

EUROPEAN PARLIAMENT

2004



2009

Session document

A6-0441/2008

12.11.2008

*****I REPORT**

on the proposal for a directive of the European Parliament and of the Council
on the safety of toys
(COM(2008)0009 – C6-0039/2008 – 2008/0018(COD))

Committee on the Internal Market and Consumer Protection

Rapporteur: Marianne Thyssen

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend the common position
- *** Assent procedure
majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend the common position
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

CONTENTS

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	79
OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY	83
OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY	144
PROCEDURE	163

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council on the safety of toys
(COM(2008)0009 – C6-0039/2008 – 2008/0018(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0009),
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0039/2008),
 - having regard to Rule 51 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection, the opinion of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Industry, Research and Energy (A6-0441/2008),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

Amendment 1

Proposal for a directive **Recital 2**

Text proposed by the Commission

(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. Thus, it sets out **only** the essential safety requirements with regard to toys, **while technical** details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) in accordance

Amendment

(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. Thus, it sets out 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**

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. Conformity with harmonised standards so set, the reference number of which is published in the Official Journal of the European Union, provides presumption of conformity to 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.***

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. Conformity with harmonised standards so set, the reference number of which is published in the Official Journal of the European Union, provides presumption of conformity to the requirements of Directive 88/378/EEC.

Justification

The essential safety requirements include not only the requirements mentioned in Article 9 of the Directive, but also the specific safety requirements mentioned in the Annex II. Moreover, given the safety problems recently encountered with toys, it is difficult to pretend that things have worked well in the toys sector.

Amendment 2

Proposal for a directive Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) Another important objective of the new system to be established by this Directive is to encourage and in certain cases to 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.

Justification

This amendment is an adaptation to the REACH Regulation (recital 12).

Amendment 3

Proposal for a directive
Recital 3 b (new)

Text proposed by the Commission

Amendment

(3b) The precautionary principle is a principle of Community law contained in jurisprudence of the Court of Justice of the European Communities and specified in the Communication from the Commission of 2 February 2000 on the precautionary principle (COM(2000)0001).

Justification

Amendment 4

Proposal for a directive
Recital 8

Text proposed by the Commission

Amendment

(8) All economic operators intervening in the supply and distribution chain should take the appropriate measures to ensure that they make available on the market only toys which are in conformity with the applicable legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.

(8) All economic operators intervening in the supply and distribution chain ***should exercise the responsibility and vigilance required to ensure that under normal and reasonably foreseeable conditions of use the toys they place on the market do not jeopardise the safety and health of children.*** Economic operators should take the appropriate measures to ensure that they make available on the market only toys which are in conformity with the applicable legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.

Justification

Simply stating that economic operators should take appropriate measures is not enough. It should also be made clear that they are liable. They must therefore remain vigilant in order to ensure the health and safety of the children using their toys, with due account being taken of the various uses to which those toys may be put.

Amendment 5

Proposal for a directive Recital 16

Text proposed by the Commission

(16) In order to ensure protection of children against **recently discovered** risks, it is also necessary to adopt new essential safety requirements. In particular, it is necessary to complete and update provisions on chemical substances in toys. These provisions should specify that toys should comply with the 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. These provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to 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 and fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. The specific limit values laid down in Directive 88/378/EEC for certain substances should be updated to take into account of the development of scientific

Amendment

(16) In order to ensure **a high level of** protection of children **and the environment** against risks, **dangerous substances, in particular CMR, and allergenic substances and elements, should, be subject to careful attention.** It is also necessary to adopt new essential safety requirements. In particular, it is necessary to complete and update provisions on chemical substances in toys. These provisions should specify that toys should comply with the 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. These provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to 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 and fragrances in toys should be provided for on account of the special risks that these substances may entail for human health.

knowledge.

The specific limit values laid down in Directive 88/378/EEC for certain substances should be updated to take into account of the development of scientific knowledge.

Justification

This amendment draws the attention to the importance to address substances of very high concern. It is an adaptation from the REACH Regulation (recital 69).

Amendment 6

Proposal for a directive

Recital 17

Text proposed by the Commission

(17) The general and specific chemical requirements in this Directive should aim at protecting the health of children from dangerous substances in toys, while environmental concerns presented by toys are addressed in *horizontal* environmental legislation applying *also* to toys, *in particular in* Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste, *Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment, in* Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste and *in* Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC.

Amendment

(17) The general and specific chemical requirements in this Directive should aim at protecting the health of children from dangerous substances in toys, while environmental concerns presented by toys are addressed in environmental legislation applying to *electrical and electronic* toys, *namely Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive 2002/96/EC of the European Parliament and on waste electrical and electronic equipment. In addition, environmental issues concerning waste are regulated by* Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste, *those concerning packaging by* Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste and *those concerning batteries and accumulators by* Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive

Justification

The current text gives the impression that environmental concerns are explicitly considered for all toys; however, only electrical and electronic toys are addressed. Horizontal legislation does not apply to toys explicitly and should not be grouped together with the directives on electrical and electronic equipment/waste electrical and electronic equipment.

Amendment 7

Proposal for a directive

Recital 17 a (new)

Text proposed by the Commission

Amendment

(17a) Toys or their parts and packaging that can reasonably be expected to be brought into contact with food should comply with the requirements of Regulation (EC) No 1935/2004 on materials intended to come into contact with food.

Justification

It is appropriate to refer to the fact that Food Contact Material legislation can be applicable to toys, e.g. children's tea/coffee sets can reasonable be expected to be brought in contact with food. This provision is needed as this has not been clear in all countries of the EU so far

Amendment 8

Proposal for a directive

Recital 19

Text proposed by the Commission

Amendment

(19) Since toys may exist or be developed which present hazards which are not covered by a particular safety requirement laid down in this Directive, it is necessary to set a general requirement of safety as the legal base for taking action against such toys. In this respect safety of toys should

(19) Since toys may exist or be developed which present hazards which are not covered by a particular safety requirement laid down in this Directive, it is necessary to set a general requirement of safety as the legal base for taking action against such toys. In this respect safety of toys should

be determined by reference to the intended use of the product while taking into account the foreseeable use, bearing in mind behaviour of children, who do not generally show the same degree of care as the average adult user.

be determined by reference to the intended use of the product while taking into account the foreseeable use, bearing in mind behaviour of children, who do not generally show the same degree of care as the average adult user. ***If scientific evidence does not allow this assessment, Member States, in particular through their competent authorities, should apply the precautionary principle.***

Justification

While all possible uses that a child may make of a toy need to be taken into account when assessing its safety, uses to which a child of a given age could not put that toy, owing to his or her stage of physical or intellectual development, etc., may be discounted.

Amendment 9

**Proposal for a directive
Recital 21**

Text proposed by the Commission

(21) The CE marking, ***materialising*** conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. ***General principles governing the use of the CE marking, and*** rules as to its affixing should therefore be set in this Directive.

Amendment

(21) The CE marking, ***indicating the*** conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. Rules as to its affixing ***to toys*** should therefore be set ***out*** in this Directive.

Justification

Technical adaptation to the goods package

Amendment 10

**Proposal for a directive
Recital 22**

Text proposed by the Commission

(22) 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 product is in conformity

Amendment

(22) It is crucial to make clear to manufacturers that by affixing the CE marking to the toy the manufacturer declares that the product is in conformity

with all applicable requirements and that he takes full responsibility thereof.

with all applicable requirements and that he takes full responsibility thereof.

Justification

The manufacturer has sole responsibility for affixing the CE marking to a toy. Manufacturers must be aware of the fact that, by using the CE marking, which attests to compliance with strict conditions, they become liable, and any misuse of the marking may be punished.

Amendment 11

Proposal for a directive

Recital 34

Text proposed by the Commission

(34) Since the objectives of *the proposed action*, namely to ensure a high level of safety of toys 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 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 *this* Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

Amendment

(34) Since the objectives 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 those objectives,

Justification

The directive's primary purpose needs to be restated.

Amendment 12

Proposal for a directive Recital 34 a (new)

Text proposed by the Commission

Amendment

(34a) In order to allow toy manufacturers and other economic operators sufficient time to adapt to the new requirements, 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 harmonized standards which are necessary for compliance with those requirements,

Amendment 13

Proposal for a directive Article 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. This Directive is based on the principle that manufacturers are obliged to ensure that toys, and any chemicals they contain, are neither harmful to children's health nor toxic, in accordance with the provisions of this Directive.

Amendment 14

Proposal for a directive Article 2 – point 1

Text proposed by the Commission

Amendment

(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

(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;

activity, whether in return for payment or free of charge **and whether or not with a profit motive**;

Justification

The supplying of toys by non-profit associations must also be regulated by this directive.

Amendment 15

Proposal for a directive Article 2 – point 3

Text proposed by the Commission

Amendment

(3) “manufacturer” **means** any natural or legal person who designs and manufactures a toy or **who** has **such** a toy designed or manufactured, under his name or trademark;

(3) “manufacturer” **shall mean** 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;

Justification

Technical adaptation to the goods package

Amendment 16

Proposal for a directive Article 2 – point 3 a (new)

Text proposed by the Commission

Amendment

(3a) “authorised representative” shall mean 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;

Justification

Technical adaptation to the goods package

Amendment 17

Proposal for a directive Article 2 – point 4

Text proposed by the Commission

(4) “distributor” **means** any natural or legal person in the supply chain, who makes a toy available on the market;

Amendment

(4) “distributor” **shall mean** any natural or legal person in the supply chain, **other than the manufacturer or the importer**, who makes a toy available on the market;

Justification

Technical adaptation to the goods package

Amendment 18

Proposal for a directive Article 2 – point 7

Text proposed by the Commission

(7) 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** in accordance with Article 6 of Directive 98/34/EC;

Amendment

(7) harmonised standard” **shall mean** 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;

Justification

Technical adaptation to the goods package

Amendment 19

Proposal for a directive Article 2 – point 7 a (new)

Text proposed by the Commission

Amendment

(7a) “Community harmonisation legislation” shall mean any Community legislation harmonising the conditions for the marketing of products;

Justification

Technical adaptation to the goods package

Amendment 20

Proposal for a directive
Article 2 – point 10 a (new)

Text proposed by the Commission

Amendment

(10a) “conformity assessment body” shall mean a body that performs conformity assessment activities, including calibration, testing, certification and inspection;

Justification

Technical adaptation to the goods package

Amendment 21

Proposal for a directive
Article 2 – point 10 b (new)

Text proposed by the Commission

Amendment

(10b) “national accreditation body” shall have the meaning assigned to it by 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 products¹.

¹ ***OJ L 218, 13.8.2008, p. 30.***

Justification

Technical adaptation to the goods package

Amendment 22

Proposal for a directive Article 2 – point 11 a (new)

Text proposed by the Commission

Amendment

(11a) "olfactory board game" shall mean a game the purpose of which is to learn to recognise different odours or flavours;

Amendment 23

Proposal for a directive Article 2 – point 11 b (new)

Text proposed by the Commission

Amendment

(11b) "cosmetic kit" shall mean 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, make-up, tooth-paste and conditioners that may contain fragrances or essential oils;

Amendment 24

Proposal for a directive Article 2 – point 11 c (new)

Text proposed by the Commission

Amendment

(11c) "gustative game" shall mean a game which may involve the use of food ingredients such as sweets, liquids, powders and aromas so as to allow children to make sweets or other culinary recipes;

Amendment 25

Proposal for a directive
Article 2 – point 13

Text proposed by the Commission

(13) “harm” means *the* physical injury or damage to health;

Amendment

(13) “harm” means physical injury or ***any other*** damage to health ***including long term health effects***;

Justification

This wording clarifies that the term ‘damage to health’ includes long term health effects such as carcinogenic and endocrine disrupting effects.

Amendment 26

Proposal for a directive
Article 2 – point 15 a (new)

Text proposed by the Commission

Amendment

(15a) "intended for use by" means that a parent or supervisor could reasonably assume a toy was intended for use by children of the stated age group. The placing of a warning on a product stating that it is not suitable for a particular age group is not deemed to make the product compliant with the safety requirements of this Directive.

Justification

Studies show warnings on toys are not an effective means of ensuring essential safety requirements. In particular a toy that could be reasonably assumed as intended for a young child should meet requirements such as the small parts test. The use of the phrases such as "clearly intended for use by children under the age of x months" in this directive should therefore be defined to prevent abuse.

Amendment 27

Proposal for a directive Article 3 – paragraph 1

Text proposed by the Commission

1. Manufacturers shall ensure that ***their toys are*** designed and manufactured in accordance with the essential safety requirements set out in Article 9 and ***in*** Annex II.

Amendment

1. ***When placing their toys on the market,*** manufacturers shall ensure that ***they have been*** designed and manufactured in accordance with the essential safety requirements set out in Article 9 and Annex II.

Justification

Technical adaptation to the goods package

Amendment 28

Proposal for a directive Article 3 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Where ***the*** compliance of ***the*** toy with the applicable requirements has been demonstrated by ***such*** procedure, manufacturers shall draw up an EC declaration of conformity, as referred to in Article 14 and affix the conformity marking ***set out in Article 16(1)***.

Amendment

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 14, and affix the conformity marking ***in accordance with Articles 15 and 16***.

Justification

Technical adaptation to the goods package

Amendment 29

Proposal for a directive Article 3 – paragraph 4

Text proposed by the Commission

4. Manufacturers shall ensure that procedures are in place ***to ensure the***

Amendment

4. Manufacturers shall ensure that procedures are in place ***for series***

continued conformity *of series production*. Changes in the product design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is **stated** shall be adequately taken into account.

Manufacturers shall, *in all cases where appropriate*, carry out sample testing of marketed toys, *investigating*, and, if necessary, *keeping* a register of complaints, and *keeping* distributors informed of such monitoring.

production to remain in conformity. Changes in the product 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, *non-conforming toys and toy recalls*, and *shall keep* distributors informed of *any* such monitoring.

Justification

Technical adaptation to the goods package

Amendment 30

Proposal for a directive Article 3 – paragraph 6

Text proposed by the Commission

6. Manufacturers shall indicate their name and the address at which they can be contacted on the toy or, where ***the size or nature of the toy does not allow it***, on its packaging or in a document accompanying the toy.

Amendment

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 must indicate a single point at which the manufacturer can be contacted.***

Justification

Technical adaptation to the goods package

Amendment 31

Proposal for a directive

Article 3 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. Manufacturers shall ensure that the toy is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Justification

Technical adaptation to the goods package

Amendment 32

Proposal for a directive

Article 3 – paragraph 7

Text proposed by the Commission

Amendment

7. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that toy into conformity **or** withdraw it **from the market and** recall it **from end users**, if appropriate. **They** shall immediately inform the national authorities of the Member States **where** they made the toy available to **this** effect, giving details, in particular, of the non-compliance and of **the** corrective measures taken.

7. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the applicable Community **harmonisation** legislation shall **immediately** take the necessary corrective measures to bring that toy into conformity, **to** withdraw it **or to** 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. **Manufactures shall immediately suspend the placing on the market of the toy until such time as it complies with the applicable Community legislation.**

Justification

Technical adaptation to the goods package

Amendment 33

Proposal for a directive Article 3 – paragraph 8

Text proposed by the Commission

8. Manufacturers shall, **on** request from **the** competent national **authorities**, provide **them** with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with **those authorities**, at **the** request **of the latter**, on any action to **avoid** the risks posed by toys which they have placed on the market.

Amendment

8. Manufacturers shall, **further to a reasoned** request from **a** competent national **authority**, provide **it** with all the information and documentation necessary to demonstrate the conformity of the toy, **in a language which can be 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.

Justification

Technical adaptation to the goods package

Amendment 34

Proposal for a directive Article 4 – title and paragraph 1

Text proposed by the Commission

Authorised representatives

1. **Manufacturers** may appoint, by a written mandate, **any natural or legal person established within the Community**, ("the authorised representative"), **to act on their behalf for specified tasks with regard to the obligations of manufacturers under this Directive**.

