enforcement and clarification of scope and concepts.

The new Directive should reduce the effects of toy related incidents as well as reduce the long term health costs imposed on consumers and Member States by substantively improving toy safety levels above those of the current regulations.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

The following options have been considered:

- (0) do nothing, whereby the level of safety in toys would not change and the Department risks infraction proceedings and an uneven playing field between Member States and third countries;
- (1) modification of the directive (the Government's preferred option that is being taken forward because it has already been agreed at EU level), which will ensure an improved level of safety, enforcement and clarification of scope and concepts.

The costs and benefits of each option specific to the UK are difficult to ascertain since the only piece of relevant evidence available has been produced by the European Commission and covers the whole of the EU.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 2015
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

SELECT SIGNATORY Sign-off For final proposal stage Impact Assessments:

***I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.
Signed by the responsible Minister***

: Date:.....

Summary: Analysis and Evidence Policy Option 1

Description:

Modification of UK regulations in line with the EU Directive

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	£32.5	£324.7m
High	Optional	£58.2m	£582.4m
Best Estimate	Unquantifiable	£45.4m	£453.5m

Description and scale of key monetised costs by 'main affected groups'

Two types of costs are quantified in the annex to this IA, although for reasons outlined below they should be considered cautiously. They may well be an over estimate of the overall costs, but may be an underestimate of the costs per business.

Annual Costs: 1) Increased Testing
2) Increased administration costs for businesses

Other key non-monetised costs by 'main affected groups'

Transitional costs: 1) Review of existing product range
2) Toy Redesign

Annual costs: 3) Enforcement Costs

Note that the cost to business of addressing the new requirements is likely to be partly passed on to consumers in the form of higher prices.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	£4.6m	£40.3m
High	Optional	£198.5m	£1,709m
Best Estimate	0		

Description and scale of key monetised benefits by 'main affected groups'

Increased health benefits by reducing the long term harmful effects to children through exposure to certain chemicals in toys. The large range is due to the uncertainty of the European Commission about the size of current and future harm. A best estimate is highly uncertain but may well be at the lower end of the spectrum.

Other key non-monetised benefits by 'main affected groups'

Benefits to industry from reduced legal uncertainty. The revision would also benefit the National Health Service by reducing the burden in terms of disease and accident prevention.

Key assumptions/sensitivities/risks

Assumed there will be effective compliance and effective enforcement to realise the benefits.

Discount rate (%)

3.5

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	AB savings:	Net:	Policy cost savings:	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Options UK wide		
From what date will the policy be implemented?			20/06/2011		
Which organisation(s) will enforce the policy?			Trading Standards		
What is the annual change in enforcement cost (£m)?			minimal		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/a	Non-traded: N/a	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			Costs: n/a	Benefits: n/a	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	Micro	< 20	Small	Medium	Large
Are any of these organisations exempt?	No	No	No	No	n/a

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on...?	Impact	Page ref within IA
Statutory equality duties¹⁵ Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	p. 17
Small firms Small Firms Impact Test guidance	Yes	p.17
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	p.18
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	

¹⁵ Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	European Commission Impact Assessment http://ec.europa.eu/enterprise/sectors/toys/files/toys_final_report_without_annexes_en.pdf
2	
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y ₀	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Transition costs										
Annual recurring cost	50.5	49.3	48.1	46.9	45.8	44.7	43.6	42.6	41.5	40.5
Total annual costs	50.5	49.3	48.1	46.9	45.8	44.7	43.6	42.6	41.5	40.5
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base (for summary sheets)

Opinion of the Regulatory Policy Committee and responses

The Committee considered the overall costs and benefits presented in this Impact Assessment could not be considered reliable.

The Committee's assessment that the costs and benefits cannot be considered reliable is not disputed. The consultation may produce some reaction on projected costs, but it has to be borne in mind that whilst the revisions to labelling, eg additional warnings and clearer age related guidance come into force shortly, the chemical restrictions which probably comprise half of projected costs, do not come into force until July 2013. This is not a long time frame, and in fact the UK argued for a longer implementation date, as the methodology of calculation of acceptable migration limits still has to be decided, after which specific limits for certain chemicals can be calculated. This is complicated by the fact that migration limits are established for around sixty chemicals commonly found in toys within the standards in the current Directive/Regulations. It is doubtful that much better estimates will be obtained during the consultation, and will probably only become apparent around the time of the post implementation review.

Specific opinions of the RPC

***Benefits to consumers.* The lower bound of the estimated benefits (£40.3m) is based on a low-ingestion/ low-damage scenario, the upper bound (£1.7bn) is based on a high-ingestion/ high-damages scenario. However, the IA provides little indication of the current level of injuries to UK consumers as a result of the use of toys. Also, as the IA does not provide any estimate of the likely reduction in these injuries from the proposed regulation it is difficult to assess which scenario is most likely to occur in the UK. In addition, the net benefit range provided in the IA is so large that it is difficult to determine with any certainty what the effects of the policy are.**

Response - Whilst there are historical figures (until 2005) of accidents amounting to some 40,000 per year involving toys, we have not quoted these figures, as many do not involve a hazard in the toy, but that simply a toy has been involved eg someone trips over one left on the floor. The labelling/warning/age/ban on toys attached to food aspects in the new Regulations should have a positive effect where the toy is responsible for a serious incident principally by making parents more aware of the risks involved eg a choking hazard. A child's accidental death is estimated to cost £1,500,000 in total costs (Treasury Green Book), so even a small reduction would be significant.

The long term benefits of any reduction in adult disease caused by the removal of any chemical hazards in toys is very much an estimate based on the Commission impact assessment: this has to be a wide range by its long term nature. The basis is that scientific knowledge of hazards has identified a number of substances which are potentially carcinogenic, mutagenic or toxic to reproduction – the further restriction in toys may be minimal, but equally may catch something very harmful: eg an asbestos equivalent. However the effects of any particular restriction is likely to not be measurable specifically for a number of years.

***Costs.* It is not clear that all the costs of the proposal have been presented. Costs are likely to fall on UK manufacturers and UK consumers, but the level of costs for each sector are not presented. The presented estimates of the total costs also have not been discounted and so are not in PV terms.**

Response - In discussion with industry, we identified the likely costs and we may learn something more from the consultation – but again with the costs of any additional chemical restrictions very much an unknown, we can only assume that industry will initially bear costs but some of these additional costs may be passed on to consumers. The extent of this is unknown and will depend partly on negotiations between manufacturers and retailers when setting prices.

The costs presented in the Impact assessment are in present value terms.

Impact on Small and Medium Sized Enterprises (SME). The Small Firms Impact Test is inadequate. As the IA says that compliance with this proposal will typically have a disproportionate effect on SMEs more evidence and analysis should be provided in the Small Firms Impact Test.

Response - In this particular case we have emphasised that virtually all the manufacturers in this industry are SMEs. Additional costs will fall on businesses in the industry, but given the general ability of larger companies to absorb additional costs, the relative effect will be higher for SMEs. Because of the way the Regulation is applied the additional costs are likely to fall disproportionately on manufacturers whose toys are complex and involve a wide range of materials, in terms of testing and quality assurance costs.

Overview

The draft revision of Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (TSD) was published on 25 January 2008. The Department regularly consulted stakeholders on the negotiations within Council and Parliament. Agreement was reached and the Directive published on 18 June 2009 as Directive 2009/48EC.

On balance the final result is close in substance to the original Commission proposal on which the EU Impact Assessment referred to below is based.

Directive 2009/48 achieves the overall objective of enhancing the level of safety of toys while maintaining the smooth functioning of the Internal Market. Three specific objectives identified.

- Strengthening, clarifying, modernising and completing the essential safety requirements for toys, in response to market developments and scientific progress, and to deal with an increased awareness of health and safety issues by consumers and enforcers.
- Improving the understanding, implementation and enforcement of the Directive within Member States.
- Providing clarity and updating the scope, concepts and definitions of the Directive, ensuring that it is in line with the general legislative framework for marketing products within the EU.

Background

The requirements of the TSD were implemented into UK Law by the Toys (Safety) Regulations 1995 (SI 1995 No. 204), (the Regulations.) The TSD was one of the first “New Approach” Directives, whereby the Directive sets the basic requirements and harmonised standards set the detail. The revised Directive 2009/48/EC also needs to be implemented into our domestic legislation, as the UK assented in Council in January 2009.

The Directive which enters into force on 20 July 2011 offers a two-year transitional period for toys already complying with 88/378/EEC, and which were placed on the market before entry into force of the revised Directive. Importantly it offers a further 2 year grace period in respect of the chemical restrictions of Directive 2009/48 in order to reduce the impact on industry and to allow the development of new harmonised standards for those chemicals. As those exact requirements have not yet been agreed, the costs associated with this aspect cannot be easily estimated.

This first deposited text on 25 January 2008 reflected the informal discussions from 2003 in Commission working groups. The Directive had a difficult passage in formal Council Working Groups as some Member States wished to make the Directive over-precautionary in respect of the limits applied to chemicals and by banning all fragrances in toys, a position reflected in the European Parliament. A

number of high-profile recalls of toys because of safety concerns in the summer of 2007 led a number of Member States to call for further restrictive measures, which would in effect ban the possibility of certain types of toy, and potentially lead to manufacturers and importers withdrawing from the market. The 2007 recalls were high-profile because they involved a leading manufacturer, but stricter legal safety assessment requirements would not have prevented these recalls. Under normal circumstances most recalls on the EU RAPEX system involve low-priced/low-quality or counterfeit toys which basically make no attempt to pass the existing standards in any case.