Amendment

Obligations of authorised representatives

1. **A Manufacturer** may appoint, by a written mandate, **an** authorised representative **as defined in Article 2(3a)**.

Justification

In order to be consistent with the titles of Articles 3 and 5. A definition for 'authorised representative' has been added to Article 2.

Amendment 35

Proposal for a directive Article 4 – paragraph 2

Text proposed by the Commission

2. The obligations **under** Article 3 (1) and the drawing up of technical documentation **may** not form part of the authorised representative's mandate.

Amendment

2. The obligations **laid down in** Article 3(1) and the drawing up of technical documentation **shall** not form part of the authorised representative's mandate.

Amendment 36

Proposal for a directive Article 4 – paragraph 3

Text proposed by the Commission

3. **Where a manufacturer has appointed an** authorised representative, **the latter shall at least** do 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;

(b) **on** request from **the** competent national **authorities**, provide **them** with all the information and documentation necessary to demonstrate the conformity of **the** toy;

(c) cooperate with the competent authorities, at **the** request **of the latter**, on any action to **avoid** the risks posed by toys covered by their mandate.

Amendment

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;

(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 their mandate.

Justification

Technical adaptation to the goods package

Amendment 37

Proposal for a directive Article 5 – paragraph 1

Text proposed by the Commission

1. *When placing a toy on the market, importers shall act with due care in relation to the applicable requirements.*

Amendment

1. **Importers shall place only compliant toys on the Community market.**

Justification

Technical adaptation to the goods package

Amendment 38

Proposal for a directive Article 5 – paragraph 2

Text proposed by the Commission

2. Before placing a toy on the market importers shall **verify** that the appropriate conformity assessment procedure has been carried out by the manufacturer.

They shall **verify** that the manufacturer has drawn up the technical documentation, that the toy bears the required conformity **marking(s)**, is accompanied by the required documents and that the manufacturer has **respected** the requirements set out in *Article 3 (5) and (6)*.

Where an importer **discovers** that **the** toy is not in conformity with the essential safety requirements set out in Article 9 and **in** Annex II, he **may** place the toy on the market **only after** it has been brought into conformity **with those requirements**.

Amendment

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 or markings and** is accompanied by the required documents, and that the manufacturer has **complied with** the requirements set out in *Article 3(5) and (6)*.

Where an importer **considers or has reason to believe** that **a** toy is not in conformity with the essential safety requirements set out in Article 9 and Annex II, he **shall not** place the toy on the market **until** it 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.**

Justification

Technical adaptation to the goods package

Amendment 39

**Proposal for a directive
Article 5 – paragraph 3**

Text proposed by the Commission

3. Importers shall indicate their name and the address at which they can be contacted on the toy or, where ***the size or nature of the toy does not allow it***, on its packaging or in a document accompanying the toy.

Amendment

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.

Justification

Technical adaptation to the goods package

Amendment 40

**Proposal for a directive
Article 5 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3a. Importers shall ensure that the toy is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Justification

Technical adaptation to the goods package

Amendment 41

Proposal for a directive

Article 5 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. 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, non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring.

Justification

Technical adaptation to the goods package

Amendment 42

Proposal for a directive

Article 5 – paragraph 5

Text proposed by the Commission

Amendment

5. Importers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the **applicable** Community legislation shall take the **necessary** corrective measures to bring that toy into conformity **or** withdraw it **from the market and** recall it **from end users**, if appropriate. **They** shall immediately inform the national authorities of the Member States **where** they made the toy available to **this** effect, giving details, in particular, of the non-compliance and of **the** corrective measures taken.

5. Importers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the Community **harmonisation** legislation **applicable** shall **immediately** take the corrective measures **necessary** to bring that toy into conformity, **to** withdraw it **or to** 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.

Justification

Technical adaptation to the goods package

Amendment 43

Proposal for a directive Article 5 – paragraph 7

Text proposed by the Commission

7. Importers shall, **on** request from **the** competent national **authorities**, provide **them** with all the information and documentation necessary to demonstrate the conformity of **the** toy. They shall cooperate with **those authorities**, at **the** request **of the latter**, on any action to **avoid** the risks posed by toys which they have placed on the market.

Amendment

7. Importers shall, **further to a reasoned** request from **a** competent national **authority**, provide **it** with all the information and documentation necessary to demonstrate the conformity of **a** toy **in a language which can be 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.

Justification

Technical adaptation to the goods package

Amendment 44

Proposal for a directive Article 6 – paragraph 2

Text proposed by the Commission

2. Before making a toy available on the market distributors shall verify that the toy bears the required conformity **marking(s)** **and** is accompanied by the required documents and that the manufacturer and the importer have complied with the requirements set out in *Article 3 (5)* and (6) and *Article 5 (3)* respectively.

Where a distributor **discovers** that a toy is not in conformity with the essential safety requirements set out in Article 9 and **in**

Amendment

2. Before making a toy available on the market distributors shall verify that the toy bears the required conformity **marking or markings, that it** is accompanied by the required documents **and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market**, and that the manufacturer and the importer have complied with the requirements set out in *Article 3(5)* and (6) and *Article 5(3)* respectively.

Where a distributor **considers or has reason to believe** that a toy is not in conformity with the essential safety

Annex II, he **may** make the toy available on the market **only after** it has been brought into conformity **with those requirements**. **The** distributor shall inform the manufacturer or the importer to **this** effect.

requirements set out in Article 9 and Annex II, he **shall not** make the toy available on the market **until** it has been brought into conformity. **Furthermore, where the product presents a risk, the** distributor shall inform the manufacturer or the importer to **that effect as well as the market surveillance authorities**.

Justification

Technical adaptation to the goods package

Amendment 45

Proposal for a directive Article 6 – paragraph 4

Text proposed by the Commission

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 **applicable** Community legislation shall **take the necessary** corrective measures to bring that toy **in** conformity **or** withdraw it **from the market and** recall it **from end users**, if appropriate. **They** shall immediately inform the national authorities of the Member States **where** they made the toy available to **this** effect, giving details, in particular, of the non-compliance and of **the** corrective measures taken.

Amendment

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 Community **harmonisation** legislation **applicable** shall **make sure that** the corrective measures **necessary** to bring that toy **into** conformity, **to** withdraw it **or to** 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.

Justification

Technical adaptation to the goods package

Amendment 46

Proposal for a directive Article 6 – paragraph 5

Text proposed by the Commission

5. Distributors shall, **on** request from **the** competent national **authorities**, provide **them** with all the information and documentation necessary to demonstrate the conformity of **the** toy. They shall cooperate with **those authorities**, at **the** request **of the latter**, on any action to **avoid** the risks posed by toys which they have made available on the market.

Amendment

5. Distributors shall, **further to a reasoned** request from **a** competent national **authority**, provide **it** with all the information and documentation necessary to demonstrate the conformity of **a** toy. They shall cooperate with **that authority**, at **its** request, on any action **taken to eliminate** the risks posed by toys which they have made available on the market.

Justification

Technical adaptation to the goods package

Amendment 47

Proposal for a directive Article 7

Text proposed by the Commission

An importer or distributor **who places a toy on the market under his name or trademark shall** be subject to the obligations of the manufacturer under Article 3.

Amendment

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 3 **where he places a toy on the market under his 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.**

An importer or a distributor, who modifies a toy in such a way that compliance with the essential safety requirements set out in Article 9 and in Annex II may be affected, shall be subject to the obligations of the manufacturer under Article 3 in respect of these modifications.

Justification

Technical adaptation to the goods package

Amendment 48

**Proposal for a directive
Article 8**

Text proposed by the Commission

Economic operators shall ***be able to*** identify the following:

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

They shall have in place appropriate systems and procedures which allow for this information to be made available to the market surveillance authorities on request, for a period of 10 years.

Amendment

Economic operators shall, ***on request***, identify the following ***to the market surveillance authorities, for a period of 10 years***:

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

Justification

Technical adaptation to the goods package

Amendment 49

**Proposal for a directive
Article 9 – paragraph 2 – subparagraph 2**

Text proposed by the Commission

The ability of the users and where appropriate their supervisors shall be taken into account, in particular, in the case of toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.

Amendment

The ability of the users and where appropriate their supervisors shall be taken into account, in particular, in the case of toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months. ***For specific categories of toys other age limits may be determined in accordance with the safety requirements***

of the harmonized standards referred to in Article 12.

Justification

This reference to only one age limit is not sufficient to cover the evolution of the standardization, where there is already a reference for children unable to be sited unaided (defined as the age between 5 and 10 months) and other age limits (e.g. 18 months) are in discussion.

Amendment 50

Proposal for a directive

Article 9 – paragraph 2 – subparagraph 3

Text proposed by the Commission

Labels on toys **or** on their packaging and the instructions for use which accompany them shall draw the attention of users or their supervisors to the inherent hazards and risks **of harms** involved in using the toys and to the ways of avoiding them

Amendment

Labels on toys **and/or** on their packaging and the instructions for use which accompany them must draw the attention of users or their supervisors to the inherent hazards **of the toys** and **the related** risks involved in using the toys and to the ways of avoiding them.

Justification

It does not always make sense to consumers when a warning only indicates which parts of a toy may cause harm or that the toy contains a specific chemical. For example, it is not clear to consumers that the warning “small balls” suggests that the toy presents a risk of choking. Warnings should therefore provide users with clear information on both the inherent harms/hazards and the related risks involved in using a toy.

Amendment 51

Proposal for a directive

Article 9 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. When competent authorities of the Member States take measures as provided for in this Directive, and in particular those referred to in Article 37, they shall take due account of the precautionary principle.

Amendment 52

Proposal for a directive

Article 10 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The warnings referred to in point 1 of Part B of Annex V shall not be used for toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.

Amendment 53

Proposal for a directive

Article 10 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

As regards the categories of toys listed in Part B of Annex V, the warnings set out therein shall be used.

As regards the categories of toys listed in ***points 2 to 5 of*** Part B of Annex V, the warnings set out therein shall be used ***as worded therein.***

Amendment 54

Proposal for a directive

Article 10 – paragraph 2– subparagraph 1

Text proposed by the Commission

Amendment

2. The manufacturer shall mark the warnings in a visible, clearly legible ***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 that are sold without packaging shall have appropriate warnings affixed to them.

2. The manufacturer shall mark the warnings in a visible, ***accurate and*** clearly legible manner on the toy, on an affixed label or on the ***consumer*** packaging and, if appropriate, on the instructions for use which accompany the toy. ***The warnings shall be marked in a language that the consumer can understand.*** Small toys that are sold without packaging shall have appropriate warnings affixed to them.

The warnings shall be preceded by the word "Warning" or "Warnings", as the case may be.

Justification

Amendment 55

Proposal for a directive

Article 10 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Warnings specifying the *minimum and maximum ages for users shall be visible, legible and conspicuously displayed at the point of sale.*

Amendment

Warnings specifying the *safety of a toy in connection with the intended use or user, as described in the second subparagraph of Article 10(1), and determining the decision to purchase it, shall appear on the packaging. If the toy is purchased online, the warning shall be conspicuously displayed on the webpage.*

Amendment 56

Proposal for a directive

Article 13 – paragraph 1

Text proposed by the Commission

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 9 and *in* 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, *hereinafter the “Committee”*, giving its arguments. The Committee shall deliver its opinion without delay.

Amendment

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 9 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.

Justification

Technical adaptation to the goods package

Amendment 57

Proposal for a directive Article 14 – paragraph 2

Text proposed by the Commission

2. The EC declaration of conformity shall **as a minimum contain the elements specified in Annex III and** shall continuously be updated. The EC declaration of conformity shall have the model structure set out in Annex III.

Amendment

2. The EC declaration of conformity shall **have the model structure set out in Annex III 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 products¹, shall contain the elements specified in the relevant modules set out in Annex II to that Decision and** shall be continuously updated. **It shall be translated into the language or languages required by the Member State in whose market the product is placed or made available.**

¹ OJ L 218, 13.8.2008, p. 82.

Justification

Technical adaptation to the goods package

Amendment 58

Proposal for a directive Article 15 – title

Text proposed by the Commission

General principles of the CE marking

Amendment

CE Marking

Justification

Technical adaptation to the goods package

Amendment 59

Proposal for a directive Article 15 – paragraph 2

Text proposed by the Commission

2. The CE marking **may only be affixed by**

Amendment

2. The CE marking **shall be subject to the**

the manufacturer or his authorised representative.

general principles set out in Article 30 of Regulation (EC) No 765/2008.

By affixing or having affixed the CE marking the manufacturer shall assume the responsibility for the conformity of the toy with the requirements laid down in this Directive.

Justification

Technical adaptation to the goods package

Amendment 60

Proposal for a directive Article 15 – paragraph 4

Text proposed by the Commission

Amendment

4. The CE marking shall be the only marking which attests conformity of the toy with the applicable requirements. **deleted**

Justification

Technical adaptation to the goods package

Amendment 61

Proposal for a directive Article 15 – paragraph 5

Text proposed by the Commission

Amendment

5. Member States shall refrain from introducing into their national regulations, or shall withdraw any reference to, a conformity marking other than the CE marking in connection with conformity to the provisions of this Directive. **deleted**

Justification

Technical adaptation to the goods package

Amendment 62

Proposal for a directive Article 15 – paragraph 6

Text proposed by the Commission

Amendment

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

deleted

Justification

Technical adaptation to the goods package

Amendment 63

Proposal for a directive Article 15 – paragraph 7

Text proposed by the Commission

Amendment

7. Toys not bearing a CE-marking *and* which do not comply with the provisions of this Directive may feature in trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that the toys do not comply with the requirements of this Directive and are not for sale or for distribution free of charge.

7. Toys not bearing a CE-marking *or* which do not *otherwise* comply with the provisions of this Directive may feature in trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that the toys do not comply with the requirements of this Directive and are not for sale or for distribution free of charge.

Justification

Toys on fairs are not considered being on the internal market, and no measures may be taken against them even if they are dangerous. A sign has to indicate to e.g. importers and distributors on the fair that they not be sold in the EU. However non compliant, most toys on fairs bear a CE mark. The present wording makes it difficult for market surveillance to force the exhibitors to put up the sign, since non compliant toys bearing a CE mark are not covered.

Amendment 64

Proposal for a directive Article 16 – title

Text proposed by the Commission

Amendment

Rules and conditions for *the* affixing of the
CE marking

Rules and conditions for affixing the CE
marking **to toys**

Justification

Technical adaptation to the goods package

Amendment 65

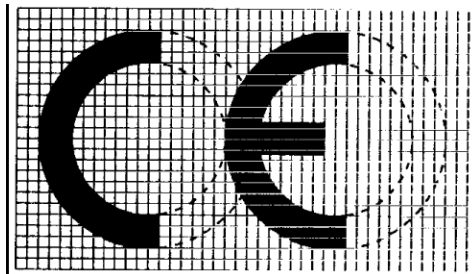
Proposal for a directive Article 16 – paragraph 1

Text proposed by the Commission

Amendment

1. ***The CE marking shall consist of
the initials “CE” taking the
following form:***

deleted



Justification

Technical adaptation to the goods package

Amendment 66

Proposal for a directive Article 16 – paragraph 2

Text proposed by the Commission

Amendment

2. ***If the CE marking is reduced or***

deleted

enlarged the proportions given in the graduated drawing in paragraph 1 must be respected.

Justification

Technical adaptation to the goods package

Amendment 67

Proposal for a directive Article 16 – paragraph 3

Text proposed by the Commission

Amendment

3. Where specific legislation does not impose specific dimensions, the CE marking shall have a height of at least 5 mm. ***deleted***

Justification

Technical adaptation to the goods package

Amendment 68

Proposal for a directive Article 17

Text proposed by the Commission

Amendment

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 and an assessment of the potential exposure to them.

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 and an assessment of the potential exposure to them. ***The lack of a history of accidents shall not automatically be considered as evidence of low risk.***

Amendment 69

Proposal for a directive Article 22 – paragraph 2

Text proposed by the Commission

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by **their** national accreditation **bodies** within the meaning of and in accordance with Regulation (EC) No [...].

Amendment

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.