The UK has consistently promoted an appropriate and proportionate level of revision. The final Directive better reflects this position.

Interaction with other Legislation

Two legislative provisions are relevant:

- The General Product Safety Regulations 2005 (GPSR) set the general safety requirement of a product by requiring that no producer may place, offer to place on the market, supply, agree to supply, expose or possess a product for supply if the product is intended for use by consumers unless the product is safe in normal and foreseeable use. Specifically, the GPSR place certain obligations on producers and distributors, including a requirement to provide adequate warnings and instructions for use, and to notify local authorities when they become aware that a product placed on the market/supplied presents a risk to consumers.
- The Consumer Protection Act 1987 (CPA): This provides the legal basis for much of the consumer safety legislation introduced in the UK, including the Regulations. Infringement of the Toys Regulations is an offence under the CPA.
- The draft Regulations also vary from the previous UK Regulations in that they take account of Regulation (EC) no 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products which is complementary to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products which came into force on 1 January 2010.

Identifying the unique aspects of the Regulations

The 1995 Regulations set out the essential safety requirements for toys and specifically limits the amounts of dangerous substances which may be used in toys, mostly harmonised standards developed by CEN. Toys that meet these standards benefit from a presumption of conformity with the essential safety requirements, as long as all the safety features of the toy are covered by the standards.

The new Directive specifies more chemicals and their limits– it also bans or introduces requirements for certain allergenic fragrances. The requirements for many of the chemical aspects remain to be refined by CEN.

The existing Regulations set out the specific steps and requirements manufacturers and importers must meet to place products on the market, which in terms of the new Directive are in part replaced by the horizontal New Legislative Framework legislation particularly in respect of obligations of economic operators, conformity assessment procedures and market surveillance.

Scale and Scope

Gross value added of the toy manufacturing industry¹⁶ in the UK was approximately £181 million in 2006, which amounted to 0.12% of total UK manufacturing GVA. In addition, the UK toy manufacturing

¹⁶ SIC 32.4 which includes: manufacture of games and toys, manufacture of professional and arcade games and toys and manufacture of other games and toys not elsewhere classified

industry has a total turnover¹⁷ of £500 million (0.1% of total manufacturing turnover). This comprises of approximately 450 businesses which employ roughly 5,000 people. The market structure of the UK toy manufacturing industry is almost entirely made up of SMEs¹⁸ with 86% of its enterprises having fewer than 9 employees.

In terms of trade of toys, the UK imported £1.5 billion worth of toys in 2006, 70% of which came from outside the European Union. According to the Commission, at EU level a large majority of the toys sold are imported and the greatest proportion (up to 90%) comes from China. In addition, industry has estimated that sales were about £2.7bn in 2009 with 250m volume sales, although this excludes some retailers.

These calculations have been made on a wider level of aggregation than the products the Directive specifically considers. Disclosure problems were encountered with ONS data when trying to drill the data down to a more detailed analysis of this specific market under consideration. It is therefore the case that the calculations undertaken (in terms of costs for this impact assessment) may be an overestimation since the fragment of the market analysed is wider than that considered in the Directive. The industry association best estimate of size comes to around 400 companies – the wider product coverage ONS figure is 640. Because of this, we have included some industry estimates of the size of the market, although these are estimates.

Problem Definition

The Directive was reviewed in 2003 as it had not been reviewed during its existence and subsequently after informal discussion in Commission Working Groups the European Commission published a revised Directive in 2008.

The main areas the draft identified where improvement was needed related to:

- labelling and warnings surrounding the use of toys,
- chemical substances contained in toys which were potentially dangerous and about which more had been learnt in the intervening period
- the need to take into account Directives which had effects on certain toys (eg low voltage Directive) and a lack of clarity on the scope of the TSD, in terms of risk assessment of a particular toy and its foreseeable use/misuse.

The market failure rationale behind the revision of the TSD is that of asymmetric information. Consumers are not always in a position to judge the toy's safety, in relation to the age and ability of their child, and in particular regarding substances that are not visible (harmfulness of chemicals, noise emissions levels and dangers of laser components). Moreover, the Directive as it stands at present does not always follow technical progress, cannot respond fully to recently identified hazards, needs to clarify general safety requirements and could provide more adequate warning requirements.

The enforcement of the Directive is based on the manufacturer's responsibility for the safety of the product; market surveillance is carried out ex-post by public authorities – generally Trading Standards in the UK. The existing TSD does not contain any explicit requirement for manufacturers to carry out, document or make available for inspection the hazard/risk analysis. The revised Directive requires the hazard/risk analysis to be available to enforcement authorities. This improves on the current requirement which simply is a requirement to test against standards – although in practice most manufacturers would conduct a risk assessment. The rules on the information provided (through CE marking) are also outdated due to Regulation (EC) No.765/2008 and EC Decision No 768/2008/EC, which further complicates the task of the surveillance authorities. Regulation in this area will help the surveillance authorities more easily ensure that toys produced or entering the EU market are hazard-free, therefore reducing the information asymmetry that exists at the moment.

¹⁷ Excluding VAT

¹⁸ Following the European Commission definition

New provisions on chemical requirements: Directive 2009/48 maintains the safety requirements existing in the TSD with regard to the use of chemicals in toys, and is enhanced by banning certain allergenic fragrances and requiring the labelling of others. The revision also bans all substances categorised as Carcinogens, Mutagens and substances toxic to Reproduction (CMRs) in accessible parts of toys unless authorised by comitology procedure, in order to reduce preventable illnesses being caused in later life by negative effects inflicted in childhood. There is however a derogation allowing the use of these substances within safe limits, which are noted in the Directive as Category 1A, 1B (0.1%) and Category II (1.0%). These limits will have to be amended in terms of specific chemicals either before the chemical aspects of the Directive enter into force in 2013 or during its lifetime. This will add costs in terms of testing of limits, but as the methodology is not yet complete, let alone individual limits for all substances costs are impossible to estimate. As stated previously this area is complicated as a number of these substances already have limits under the standards set under the existing Directive.

New provisions on warnings: The current Directive covers some warnings on toys. The new measures are designed to improve their effectiveness in preventing accidents. They provide for the mandatory display of minimum/maximum age for users at point of sale and specific warnings will be required on age or ability, as well as the minimum/maximum user weight and the need for the relevant toys to be used under adult supervision.

New provisions on choking and suffocation risks: The Directive currently covers the risk of inhalation of small parts from toys intended for children under 36 months. It has been decided that this provision needs to be extended to any toys intended to be put in the mouth, regardless of age. The Directive currently covers the risk of *external* airway obstruction of the mouth and nose. The proposal is to extend this definition to *internal* airway obstruction to deal with the risk presented by new toys such as those with suction cups. The new draft also covers risks of strangulation and asphyxiation. This has largely been covered by standards, but has never been specified as an essential safety requirement in the legislation.

New provisions on airway obstruction as a result of the association of toys and food items: The current Directive contains no specific provisions for toys in food. The revision addresses this problem with a new requirement that i) toys should be marketed in a package separating them from the food items they are attached to; ii) the packaging itself should not present a choking hazard, and iii) there will be a ban on 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. There have been deaths in the EU and the UK because of this type of toy; an accidental death of a child is estimated to have associated costs of around £1 million.

New provisions on reinforcement of Market Surveillance measures: The revision reinforces the Directive's relationship with the Regulation on Accreditation and Market Surveillance and General Product Safety Directive, particularly in relation to specific powers for market surveillance authorities and enforcement cooperation between Member States.

New provisions on information on chemicals in the technical files: The revision will require further information on the chemical composition of certain components and materials used in toys.

New provision on CE Marking: The revision extends the CE Marking requirements of the Directive, requiring the marking to be affixed to the packaging of the toy if the marking on the toy is not visible through the packaging. This incorporates the requirements of Regulation (EC) No. 765/2008 and EC Decision No 768/2008/EC.

New provision on the Safety Assessment: Manufacturers and importers etc. will in future be required to perform an analysis of the hazards that the toy may present and make it available as part of the toy's technical file to market surveillance authorities for inspection, although many manufacturers will have been undertaking this as a matter of course.

Alignment of the Directive with the provisions of the Council and Parliament Decision on the marketing of goods: The revision of the TSD is aligned to the Common Framework on the Marketing of Goods Decision 768/2008/EC. This ensures consistency between all New Approach Directives, particularly in areas such as conformity assessment bodies, definitions, routes to conformity and rules for CE Marking.

Clarification of the scope of the Directive: The revision will aim to complete the list of products which are not within its scope with regards to new products such as videogames and their peripherals. The new Directive will also include further definitions specific to the toys sector such as activity toys etc. More widely it requires more consideration of the risks, requiring thought be given to the use of toys used in a foreseeable way as in the existing Directive, but adding “bearing in mind the behaviour of children” – in other words foreseeable misuse.

Rationale for Government Intervention

The UK has existing Regulations covering toy safety. Without Government intervention the UK manufacturers would be left with considerable uncertainty. The requirements under the existing UK Regulations will differ from those required under European law, meaning that companies that export would need to comply with two different sets of Regulations and hence two different manufacturing standards. The safety of toys sold in the UK would be less safe than those sold elsewhere in the EU. Without Government action the UK would also be open to infraction proceedings. The industry is already gearing up to conform with the new Directive and would not welcome such a situation, nor indeed voluntary compliance with the new Directive which would also leave the enforcement authorities with substantial dilemmas. We would also attract substantial, and perhaps justified criticism from safety organisations, given that this Directive relates to the safety of children.

IDENTIFICATION OF OPTIONS

There are two main options under consideration in this Impact Assessment:

Option (i) Do nothing

Option (ii) Modifications to the directive (as detailed above)

We now proceed to develop arguments for these two options:

Option (i) – Do nothing

The first option to consider is to do nothing, which would mean that the UK would not transpose the revision of the Directive and would therefore be (i) almost certainly liable to EU infraction, (ii) contravening EU internal market rules and (iii) breaching Article 10 of the EC Treaty, the duty of loyal co-operation. This approach leads to both internal market problems for UK exporters whose goods would have to meet the new requirements and safety issues. To do nothing would also mean that problems such as safety requirements, enforcement and clarification of scope and concepts would not be dealt with; as a consequence the risk of health incidents related to toys would persist. The do nothing approach is used in this Impact Assessment (as is common practice) as the baseline to our analysis.

Option (ii) – Regulatory Approach through Modifications to the UK Regulations

These are considered to improve the Directive’s efficiency, functioning, reliability and transparency. The relevant authorities in Member States will in theory benefit from a clarification of responsibilities and information, and from the enhanced accessibility of the data. The revision of the Directive would make these authorities’ duties easier and reduce costs. Manufacturers would in theory benefit from the clarification of definitions and responsibility. Other benefits claimed by the Commission’s impact assessment which would accrue to manufacturers would be the reduction of the level of counterfeiting

that currently takes place in the EU market. However the main benefits from the revision of the Directive would benefit consumers as stated below.

The option of voluntary standards or guidelines was considered at an early stage, but rejected on the grounds that:

- It would certainly not offer justified protection to consumers;
- It would disadvantage legitimate players who tried to conform to the standards
- Companies exporting to Europe would have to conform to the EU standards and would be further disadvantaged in the UK market
- There would be no recourse on dangerous products imported from outside of the EU.

Benefits to the consumer

The main social benefits of the Directive's revision would be to consumers, in particular children. The revision of the Directive would have benefits through reductions in the number of toy-related incidents. In particular, the most significant benefits would arise from modifications to the chemical safety requirements which would help reduce the number of children developing diseases and other chemical-related harmful medium and long-term effects. It is believed the revision of the Directive would also produce benefits in terms of a reduction in the burden on the health systems of the Member States in the longer term. The reduction to the health systems' burden was not quantified in the Commission's Impact Assessment and it is out of the scope of this Impact Assessment.

Health benefits were quantified in the Commission's Impact Assessment in terms of Disability Adjusted Life Years (DALYs) for the EU as a whole. Those results are not easily translated into quantifiable benefits for the UK. However, it is worth mentioning that benefits accrued by the different EU options range from €1.2 billion Present Value (for low ingestion and low damages) to €50.9 billion PV on a high-ingestion/high-damages scenario to 2051. In the previous UK impact assessment, to monetise the benefits accrued to the UK from the revision of the Directive we weighted the European Commission's calculations of benefits according to the proportion of the EU total population accounted for by the UK; and calculated the benefits on a 10 year basis to be consistent with our calculation of costs and discounted them at the standard 3.5% rate. Based on this, we estimate benefits specific to the UK could range from £40.3 million to £1.7 billion.

It is clear that this range is very large and it is not clear to what extent the issues identified in the directive as requiring regulation actually cause harm to consumers. It is therefore difficult to accurately assess at which end of the range the best estimate would lie for the UK.

A WHO report in 2007¹⁹ states that the current main threats to children's health were increasingly connected to the environment, including chemicals in the environment (air, food, water) and from proximity to individual exposures. Chronic illnesses – including asthma, paediatric cancer, developmental and behavioural disorders and congenital defects – are becoming an increasing burden to society. Noise can induce hearing impairment. Moreover, the human body is vulnerable to the output of certain lasers and under some circumstances exposure can result in damage to the eye and skin. These items are covered by harmonised standards, but not included in the essential safety requirements of toys. Market surveillance surveys carried out in Member States have highlighted the presence of dangerous chemicals in toys, some of which are not currently regulated at Community level, such as allergens and nitrosamines.

The current TSD maintains that toys cannot contain dangerous substances within 67/548/EEC and 88/379/EEC in amounts which might harm the health of children. The new Directive extends the provisions on the use of certain dangerous substances in toys, such as CMRs (substances which are or may be carcinogenic, mutagenic or toxic to reproduction) or allergenic fragrances and takes account of Regulation (EC) No 1272/2008 of 16 December 2008 which provides for the harmonisation of the

¹⁹ 'Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals'

classification and labelling of substances and mixtures by aligning existing EU legislation with the United Nations Globally Harmonised System (GHS) and contributes to the GHS aim that the same hazards will be described and labelled in the same way all around the world. It substantively changes hazard descriptions and classes from the previous EU legislation covering dangerous substances: Council Directive 67/548/EEC.

Therefore, it is important to prevent these negative health effects associated with exposure to chemicals from toys from affecting children, as they are more sensitive than adults to the effects of certain chemicals and have also different behaviour patterns, such as being more likely to mouth objects which result in greater intake of migratable substances.

Costs

We now look at the main issues in the revision from the point of view of cost impacts:

- **Chemical requirements:** The Commission's impact assessment considers three different approaches when considering the revision of the provisions on chemicals requirements in relation to REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals). The chosen approach would be the most stringent one, whereby there would be a ban on allergenic substances and on all CMRs in Category Ia, Ib and II, unless authorised by dedicated comitology procedure. CMR category 1a, and 1b, are proven and evidenced CMRs, and category II are suspected CMRs.

The current approach to CMRs bans them in toy parts that are accessible. This approach will lead to some substitution of chemicals or in some cases possibly the withdrawal of certain toys from the market. Some Member States had been pressing for a complete ban on CMRs in all toys. This was dropped as Member States concluded that this was a disproportionate approach and would have the effect of precluding the manufacture of any toy containing a motor (train sets etc.) or electronic components, toys containing batteries and potentially anything using HDF or MDF (fibreboard) (where formaldehyde is used as a preservative).

It may also have had a counterproductive effect, as children would use more alternative objects (computers, mobile phones or a household object to represent the non-existent toy) where safety standards are less rigorous and where they would be exposed to the same or greater risks from the same chemicals that would have been excluded from toys.

The Directive specifies that CMRs in accessible parts should be cleared on a positive basis by the Scientific Committee on Consumer Products, except where there are minimal concentration limits. These will need to be refined by reference to migration limits (the amount of a substance released). The stricter approach would have involved substantial extra costs to manufacturers in presentation of scientific evidence that a wide range of products are safe. The rationale behind choosing a strict approach is that children are particularly vulnerable consumers. It is difficult to detangle the costs of this approach to reflect costs in the UK toy market. The Commission's estimates are believed to be an indication and are caveated in a number of ways.

The **implementation** of the Directive's chemical requirements revision is not likely to happen before **2013** due to the complexity of the issues under consideration. The rest of the issues raised by the Directive will most likely be implemented in 2011.

- **More stringent requirements on warnings:** minimum and maximum age would be displayed at the point of sale, since this is considered the most important information for the consumer to ensure the toy is used under safe conditions. According to the Commission's Impact Assessment, the cost of the proposed modification will, as would be expected, hit SMEs harder than multinationals with an estimated cost per SME of £12,700 to £63,800 for modifying warning labels although there was no information gathered on the costs of assessing the appropriate ages for each toy.
- **Changes on requirements of choking risk:** It has been considered disproportionate to raise the age limit from 36 months in respect of choking etc hazards in respect of all toys. However, it is

proportionate for the Directive to extend choking risks requirements to toys which are intended to be put in the mouth (i.e. toy instruments).

- **Clarifying the suffocation risk:** The Commission's chosen regulatory approach covers the risk of internal airway obstruction for the toy only. Standards already cover the risk of internal airway obstruction but including it in the Directive will ensure a legal base for guaranteeing a high level of safety in the future. The requirement will not impose any additional cost.
- **Clarifying the general requirement for safety:** A clear general safety definition is essential since it is the only legal basis for taking dangerous toys out of the market. The new wording in this revised provision referring to the 'behaviour of children' as opposed to the 'normal behaviour' of children is unlikely to create major new costs for industry, although it may require some design changes for some toys. The option to clarify the definition does not seem to affect procedures for assessing safety.
- **Special requirements for toys in food:** These new provisions ban toys sold directly attached to food, and recognises that current standards for toy/food products, (e.g. Kinder eggs) should prevent further suffocation incidents. Specific warnings for products where a toy is combined with food are likely to reduce risk levels. According to the Commission, these measures appear consistent with the main precautionary principles approach of proportionality and non-discrimination. Costs of regulatory action to industry are likely to be minimal.
- **Information on chemicals in the technical profile:** Industry will face some administrative costs associated with redrafting their technical files but it is not envisaged that these will be high in the longer term. There will be some additional permanent costs arising from the extended requirements on testing.
- **Affixing of CE-marking:** The Commission considered the costs of affixing the amended rules on CE marking which would involve the modification of existing moulds and designs (for plastic toys) and text on labels and packaging in plush toys. The extension of the Directive in this specific instance would involve the requirement that the CE marking be affixed to the toy or the packaging and (if not visible from outside) the (transparent) packaging, it should always be affixed at least to the packaging. This would facilitate the surveillance authority's task with minimal costs to industry. However these requirements would have to be met anyway as they result from Regulation (EC) No. 765/2008 and EC Decision No 768/2008/EC.
- **Conformity assessment procedures:** Mandatory third-party verification was considered disproportionately costly to industry in view of the expected benefits. However, harmonised standards covering all safety aspects of all toys do not exist, EC type approval is deemed necessary. The estimated compliance costs of such an approach will be minimal since the large majority of toys are subject to harmonised standards.