Justification

Technical adaptation to the goods package

Amendment 70

Proposal for a directive Article 22 – paragraph 3

Text proposed by the Commission

3. Where the notifying authority delegates, **subcontracts** or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, **the delegated, sub-contracted or otherwise entrusted** body shall be a legal entity and shall have arrangements to cover liabilities arising **from** its activities.

Amendment

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 23(1) to (6). In addition it shall** have arrangements to cover liabilities arising **out of** its activities.

Justification

Technical adaptation to the goods package

Amendment 71

Proposal for a directive Article 22 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

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

Justification

Technical adaptation to the goods package

Amendment 72

Proposal for a directive Article 22 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. The notifying authority shall establish Safety Notification Points at which childcare professionals and consumers may report the non-conformity of toys or accidents related to the use of a toy.

Justification

Setting Safety Notification Points in Member States would empower consumers and facilitate direct communication with manufacturers and producers in the case of a problem with a particular product. Manufacturers and producers could then react more directly to the demands of their consumer

Amendment 73

Proposal for a directive Article 23 – paragraph 1

Text proposed by the Commission

Amendment

1. The notifying authority shall meet the requirements set out in paragraphs 2 to 7 ***deleted***

Justification

Technical adaptation to the goods package

Amendment 74

**Proposal for a directive
Article 23 – paragraph 5**

Text proposed by the Commission

Amendment

5. The notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy.

5. The notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy ***services on a commercial or competitive basis.***

Justification

Technical adaptation to the goods package

Amendment 75

**Proposal for a directive
Article 23 – paragraph 6**

Text proposed by the Commission

Amendment

6. The notifying authority shall ***have adequate arrangements to*** safeguard the confidentiality of the information ***obtained.***

6. The notifying authority shall safeguard the confidentiality of the information ***it obtains.***

Justification

Technical adaptation to the goods package

Amendment 76

**Proposal for a directive
Article 24 - paragraph 1**

Text proposed by the Commission

Amendment

Member States shall inform the Commission ***and the other Member States*** of their ***national*** procedures for the assessment and notification of conformity

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of

assessment bodies and the monitoring of notified bodies, and of any changes ***to that information***.

notified bodies, and of any changes ***thereto***.

Justification

Technical adaptation to the goods package

Amendment 77

**Proposal for a directive
Article 25 – paragraph 3**

Text proposed by the Commission

3. The conformity assessment body shall be a third-party body independent ***from*** the organisation or the product it assesses.

Amendment

3. The conformity assessment body shall be a third-party body independent ***of*** the organisation or the product 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.

Justification

Technical adaptation to the goods package

Amendment 78

**Proposal for a directive
Article 25 – paragraph 4**

Text proposed by the Commission

4. The 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 ***products*** which they assess, nor the authorised

Amendment

4. The 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. ***Nor shall they become*** directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those ***products***, ***nor*** represent the parties engaged in those activities.

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 products for personal purposes.***

The 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, manufacture or construction, 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.***

They shall not ***provide consultancy related to the*** conformity assessment activities for which they are notified ***and relating to products intended to be placed on the Community market. This shall not preclude the possibility of exchanges of technical information between the manufacturer and the conformity assessment body and the use of assessed products that are necessary for the operations of the conformity assessment body.***

The conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity ***and*** impartiality of its conformity assessment activities.

The conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity ***or*** impartiality of its conformity assessment activities.

Justification

Technical adaptation to the goods package

Amendment 79

Proposal for a directive Article 25 – paragraph 6

Text proposed by the Commission

6. The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to ***such a body by the provisions of*** Article 19 and ***for*** which it has 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 ***for*** each kind or category of ***products for*** which it ***is*** notified, the conformity assessment body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks. It 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.

Amendment

6. The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to ***it*** by Article 19 and ***in relation to*** which it has 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 ***product in relation to*** which it ***has been*** notified, the 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 the 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 product technology in question and the mass or serial nature of the production process.

It 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.

Justification

Technical adaptation to the goods package

Amendment 80

Proposal for a directive

Article 25 – paragraph 7 – point c

Text proposed by the Commission

(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of **the relevant** Community legislation and **relevant** implementing regulations;

Amendment

(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Community **harmonisation** legislation and of its implementing regulations;

Justification

Technical adaptation to the goods package

Amendment 81

Proposal for a directive

Article 25 – paragraph 11

Text proposed by the Commission

11. The conformity assessment body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body **co-ordination** group established under **Article 36** and apply as general guidance the administrative

Amendment

11. The conformity assessment body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body coordination group established under **the relevant Community harmonisation legislation** and apply as

decisions and documents produced as a work **result** of that group.

general guidance the administrative decisions and documents produced as a **result of the** work of that group.

Justification

Technical adaptation to the goods package

Amendment 82

**Proposal for a directive
Article 26**

Text proposed by the Commission

Where a conformity assessment body **can demonstrate** its conformity with the criteria laid down in the harmonised standards, 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 25

Amendment

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 25 **insofar as the applicable harmonised standards cover those requirements.**

Justification

Technical adaptation to the goods package

Amendment 83

**Proposal for a directive
Article 26 a (new)**

Text proposed by the Commission

Amendment

Article 26a

Formal objection to a harmonised standard

Where a Member State or the Commission has a formal objection against the harmonised standards referred to in Article 26, the provisions of Article 13 shall apply.

Justification

Technical adaptation to the goods package

Amendment 84

**Proposal for a directive
Article 27 – paragraph 1**

Text proposed by the Commission

1. Where the **conformity assessment** body subcontracts specific tasks connected with **the assessment of** conformity or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 25.

Amendment

1. Where the **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 25 **and shall inform the notifying authority accordingly**.

Justification

Technical adaptation to the goods package

Amendment 85

**Proposal for a directive
Article 27 – paragraph 2**

Text proposed by the Commission

2. The **conformity assessment** body shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

Amendment

2. The **notified** body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

Justification

Technical adaptation to the goods package

Amendment 86

Proposal for a directive Article 27 – paragraph 4

Text proposed by the Commission

4. The **conformity assessment** body shall keep at the disposal of the **national authorities** the relevant documents concerning the assessment of the **subcontractor's or subsidiary's** qualifications and the work carried out by **the subcontractor or the subsidiary** under Article 19.

Amendment

4. The **notified** body 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 19.

Justification

Technical adaptation to the goods package

Amendment 87

Proposal for a directive Article 29 – paragraph 4

Text proposed by the Commission

4. Where a notification is not based on an accreditation certificate referred to in Article 28(2), the notifying authority shall provide the Commission and the other Member States with **all** documentary evidence **necessary for the verification of** the conformity assessment body's competence.

Amendment

4. Where a notification is not based on an accreditation certificate **as** referred to in Article 28(2), the notifying authority shall provide the Commission and the other Member States with **the** 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 25.**

Justification

Technical adaptation to the goods package

Amendment 88

Proposal for a directive Article 29 – paragraph 5

Text proposed by the Commission

5. The body concerned may perform the activities of a notified body only where no objections ***have been*** raised by the Commission ***and*** the other Member States within two months ***following that*** notification.

Only such a body shall be considered ***as*** a notified body for the purpose of this Directive.

Amendment

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 purpose of this Directive.

Justification

Technical adaptation to the goods package

Amendment 89

Proposal for a directive Article 31 – paragraph 1

Text proposed by the Commission

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements ***set out*** in Article 25, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw ***the*** notification as appropriate. It shall immediately inform the Commission and the other Member States ***thereof.***

Amendment

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements ***laid down*** in Article 25, 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.***

Justification

Technical adaptation to the goods package

Amendment 90

Proposal for a directive Article 32 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Justification

Technical adaptation to the goods package

Amendment 91

Proposal for a directive Article 33 – paragraph 2

Text proposed by the Commission

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burden for economic operators, **in particular** taking **into consideration** the size **of companies and** the **relative** complexity of the technology **used by the toys**.

Amendment

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 product technology 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 the provisions of this Directive.

Justification

Technical adaptation to the goods package

Amendment 92

Proposal for a directive

Article 34 – paragraph 1 – point c

Text proposed by the Commission

(c) any request for information which they have received from market surveillance authorities;

Amendment

(c) any request for information which they have received from market surveillance authorities ***regarding conformity assessment activities***;

Justification

Technical adaptation to the goods package

Amendment 93

Proposal for a directive

Article 36 – paragraph 2

Text proposed by the Commission

Member States shall ensure that the bodies notified by them participate in the work of that group.

Amendment

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***.

Justification

Technical adaptation to the goods package

Amendment 94

Proposal for a directive

Article 37

Text proposed by the Commission

Member States shall organise and perform surveillance in accordance with ***Articles 6, 8 and 9 of Directive 2001/95/EC***. In addition to those provisions, ***Articles 38, 39 and 40*** of this Directive shall apply.

Amendment

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 provisions, ***Article 39*** of this Directive shall apply.

Justification

Technical adaptation to the goods package

Amendment 95

**Proposal for a directive
Article 38**

Text proposed by the Commission

Amendment

Article 38

deleted

Powers of market surveillance authorities

1. The market surveillance authorities may require from the economic operators concerned any information considered necessary for the purposes of effective market surveillance, including the technical documentation referred to in Article 20.

2. The market surveillance authorities may ask 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.

3. The market surveillance authorities shall be entitled to enter the premises of the economic operators concerned where it appears necessary for the purposes of carrying out the surveillance of toys in accordance with Article 37.

Justification

Technical adaptation to the goods package

Amendment 96

Proposal for a directive

Article 39 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1. The market surveillance authorities may ask 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.

Justification

Technical adaptation to the goods package

Amendment 97

Proposal for a directive

Article 40

Text proposed by the Commission

Amendment

Article 40

deleted

Co-operation for market surveillance

1. Member States shall ensure efficient co-operation and exchange of information on all issues relating to toys presenting a risk between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Community Agencies.

2. For the purposes of paragraph 1, the market surveillance authorities of one Member State shall provide, on request, assistance to market surveillance authorities of other Member States by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure or by participating in investigations initiated in

other Member States.

Justification

Technical adaptation to the goods package

Amendment 98

**Proposal for a directive
Article 41 – paragraph 1**

Text proposed by the Commission

1. Where the market surveillance authorities of one Member State have taken action referred to in **Article 12** of **Directive 2001/95/EC** or where they have sufficient reason to believe that a toy covered by this Directive presents a risk **for** the health or safety of persons they shall, **together with the relevant economic operators, perform an** evaluation in relation to the toy concerned covering all the requirements laid down **by** this Directive.

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down **by** this Directive, they shall require the relevant economic operator to take all appropriate corrective **actions** to bring the toy into compliance with those requirements **or** to withdraw the toy from the market or recall it within **such** reasonable period, commensurate with the nature of the risk, as they may prescribe.

Amendment

1. Where the market surveillance authorities of one Member State have taken action referred to in **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 **or to other aspects of public interest protection covered by this Directive**, 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 all 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 to in the second subparagraph of this paragraph.

Justification

Technical adaptation to the goods package

Amendment 99

**Proposal for a directive
Article 41 – paragraph 3**

Text proposed by the Commission

3. The economic operator shall ensure that **any** corrective **actions are** taken in respect of all the toys concerned **which he** has made available on the market throughout the Community.

Amendment

3. The economic operator shall ensure that **all appropriate** corrective **action is** taken in respect of all the toys concerned **that it** has made available on the market throughout the Community.

Justification

Technical adaptation to the goods package

Amendment 100

**Proposal for a directive
Article 41 – paragraph 5 – introductory wording**

Text proposed by the Commission

5. The information referred to in paragraph 4 shall provide all available details, in particular as regards the **necessary** data for the identification of the non-compliant toy, the origin of the toy, the nature of the risk involved, the nature and duration of national measures taken. In particular, the market surveillance authorities shall indicate whether the **non compliance** is due to either **of the following**:

Amendment

5. The information referred to in paragraph 4 shall provide all available details, in particular as regards the data **necessary** for the identification of the non-compliant toy, the origin of the toy, the nature of the **non-compliance alleged 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:

Justification

Technical adaptation to the goods package

Amendment 101

Proposal for a directive

Article 41 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. 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.

Justification

Technical adaptation to the goods package

Amendment 102

Proposal for a directive

Article 42 – paragraph 3

Text proposed by the Commission

Amendment

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 ***as*** referred to in Article 41(5)(b), the Commission ***or the Member State*** shall bring the matter before the ***Standing*** Committee set up ***under*** Article 5 of Directive 98/34/EC.

3. Where the national measure is considered justified and the non-compliance of the toy is attributed to shortcomings in the harmonised standards referred to in Article 41(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.***

Justification

Technical adaptation to the goods package

Amendment 103

Proposal for a directive

Article 43 – introductory wording

Text proposed by the Commission

If a measure referred to in *Article 41 (4)* is a type of measure which is required under **Article 12 of Directive 2001/95/EC** to be notified through the Community Rapid Information Exchange System (RAPEX), it shall not be necessary to make a separate notification under Article 41(4) of this Directive, provided that the following conditions are met:

Amendment

If a measure referred to in *Article 41(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 (RAPEX), it shall not be necessary to make a separate notification under Article 41(4) of this Directive, provided that the following conditions are met:

Justification

Technical adaptation to the goods package

Amendment 104

Proposal for a directive

Article 44 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) technical documentation is either not available or not complete.

Justification

Technical adaptation to the goods package

Amendment 105

Proposal for a directive

Article 45 - paragraph 1 - subparagraph 1

Text proposed by the Commission

Amendment

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

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

(-a) Annex I;

- (a) Points 7 and 8 in Part III of Annex II;
(b) Annex V.

- (a) Points 7 and 8 in Part III of Annex II;
(b) Annex V.

Justification

This article concerns fragrances and heavy metals (as well as warnings). This only allows adaptations to be made under the comitology procedure to take account of technical and scientific progress: therefore the word “practicable” needs to be included as a reason for an amendment of the relevant annexes.

Amendment 106

Proposal for a directive

Article 45 - paragraph 1 - subparagraph 2

Text proposed by the Commission

Those measures, designed to amend non-essential elements of this **Regulation**, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 46 (2).

Amendment

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 46(2).

Amendment 107

Proposal for a directive

Article 45 - paragraph 2

Text proposed by the Commission

2. The Commission may decide upon the **use** in toys of substances or preparations classified as carcinogenic, mutagenic or toxic to reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC.

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 46(2).

Amendment

2. The Commission may decide upon the **content** in toys of substances or preparations classified as carcinogenic, mutagenic or toxic to reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC.

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 46(2) **and, as appropriate, after the opinion of the relevant Scientific Committee.**

Justification

Change the word “use” to “content”. This adds clarification to the Directive. It also makes it clear that it is the action of the placing a toy on the market that is regulated (wherever the toy is manufactured) and not the process of manufacture of the toy that is covered. The other amendment simply clarifies in the Directive the involvement of the scientific committee as established in the chemicals annex.

Amendment 108

Proposal for a directive Article 52

Text proposed by the Commission

Member States shall not impede the **placing** on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before this Directive entered into force or **at the latest 2 years** after this Directive entered into force.

Amendment

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 this Directive entered into force or **during a period of two years after** this Directive entered into force.

2. By way of derogation from paragraph 1, Member States shall not impede the making available on the market of toys which comply with the requirements of this Directive with the exception of the requirements set out in Annex II, Part III, provided that toys which do not comply with the requirements set out in Annex II, Part III of this Directive comply with the requirements set out in Section 3 of Part II of Annex II of Directive 88/378/EEC and were placed on the market within four years of the date of entry into force of this Directive.

Justification

The amendment is intended to clarify that the new Directive has no retroactive effects and that the minimum 2-year transitional period should be observed when transposing the Directive.