Cost Impacts

BIS met some members of industry who outlined the major impacts that the set of regulations are likely to lead to. It is worth outlining that due to the fact that the chemical requirements have not been announced, the industry are unsure as to the extent of the costs that will be imposed. However, they identified four areas in which costs are likely to occur. Although industry stakeholders were helpful in outlining the types of costs that are likely to arise, they were unable to provide quantification of the costs.

Transitional costs

- **Review of existing product lines:** The first transitional impact will be the need of manufacturers and importers to review their existing product lines. This will involve removing some product lines that will not meet the requirements or where it is not deemed cost beneficial to redesign.

In addition, due to the change in definitions, some products that were not previously classified as toys will now need to be assessed as toys, such as musical instruments and crayons. It is uncertain

at this stage what impact this will have on these industries, especially without the chemical requirements not being announced.

Finally, included in the review of the existing product ranges is a need to review the warning labels on packaging. This may involve expanding the warning labels and increasing the packaging used so the directives' requirements are complied with.

- **Toys Redesign:** In discussion with industry, they considered that they potentially may have to redesign toys twice, once for July 2011 and again for 2013 when the chemical requirements come in to force. The first redesign will be to include warnings and address details of the manufacturers on the toys themselves.

However this does not necessarily mean that all these costs could be accounted for by the directive for two reasons. First, some toys are periodically redesigned during normal course of business so as they are redesigned, they can incorporate the new requirements without any additional cost to business. Second, some toys have a short product lifecycle and thus would not be renewed and new toys being designed could already incorporate the requirements of the directive.

Despite these caveats, a number of toys will need to be redesigned and this will have to happen both in 2011 where a number of requirements come into force and then again in 2013 where the chemical requirements come into force.

Recurring costs

- **Enhancement of safety requirements including testing requirements:** (new provisions on chemical requirements, more stringent requirements on warnings, changes to requirements around the choking risk, clarification of suffocation risk, and general requirement of safety, and special requirements for toys in food);

As a result of the directive and particularly the chemical requirements, most toys will need to be tested to ensure that they comply with the requirements and to provide reassurance to retailers.

Industry representatives estimated that this could increase the amount of testing by a scale of four (this is a preliminary worst case estimate as the methodology for testing, let alone limits for individual substances is not yet agreed) compared to current practice because of expected more stringent testing limits and the need for more refined testing equipment if this is the case. This will clearly have implications on both the cost to businesses and resource requirements for testing houses. There have been concerns that the testing industry is not yet ready for the additional demand on its services and this is likely to lead to an increase in the cost of each individual test. There may also be a likely increase in safety assessments for toys and product risk assessments.

There are circumstances under which testing may not be required, for example if all the inputs are known to the manufacturer. However, if this is not the case, testing is likely to be required. These requirements are expected to have the largest impact on SMEs who do not always make all their inputs and will be relying on their supplier to provide information about the inputs.

- **Additional administrative cost to companies:** One of the major impacts of the directive will be the additional compliance requirements for toys. It is believed that this will mean that there may be a 30-40% increase in the amount of quality assurance work required, especially with the increased testing. Industry representatives estimated that a great deal of SME's will either need to employ one more person to do this work or outsource the work. However, there are not thought to be a large number of companies with the capacity to outsource this work to.
- **Costs of enforcement:** (changes in technical files in information on chemicals, CE marking and traceability information and conformity assessment procedures.) It is currently very difficult to

assess whether enforcement costs will increase or decrease. Currently, the obligation to prove a toy is unsafe lies with Trading Standards. However, under the Directive, the more specific technical file containing the information about chemicals and hazards and risks should be available to Trading Standards on request. Because of this, the time required for each inspection may decrease.

EU Impact assessment costs

According to the Commission's Impact Assessment and considering the factors explained above it can be concluded that the costs of the revision of the Directive are acceptable, as long as they are necessary and remain proportionate in attaining the objective. There is difficulty in achieving a meaningful aggregate estimate for total costs of the revision of the Directive considering the complex structure of the market and the lack of reliable, specific information on costs. The Commission has used a case-study approach to arrive at an aggregate estimate and at this point in time this is probably the most reliable estimate we have on the cost of the revision to businesses in the UK.

TABLE 1			
Percentage Increase in Production Costs by Case Study Company and Cost Scenario			
	Cost Scenario		
	Low	Medium	High
Modifications to the Proposed TSD addressing the Safety of Toys			
Multinational	+0.26%	+0.91%	+1.89%
SME	+1.6%	+4.6%	+8.9%

Source: European Commission

Table 1 above gives an indication of the percentage increase in production costs from an individual company case study. These estimates exclude chemical requirements and therefore do not give a complete picture of the overall costs incurred by each type of business. Although consumers are likely to be the main beneficiaries of the revision of the Directive, it is unclear to what extent the increase in costs will be passed on to them. Manufacturers pointed to the fact that retailers have target price ranges and toys which do not fall within the price range would not be stocked, or the manufacturer would have to accept a cut in their margin. Alternatively, retailers may have to adjust their target price ranges due to the increased costs, which would then mean consumers would bear the costs of the Directive.

As for the changes in ongoing costs associated with the revision to chemical requirements over 2008-2051 (and as specified in the annex to the impact assessment) these would on average be 6% for manufacturers as well as importers, with the heaviest burden falling onto SMEs (around 7.6% for SME manufacturers).

The main costs of a revision on chemical requirements are administrative, distributional and manufacturing process costs. These costs have been estimated by the Commission to total €3.7 billion (£9.3 billion at 2007 exchange rates) up to 2051²⁰ for the whole of the EU. Other costs not accounted for are enforcement and compliance costs, costs of delay to innovation and the associated administrative burden.

²⁰ Unless otherwise specified the analysis of costs and benefits has been calculated to 2051

The Commission also estimates that 3,300 jobs would be lost in the toy manufacturing industry EU-wide. The exact share of these costs that would fall on the UK is difficult to determine. However the calculation itself is, according to the Commission, subject to a number of uncertainties. This includes the possibility that future cost estimates have been overestimated by stakeholders, as well as an assumption that additional manufacturing costs are incurred every year, implying that manufacturers would not adjust their processes over time. Moreover, the Commission considers distributional costs to be an overestimation.

For these reasons and the fact that the issue under consideration is the safety of particularly vulnerable consumers, the Commission has chosen the approach under which net costs outweigh net benefits. We do not have enough information on this area to be able to carry out the same analysis focused on the UK. Administrative costs associated with the revision on chemical requirements would mainly fall on SMEs (which are also the only category of producers in the UK). The likely increase in ongoing costs for SMEs under the Commission's preferred approach is estimated to be 7.6% for SME manufacturers and 6% for SME importers. Price increases would therefore be likely (passing the cost on to consumers), with the Commission estimating the degree of pass-through to result in SMEs increasing their prices by 5%.

On calculating the likely costs of the extension of the Directive we have assumed a 1% annual growth of the UK toy industry to 2051. This assumption is made on the basis that certain products are likely to contribute to secure and stable sales in the future such as products attached to the promotion of sports, film and music (character licensing and branding); the revival of classic toy brands and the focus of SMEs on niche markets. According to the Commission stable and secure sales would most likely be supported by stable demand trends.

As we have seen above, the Commission makes an estimate of the costs of the proposal as a percentage increase in production costs to industry, with a lower bound to manufacturers of 9.2% of production costs (to account for a 1.6% increase in production costs arising from modifications to address the safety of toys and 7.6% to address chemical requirements) and an upper bound of 16.5% (to account for 8.9% increase in production costs to manufacturers and a 7.6% for chemical requirements). To calculate the costs of the Directive's revision we have estimated production costs to the industry under SIC 32.4 (which includes products that would not be covered by the Directive *per se* as explained in page 6).

Under these assumptions the average annual costs to the toy industry of complying with the Directive would range from £32.5 million to £58.2 million of which £28.2 million per annum would cover the chemical requirements. The rest of the Directive's provisions have been estimated to cost industry between £4.9 million and £27.3 million per annum. The estimated total costs to industry (discounted at the standard 3.5% rate) range from £325 million to £582 million. According to the Commission's Impact Assessment (specifically in terms of the revision of chemical requirements) the burden of costs associated with the proposed TSD could fall disproportionately on smaller companies. At this point in time we are unable to forecast which part of these costs could be passed on to consumers and which part would not.

According to the Commission's Impact Assessment the likely costs to the Competent and Market Surveillance Authorities are expected to be minimal.