Amendment 109

Proposal for a directive Article 54 – paragraph 1

Text proposed by the Commission

Directive 88/378/EEC *is repealed from the date set out in the second paragraph of Article 53.*

Amendment

Directive 88/378/EEC, *with the exception of Article 2(1) and Section 3 of Part II of Annex II*, is repealed *with effect from [2 years from the date of entry into force of this Directive]. Article 2(1) and Section 3 of Part II of Annex II of that Directive are repealed with effect from [4 years from the date of entry into force of this Directive].*

Amendment 110

Proposal for a directive Annex I – point 4

Text proposed by the Commission

4. **Bicycles**, scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;

Amendment

4. Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;

Bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the upper surface of the saddle, with the saddle in a horizontal position and the seatpost adjusted to the lowest insertion mark;

Justification

Current European legislation on children's bicycles is unclear and makes a distinction between bicycles with a maximum saddle height of less than 435 mm (EN 71-1), bicycles with a maximum saddle height of more than 435 mm and less than 635 mm (EN14765) and bicycles of over 635 mm (EN 14764). The first kind of bicycle is not intended to be used on public roads and, depending on the legislation in the Member State, is or is not deemed to be a bicycle. This inconsistency gives rise to a lack of clarity for both market surveillance and manufacturers.

Amendment 111

Proposal for a directive Annex I – point 17 a (new)

Text proposed by the Commission

Amendment

17a. Children's books designed or clearly intended for use by children that are made only of cardboard or paper and that do not contain any elements other than those made of cardboard or paper.

Amendment 112

Proposal for a directive Annex II – Part I – point 4 – paragraph 1

Text proposed by the Commission

Amendment

4. Toys and their parts must not present risk of ***asphyxiation caused, in particular, by*** strangulation ***or suffocation***.

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

Justification

Some shapes of toys have caused many severe accidents and have now been banned in the standard. The same rules should apply to packaging since children often play also with packaging. Most vending machine manufacturers and the main manufacturer of surprise-eggs have already been taking measures and replaced this kind of capsule with a substantially more safe one, a change that we warmly welcome, however all packaging should fulfil the same high safety standards and it is necessary to regulate in order to avoid less responsible manufacturers re-introducing the now obsolete capsule.

Amendment 113

Proposal for a directive Annex II – Part I – point 4 – paragraph 2

Text proposed by the Commission

Amendment

The packaging in which toys are contained for retail sale must not present risk of strangulation ***or asphyxiation*** caused by

The packaging in which toys are contained for retail sale must not present risk of strangulation or ***of closing off the flow of***

airway obstruction external to the mouth and nose.

air as a result of airway obstruction external to the mouth and nose. ***Spherical, egg shaped or ellipsoidal packaging may not have dimensions that can cause internal airways obstruction by being wedged in the mouth or pharynx.***

Justification

Some shapes of toys have caused many severe accidents and have now been banned in the standard. The same rules should apply to packaging since children often play also with packaging. Most vending machine manufacturers and the main manufacturer of surprise-eggs have already been taking measures and replaced this kind of capsule with a substantially more safe one, a change that we warmly welcome, however all packaging should fulfil the same high safety standards and it is necessary to regulate in order to avoid less responsible manufacturers re-introducing the now obsolete capsule.

Amendment 114

Proposal for a directive

Annex II – Part I – point 4 - paragraph 2 a (new)

Text proposed by the Commission

Amendment

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

Justification

Some shapes of toys have caused many severe accidents and have now been banned in the standard. The same rules should apply to packaging since children often play also with packaging. Most vending machine manufacturers and the main manufacturer of surprise-eggs have already been taking measures and replaced this kind of capsule with a substantially more safe one, a change that we warmly welcome, however all packaging should fulfil the same high safety standards and it is necessary to regulate in order to avoid less responsible manufacturers re-introducing the now obsolete capsule.

Amendment 115

Proposal for a directive

Annex II – part I – point 4 – paragraph 3

Text proposed by the Commission

Amendment

Toys, which are clearly intended for use by

Toys which, ***by virtue of their functions,***

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 and/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.

dimensions and characteristics, 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 and/or inhaled. This also applies to *the mouthpieces of* other toys which, *by virtue of their functions, dimensions and characteristics*, are intended to be put in the mouth, and to their component parts and any detachable parts *of the mouthpieces, regardless of the age group for which the toy is intended.*

Justification

The current wording is too restrictive, in that a toy for older children that is intended to be put in the mouth must not have any small component parts.

Amendment 116

Proposal for a directive

Annex II – Part I – point 4 – paragraph 4

Text proposed by the Commission

Toys contained within food or co-mingled with a food must have their own packaging. This packaging, in its supplied condition, must be of such dimensions as to prevent it being swallowed and/or inhaled.

Amendment

Toys contained within food or co-mingled with a food must have their own packaging. This packaging, in its supplied condition, must be of such dimensions as to prevent it being swallowed and/or inhaled, *and must fulfil the other requirements for toy packaging set out in paragraph 2 of this point. Cylindrical inner packaging with rounded ends that as supplied can be divided in two individual halves may not have dimensions that can cause internal airways obstruction.*

Justification

Some shapes of toys have caused many severe accidents and have now been banned in the standard. The same rules should apply to packaging since children often play also with packaging. Most vending machine manufacturers and the main manufacturer of surprise-eggs have already been taking measures and replaced this kind of capsule with a substantially more safe one, a change that we warmly welcome, however all packaging should fulfil the same high safety standards and it is necessary to regulate in order to avoid less responsible

manufacturers re-introducing the now obsolete capsule.

Amendment 117

Proposal for a directive

Annex II – Part I – point 4 – paragraph 5

Text proposed by the Commission

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.

Amendment

Toys firmly attached to a food product at the moment of consumption, in such a way that the food products 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 paragraph 2a of this point.***

Justification

Some shapes of toys have caused many severe accidents and have now been banned in the standard. The same rules should apply to packaging since children often play also with packaging. Most vending machine manufacturers and the main manufacturer of surprise-eggs have already been taking measures and replaced this kind of capsule with a substantially more safe one, a change that we warmly welcome, however all packaging should fulfil the same high safety standards and it is necessary to regulate in order to avoid less responsible manufacturers re-introducing the now obsolete capsule.

Amendment 118

Proposal for a directive

Annex II – Part I – point 10

Text proposed by the Commission

10. Toys which are designed to emit a sound should be so designed and constructed so that the sound from them is not able to impair children's hearing.

Amendment

10. Toys which are designed to emit a sound should be so designed and constructed so that the sound from them is not able to impair children's hearing. ***This shall apply to all toys irrespective of the age group targeted. The limit for toys with impulse noise should be 115 dB LpC peak at the ear. The limit for toys with prolonged noise should be 80 dB LpC peak at the ear.***

Justification

Studies show that prolonged exposure to noise over 80 dB can cause damage to hearing. Children are particularly vulnerable as their ears are more sensitive to high decibel levels than those of adults, as reflected in the increase in recent years in damage to children's hearing. The decibel level for particularly harmful toys, so-called impulse noise toys, should therefore be set at 115 dB.

Amendment 119

Proposal for a directive Annex II – Part III – point 1

Text proposed by the Commission

1. Toys shall be so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed or which they contain, when the toys are used as specified in the first subparagraph of *Article 9 (2)*.

Amendment

1. Toys shall be so designed and constructed that there are no risks of adverse effects on human health ***or the environment*** due to exposure to the chemical substances or preparations of which the toys are composed or which they contain, when the toys are used as specified in the first subparagraph of *Article 9(2)*.

Justification

See justification for Amendment 3.

Amendment 120

Proposal for a directive Annex II – Part III – point 3

Text proposed by the Commission

3. Without prejudice to the application of the restrictions under the first sentence of point 2, the use in toys of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to Directive 67/548/EEC in individual concentrations equal to or greater than the relevant concentrations established for the classification of preparations containing the substances in accordance with the provisions of Directive 1999/45/EC shall

Amendment

3. Without prejudice to the application of the restrictions under the first sentence of point 2, the use in toys of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to Directive 67/548/EEC in individual concentrations equal to or greater than the relevant concentrations established for the classification of preparations containing the substances in accordance with the provisions of Directive 1999/45/EC shall

be prohibited, except if the substances are contained in components of toys or micro-structurally distinct parts of toys that are not accessible to any physical contact by children.

be prohibited, except if the substances are contained in components of toys or micro-structurally distinct parts of toys that are not accessible to any physical contact, ***including inhalation***, by children ***if used in accordance with the first subparagraph of Article 9(2)***.

Justification

Amendment 121

Proposal for a directive Annex II – Part III – point 4

Text proposed by the Commission

4. Substances or preparations classified as CMR category 1 and 2 *according to* Directive 67/548/EEC ***may be used in toys provided that*** the following conditions are met:

4.1 use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and a Decision as referred to in *Article 45 (2)* has been taken;

4.2 there are no suitable alternative substances available, as documented in an analysis of alternatives,

4.3 they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

The Commission shall mandate the relevant Scientific Committee to re-evaluate ***those*** substances or preparations as soon as safety concerns arise and at the latest every 5 years from the date that a decision in accordance with *Article 45 (2)*

Amendment

4. Substances or preparations classified as CMR category 1 and 2 *under* Directive 67/548/EEC ***shall be prohibited unless*** the following conditions are met:

(a) use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and a Decision as referred to in *Article 45(2)* has been taken;

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

(c) they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

The following uses of substances or preparations shall be exempt from the prohibition set out in point 3:

[add list]

The Commission shall mandate the relevant Scientific Committee to re-evaluate ***the*** substances or preparations ***included in the list set out in the second paragraph*** as soon as safety concerns arise and at the latest every 5 years from the date

was taken.

that a decision was taken in accordance with Article 45(2).

Amendment 122

Proposal for a directive Annex II – Part III – point 5

Text proposed by the Commission

5. Substances or preparations classified as CMR category 3 *according to* Directive 67/548/EEC **may be used** in toys **if** use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, **and following** a *Decision* as referred to in Article 45 (2) and **provided that** they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

Amendment

5. Substances or preparations classified as CMR category 3 *under* Directive 67/548/EEC **shall be prohibited for use** in toys **unless**:

- (a) **the** use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;
- (b) a *decision* as referred to in Article 45(2) has been taken; and
- (c) they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

Amendment 123

Proposal for a directive Annex II – Part III – point 5 a (new)

Text proposed by the Commission

Amendment

5a. Specific requirements shall be adopted for toys or toy parts that are designed to be placed in the mouth, regardless of the age group for which the toy is intended, based upon the packaging requirements for food as laid down in 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 and the related specific measures for particular materials. These requirements shall be adopted on the basis of the opinion of the competent scientific committee and by decision pursuant to Article 45, paragraph 2, taking account of the differences between toys and materials which come into contact with food.

Amendment 124

Proposal for a directive
Annex II – Part III – point 5 b (new)

Text proposed by the Commission

Amendment

5b. Toys or parts of toys, irrespective of the age of the children for which they are intended, must comply with the provisions on the release of nitrosamines and nitrosatable substances from elastomer or rubber teats set out in Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.

Justification

The use of hazardous substances in toys is not limited to CMR substances, fragrances or substances containing certain elements. All hazardous substances should be subject to regular evaluation by the Commission. In case this evaluation reveals an unacceptable risk, the Commission should be empowered to take appropriate action in comitology.

Amendment 125

Proposal for a directive
Annex II – Part III – point 5 c (new)

Text proposed by the Commission

Amendment

5c. The Commission shall establish a

programme aimed at systematically and regularly evaluating the occurrence of hazardous substances or materials in toys. The programme shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders. The Commission shall decide, following the opinion of the relevant Scientific Committee, to take appropriate restrictive measures, if necessary. 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 46(2).

Justification

The use of hazardous substances in toys is not limited to CMR substances, fragrances or substances containing certain elements. All hazardous substances should be subject to regular evaluation by the Commission. In case this evaluation reveals an unacceptable risk, the Commission should be empowered to take appropriate action in comitology.

Amendment 126

**Proposal for a directive
Annex II – part III – point 6 a (new)**

Text proposed by the Commission

Amendment

6a. Toys that are designed to come into frequent contact with the skin, such as finger paints or modelling clay, shall comply with the requirements on composition and labelling contained in Directive 76/768/EEC.

Justification

There is no reason for the toy directive to lay down rules for toys that come into frequent contact with the skin that are less strict than those contained in the cosmetics directive.

Amendment 127

Proposal for a directive
Annex II – Part III – point 7

Text proposed by the Commission

7. Toys shall not contain the following allergenic fragrances:

- (1) Alanroot (*Inula helenium*)
- (2) Allylisothiocyanate
- (3) Benzyl cyanide
- (4) 4 tert-Butylphenol
- (5) Chenopodium oil
- (6) Cyclamen alcohol
- (7) Diethyl maleate
- (8) Dihydrocoumarin
- (9) 2,4-Dihydroxy-3-methylbenzaldehyde
- (10) 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)
- (11) 4,6-Dimethyl-8-tert-butylcoumarin
- (12) Dimethyl citraconate
- (13) 7,11-Dimethyl-4,6,10-dodecatrien-3-one
- (14) 6,10-Dimethyl-3,5,9-undecatrien-2-one
- (15) Diphenylamine
- (16) Ethyl acrylate
- (17) Fig leaf, fresh and preparations
- (18) trans-2-Heptenal
- (19) trans-2-Hexenal diethyl acetal
- (20) trans-2-Hexenal dimethyl acetal
- (21) Hydroabietyl alcohol
- (22) 4-Ethoxy-phenol
- (23) 6-Isopropyl-2-decahydronaphthalenol
- (24) 7-Methoxycoumarin
- (25) 4-Methoxyphenol
- (26) 4-(p-Methoxyphenyl)-3-butene-2-one
- (27) 1-(p-Methoxyphenyl)-1-penten-3-one
- (28) Methyl trans-2-butenate
- (29) 6-Methylcoumarin
- (30) 7-Methylcoumarin
- (31) 5-Methyl-2,3-hexanedione
- (32) Costus root oil (*Saussurea lappa* Clarke)
- (33) 7-Ethoxy-4-methylcoumarin
- (34) Hexahydrocoumarin
- (35) Peru balsam (*Myroxylonpereiarae* Klotzsch)
- (36) 2-Pentylidene-cyclohexanone

Amendment

7. Toys shall not contain the following allergenic fragrances:

- (1) Alanroot (*Inula helenium*)
- (2) Allylisothiocyanate
- (3) Benzyl cyanide
- (4) 4 tert-Butylphenol
- (5) Chenopodium oil
- (6) Cyclamen alcohol
- (7) Diethyl maleate
- (8) Dihydrocoumarin
- (9) 2,4-Dihydroxy-3-methylbenzaldehyde
- (10) 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)
- (11) 4,6-Dimethyl-8-tert-butylcoumarin
- (12) Dimethyl citraconate
- (13) 7,11-Dimethyl-4,6,10-dodecatrien-3-one
- (14) 6,10-Dimethyl-3,5,9-undecatrien-2-one
- (15) Diphenylamine
- (16) Ethyl acrylate
- (17) Fig leaf, fresh and preparations
- (18) trans-2-Heptenal
- (19) trans-2-Hexenal diethyl acetal
- (20) trans-2-Hexenal dimethyl acetal
- (21) Hydroabietyl alcohol
- (22) 4-Ethoxy-phenol
- (23) 6-Isopropyl-2-decahydronaphthalenol
- (24) 7-Methoxycoumarin
- (25) 4-Methoxyphenol
- (26) 4-(p-Methoxyphenyl)-3-butene-2-one
- (27) 1-(p-Methoxyphenyl)-1-penten-3-one
- (28) Methyl trans-2-butenate
- (29) 6-Methylcoumarin
- (30) 7-Methylcoumarin
- (31) 5-Methyl-2,3-hexanedione
- (32) Costus root oil (*Saussurea lappa* Clarke)
- (33) 7-Ethoxy-4-methylcoumarin
- (34) Hexahydrocoumarin
- (35) Peru balsam (*Myroxylonpereiarae* Klotzsch)
- (36) 2-Pentylidene-cyclohexanone

- (37) 3,6,10-Trimethyl-3,5,9-undecatrien-2-one
 (38) Verbana oil (Lippia citriodora Kunth).

However, the presence of traces of these substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice.