Costs to importers are difficult to ascertain since we do not know to what an extent the products imported into the UK would already comply with the TSD hence we have not been able to monetise them for the purposes of this Impact Assessment. Some manufacturers are also importers and might ask for the product to comply with specific standards but it is not clear how these costs would be subsumed by each firm.

Wider Impacts

With these new requirements being imposed with the costs associated with complying for each product line, there could be wider implications for the number of product lines and therefore choice that

customers will have available. Given the majority of costs are likely to be per product line, importers may well have to reduce the number of lines they import. To what extent this will impact on competition is unclear.

Competition Assessment

The Directive will apply to all Member States of the EU. It is unlikely that the proposals will directly limit the range of suppliers, their ability or incentives to compete. However it may well indirectly affect the range of products, as discussed above, because of the additional testing requirements. However it is believed that is unlikely to have the effect of distorting or removing competition in the market. The Commission's Impact Assessment thinks it plausible that overall market competitiveness will not be affected since EU and non-EU manufacturers would need to adhere to the same standards if they wish to sell their products in the EU. However those manufacturers exporting outside the EU might have some contained cost increase in foreign markets as they will not be likely to develop two different production chains.

Small Firms Impact test

Most toy manufacturers and retailers in the UK are SMEs, and as has been specified in this Impact Assessment small firms would be those most affected by revisions to the Directive. The Commission analysis indicates that the larger the company in terms of turnover, the lower the impact of the proposed TSD costs, suggesting the burden of costs would fall disproportionately on small companies. However this very much depends on the range of materials used and toys designed.

Impact on the Public Sector – Enforcement and Sanctions

The Toys (Safety) Regulations 1995 are enforced by local authorities' trading standards departments. It is the responsibility of the manufacturers of toys made in the EU or importers of finished products to ensure that products comply with the Regulations.

Trading Standards will have to enforce these additional requirements. It is difficult to predict the costs involved, but it is not believed these additions to the Regulations will have any major substantive impact on their costs.

Health Impact Assessment

The proposed revision of the Directive will benefit consumers, in particular children. The extension of the Directive would have benefits through reductions in the number of toy-related incidents. In particular, the most significant benefits would arise from modifications to the chemical safety requirements which would help reduce the number of children developing diseases and other chemical-related harmful medium and long-term effects.

Gender Equality Impact Test

This has been considered and it is not thought that there will be any possibility of consumers being excluded from benefiting from any potential changes on the ground of their gender. In terms of costs, it has not been possible to ascertain the extent to which any revision to the Directive would fall disproportionately on a particular gender.

Disability Equality Impact Test

This has been considered and it is not thought that there will be any possibility of consumers being excluded from benefiting from any potential changes on the ground of any disability. In terms of costs, it

has not been possible to ascertain the extent to which any revision to the Directive would fall disproportionately on those with disabilities

Race Equality Impact Test

This has been considered and it is not thought that there will be any possibility of consumers being excluded from benefiting from any potential changes on the ground of their ethnicity. In terms of costs, it has not been possible to ascertain the extent to which any revision to the Directive would fall disproportionately on a particular ethnicity.

Environmental Impact Test

Consideration of the effect of the revision of the Directive in the environment has been considered. Environmental protection is not within the objectives of the Directive therefore no direct environmental impacts are expected from this proposal. The only modifications which could potentially result in (indirect) environmental impacts are the proposed restrictions of the use of chemicals in toys. The forthcoming limits/ban on certain dangerous chemicals would limit the amount of these chemicals which could potentially enter the environment

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

<p>Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];</p> <p>The Commission intends for Member States to report on the application of the Directive 3 years after it is implemented and every 5 years thereafter. A summary of Member States' reports will be published by the Commission.</p>
<p>Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]</p> <p>The objective of the PIR will be to assess whether the policy has had the intended effects, in particular reducing the number and effect of toy-related incidents.</p>
<p>Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]</p> <p>The PIR will be based on a mix of qualitative and quantitative evidence, gathered from enforcement teams (in this case, Trading Standards) and industry participants, hopefully supported by evidence from accident-related statistics.</p>
<p>Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]</p> <p>The current number and effect of toy-related incidents provides the baseline against which the effect of the policy can be judged.</p>
<p>Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]</p> <p>Success of the policy will be evident from a reduction in the number and effects of toy-related incidents. However, it is important to note that other factors may be involved, such as increased consumer awareness leading to increased reporting of incidents.</p>
<p>Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection of monitoring information for future policy review]</p> <p>Market surveillance activities are required under EC Regulations. In the UK market surveillance activities generally undertaken by Trading Standards, will allow a systematic collection of relevant information.</p>
<p>Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]</p> <p>N/A</p>

Annex D - European Directive 2009/48

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

DIRECTIVES

DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 June 2009 on

the safety of toys

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (¹),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (²),

Whereas:

- (1) Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (³) was adopted in the context of establishing the internal market in order to harmonise the safety levels of toys throughout the Member States and to remove obstacles to trade in toys between Member States.
- (2) Directive 88/378/EEC is based on the New Approach principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (⁴). Thus, it sets out only the essential safety requirements with regard to toys, including the particular safety requirements regarding physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity. Technical details are adopted by the European Committee for Standardisation (CEN) and the

European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (⁵). Conformity with harmonised standards so set, the reference number of which is published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 88/378/EEC. Experience has shown that these basic principles have worked well in the toys sector and should be maintained.

- (3) Technological developments in the toys market have, however, raised new issues with respect to the safety of toys and have given rise to increased consumer concerns. In order to take account of those developments and to provide clarification in relation to the framework within which toys may be marketed, certain aspects of Directive 88/378/EEC should be revised and enhanced and, in the interests of clarity, that Directive should be replaced by this Directive.
- (4) Toys are also subject to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (⁶), which applies in a complementary manner to specific sectoral legislation.
- (5) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (⁷) lays down horizontal provisions on the accreditation of conformity assessment bodies, on the CE marking and on the Community market surveillance framework for, and controls of, products entering the Community market which also apply to the toys sector.

¹) OJ C 77, 31.3.2009, p. 8.

²) Opinion of the European Parliament of 18 December 2008 (not yet published in the Official Journal) and Council Decision of 11 May 2009.

³) OJ L 187, 16.7.1988, p. 1.

⁴) OJ C 136, 4.6.1985, p. 1.

⁵) OJ L 204, 21.7.1998, p. 37.

⁶) OJ L 11, 15.1.2002, p. 4.

⁷) OJ L 218, 13.8.2008, p. 30.

- (6) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products ⁽¹⁾ provides common principles and reference provisions for the purposes of legislation based on the New Approach principles. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Directive to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, formal objections against harmonised standards, rules for the CE marking, requirements for conformity assessment bodies and notification procedures and the provisions concerning procedures dealing with products presenting a risk should be aligned to that Decision.
- (7) In order to facilitate the application of this Directive by manufacturers and national authorities, the scope of this Directive should be clarified by completing the list of products which are not within its scope, in particular as regards certain new products, such as videogames and peripherals.
- (8) It is appropriate to provide for certain new definitions specific to the toys sector in order to facilitate the understanding and uniform application of this Directive.
- (9) Toys that are placed on the Community market should comply with the relevant Community legislation, and economic operators should be responsible for the compliance of toys, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of consumers and of the environment, and to guarantee fair competition on the Community market.
- (10) All economic operators are expected to act responsibly and in full accordance with the legal requirements applicable when placing or making toys available on the market.
- (11) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that under normal and reasonably foreseeable conditions of use, the toys they place on market do not jeopardise the safety and health of children and that they make available on the market only toys which comply with the relevant Community legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.
- (12) As certain tasks can be executed only by the manufacturer, it is necessary to distinguish clearly between the manufacturer and operators further down the distribution chain. It is also necessary to distinguish clearly between the importer and the distributor, as the importer introduces toys from third countries to the Community market. The importer has thus to make sure that those toys comply with the applicable Community requirements.
- (13) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure for toys. Conformity assessment should therefore remain the obligation of the manufacturer alone.
- (14) It is necessary to ensure that toys from third countries entering the Community market comply with all applicable Community requirements, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those toys. Provision should therefore be made for importers to make sure that the toys they place on the market comply with the applicable requirements and that they do not place on the market toys which do not comply with such requirements or which present a risk. For the same reason, provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.
- (15) Where the distributor makes a toy available on the market after the toy has been placed on the market by the manufacturer or the importer, it should act with due care to ensure that its handling of the toy does not adversely affect the compliance of the toy. Both importers and distributors are expected to act with due care in relation to the requirements applicable when placing or making toys available on the market.
- (16) When placing a toy on the market, importers should indicate on the toy their name and the address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the toy does not allow for such an indication. This includes cases where importers would have to open the packaging to put their name and address on the product.
- (17) Any economic operator that either places a toy on the market under its own name or trademark or modifies a toy in such a way that compliance with applicable requirements may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the toy concerned.

⁽¹⁾ OJ L 218, 13.8.2008, p. 82.

- (19) Ensuring traceability of a toy throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant toys available on the market.
- (20) Certain essential safety requirements which were laid down in Directive 88/378/EEC should be updated to take account of technical progress since the adoption of that Directive. In particular, in the field of electrical properties, technical progress has made it possible to allow the limit of 24 volts set in Directive 88/378/EEC to be exceeded, while guaranteeing the safe use of the toy concerned.
- (21) It is also necessary to adopt new essential safety requirements. In order to ensure a high level of protection of children against risks caused by chemical substances in toys, the use of dangerous substances, in particular substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), and allergenic substances and certain metals, should be subject to careful attention. It is therefore in particular necessary to complete and update the provisions on chemical substances in toys to specify that toys should comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (¹). Those provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on CMR substances, in accordance with applicable Community legislation on the classification, labelling and packaging of substances and mixtures, and on fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. Nickel in stainless steel has proven to be safe, and consequently it is appropriate that it can be used in toys.
- (22) The specific limit values laid down in Directive 88/378/EEC for certain substances should also be updated to take account of the development of scientific knowledge. Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those
- considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.
- (23) Toys or their parts and their packaging that can reasonably be expected to be brought into contact with food should comply with Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (²).
- (24) In order to ensure adequate protection in the case of toys involving a high degree of exposure, it should be possible to adopt implementing measures establishing specific limit values for chemicals used in toys intended for use by children under 36 months and in other toys intended to be put in the mouth, taking into account the requirements of Regulation (EC) No 1935/2004 and the differences between toys and materials which come into contact with food.
- (25) The general and specific chemical requirements laid down by this Directive should aim at protecting the health of children from certain substances in toys, while the environmental concerns presented by toys are addressed by horizontal environmental legislation applying to electrical and electronic toys, namely Directive 2002/95/EC of the European Parliament and of the Council of 18 December 2002 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (³) and Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (⁴). In addition, environmental issues on waste are regulated by Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 (⁵), those on packaging and packaging waste by Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 (⁶) and those on batteries and accumulators and waste batteries and accumulators by Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 (⁷).
- (26) The system established by this Directive should also encourage, and in certain cases ensure, that dangerous substances and materials used in toys are replaced by less dangerous substances or technologies, where suitable economically and technically viable alternatives are available.

¹) OJ L 396, 30.12.2006, p. 1.

²) OJ L 338, 13.11.2004, p. 4.

³) OJ L 37, 13.2.2003, p. 19.

⁴) OJ L 37, 13.2.2003, p. 24.

⁵) OJ L 114, 27.4.2006, p. 9.

⁶) OJ L 365, 31.12.1994, p. 10.

⁷) OJ L 266, 26.9.2006, p. 1.

- (27) In order to protect children from the risk of impairment of hearing caused by sound-emitting toys, more stringent and comprehensive standards to limit the maximum values for both impulse noise and continuous noise emitted by toys should be established. It is therefore necessary to lay down a new essential safety requirement concerning the sound from such toys.
- (28) In line with the precautionary principle, it is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys in food, since the association of a toy and food could be the cause of a risk of choking that is distinct from the risks presented by the toy alone and which is, therefore, not covered by any specific measure at Community level.
- (29) Since it is possible that toys which present hazards which are not covered by a particular safety requirement laid down in this Directive might exist or be developed, it is necessary to set a general requirement of safety as the legal basis for taking action in respect of such toys. In this respect, the safety of toys should be determined by reference to the intended use, while taking into account the foreseeable use, and bearing in mind the behaviour of children, who do not generally show the same degree of care as the average adult user. Where a hazard cannot be sufficiently minimised by design or safeguards, the residual risk could be addressed by product-related information directed at the supervisors, taking into account their capacity to cope with the residual risk. According to acknowledged methods of risk assessment, it is not appropriate for information to supervisors or a lack of history of accidents to be used as a substitute for design improvements.
- (30) In order to further promote safe conditions of use of toys, it is necessary to supplement the provisions on warnings which should accompany the toy. In order to prevent the misuse of warnings to circumvent the applicable safety requirements, which has occurred in particular in case of the warning stating that the toy is not suitable for children under 36 months, it is necessary to provide explicitly that the warnings provided for certain categories of toy may not be used if they conflict with the intended use of the toy.
- (31) The CE marking, indicating the conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (32) It is crucial to make clear to both manufacturers and users that by affixing the CE marking to the toy, the manufacturer declares that the toy is in conformity with all applicable requirements and that the manufacturer takes full responsibility therefore.
- (33) The CE marking should be the only marking of conformity indicating that the toy is in conformity with Community harmonisation legislation. However, other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation.
- (34) It is appropriate to lay down rules on the affixing of CE marking which ensure sufficient visibility of the marking in order to facilitate market surveillance of toys.
- (35) In order to ensure compliance with the essential safety requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. To complete the legal obligations of the manufacturer which aim at ensuring the safety of toys, an explicit obligation to carry out an analysis of the various hazards that the toy may present and an assessment of the potential exposure to them, which for chemicals includes an assessment of the likelihood of the presence in the toy of prohibited or restricted substances, should be included in this Directive, and manufacturers should be obliged to keep this safety assessment in the technical documentation to allow market surveillance authorities to perform their tasks efficiently. Internal production control based on the manufacturer's own responsibility for the conformity assessment has proven adequate in cases where it has followed the harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all the safety requirements for the toy. In cases where such harmonised standards do not exist, the toy should be submitted to third party verification, in this case EC-type examination. The same should apply if one or more such standards has been published with a restriction in the *Official Journal of the European Union*, or if the manufacturer has not followed such standards completely, or only in part. The manufacturer should submit the toy to EC-type examination in cases where it considers that the nature, design, construction or purpose of the toy necessitates third party verification.
- (36) Since it is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of toys throughout the Community, and since all such bodies should perform their functions to the same level and under conditions of fair competition, obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services under this Directive.

- (37) In order to ensure a consistent level of quality in the performance of conformity assessment of toys, it is necessary not only to consolidate the requirements that conformity assessment bodies wishing to be notified must fulfil, but also, in parallel, to set requirements that notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies must fulfil.
- (38) Where the available scientific evidence is insufficient to allow an accurate risk assessment, Member States, when taking measures under this Directive, should apply the precautionary principle, which is a principle of Community law outlined, *inter alia*, in the Communication from the Commission of 2 February 2000, while taking due consideration of the other rules and principles contained in this Directive, such as the free movement of goods and the presumption of conformity.
- (39) Regulation (EC) No 765/2008 complements and strengthens the existing framework for the market surveillance of products covered by Community harmonisation legislation, including toys. Member States should therefore organise and carry out market surveillance of toys in accordance with that Regulation. In accordance with that Regulation, its application does not prevent the market surveillance authorities from taking more specific market surveillance measures as are available under Directive 2001/95/EC. Furthermore, specific measures concerning the possibility for a market surveillance authority to request information from a notified body and to give instructions to it should be included in this Directive in order to strengthen the possibilities for action by market surveillance authorities in the case of toys covered by an EC-type examination certificate.
- (40) Directive 88/378/EEC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against toys it considers to be non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with the aim of making it more efficient and of drawing on expertise available in the Member States.
- (41) The existing system should be complemented by a procedure allowing interested parties to be informed of measures taken with regard to toys presenting a risk to the health and safety of persons or other issues of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such toys.
- (42) Where Member States and the Commission agree as to the justification for a measure taken by a Member State, no further involvement of the Commission should be required.
- (43) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (¹).
- (44) In particular, the Commission should be empowered to adapt requirements concerning chemical properties in certain well-defined cases and to grant exemptions from the prohibition of CMR substances in certain cases, as well as to adapt the wording of the specific warnings for certain categories of toy. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (45) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (²) applies, *inter alia*, to toys which are not in conformity with Community harmonisation legislation. Manufacturers and importers who have placed non-compliant toys on the Community market are liable for damages under that Directive.
- (46) Member States should provide for penalties applicable to infringements of this Directive. Those penalties should be effective, proportionate and dissuasive.
- (47) In order to allow toy manufacturers and other economic operators sufficient time to adapt to the requirements laid down by this Directive, it is necessary to provide for a transitional period of two years after the entry into force of this Directive during which toys which comply with Directive 88/378/EEC may be placed on the market. In the case of chemical requirements, this period should be set at four years so as to allow the development of the harmonised standards which are necessary for compliance with those requirements.

(¹) OJ L 184, 17.7.1999, p. 23.

(²) OJ L 210, 7.8.1985, p. 29.

(48) Since the objective of this Directive, namely to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market by setting harmonised safety requirements for toys and minimum requirements for market surveillance, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject-matter

This Directive lays down rules on the safety of toys and on their free movement in the Community.

Article 2

Scope

1. This Directive 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).

The products listed in Annex I shall not be considered as toys within the meaning of this Directive.

2. This Directive shall not apply to the following toys:

- (a) playground equipment intended for public use;
- (b) automatic playing machines, whether coin operated or not, intended for public use;
- (c) toy vehicles equipped with combustion engines;
- (d) toy steam engines; and
- (e) slings and catapults.