In addition the following allergenic fragrances shall be listed *if added to toys, as such, at concentrations exceeding 0,01 % by weight*:

- (1) Amyl cinnamal
(2) Amylcinnamyl alcohol
(3) Anisyl alcohol
(4) Benzyl alcohol
 (5) Benzyl benzoate
 (6) Benzyl cinnamate
(7) Benzyl salicylate
(8) Cinnamal
(9) Cinnamyl alcohol
(10) Citral
 (11) Citronellol
(12) Coumarin
(13) Eugenol
 (14) Farnesol
(15) Geraniol
 (16) Hexyl cinnamaldehyde
(17) Hydroxy-citronellal

- (37) 3,6,10-Trimethyl-3,5,9-undecatrien-2-one
 (38) Verbana oil (Lippia citriodora Kunth)
(39) Musk ambrette
(40) 4-Phenyl-3-buten-2-one
(41) Amyl cinnamal
(42) Amylcinnamyl alcohol
(43) Benzyl alcohol
(44) Benzyl salicylate
(45) Cinnamyl alcohol
(46) Cinnamal
(47) Citral
(48) Coumarin
(49) Eugenol
(50) Geraniol
(51) Hydroxycitronellal
(52) Hydroxymethylpentylcyclohexenecarboxaldehyde
(53) Isoeugenol
(54) Oakmoss extracts
(55) Treemoss extracts.

However, the presence of traces of these substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice **and does not exceed 10 ppm.**

In addition the following allergenic fragrances, *if added to toys, as such, at concentrations exceeding 0,01 % by weight*, shall be listed **on the packaging and in instructions attached to the toy**:

- (1) Anisyl alcohol

 (5) Benzyl benzoate
 (6) Benzyl cinnamate

 (11) Citronellol

 (14) Farnesol
 (16) Hexyl cinnamaldehyde

(18) Hydroxy-methylpentylcyclohexenecarboxaldehyde

(19) Isoeugenol

(20) Lilial (referred to in the Cosmetics

Directive in entry 83 as: 2-(4-tert-Butylbenzyl) propionaldehyde

(21) d-Limonene

(22) Linalool

(23) Methyl heptine carbonate

(24) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one

(25) Oakmoss extracts

(26) Treemoss extracts

(20) Lilial

(21) d-Limonene

(22) Linalool

(23) Methyl heptine carbonate

(24) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one

Justification

Amendment 128

Proposal for a directive

Annex II – Part III – point 7 a (new)

Text proposed by the Commission

Amendment

7a. The use of the fragrances set out in points 41 to 55 in the list set out in the first paragraph of point 7 and of the fragrances set out in points 1 to 11 in 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 "contains allergenic fragrances";

(ii) the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC [Cosmetics Directive]; and

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

Such olfactory board games, cosmetic kits and gustative games shall not be permitted to be used by children under 36 months and shall comply with the provisions of section 1 of Part B of Annex

Amendment 129**Proposal for a directive****Annex II – Part III – point 8 - table**

<i>Text proposed by the Commission</i>			<i>Amendment by Parliament</i>		
Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material
Aluminium	5625	1406	Aluminium	5625	1406
Antimony	45	11.3	Antimony	45	11.3
<i>Arsenic</i>	<i>7,5</i>	<i>1,9</i>			
Barium	4500	1125	Barium	4500	1125
Boron	1200	300	Boron	1200	300
<i>Cadmium</i>	<i>3,8</i>	<i>0,9</i>			
Chromium (III)	37.5	9.4	Chromium (III)	37.5	9.4
<i>Chromium (VI)</i>	<i>0,04</i>	<i>0,01</i>			
Cobalt	10.5	2.6	Cobalt	10.5	2.6
Copper	622.5	156	Copper	622.5	156
<i>Lead</i>	<i>27</i>	<i>6,8</i>			
Manganese	1200	300	Manganese	1200	300
<i>Mercury</i>	<i>15</i>	<i>3,8</i>			
Nickel	75	18.8	Nickel	75	18.8
Selenium	37.5	9.4	Selenium	37.5	9.4
Strontium	4500	1125	Strontium	4500	1125
Tin	15000	3750	Tin	15000	3750
<i>Organic tin</i>	<i>1,9</i>	<i>0,5</i>			
Zinc	3750	938	Zinc	3750	938

Justification

Arsenic, cadmium, lead, chromium VI, mercury and organic tin are highly toxic and should be totally banned from toys. Cadmium, lead, chromium VI, and mercury are already banned

in cars and electrical and electronic devices. Chromium VI in cement needs to be reduced to a harmless form by the addition of ferrous sulphate. Arsenic is banned in paint and in wood treatment (with some exceptions). Organic tins are banned as biocides. Clearly, these substances have no place in toys.

Amendment 130

Proposal for a directive

Annex II – Part III – point 8 a (new)

Text proposed by the Commission

Amendment

8a. The use of arsenic, cadmium, chromium (VI), lead, mercury and organic tin in toys shall be prohibited. Traces of those substances may be allowed unless their presence is technically unavoidable in accordance with good manufacturing practice.

This point applies without prejudice to points 3 to 5.

Amendment 131

Proposal for a directive

Annex II – Part V – point 2

Text proposed by the Commission

Amendment

2. Textile toys for children under 36 months shall be washable and shall fulfil the safety requirements also after washing.

2. Textile toys for children under 36 months shall be washable and shall ***function and*** fulfil the safety requirements also after washing.

Justification

It should be possible to ensure high standards of hygiene while still having a toy that works and is safe.

Amendment 132

Proposal for a directive Annex III – point 2

Text proposed by the Commission

Amendment

2. Name and address of **(authorised representative of the)** manufacturer:

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

Justification

Technical adaptation to the goods package

Amendment 133

Proposal for a directive Annex III – point 4

Text proposed by the Commission

Amendment

4. Object of the declaration (identification of toy allowing traceability):

4. Object of the declaration (identification of toy allowing traceability). **It may include a photograph, where appropriate**:

Justification

Technical adaptation to the goods package

Amendment 134

Proposal for a directive Annex III – point 7

Text proposed by the Commission

Amendment

7. The notified body ... (name, number)... performed... (description of intervention)... and issued the certificate: ...

7. **Where applicable**, the notified body ... (name, number)... performed... (description of intervention)... and issued the certificate: ...

Justification

Technical adaptation to the goods package

Amendment 135

Proposal for a directive
Annex V - Part A - paragraph 1 a (new)

Text proposed by the Commission

Amendment

All warnings, by way of phrase or pictogram, shall be preceded by the word “Warning”.

Justification

To make it clear to the consumer that the text relates to safety and to draw proper attention to the message, all warnings should begin with the word “Warning”. This is particularly valid for pictogram warnings.

Amendment 136

Proposal for a directive
Annex V - Part B - point 1

Text proposed by the Commission

Amendment

1. Toys which might be dangerous for children under 36 months of age shall bear a warning, for example: 'Warning: Not suitable for children under 36 months' or 'Warning: Not suitable for children under three years' or the word “Warning” together with the following graphic:

[Pictogram]

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

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

1. Toys which might be dangerous for children under 36 months of age shall bear a warning, for example: 'Warning: Not suitable for children under 36 months' or 'Warning: Not suitable for children under three years' or the word “Warning” together with the following graphic:

[Pictogram]

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

These warnings may not be used for toys designed or, by virtue of their functions, dimensions and characteristics, intended for use by children of under 36 months.

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

Justification

The small parts warning is presently being misused and toys which are in fact intended for small children carry the warning in order to legalise the presence of small parts that small children may choke on. In particular, soft-filled toys such as teddy bears and soft dolls should never have small, loose parts, since they are likely to be played with by children regardless of the intention of the manufacturer.

Amendment 137

Proposal for a directive Annex V – Part B – point 7

Text proposed by the Commission

Toys contained in food or co-mingled with food shall contain the warning:

“Adult supervision recommended”.

Amendment

Toys contained in food or co-mingled with food shall contain the warning:

“***Toy inside.*** Adult supervision recommended”.

Justification

Amendment 138

Proposal for a directive Annex V - Part B - point 7 a (new)

Text proposed by the Commission

Amendment

7a. Imitations of protective masks and helmets

Imitations of protective masks and helmets shall contain the warning:

“This toy does not provide protection”.

Justification

Warnings should be self-explanatory in order to ensure that consumers will understand their meaning and will take adequate protection measures.

Amendment 139

Proposal for a directive
Annex V - Part B - point 7 b (new)

Text proposed by the Commission

Amendment

7b. 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 consumer packaging, which shall be permanently marked on the toy:

“To prevent possible injury by entanglement, remove this toy when the child begins to push up on its hands and knees”.

EXPLANATORY STATEMENT

1. Background to the proposal and the innovations it introduces

The Commission proposal serves to repeal and replace Directive 88/378/EEC of 3 May 1988 on the safety of toys.

Directive 88/378/EEC was the first directive introduced under the ‘new approach’ whereby the essential safety requirements are incorporated in the directive itself and harmonised standards are referred to for the technical specifications. The proposed new directive is based on the same principles.

Although the 1988 directive lived up to expectations and has already ensured a high level of toy safety in the European Union, after 20 years it is in need of modernisation. Account must also be taken of new safety risks which (may) arise as a result of the development and marketing of new kinds of toy, possibly made from new materials.

The main features of the revision are, according to the Commission:

- a. the introduction of better safety requirements, mainly in connection with the use of chemical substances and electrical properties. Physical and mechanical properties are also brought into line (risks of suffocation and strangulation);
- b. clarification of the scope and concepts of the directive;
- c. more efficient and coherent enforcement of the directive. This takes the form of market surveillance being reinforced by the Member States, clear requirements being set out for the technical documentation that toy manufacturers must draw up, the rules on the affixing of the CE mark being brought into line with the changed legislative framework, and the adoption of a new requirement for manufacturers to include as part of the technical specification an analysis of the dangers that the toy may represent;
- d. an alignment to the general legislative framework on the marketing of products.

The proposed directive only covers the (physical) safety of toys and contains no provisions on their educational value or moral aspects.

2. Alignment of the proposal with the new rules adopted under the ‘goods package’

The legislative framework for the marketing of goods is due to be changed shortly.

This will take the form of:

- a new regulation on the marketing of products; the regulation contains rules on

accreditation and market surveillance;

- a new decision on the marketing of products; the decision contains, inter alia, standard articles for future ‘new approach’ directives.

The new directive must be brought into line with this new legislative framework. The Commission proposal is in line with the regulation and decision originally proposed by the Commission, but not yet in line with the text which was adopted by the European Parliament on 21 February 2008 and may be approved by the Council. The Commission has announced that it will not present an amended proposal for a toys directive in order to come into line with the new ‘goods package’.

In order to move forward with the proposed directive, your rapporteur proposes that Parliament introduce the technical adjustments to the text of the proposal to bring it into line with the framework texts recently adopted by the European Parliament (the ‘goods package’). The amendments relate to:

- definitions
- general requirements for market players
- presumption of conformity
- formal objection to harmonised standards
- rules on the CE mark
- requirements for conformity assessment bodies
- notification procedures
- procedures for products presenting a risk.

Amendments 1 to 79 inclusive relate to these technical adjustments to the new legislative framework. They are in line with the choices and decisions made by the European Parliament as regards this legislative framework.

3. Assessment

– *general*

Your rapporteur takes the view that children, as the most vulnerable of all consumers, must be given the fullest protection possible and that their parents and carers must be able to feel confident that the toys offered on the European market comply with rigorous safety standards.

She therefore agrees with the aims set out by the Commission: modernisation, clarification and reinforcement of the directive’s safety requirements and the arrangements for its enforcement.

She is also in agreement by and large with the additions and changes proposed by the Commission to the provisions of the existing Directive 88/378/EEC.

Detailed explanation of the rapporteur’s proposed amendments:

– *chemical properties*

Your rapporteur is in complete agreement with the introduction of specific requirements for the use of substances that are carcinogenic, mutagenic or toxic for reproduction (CMR), but suggests making these requirements be made even stricter. She sees no reason to make a distinction between Category 1 and 2 substances on the one hand and Category 3 substances on the other¹ as far as authorising exceptions is concerned.

She proposes making the conditions for the exceptional authorisation of these substances the same for the three categories, namely that the Scientific Committee should have evaluated the use of the substance in toys and found it acceptable, and that no suitable alternative is available.

Your rapporteur also proposes a complete ban on the use of allergenic substances in toys.

– ***mechanical properties***

Although she is concerned about the risks that may arise from the use of small but very powerful magnets in toys, the rapporteur takes the view that it is not necessary to include a specific provision on magnets in the directive.

A specific rule on magnetic toys is being prepared by the CEN, and the Commission has made interim arrangements (requirement to affix a warning that danger can arise if more than one magnet is swallowed).

– ***artisanally made or non-mass-produced toys***

Your rapporteur is aware that it is not easy for small and medium-sized firms that produce toys artisanally or, at the least, do not mass-produce them to meet the directive's more rigorous requirements. She is working on a solution, but has not yet found a legally watertight approach. She would be very happy to hear the opinion of colleagues on this.

– ***toys that are obviously designed or intended for children of a certain age group***

All too often toys that are obviously intended for babies and very young children are marked with a warning that they are unsuitable for children under 36 months. By doing this, the manufacturer is trying to sidestep strict safety rules and to evade any possible liability. This is irresponsible and must be forbidden.

This incorrect age group indication is also very confusing for purchasers and not conducive to the confidence that consumers should have in the safety of toys.

The relevant provisions of Article 10 of the directive must be made clearer.

¹ Category I: 'substances known to be carcinogenic to man'; Category II: 'substances which should be regarded as if they are carcinogenic to man'; Category III: 'substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment'.

– ***toys that come into contact with the mouth or the skin***

Toys that are designed to be put frequently in the mouth (such as toy musical instruments, teething rings, etc.), regardless of the age group for which they are intended, must meet the same strict migration limits, as set out in Directive 1935/2004/EG.

Toys that are designed to come into frequent contact with children's skin, regardless of age group, must meet the labelling and composition requirements set out in the cosmetics directive.

– ***toy safety notification point***

In some Member States and regions, notification points have been set up for unsafe toys, where childcare professionals and also consumers/parents can report both unsafe aspects of toys and accidents or near-accidents with toys.

Without advocating the setting up of such notification points in every Member State, your rapporteur takes the view that it could be useful to investigate whether consumers know that when they come across unsafe toys they can report this to a body that can make use of the information.

– ***language***

It is essential that the warnings required by the directive, not to mention instructions, should be expressed in a language that consumers understand. In accordance with the subsidiarity principle, the Member States can determine the language or languages that can be understood by consumers.

15.10.2008

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

for the Committee on the Internal Market and Consumer Protection

on the proposal for a directive of the European Parliament and of the Council on the safety of toys
(COM(2008)0009 – C6-0039/2008 – 2008/0018(COD))

Rapporteur: Anne Ferreira

SHORT JUSTIFICATION

The safety of toys is covered by a directive adopted in 1988 and amended in 1993, which harmonised the rules in place within the Member States and ensured better protection for children.

Suitable adjustments now need to be made to the directive to bring it into line with today's economic situation and the new scientific knowledge available and to incorporate risk-related statistics and take account of new societal requirements.

New factors to be taken into account

Economic context

The increase in trade has resulted in considerable changes in the toys sector.

Some 80% of the toys placed on the market in the EU are imported, and it should be remembered that in 2007 millions of toys manufactured in China were recalled because they failed to comply with European standards. Modern-day trade flows call for a review of the rules governing the placing on the market of goods and checks on compliance with standards.

New scientific knowledge

In view of the fact that toys contain increasing amounts of chemicals, the legislation needs to be adjusted to take account of the risks arising from the presence of such products in toys and of the way toys are used by children (sucking, throwing, etc.).

Statistics and risk management

In general, only serious toy-related accidents are reported. All types of accidents need to be taken into account in order to gain a clearer picture of the risks and hazards arising from the use of toys.

With a view to ensuring better toy-related accident prevention, we need to base our action on the scientific findings and risk assessments available.

The precautionary principle should not apply to one specific category of products but to all products.