Article 3

Definitions

For the purposes of this Directive the following definitions shall apply:

- 1. 'making available on the market' means any supply of a toy for distribution, consumption or use on the Community

market in the course of a commercial activity, whether in return for payment or free of charge;

- 2. 'placing on the market' means the first making available of a toy on the Community market;
- 3. '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;
- 4. 'authorised representative' means any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- 5. 'importer' means any natural or legal person established within the Community who places a toy from a third country on the Community market;
- 6. '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;
- 7. 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- 8. 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive;
- 9. 'Community harmonisation legislation' means any Community legislation harmonising the conditions for the marketing of products;
- 10. 'accreditation' shall have the meaning assigned to it by Regulation (EC) No 765/2008;
- 11. 'conformity assessment' means the process demonstrating whether specified requirements relating to a toy have been fulfilled;
- 12. 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;
- 13. 'recall' means any measure aimed at achieving the return of a toy that has already been made available to the end user;
- 14. 'withdrawal' means any measure aimed at preventing a toy in the supply chain from being made available on the market;
- 15. 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that toys comply with the applicable requirements set out in Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

16. 'CE marking' means a 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;
17. '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;
18. '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;
19. 'aquatic toy' means a toy intended for use in shallow water which is capable of carrying or supporting a child on the water;
20. 'design speed' means representative potential operating speed that is determined by the design of the toy;
21. '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;
22. '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;
23. 'olfactory board game' means a toy the purpose of which is to assist a child to learn to recognise different odours or flavours;
24. '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;
25. '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;
26. 'harm' means physical injury or any other damage to health, including long-term health effects;
27. 'hazard' means a potential source of harm;
28. 'risk' means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm;
29. '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.

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 4

Obligations of manufacturers

1. When placing their toys on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Article 10 and Annex II.

2. Manufacturers shall draw up the required technical documentation in accordance with Article 21 and carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19.

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 Article 15, and affix the CE marking, as set out in Article 17(1).

3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market.

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.

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, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of any such monitoring.

5. 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.

6. 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.

7. Manufacturers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

8. 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 competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy, in a language easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.

Article 5

Authorised representatives

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

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

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

- (a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of 10 years after the toy has been placed on the market;
- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by toys covered by the mandate.

Article 6

Obligations of importers

1. Importers shall place only compliant toys on the 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 Article 4(5) and (6).

Where an importer considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 10 and Annex II, 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 authorities to that effect.

3. Importers 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.

4. Importers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

5. 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 Article 10 and Annex II.

6. 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, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring.

7. 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, importers shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for a period of 10 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 authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy in a language easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by toys which they have placed on the market.

Article 7

Obligations of distributors

1. When making a toy available on the 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 a language or languages easily understood by consumers in the Member State in which the toy is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 4(5) and (6) and Article 6(3).

Where a distributor considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 10 and Annex II, 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 authorities, to that effect.

3. 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 Article 10 and Annex II.

4. 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 competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate

the conformity of the toy. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have made available on the market.

Article 8

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and be subject to the obligations of the manufacturer under Article 4 where 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.

Article 9

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a toy;
- (b) any economic operator to whom they have supplied a toy.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after the toy has been placed on the market, in the case of the manufacturer, and for a period of 10 years after they have been supplied with the toy, in the case of other economic operators.

CHAPTER III

CONFORMITY OF TOYS

Article 10

Essential safety requirements

1. Member States shall take all measures necessary to ensure that toys may not be placed on the market unless they comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2, and, as far as the particular safety requirements are concerned, in Annex II.

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

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

Labels affixed in accordance with Article 11(2) 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.

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

Article 11

Warnings

1. Where appropriate for safe use, warnings made for the purposes of Article 10(2) shall specify appropriate user limitations in accordance with Part A of Annex V.

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

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

2. 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.

The warnings shall be preceded by the words 'Warning' or 'Warnings', as the case may be.

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

3. In accordance with Article 4(7), a Member State may, within its territory, stipulate that those warnings and the safety instructions shall be written in a language or languages easily understood by consumers, as determined by that Member State.

Article 12

Free movement

Members States shall not impede the making available on the market in their territory of toys which comply with this Directive.

Article 13

Presumption of conformity

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 Article 10 and Annex II.

Article 14

Formal objection to a harmonised standard

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Article 10 and Annex II, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.

2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

Article 15

EC declaration of conformity

1. The EC declaration of conformity shall state that the fulfilment of the requirements set out in Article 10 and Annex II has been demonstrated.

2. The EC declaration of conformity shall as a minimum contain the elements specified in Annex III to this Directive and the relevant modules set out in Annex II to Decision No 768/2008/EC and shall be continuously updated. It shall have the model structure set out in Annex III to this Directive. It shall be translated into the language or languages required by the Member State in whose market the toy is placed or made available.

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

Article 16

General principles of the CE marking

1. Toys made available on the market shall bear the CE marking.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. Member States shall presume that toys bearing the CE marking comply with this Directive.

4. Toys not bearing a CE marking or which do not otherwise comply with this Directive may be shown and used at trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that they do not comply with this Directive and that they will not be made available in the Community before being brought into conformity.

Article 17

Rules and conditions for affixing the CE marking

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

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

2. 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.

CHAPTER IV

CONFORMITY ASSESSMENT

Article 18

Safety assessments

Manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

Article 19

Applicable conformity assessment procedures

1. Before placing a toy on the market, manufacturers shall use the conformity assessment procedures referred to in paragraphs 2 and 3 to demonstrate that the toy complies with the requirements set out in Article 10 and Annex II.

2. 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 Module A of Annex II to Decision No 768/2008/EC.

3. In the following cases, the toy shall be submitted to EC-type examination, as referred to in Article 20, together with the conformity to type procedure set out in Module C of Annex II to Decision No 768/2008/EC:

- (a) where harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, do not exist;
- (b) where the harmonised standards referred to in point (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 point (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.

Article 20

EC-type examination

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

EC-type examination shall be carried out in the manner specified in the second indent of point 2 of that Module.

In addition to those provisions, the requirements laid down in paragraphs 2 to 5 of this Article shall apply.

2. 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.

3. When a conformity assessment body notified under Article 22 (hereinafter referred to as a 'notified body') carries out the EC-type examination, it shall evaluate, if necessary together with the manufacturer, the analysis of the hazards that the toy may present carried out by the manufacturer in accordance with Article 18.

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

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.

The EC-type examination certificate shall be withdrawn if the toy fails to comply with the requirements set out in Article 10 and Annex II.

Member States shall ensure that their notified bodies do not grant an EC-type examination certificate for a toy in respect of which a certificate has been refused or withdrawn.

5. The technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

Article 21

Technical documentation

1. The technical documentation referred to in Article 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 Article 10 and Annex II. It shall, in particular, contain the documents listed in Annex IV.

2. The technical documentation shall be drawn up in one of the official languages of the Community, subject to the requirement set out in Article 20(5).

3. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State.

When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may fix a deadline for receipt of such file or translation, which shall be 30 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 paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by a notified body at its own expense within a specified period in order to verify compliance with the harmonised standards and essential safety requirements.

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 22

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under Article 20.

Article 23

Notifying authorities

1. Member States shall designate a notifying authority that 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 this Directive, and for the monitoring of notified bodies, including compliance with Article 29.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 24(1) to (5). In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 24

Requirements relating to notifying authorities

1. Notifying authorities shall be established in such a way that no conflict of interest with a conformity assessment body occurs.

2. Notifying authorities shall be organised and operated so as to safeguard the objectivity and impartiality of their activities.

3. Notifying authorities shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform, nor shall they offer or provide consultancy services on a commercial or competitive basis.

5. Notifying authorities shall safeguard the confidentiality of the information they obtain.

6. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.

*Article 25***Information obligation of notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

*Article 26***Requirements relating to notified bodies**

1. For the purposes of notification under this Directive, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. Conformity assessment bodies shall be established under national law and shall have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the toy it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of toys which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. 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.

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.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. Conformity assessment bodies shall be capable of carrying out the conformity assessment tasks assigned to them by the provisions of Article 20 and in relation to which they have been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

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:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

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.

7. 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.

8. 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.

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

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 20 or any provision of national law giving effect to that Article, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. 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 Article 38, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 27

Presumption of conformity

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 Article 26 insofar as the applicable harmonised standards cover those requirements.

Article 28

Formal objection to a harmonised standard

Where a Member State or the Commission has a formal objection to the harmonised standards referred to in Article 27, Article 14 shall apply.

Article 29

Subsidiaries of and subcontracting by notified bodies

1. 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 Article 26, and shall inform the notifying authority accordingly.

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

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

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 20.

Article 30

Application for notification

1. A conformity assessment body shall submit an application for notification under this Directive to the notifying authority of the Member State in which it is established.

2. The application referred to in paragraph 1 shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the toy or toys for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

Article 31

Notification procedure

1. Notifying authorities may only notify conformity assessment bodies which have satisfied the requirements laid down in Article 26.

2. Notifying authorities shall notify conformity assessment bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. 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.

4. Where a notification is not based on an accreditation certificate as referred to in Article 30(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26.

5. 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 where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 32

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to each notified body.

It shall assign a single identification number even where the same body is notified under several Community acts.

2. The Commission shall make publicly available a list of bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 33

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26, or that it is failing to fulfil its obligations, the notifying authority 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.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State 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.

Article 34

Challenge to the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State 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.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 35

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 20.

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 this Directive.

3. Where a notified body finds that the requirements set out in Article 10 and Annex II 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 Article 20(4).

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.

Article 36

Information obligation of notified bodies

1. Notified bodies shall inform the notifying authority 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.

2. Notified bodies shall provide the other bodies notified under this Directive which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 37

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 38

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or groups, directly or by means of designated representatives.

CHAPTER VI

OBLIGATIONS AND POWERS OF MEMBER STATES

Article 39

Precautionary principle

When competent authorities of the Member States take measures as provided for in this Directive, and in particular those referred to in Article 40, they shall take due account of the precautionary principle.