New societal requirements

In line with the general trend in modern-day society, there are an increasing number and variety of toys. Toys form an integral part of a child's intellectual and emotional development, both at home and at school.

End users have a right to expect and demand high-quality products that do not pose a health risk to children or those looking after them.

Today's eco-aware consumers also expect products to be environment-friendly. This extends to a toy's life cycle, its packaging and its durability. Research shows that many toys placed on the market are not sufficiently sturdy and swiftly become waste.

While the Commission proposal is a step forward, it requires clarification. Accordingly, a number of amendments have been tabled, in particular on:

The importance of warnings and the documents that must travel with the product

The terms used need to be defined in a readily understandable way, with reference to the Community nomenclature, for example as regards asphyxia.

Furthermore, the documents must be easy to read. It is also essential for them to be supplied in the official language(s) of the Member State(s) in which the relevant product is sold.

The provisions on time limits for responding to requests and on warnings need to be made clearer, as do those on corrective measures and the withdrawal or recall of non-compliant toys.

Product quality and risks arising from the presence of chemicals

Toys are designed specifically for children. Proper account therefore needs to be taken of the fact that children are more sensitive to their environment than adults.

Children's organs are not fully developed. Therefore, CMRs represent a risk to a child's development and long-term health. Reference accordingly needs to be made to other pieces of legislation (on food packaging, cosmetics, etc.) in which limit values are set for the presence or migration of chemicals, to be assessed on the basis of the possible uses to which a child may put a toy (sucking, contact with the skin, etc.).

Your rapporteur considers that the provisions on chemicals should be extended to cover PBTs, etc.

The proposal gives freedom of movement precedence over toy safety. In this connection, in line with REACH, the burden of proof needs to be reversed, with economic operators being required to demonstrate that their toys are safe and are not a risk to children's health.

Following the relocation of a large number of manufacturing plants, 80% of the toys placed on the market in the EU are imported – mainly from China, where labour and environmental standards are low.

A large number of people therefore have a responsibility for toy safety. However, since large western toy manufacturers and buyers still dominate the market, it is their job, and the job of importers and distributors, to ensure that specifications in keeping with Community legislation are laid down and complied with, thus ensuring a high level of protection for our children's health.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) The precautionary principle was expressly laid down in the Treaty in 1992 and the Court of Justice of the European Communities has, on numerous occasions, clarified the substance and scope of this principle of Community law as one of the foundations of Community protection policy in the environment and health spheres¹.

¹ Judgment of 23 September 2003 in Case C-192/01, *Commission v Denmark*, ECR 2003, p. I-

9693; judgment of 7 September 2004 in Case C-127/02, *Landelijke Vereniging tot Behoud van de Waddenzee, Nederlandse Vereniging tot Bescherming van Vogels v Staatssecretaris van Landbouw, Natuurbeheer en Visserij*, ECR 2004, p. I-7405.

Justification

Owing to the lack of statistics on the risks and hazards that toys can pose to the safety and health of children, and given that children are classified as a vulnerable or very vulnerable social group, depending on their age, the precautionary principle needs to be incorporated into legislation on toy safety in order to enable the competent authorities in the Member States and economic operators to take action to prevent certain toys from being placed on the market. The principle must apply across the board.

Amendment 2

Proposal for a directive

Recital 8

Text proposed by the Commission

(8) All economic operators intervening in the supply and distribution chain should take the appropriate measures to ensure that they make available on the market only toys which are in conformity with the applicable legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.

Amendment

(8) All economic operators intervening in the supply and distribution chain should ***exercise the responsibility and vigilance required to ensure that under normal and reasonably foreseeable conditions of use the toys they place on the market do not jeopardise the safety and health of children.*** Economic operators should take the appropriate measures to ensure that they make available on the market only toys which are in conformity with the applicable legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.

Justification

Simply stating that economic operators should take appropriate measures is not enough. It should also be made clear that they are liable. They must therefore remain vigilant in order to ensure the health and safety of the children using their toys, with due account being taken of the various uses to which those toys may be put.

Amendment 3

Proposal for a directive Recital 16

Text proposed by the Commission

(16) In order to ensure protection of **children** against **recently discovered** risks, it is also necessary to adopt new essential safety requirements. In particular, it is necessary to complete and update provisions on chemical substances in toys. These provisions should specify that toys should comply with the 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC . These provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to 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 and fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. The specific limit values laid down in Directive 88/378/EEC for certain substances should be updated to take into account of the development of scientific knowledge.

Amendment

(16) In order to ensure **a high level of** protection of **children's health and safety and of the environment** against **various** risks, **special vigilance should be exercised in respect of hazardous and very hazardous substances**. **It** is also necessary to adopt new essential safety requirements. In particular, it is necessary to complete and update provisions on chemical substances in toys. These provisions should specify that toys should comply with the 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC . These provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to 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 and fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. The specific limit values laid down in Directive 88/378/EEC for certain

substances should be updated to take into account of the development of scientific knowledge.

Justification

The Treaties and relevant Community legislation systematically refer to the objective of a high level of protection for human health and the environment. The revised legislation on toy safety should follow suit. Given that this recital deals with chemicals, it is essential for reference to be made to hazardous and very hazardous substances.

Amendment 4

Proposal for a directive
Recital 16 a (new)

Text proposed by the Commission

Amendment

(16a) Economic operators applying for an exemption in respect of the use of a very hazardous substance in a toy should demonstrate that no safer alternative substance is available.

Justification

The use of very hazardous substances should be avoided as a general rule, owing to the impact that this could have on children's health, either directly or in the long term. The use of such substances should nonetheless be permitted where the manufacturer can demonstrate that no alternative (i.e. safer) substances exist. This amendment refers back to the 'principle' of the reversal of the burden of proof established in the REACH legislation, with the manufacturer being required to demonstrate that there is no alternative to the use of a very hazardous substance.

Amendment 5

Proposal for a directive
Recital 16 b (new)

Text proposed by the Commission

Amendment

(16b) Responsibility for management of the risks posed by toys, particularly those connected with the use therein of chemicals, should lie with the natural or legal persons who manufacture, import or

market the toys.

Justification

Economic operators in the toy sector should also be fully aware of the potential adverse effects on children's health of the use of certain chemical substances or preparations. They must therefore ensure that risk management takes due account of the presence of any chemicals.

Amendment 6

Proposal for a directive

Recital 17

Text proposed by the Commission

(17) The general and specific chemical requirements in this Directive should aim at protecting the health of children from dangerous substances in toys, while environmental concerns presented by toys are addressed in *horizontal* environmental legislation applying *also* to toys, in ***particular in Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste***, Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment, in Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste and in Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC.

Amendment

(17) The general and specific chemical requirements in this Directive should aim at protecting the health of children from dangerous substances in toys, while environmental concerns presented by toys are addressed in environmental legislation applying to ***electrical and electronic*** toys, in Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ***and*** in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment. ***In addition, environmental issues concerning waste are regulated in Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste, those concerning packaging are regulated*** in Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste, and ***those concerning batteries and accumulators are regulated*** in Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive

Justification

The Commission text gives the impression that environmental concerns are explicitly considered for all toys when only electrical and electronic toys are addressed.

Horizontal legislation does not apply to toys explicitly and should not be grouped together with the directives on EEE and WEEE.

Amendment 7

Proposal for a directive
Recital 18

Text proposed by the Commission

(18) It is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys inside food ***in line with the precautionary principle***, 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 measures at Community level.

Amendment

(18) It is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys inside 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 measures at Community level.

Justification

The precautionary principle should apply across the board in this revised directive. This amendment is linked to Amendment 1 (Recital 3a).

Amendment 8

Proposal for a directive
Recital 19

Text proposed by the Commission

(19) Since toys may exist or be developed which present hazards which are not covered by a particular safety requirement laid down in this Directive, it is necessary to set a general requirement of safety as the legal base for taking action against such

Amendment

(19) Since toys may exist or be developed which present hazards which are not covered by a particular safety requirement laid down in this Directive, it is necessary to set a general requirement of safety as the legal base for taking action against such

toys. In this respect safety of toys should be determined by reference to the intended use of the product while taking into account the foreseeable use, bearing in mind behaviour of children, who do not generally show the same degree of care as the average adult user.

toys. In this respect safety of toys should be determined by reference to the intended use of the product while taking into account the **reasonably** foreseeable use, bearing in mind behaviour of children, who do not generally show the same degree of care as the average adult user.

Justification

While all possible uses that a child may make of a toy need to be taken into account when assessing its safety, uses to which a child of a given age could not put that toy, owing to his or her stage of physical or intellectual development, etc., may be discounted.

Amendment 9

Proposal for a directive Recital 21

Text proposed by the Commission

(21) The CE marking, **materialising** conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the use of the CE marking, and rules as to its affixing should therefore be set in this Directive.

Amendment

(21) The CE marking, **indicating** conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the use of the CE marking, and rules as to its affixing should therefore be set in this Directive.

Justification

The considerable number of toys bearing the CE marking that were recalled in 2007 brought it home to European consumers that compliance is not synonymous with a high level of toy safety. It is therefore inappropriate to state that the CE marking ensures conformity, thus implying that it ensures safety.

Amendment 10

Proposal for a directive Recital 22

Text proposed by the Commission

(22) It is crucial to make clear to **both** manufacturers **and users** that by affixing

Amendment

(22) It is crucial to make clear to manufacturers that by affixing the CE

the CE marking to the toy the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility thereof.

marking to the toy the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility thereof.

Justification

The manufacturer has sole responsibility for affixing the CE marking to a toy. Manufacturers must be aware of the fact that, by using the CE marking, which attests to compliance with strict conditions, they become liable, and any misuse of the marking may be punished. Linked to Amendment 8.

Amendment 11

**Proposal for a directive
Recital 32**

Text proposed by the Commission

(32) In particular power should be conferred on the Commission in order to adapt the chemical requirements in certain well defined cases and 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 toys. Since those measures are of general scope and are designed to amend non-essential elements of this Directive and/ or to supplement this Directive by the addition of 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.

Amendment

(32) In particular power should be conferred on the Commission in order to adapt the chemical requirements in certain well defined cases and grant exemptions from the prohibition of **very hazardous substances and** CMR substances in certain cases as well as to adapt the wording of the specific warnings for certain categories of toys. Since those measures are of general scope and are designed to amend non-essential elements of this Directive and/ or to supplement this Directive by the addition of 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.

Justification

Amendment linked to the amendments to Recital 16, Article 47 and Annex II, part III.

Amendment 12

Proposal for a directive Recital 34

Text proposed by the Commission

(34) Since the objectives of the proposed action, namely to ensure a high level of safety of toys 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 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 this Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

Amendment

(34) Since the objectives of the proposed action, namely to ensure a high level of safety of toys ***with a view to ensuring children's health and safety*** 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 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 this Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

Justification

The directive's primary purpose needs to be restated.

Amendment 13

Proposal for a directive Article 1 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. This Directive is based on the principle that manufacturers, importers and other economic operators ensure that the manufacture or marketing of toys, and, in particular, any chemicals they contain, are not harmful or toxic to children's health and the environment. These measures are based on the

precautionary principle.

Justification

The Treaties and relevant Community legislation systematically refer to the objective of a high level of protection for human health and the environment. The revised legislation on toy safety should follow suit, including as regards chemicals used in the manufacture of toys. The precautionary principle needs to be incorporated into toy safety legislation.

Amendment 14

**Proposal for a directive
Article 2 – point 8 a (new)**

Text proposed by the Commission

Amendment

(8a) “warning” means special wording drawing the end user's or a supervisor's attention to the conditions for use or assembly of a toy;

Justification

The term 'warning' needs to be defined in order to avoid any confusion with labelling.

Amendment 15

**Proposal for a directive
Article 2 – point 9**

Text proposed by the Commission

Amendment

(9) “withdrawal” means any measure aimed at preventing the making available on the market of a toy in the supply chain;

(9) “withdrawal” means any measure aimed at preventing the making available, ***distribution, offer or display*** on the market of a toy in the supply chain;

Justification

It needs to be specified exactly what withdrawal covers.

Amendment 16

Proposal for a directive Article 2 – point 11 a (new)

Text proposed by the Commission

Amendment

(11a) “asphyxia” means failure of the vital organs resulting from a lack of oxygen, which may have five different causes, namely choking on an object, drowning, suffocation, strangulation or crushing;

Justification

Asphyxia must be defined because it covers various oxygen deprivation scenarios. Asphyxia is the result of one of five events resulting in oxygen deprivation that pose a serious or life-threatening risk to children.

Amendment 17

Proposal for a directive Article 2 – point 13

Text proposed by the Commission

Amendment

(13) “harm” means the physical injury or damage to health;

(13) “harm” means the physical injury or ***any other*** damage to health, ***including long-term damage***;

Justification

This definition needs to be clarified by including damage other than physical damage that a toy that does not comply with the regulations may cause, as well as long-term damage resulting from the use of certain substances.

Amendment 18

Proposal for a directive Article 2 – point 14

Text proposed by the Commission

Amendment

(14) “hazard” means a potential source of harm;

(14) “hazard” means a potential source of harm ***to human health or wellbeing***;

Justification

Exactly what may be harmed needs to be spelled out.

Amendment 19

**Proposal for a directive
Article 2 – point 15 a (new)**

Text proposed by the Commission

Amendment

(15a) 'Specifically designed or intended for children of the age group x': a term that means that children must possess the dexterity and mental abilities corresponding to this particular age group.

Justification

Efforts must be made to ensure that the manufacturer does not knowingly put a fictitious age group on the label in order to avoid certain obligations and/or responsibilities.

Amendment 20

**Proposal for a directive
Article 3 – paragraph 8**

Text proposed by the Commission

Amendment

8. Manufacturers shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have placed on the market.

8. Manufacturers shall, on request from the competent national authorities, provide them, ***within two weeks***, with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have placed on the market.

Justification

The time limit for forwarding the necessary information and documentation needs to be specified with a view to ensuring better implementation of the safety measures intended to protect children's health.

Amendment 21

Proposal for a directive

Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Manufacturers who appoint an authorised representative shall notify that appointment to the competent national authorities of the territory in which their toys are made available not later than four weeks after the date on which the appointment was made.

Justification

Such notification is necessary and must be performed within a specific time limit.

Amendment 22

Proposal for a directive

Article 4 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. Such notification shall, as a minimum requirement, include the authorised representative's particulars (name, postal address, telephone number, e-mail address and web site address), details of the toys in respect of which the authorised representative is subject to the obligations set out in paragraph 3 of this article, and the unique identification numbers of those toys.

Justification

The minimum details that the manufacturer must supply to the competent national authorities following the appointment of an authorised representative need to be specified, with a view to ensuring that the aims of this directive are met.

Amendment 23

Proposal for a directive

Article 4 – paragraph 3 – point (b)

Text proposed by the Commission

(b) on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy;

Amendment

(b) on request from the competent national authorities, provide them, ***within two weeks***, with all the information and documentation necessary to demonstrate the conformity of the toy;

Justification

The time limit for forwarding the necessary information and documentation needs to be specified with a view to ensuring better implementation of the safety measures intended to protect children's health.

Amendment 24

Proposal for a directive

Article 5 – paragraph 1

Text proposed by the Commission

1. When placing a toy on the market, importers shall ***act with due care in relation to the applicable requirements***.

Amendment

1. When placing a toy on the market, importers shall ***ensure that the toys they place on the market within the Union comply with this Directive and are safe***.

Justification

It is essential for importers to be given a share of the responsibility for implementation of this directive and for ensuring compliance with its objectives.

Amendment 25

Proposal for a directive

Article 5 – paragraph 2

Text proposed by the Commission

2. Before placing a toy on the market importers shall verify that the appropriate conformity assessment procedure has been

Amendment

2. Before placing a toy on the market importers shall verify that the appropriate conformity assessment procedure has been carried out by the manufacturer ***in***

carried out by the manufacturer.

They shall verify that the manufacturer has drawn up the technical documentation, that the toy bears the required conformity marking(s), is accompanied by the required documents and that the manufacturer has respected the requirements set out in Article 3 (5) and (6).

Where an importer discovers that the toy is not in conformity with the essential safety requirements set out in Article 9 and in Annex II, he may place the toy on the market only after it has been brought into conformity with those requirements.

accordance with Articles 18 and 19.

They shall verify that the manufacturer has drawn up the technical documentation ***in accordance with Article 20***, that the toy bears the required conformity marking(s), is accompanied by the required documents and that the manufacturer has respected the requirements set out in Article 3 (5) and (6), ***Article 9 and Annex II.***

Where an importer discovers that the toy is not in conformity with the essential safety requirements set out in Article 9 and in Annex II, he may place the toy on the market only after it has been brought into conformity with those requirements.

Justification

The relevant provisions of the directive need to be specified.

Amendment 26

Proposal for a directive Article 5 – paragraph 3

Text proposed by the Commission

3. Importers shall indicate their name and the address at which they can be contacted on the toy or, where the size or nature of the toy does not allow it, on its packaging or in a document accompanying the toy.

Amendment

3. Importers shall indicate, ***in a visible and clearly legible manner***, their name and the address, ***telephone number and e-mail address*** at which they can be contacted on the toy or, where the size or nature of the toy does not allow it, on its packaging or in a document accompanying the toy, ***in such a way that it is visible and distinct from the description of the toy.***

Justification

The information referred to in the proposal needs to be fleshed out and should be easily and rapidly accessible.

Amendment 27

Proposal for a directive Article 5 – paragraph 7

Text proposed by the Commission

7. Importers shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have placed on the market.

Amendment

7. Importers shall, on request from the competent national authorities, provide them, ***within two weeks***, with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have placed on the market.

Justification

See justification for Amendment 26.

Amendment 28

Proposal for a directive Article 6 – paragraph 1

Text proposed by the Commission

1. When making a toy available on the market, distributors shall ***act with due care in relation to the applicable requirements***.

Amendment

1. When placing a toy on the market, distributors shall ***ensure that the toys they place on the market within the Union comply with this Directive, in order to ensure that the toys they place on the market within the Union are safe***.

Justification

See justification to Amendment 27.

Amendment 29

Proposal for a directive Article 6 – paragraph 5

Text proposed by the Commission

5. Distributors shall, on request from the

Amendment

5. Distributors shall, on request from the

competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have made available on the market.

competent national authorities, provide them, ***within two weeks***, with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have made available on the market.

Justification

See justification for Amendment 26.

Amendment 30

**Proposal for a directive
Article 7 a (new)**

Text proposed by the Commission

Amendment

Article 7a

Register

Economic operators in the toy sector, as defined in Article 1, shall keep a register of corrective measures, withdrawals, recalls and complaints received from other economic operators and end users and of the action taken on each of the above measures.

For each of the above measures, the register shall clearly set out the reasons for the measure, the unique identification number of the toy concerned and the identification of the toy allowing traceability, together with the date of receipt of the complaint and the date on which notification of the action taken thereon was sent.

The register shall be kept for 10 years. Operators shall make such registers available to the competent national authorities, at their request.

Justification

Article 3(4) refers to a register to be kept by manufacturers. The arrangements for keeping

such registers therefore need to be specified.

Amendment 31

Proposal for a directive Article 8 – subparagraph 2

Text proposed by the Commission

They shall have in place appropriate systems and procedures which allow for this information to be made available to the market surveillance authorities on request, for a period of 10 years.

Amendment

They shall have in place appropriate systems and procedures which allow for this information to be made available ***within two weeks*** to the market surveillance authorities on request, for a period of 10 years.

Justification

See justification for Amendment 23.

Amendment 32

Proposal for a directive Article 9 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1. Children are a vulnerable group owing to the fact that their organisms are less robust and are biologically more sensitive to the presence of certain substances. Furthermore, the risks involved in their exposure to chemicals are greater than they are for adults, since their organisms are not fully developed.

Justification

It is essential to point out in this article laying down essential safety requirements that children are a vulnerable or very vulnerable population, depending on their age. Due account needs to be taken of this in connection with safety requirements to protect the health of children using toys, particularly against chemicals.

Amendment 33

Proposal for a directive

Article 9 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Member States shall act in accordance with the precautionary principle.

Justification

See justification for Amendment 1.

Amendment 34

Proposal for a directive

Article 9 – paragraph 2

Text proposed by the Commission

Amendment

2. Toys shall not jeopardize the safety or health of users or third parties when they are used as intended **or** in a foreseeable way, bearing in mind 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, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.

Labels on toys or on their packaging and the instructions for use which accompany them shall draw the attention of users or their supervisors to the inherent hazards and risks of harms involved in using the toys and to the ways of avoiding them.

2. Toys shall not jeopardize the safety or health of users or third parties when they are used as intended **and** in a **reasonably** foreseeable way, bearing in mind behaviour of children.

The ability of the users shall be taken into account, in particular, in the case of toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.

Labels on toys or on their packaging and the instructions for use which accompany them shall draw the attention of users or their supervisors to the inherent hazards and risks of harms involved in using the toys and to the ways of avoiding them.

Justification

See justification for Amendment 7 for the first point. With a view to assessing essential safety requirements, the presence of a supervisor should not be taken into account, because what needs to be assessed is the intrinsic safety of the toys. Supervision is necessary, but not at all times, because the child must be able – and needs – to play alone in order to grow and

become self-sufficient.

Amendment 35

Proposal for a directive Article 9 – paragraph 3

Text proposed by the Commission

Amendment

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

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

Justification

See justification for Amendment 2.

Amendment 36

Proposal for a directive Article 10 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The warnings referred to in point 1 of Part B of Annex V shall not be used for toys which, by virtue of their functions, dimensions or other characteristics, with the exception of weight, are intended for use by children of under 36 months.

Justification

Toys intended for children under three years of age often bear the wording ‘not suitable for children under three years of age’. Some manufacturers do this to try to evade their responsibilities or to cover themselves against liability. Given that Annex V does not explicitly forbid the use of this wording, it will make it much easier for market surveillance purposes to enforce the law if the wording is included in the directive.

Amendment 37

Proposal for a directive

Article 10 – paragraph 1 – subparagraph 2

Text proposed by the Commission

As regards the categories of toys listed in Part B of Annex V, the warnings set out therein shall be used.

Amendment

As regards the categories of toys listed in **points 2 to 5 in** Part B of Annex V, the warnings set out therein shall be used **as worded therein**.

Justification

In line with Amendment 102. Furthermore, the scope of this provision requires clarification.

Amendment 38

Proposal for a directive

Article 10 – paragraph 2

Text proposed by the Commission

2. The **manufacturer shall mark the** warnings in **a** visible, clearly legible 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 that are sold without packaging shall have appropriate warnings affixed to them.

Warnings specifying the minimum and maximum ages for users shall be visible, legible and conspicuously displayed at the point of sale.

Amendment

2. The warnings **shall be worded in an accurate**, visible, clearly legible and **easy-to-read** manner **so that they may be understood by the users or their supervisors and shall be affixed to** the toy **or, where this is impossible for technical reasons**, on **a** label **affixed to the toy** or on the **consumer** packaging. **They shall also appear** on the instructions for use which accompany the toy. Small toys that are sold without packaging shall have appropriate warnings affixed to them.

Warnings specifying the minimum and maximum ages for users shall be visible, **clearly legible and easy to read, accurate** and conspicuously displayed **on the packaging of toys and** at the point of sale. **The authorised representatives, importers and distributors must be notified of these warnings so that warnings specifying the minimum and maximum ages for users may be correctly affixed at the point of**

sale.

Warnings must alternate so that they appear regularly. Warnings shall be printed on the most visible surface of the unit packet and on all external packaging, with the exception of transparent packaging, used for the retail sale of the toy in question.

Member States may determine the location of the warnings to appear on the surfaces in question in the light of linguistic requirements.

In order to accommodate linguistic requirements, Member States shall have the right to determine the point size of the font, provided that the font size specified in their legislation is such as to ensure that the warning is very clear and easy to read.

Warnings shall be written in the official language or languages of the Member State where the toy is placed on the market.

Amendment 39

Proposal for a directive Article 10 – paragraph 3

Text proposed by the Commission

3. **Member States may require** warnings and safety instructions, **or some of them, to** be presented in **their own** official language or languages when the toys are placed on the market in **their** territory.

Amendment

3. Warnings, **as referred to in this article and in Annex V**, and safety instructions **shall** be presented in **the** official language or languages **of the Member State concerned** when the toys are placed on the market in **its** territory.

Justification

The production of warnings and safety instructions in the official language(s) of the Member State in which the toys are placed on the market is of essential importance to children's safety and health.

Amendment 40

**Proposal for a directive
Article 10 b (new)**

Text proposed by the Commission

Amendment

Article 10b

Common provisions for economic operators concerning measures to withdraw toys in the event of their non-conformity or of doubts as to their conformity

1. In accordance with Articles 3, 5 and 6, where there is a problem or doubt concerning conformity with the provisions on the safety of toys, the economic operators concerned shall immediately take action to withdraw the toys.

2. Where there is a problem or doubt concerning conformity with the provisions on the safety of toys, the economic operators concerned shall immediately inform the other economic operators concerned, the consumer organisations and the national authorities of the Member States where they made the toy available to this effect, giving an accurate description, in particular, of the non-compliance problem and of the withdrawal measures taken.

3. The withdrawal measures shall be taken without delay and completed as swiftly as possible and at the latest within two weeks of the date on which the conformity problem was detected.

Where it is impossible to meet the above deadline, the economic operators concerned shall immediately inform the other economic operators concerned and the competent national authorities to this effect and shall duly justify the need for the deadline to be extended in order to take the steps necessary to ensure conformity. The competent national authorities shall, at the earliest

opportunity, consider the application for an extension and shall, at the earliest opportunity, inform the economic operators concerned of their decision, particularly as to any deadline for bringing the toys concerned into conformity.

4. The process of making the toys available to end users shall be suspended until further notice.

Once the toys that have been withdrawn have been brought into conformity, they shall be deemed to be new toys and shall comply with all the provisions of this Directive when made available once again to end users.

Justification

The provisions on withdrawal measures set out in Article 3, 5 and 6 of the directive require further clarification in order to strengthen the provisions on toy safety and children's health. The provisions on withdrawals need to be more stringent than those on remedial action because the potential impact in terms of toy safety and children's health is greater.

Amendment 41

Proposal for a directive

Article 17 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Toy safety assessments shall take due account of all relevant factors, including the situation of children who are very vulnerable or have specific vulnerabilities, such as children with special needs.

Justification

In addition to restating the basic purpose of such assessments, attention needs to be drawn to additional aspects, such as the need to take due account of children with disabilities.

Amendment 42

Proposal for a directive

Article 17 – subparagraph 1 b (new)

Text proposed by the Commission

Amendment

Greater account should be taken of all accidents suffered by children, including minor and relatively serious accidents, in order to determine the level of risk and danger associated with toys.

Justification

This amendment seeks to ensure that greater account is taken of relatively serious accidents and, in particular, minor accidents, in order to gain a clearer picture of toy-related accident patterns.

Amendment 43

Proposal for a directive

Article 19 – paragraph 3

Text proposed by the Commission

Amendment

3. When a conformity assessment body notified under Article 21, hereinafter "notified body", carries out the EC type-examination, it shall evaluate, ***if necessary***, jointly with the manufacturer, the analysis performed by the manufacturer in accordance with Article 17 of the hazards that the toy may present.

3. When a conformity assessment body notified under Article 21, hereinafter "notified body", carries out the EC type-examination, it shall evaluate, jointly with the manufacturer, the analysis performed by the manufacturer in accordance with Article 17 of the hazards that the toy may present.

Justification

Given that aim of the directive is to make toys safer, this evaluation cannot be optional.

Amendment 44

Proposal for a directive

Article 19 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Amendment

The certificate shall be reviewed at any

The certificate shall be reviewed at any

time where necessary, in particular in case of a modification in the manufacturing process, in the raw materials or the components of the toy and, in any case, every 5 years.

time where necessary, in particular in case of a modification in the manufacturing process, in the raw materials or the components of the toy and, in any case, every 3 years.

Justification

Given that aim of the directive is to make toys safer, the interval should be shortened.

Amendment 45

Proposal for a directive

Article 20 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1. Manufacturers shall make available to the competent national authorities, at those authorities' request, the technical documentation referred to in Article 3(2), for inspection and checking on their territory, pursuant to Article 38(3a).

Justification

Technical documentation must be kept available for inspection and checking at the manufacturer's premises.

Amendment 46

Proposal for a directive

Article 20 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Amendment

When ***a market surveillance authority requests*** the technical documentation or a translation of parts of it from a manufacturer, ***it may fix a deadline for doing so which shall be 30*** days unless a shorter deadline is justified because there is a serious and immediate risk.

When ***the competent national authorities request*** the technical documentation or a translation of parts of it from a manufacturer, ***that manufacturer or his authorised representative shall supply that documentation or translation within no more than 14*** days unless a shorter deadline is justified because there is a serious and immediate risk.

Justification

A hard and fast time limit for the forwarding of documentation is required in order to enhance toy safety and ensure children's safety and health.

Amendment 47

Proposal for a directive
Article 20 – paragraph 4

Text proposed by the Commission

4. If the manufacturer does not observe the obligations foreseen in paragraphs 1, 2 and 3, the market surveillance authority **may** require him to have a test performed by a **notified** body at his own expense within **a specified period** in order to **verify** compliance with the harmonised standards and essential safety requirements.

Amendment

4. If the manufacturer does not observe the obligations foreseen in paragraphs **-1**, 1, 2 and 3, the market surveillance authority **shall** require him to have a test performed by a **certified external** body at his own expense within **no more than 14 days** in order to **certify** compliance with the harmonised standards and essential safety requirements.

Justification

Amendment 48

Proposal for a directive
Article 20 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. If the manufacturer does not observe the obligations foreseen in paragraph 4, the market surveillance authority shall take the steps it considers necessary to ensure that the toys concerned are not made available on the market and in the distribution networks on the territory coming under its supervision.

Justification

This article needs to be fleshed out. If a manufacturer does not fulfil his obligations, the competent national authorities should be able to take steps to ensure children's safety and

health.

Amendment 49

Proposal for a directive

Article 22 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The notifying authority shall establish Safety Notification Points at which childcare professionals and consumers may report the non-conformity of toys or accidents related to the use of a toy.

Justification

Setting Safety Notification Points in Member States would empower consumers and facilitate direct communication with manufacturers and producers in the case of a problem with a particular product. Manufacturers and producers could then react more directly to the demands of their consumer

Amendment 50

Proposal for a directive

Article 25 – paragraph 7 – point a

Text proposed by the Commission

Amendment

(a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for which the conformity assessment body has been notified;

(a) sound technical and vocational training, ***as attested by, inter alia, formal qualifications, professional experience or certificates,*** covering all the conformity assessment activities of the relevant scope for which the conformity assessment body has been notified;

Justification

Evidence of the technical and vocational training of the staff working for notified bodies is required.

Amendment 51

Proposal for a directive

Article 25 – paragraph 11 a (new)

Text proposed by the Commission

Amendment

11a. The conformity assessment body shall seek ISO 9001:2000 certification.

Justification

Such certification provides a further guarantee as to the quality of the evaluation and its performance in accordance with the relevant standards.

Amendment 52

Proposal for a directive

Article 27 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Subsidiaries and sub-contractors shall have ISO 9001:2000 certification.

Justification

Such certification provides a further guarantee as to the quality of production processes and regular assessments of and checks thereon.

Amendment 53

Proposal for a directive

Article 38 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. For the purposes of surveillance, pursuant to Article 37, of toys placed on the market, market surveillance authorities or any certified body they have duly designated for this purpose, shall be empowered to carry out unannounced inspections at the premises of economic operators once a year, wherever possible, and no less frequently than every two

years.

Justification

Inspections at economic operators' premises should not take place only when they prove necessary. They should be carried out without prior notification and as regularly as possible. Every two years is a reasonable requirement.