Article 40

General obligation to organise market surveillance

Member States 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, Article 41 of this Directive shall apply.

Article 41

Instructions to the notified body

1. Market surveillance authorities 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.

2. If a market surveillance authority finds that a toy is not in conformity with the requirements set out in Article 10 and Annex II, it shall, where appropriate, instruct the notified body to withdraw the EC-type examination certificate in respect of that toy.

3. Where necessary, and in particular in the cases specified in the second subparagraph of Article 20(4), the market surveillance authority shall instruct the notified body to review the EC-type examination certificate.

Article 42

Procedure for dealing with toys presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a toy covered by this Directive presents a risk to the health or safety of persons, they shall carry out an evaluation in relation to the toy concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down in this Directive, they 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.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they 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.

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

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take appropriate provisional measures to prohibit or restrict the toy being made available on their national market, to withdraw the toy from that market or to recall it.

They shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 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 authorities 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 Article 13 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure 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.

7. Where, within three months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed to be justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the toy concerned, such as withdrawal of the toy from their market, without delay.

Article 43

Community safeguard procedure

1. Where, on completion of the procedure set out in Article 42(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Community legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure.

On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant toy is withdrawn from their market, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw it.

3. Where the national measure is considered to be justified and the non-compliance of the toy is attributed to shortcomings in the harmonised standards referred to in Article 42(5)(b), the Commission shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay.

Article 44

Exchange of information — Community Rapid Information Exchange System

If a measure referred to in Article 42(4) 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 Article 42(4) of this Directive, 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 this Directive;
- (b) the supporting evidence referred to in Article 42(5) is enclosed with the Community Rapid Information Exchange notification.

Article 45

Formal non-compliance

1. Without prejudice to Article 42, where a Member State 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 Article 16 or 17;
- (b) that the CE marking has not been affixed;
- (c) that the EC declaration of conformity has not been drawn up;
- (d) that the EC declaration of conformity has not been drawn up correctly;
- (e) that technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned 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.

CHAPTER VII

COMMITTEE PROCEDURES

Article 46

Amendments and implementing measures

1. The Commission may, for the purposes of adapting them to technical and scientific developments, amend the following:

- (a) Annex I;
- (b) points 11 and 13 of Part III of Annex II;
- (c) Annex V.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2).

2. The Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid

down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food. The Commission shall amend Appendix C to Annex II to this Directive accordingly. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2) of this Directive.

3. The Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 5 of Appendix B to Annex II and have been evaluated by the relevant Scientific Committee, and may amend Appendix A to Annex II accordingly. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2).

Article 47

Committee procedure

1. The Commission shall be assisted by a committee.
2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

CHAPTER VIII

SPECIFIC ADMINISTRATIVE PROVISIONS

Article 48

Reporting

By 20 July 2014 and every five years thereafter, Member States shall send the Commission a report on the application of this Directive.

That report shall contain an evaluation of the situation concerning the safety of toys and of the effectiveness of this Directive, as well as a presentation of the market surveillance activities performed by that Member State.

The Commission shall draw up and publish a summary of the national reports.

Article 49

Transparency and confidentiality

When the competent authorities of the Member States and the Commission adopt measures under this Directive, the requirements of transparency and confidentiality provided for in Article 16 of Directive 2001/95/EC shall apply.

*Article 50***Motivation of measures**

Any measure taken pursuant to this Directive to prohibit or restrict the placing on the market of a toy, to withdraw a toy or to recall a toy from the market shall state the exact grounds on which it is based.

Such a measure shall be notified without delay to the party concerned, which shall at the same time be informed of the remedies available to it under the laws in force in the Member State in question and of the time limits applicable to them.

*Article 51***Penalties**

Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to this Directive, and shall take all measures necessary to ensure that they are implemented.

The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of this Directive.

The Member States shall notify the Commission of those rules by 20 July 2011, and shall notify it without delay of any subsequent amendment to them.

CHAPTER IX

FINAL AND TRANSITIONAL PROVISIONS*Article 52***Application of Directives 85/374/EEC and 2001/95/EC**

1. This Directive is without prejudice to Directive 85/374/EEC.
2. Directive 2001/95/EC shall apply to toys in accordance with Article 1(2) thereof.

*Article 53***Transitional periods**

1. Member States shall not impede the making available on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before 20 July 2011.
2. In addition to the requirement of paragraph 1, Member States shall not impede the making available on the market of toys which are in accordance with the requirements of this Directive, except those set out in Part III of Annex II, provided that such toys meet the requirements set out in Part

3 of Annex II to Directive 88/378/EEC and were placed on the market before 20 July 2013.

*Article 54***Transposition**

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 January 2011. They shall forthwith inform the Commission thereof.

They shall apply those measures with effect from 20 July 2011.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

*Article 55***Repeal**

Directive 88/378/EEC, except Article 2(1) and Part 3 of Annex II, is repealed with effect from 20 July 2011. Article 2(1) thereof and Part 3 of Annex II thereto are repealed with effect from 20 July 2013.

References to the repealed Directive shall be construed as references to this Directive.

*Article 56***Entry into force**

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

*Article 57***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 18 June 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
Š. FÜLE

*ANNEX I***List of products that, in particular, are not considered as toys within the meaning of this Directive**

(as referred to in Article 2(1))

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

*ANNEX II***PARTICULAR SAFETY REQUIREMENTS****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 and/or inhaled.

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

(h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, 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 in Section 1 of Appendix B, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.
3. Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in the first subparagraph of Article 10(2).
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

1. 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 the first subparagraph of Article 10(2).

Toys shall comply with the relevant 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 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽¹⁾, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽²⁾ and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ⁽³⁾, 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 Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:
 - (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
 - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);
 - (c) a decision in accordance with Article 46(3) 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 Appendix A.

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.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:
 - (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
 - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); or

⁽¹⁾ OJ L 196, 16.8.1967, p. 1. ⁽²⁾ OJ L 200, 30.7.1999, p. 1.

⁽³⁾ OJ L 353, 31.12.2008, p. 1.

- (c) a decision in accordance with Article 46(3) 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 Appendix A.

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

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.
7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C, or, until such provisions have been laid down, but not later than 20 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.
8. 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.
9. The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.
10. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ⁽¹⁾.
11. 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

⁽¹⁾ OJ L 262, 27.9.1976, p. 169.

No	Name of the allergenic fragrance	CAS number
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
(14)	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2-Hexenal diethyl acetal	67746-30-9
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8
(23)	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenolate	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

No	Name of the allergenic fragrance	CAS number
(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

12. The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point 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 Annex V;

(ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC; 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 Annex V.

13. 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	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	4 500	1 125	56 000
Boron	1 200	300	15 000
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	7 700
Lead	13,5	3,4	160
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values 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 the first subparagraph of Article 10(2).

IV. Electrical Properties

1. 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.

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 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.

V. 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 soaked. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

VI. Radioactivity

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

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

Substance	Classification	Permitted use
Nickel	CMR 2	In stainless steel

*Appendix B***CLASSIFICATION OF SUBSTANCES AND MIXTURES**

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.

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

A. Criteria to be applied from 20 July 2011 until 31 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:

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

Mixtures

The mixture is dangerous within the meaning of Directive 67/548/EEC.

B. Criteria to be applied from 1 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:

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

2. Community legal acts governing the use of certain substances for the purposes of points 4(a) and 5(a) of Part III

From 20 July 2011 until 31 May 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Directive 1999/45/EC.

From 1 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.

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

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

Mixtures

From 20 July 2011 until 31 May 2015, point 4 of Part III concerns mixtures classified as CMR category 1 and 2 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, point 4 of Part III concerns mixtures classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

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

Substances

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

Mixtures

From 20 July 2011 until 31 May 2015, point 5 of Part III concerns mixtures classified as CMR category 3 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, point 5 of Part III concerns mixtures classified as CMR category 2 under Regulation (EC) No 1272/2008.

5. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of Article 46(3)

Substances

Article 46(3) concerns substances classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

Mixtures

From 20 July 2011 until 31 May 2015, Article 46(3) concerns mixtures classified as CMR category 1, 21999 and 3 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, Article 46(3) concerns mixtures classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

Appendix C

Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2)

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*ANNEX III***EC DECLARATION OF CONFORMITY**

1. No ... (unique identification of the toy(s))
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy.
5. The object of the declaration described in point 4 is in conformity with the relevant 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 ... (name, number) ... performed ... (description of intervention) ... and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue)

(name, function)(signature)

*ANNEX IV***TECHNICAL DOCUMENTATION**

The technical documentation referred to in Article 21 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(s) carried out in accordance with Article 18;
 - (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 Article 19(2); 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 Article 19(3).
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ANNEX V

WARNINGS

(as referred to in Article 11)

PART A

GENERAL WARNINGS

The user limitations referred to in Article 11(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 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 (*) years. For use under adult supervision'.

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

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

Where these toys are offered for sale as toys, they 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 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'.

(*) Age to be specified by the manufacturer.

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

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part III of Annex II 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’.

Annex E – Code of Practice on Consultation

The Consultation Code of Practice Criteria

1. Formal consultation should take place at a stage when there is scope to influence policy outcome.
2. Consultation should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.
3. Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.
4. Consultation exercise should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.
5. Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.
6. Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.
7. Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

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