Amendment 54

**Proposal for a directive
Article 41 – paragraph 1**

Text proposed by the Commission

1. Where the market surveillance authorities of one Member State have taken action referred to in Article 12 of Directive 2001/95/EC or where they ***have sufficient reason to believe*** that a toy covered by this Directive ***presents*** a risk for the health or safety of persons they shall, ***together with the relevant economic operators***, perform ***an evaluation*** in relation to the toy concerned covering all the requirements laid down by this Directive.

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down by this Directive, they shall require the relevant economic operator to take all appropriate corrective actions to bring the toy into compliance with those requirements or to withdraw the toy from the market or recall it within ***such reasonable period, commensurate with the nature of the risk, as they may prescribe.***

Amendment

1. Where the market surveillance authorities of one Member State have taken action referred to in Article 12 of Directive 2001/95/EC or where they ***suspect*** that a toy covered by this Directive ***may present*** a risk for the health or safety of persons they shall, ***without delay***, perform ***the necessary evaluations*** in relation to the toy concerned covering all the requirements laid down by this Directive. ***The economic operators shall, within two weeks, supply the authorities with any information or item they may request.***

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down by this Directive, they shall require the relevant economic operator to take all appropriate corrective actions to bring the toy into compliance with those requirements or to withdraw the toy from the market or recall it within ***the time limits provided for in Articles 10a to 10c.***

Justification

All conformity problems need to be assessed immediately. The involvement of the economic operators concerned should be confined to providing information required for evaluation of the toy concerned. If it is found to be non-compliant, appropriate remedial action should be taken within the appointed time limits.

Amendment 55

Proposal for a directive

Article 41 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down by this Directive, they shall require the relevant economic operator to take all appropriate corrective actions to bring the toy into compliance with those requirements or to withdraw the toy from the market or recall it within such reasonable period, commensurate with the nature of the risk, as they may prescribe.

Amendment

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down by this Directive, they shall require the relevant economic operator, ***while at the same time notifying consumers***, to take all appropriate corrective actions to bring the toy into compliance with those requirements or to withdraw the toy from the market or recall it within such reasonable period, commensurate with the nature of the risk, as they may prescribe.

Justification

The immediate notification of consumers is a vital step to ensure that risks are averted.

Amendment 56

Proposal for a directive

Article 41 – paragraph 2

Text proposed by the Commission

2. Where the market surveillance authorities consider that the non-compliance is not limited to the 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 economic operator to take.

Amendment

2. Where the market surveillance authorities consider that the non-compliance is not limited to the 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 economic operator to take. ***They shall officially notify Member States and the Commission of the answer and the intention to comply or not to comply issued by the economic operator.***

Justification

As part of measures to provide the public with integrated information and transparency, the economic operator should reply and this reply should be notified to Member States and the Commission.

Amendment 57

Proposal for a directive Article 41 – paragraph 3

Text proposed by the Commission

3. The economic operator shall ensure that any corrective actions are taken in respect of all the toys concerned which **he has** made available on the market throughout the Community.

Amendment

3. The economic operator **or the economic operators concerned** shall ensure that any corrective, **withdrawal or recall** actions are taken in respect of all the toys concerned which **they have** made available on the market throughout the Community.

Justification

For the sake of precision, all the economic operators and operations connected with action to be taken in the event of non-conformity should be specified.

Amendment 58

Proposal for a directive Article 41 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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

Amendment

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

Justification

See justification for Amendment 64.

Amendment 59

Proposal for a directive Article 41 – paragraph 7

Text proposed by the Commission

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 in relation to the toy concerned, the measure shall be deemed justified.

Amendment

7. Where, within **four weeks** 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 in relation to the toy concerned, the measure shall be deemed justified.

Justification

The measures proposed by the competent national authorities should be considered by the various parties within a reasonable period of time, with a view to taking a decision on the non-conformity action that a competent national authority is asking the relevant economic operators to take.

Amendment 60

Proposal for a directive Article 42 – paragraph 2 – subparagraph 1

Text proposed by the Commission

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

Amendment

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant toy is withdrawn from their markets **or recalled**. Member States shall inform the Commission thereof.

Justification

See justification for Amendment 64.

Amendment 61

Proposal for a directive Article 42 – paragraph 3

Text proposed by the Commission

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 as referred to in Article 41(5)(b), the Commission or the Member State shall bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC.

Amendment

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 as referred to in Article 41(5)(b), the Commission or the Member State shall, ***within two weeks***, bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC.

Justification

Shortcomings in harmonised standards leading to non-compliance of a toy need to be made good with due haste.

Amendment 62

Proposal for a directive Article 44 – paragraph 2

Text proposed by the Commission

2. Where the non-compliance referred to in paragraph 1 continues, the Member State shall take all appropriate measures to restrict or prohibit the making available on the market of the toy or ensure that it is recalled or withdrawn from the market.

Amendment

2. Where the non-compliance referred to in paragraph 1 continues, the Member State shall ***immediately*** take all appropriate measures to restrict or prohibit the making available on the market of the toy or ensure that it is recalled or withdrawn from the market.

Justification

Speed is essential in order to ensure toy safety and children's health.

Amendment 63

Proposal for a directive

Article 45 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

(a) **Points 7 and 8 in** Part III of Annex II;

(b) Annex V.

Amendment

1. The Commission **shall**, for the purposes of adapting them to technical and scientific developments, amend the following **as soon as new information comes to its attention**:

(-a) Annex I;

(a) Part III of Annex II, **with the exception of points 1 and 2**;

(b) Annex V.

Justification

The comitology procedure chosen cannot apply to the above points only, but must be extended to cover other issues, since standardisation or harmonisation procedures are too slow to be used where urgent changes need to be made, as is illustrated by the hazards and risks to children's health posed by magnets.

Amendment 64

Proposal for a directive

Article 45 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Those measures, designed to amend non-essential elements of this **Regulation**, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 46 (2).

Amendment

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 46 (2).

Justification

Correction.

Amendment 65

Proposal for a directive
Article 45 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Without prejudice to the restrictions laid down in Part III of Annex II, the Commission may, where appropriate and in accordance with the regulatory procedure with scrutiny referred to in Article 46(2), amend Annex II with a view to:

– defining limit values or other restrictions for substances or preparations posing a risk to health other than those listed in points 7 and 8 in Part III of Annex II;

– adopting or adapting limit values for noise and speed.

Justification

The Commission should be empowered to adopt restrictions on other substances or limit values for noise in comitology.

Amendment 66

Proposal for a directive
Article 47

Text proposed by the Commission

Amendment

Three years following the date of application of this Directive referred to in the second paragraph of Article 53 and every ***five*** years thereafter, Member States shall send the Commission a report on the application of this Directive. This 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 the Member State. The Commission shall draw up and publish a summary of those national reports.

Three years following the date of application of this Directive referred to in the second paragraph of Article 53 and every ***three*** years thereafter, Member States shall send the Commission a report on the application of this Directive. This 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 the Member State. The Commission shall, ***at the earliest opportunity***, draw up and publish ***a report***

containing, where appropriate, proposals for the amendment or revision of this Directive. It shall forward this report to the European Parliament and to the Council. It shall immediately publish at least a summary and the conclusions of the report on its web site in all the official languages of the European Union.

Justification

The Commission must draw up a report on the national reports assessing the directive's implementation in the Member States. It should submit this report to the co-legislators and publish either the entire report or a summary together with the conclusions on its web site without delay. This amendment seeks to ensure a minimum degree of transparency.

Amendment 67

Proposal for a directive
Article 50 – subparagraph 1

Text proposed by the Commission

Member States shall lay down the rules on penalties, which may include criminal sanctions for serious infringements, applicable to infringements to 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.

Amendment

Member States shall lay down **and implement** the rules on penalties, which may include criminal sanctions for serious infringements, applicable to infringements to 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.

Justification

It is not enough for Member States simply to lay down rules on penalties for the infringement of this Directive. It must also implement those rules in order to bring the penalties to bear.

Amendment 68

Proposal for a directive
Article 52

Text proposed by the Commission

Member States shall not impede the

Amendment

Member States shall not impede the

placing on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before this Directive entered into force or at the latest **2 years** after this Directive entered into force.

placing on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before this Directive entered into force or at the latest **3 years** after this Directive entered into force.

Amendment 69

Proposal for a directive Article 54 a (new)

Text proposed by the Commission

Amendment

Article 54a

Review

The Commission shall review this Directive, based on the evaluations of the relevant Scientific Committee and the opinion of the expert group, every eight years.

Justification

A revision of the directive, at least every 8 years or sooner if necessary due to new findings or accidents, is needed in order to ensure that the safety requirements of the directive are sufficient to cover the risks that may arise from e.g. new toys and new technologies, but also new scientific evidence.

Amendment 70

Proposal for a directive Annex II – Part I – point 2

Text proposed by the Commission

Amendment

2. Accessible edges, protrusions, cords, cables and fastenings on toys must be so designed and constructed that the risks of physical injury from contact with them are **reduced as far as possible**.

2. Accessible edges, protrusions, cords, cables and fastenings on toys must be so designed and constructed that the risks of physical injury from contact with them are **minimised**.

Justification

It is essential to reduce the risks to the utmost possible extent in order to make toys safer and

ensure the health and wellbeing of children.

Amendment 71

Proposal for a directive

Annex II – Part I – point 4 – subparagraph 2

Text proposed by the Commission

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

Amendment

2. The packaging in which toys are contained for retail sale must not present risk of strangulation or asphyxiation caused by **an internal obstruction of the lower airways and the airways** external to the mouth and nose.

Amendment 72

Proposal for a directive

Annex II – Part I – point 5

Text proposed by the Commission

5. Toys intended for use in shallow water which are capable of carrying or supporting a child on the water must be designed and constructed 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.

Amendment

5. Toys intended for use in shallow water which are capable of carrying or supporting a child on the water must be designed and constructed so as to **minimise**, taking into account the recommended **and reasonably foreseeable** use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.

Justification

See justifications for Amendments 74 and 2.

Amendment 73

Proposal for a directive

Annex II – Part I – point 7 – subparagraph 1

Text proposed by the Commission

7. Toys conferring mobility on their users

Amendment

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 developed 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.

must incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy developed 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.

Justification

A significant number of toys fitted with wheels have an inadequate braking system or no braking system at all. Stricter rules are required to make these toys safer for children to use.

Amendment 74

Proposal for a directive Annex II – Part I – point 10

Text proposed by the Commission

10. Toys which are designed to emit a sound should be so designed and constructed so that the sound from them is not able to impair children's hearing.

Amendment

10. Toys which are designed to emit a sound should be so designed and constructed that the sound from them is not able to impair children's hearing. ***This shall apply to all toys irrespective of the age group targeted. The limit for impulse noise should be 135 dB LpC peak at the ear. Limits for continuous noise shall be set on the basis of the sensitivity of the ear of an infant under 36 months of age.***

Justification

Current standards for noise limits do not adequately deal with possible impairment of children's hearing. Firstly, they are not applicable for all toys (e.g. the standard for "close to the ear toys" only applies to children under 10 months of age. Secondly, a lower limit needs to be set for impulse noise. In light of the real life situation of children of different ages in a family, noise limits should be set on the basis of the most vulnerable, that is children under the age of 36 months.

Amendment 75

Proposal for a directive Annex II – Part I – point 11

Text proposed by the Commission

11. Activity toys shall be constructed so as to **reduce** the risk of crushing or trapping of body parts or trapping of clothing and the risk of falls, impacts and drowning **as far as possible**.

Amendment

11. Activity toys shall be constructed so as to **minimise** the risk of crushing or trapping of body parts or trapping of clothing and the risk of falls, impacts and drowning.

Justification

See justification for Amendment 74.

Amendment 76

Proposal for a directive Annex II – Part III – point 1

Text proposed by the Commission

1. Toys shall be so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed or which they contain, when the toys are used as specified in the first subparagraph of Article 9 (2).

Amendment

1. Toys shall be so designed and constructed that there are no risks of adverse effects on human health **or the environment** due to exposure to the chemical substances or preparations of which the toys are composed or which they contain, when the toys are used as specified in the first subparagraph of Article 9 (2).

Justification

See justification for Amendment 3.

Amendment 77

Proposal for a directive Annex II – Part III – point 3

Text proposed by the Commission

3. Without prejudice to the application of the restrictions under the first sentence of

Amendment

3. Without prejudice to the application of the restrictions under the first sentence of

point 2, the use in toys of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to Directive 67/548/EEC in individual concentrations equal to or greater than the relevant concentrations established for the classification of preparations containing the substances in accordance with the provisions of Directive 1999/45/EC shall be prohibited, except if the substances are contained in components of toys or micro-structurally distinct parts of toys that are not accessible to any physical contact by children.

point 2, the use in toys of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) **category 1 and 2** according to Directive 67/548/EEC in individual concentrations equal to or greater than the relevant concentrations established for the classification of preparations containing the substances in accordance with the provisions of Directive 1999/45/EC shall be prohibited, except if the substances are contained in components of toys or micro-structurally distinct parts of toys that are not accessible to any physical contact by children.

The use in toys of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 3 in accordance with Directive 67/548/EEC in individual concentrations equal to or greater than 0,1 % shall be prohibited. At the earliest opportunity, this limit shall be reviewed on the basis of an opinion of the competent scientific committee and a decision as referred to in Article 45(2).

Justification

The presence of substances classified as CMR in excess of the appointed threshold should be prohibited in order to ensure a high level of children's health protection. That Threshold should be brought down under a comitology procedure as soon as possible, on the basis of new information.

Amendment 78

Proposal for a directive Annex II – Part III – point 4

Text proposed by the Commission

4. Substances or preparations classified as CMR category 1 **and** 2 according to Directive 67/548/EEC may be used in toys provided that the following conditions are met:

Amendment

4. Substances or preparations classified as CMR category 1, 2 **and** 3 according to Directive 67/548/EEC may be used in toys provided that the following conditions are met:

Justification

All CMRs must be treated in the same way, since the health of children, who are more vulnerable than adults, is at stake. CMRs should only be used if the conditions set out in point 4 are met.

Amendment 79

**Proposal for a directive
Annex II – Part III – point 4.2**

Text proposed by the Commission

4.2. there are no suitable alternative substances available, as documented in an analysis of alternatives,

Amendment

4.2. there are no suitable alternative substances **or materials** available, as documented in an analysis of alternatives,

Justification

Clarification.

Amendment 80

**Proposal for a directive
Annex II – Part III – point 4.3 a (new)**

Text proposed by the Commission

Amendment

4.3a. Toys or parts of toys which are intended to be put in the mouth must comply with the provisions for migration limit values for food packaging, irrespective of the age of the children for which they are intended, as set out in 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..

Amendment 81

Proposal for a directive

Annex II – Part III – point 4.3 – subparagraph 2

Text proposed by the Commission

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or preparations as soon as safety concerns arise and at the latest every **5** years from the date that a decision in accordance with Article 45 (2) was taken.

Amendment

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or preparations as soon as safety concerns arise and at the latest every **3** years from the date that a decision in accordance with Article 45 (2) was taken.

Justification

The interval between re-evaluations of substances or preparations should be shorter.

Amendment 82

Proposal for a directive

Annex II – Part III – point 4 a (new)

Text proposed by the Commission

Amendment

4a. The use of substances classified as endocrine disruptors and entered on the EU's priority list shall be prohibited in toys and their component parts unless the manufacturer is able to demonstrate that no alternative substances that are safer and less harmful to health are available.

Justification

Endocrine disruptors pose a serious risk to a child's development and its health in later life. They should therefore be prohibited in principle, with their use being allowed only if the manufacturer is able to prove that there are no safer and less harmful substances that might be used.

Amendment 83

Proposal for a directive

Annex II – Part III – point 4 b (new)

Text proposed by the Commission

Amendment

4b. The use of substances classified as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) shall be prohibited in toys and their component parts unless the manufacturer is able to demonstrate that no alternative substances that are safer and less harmful to health are available.

Justification

Same comments as in the justification for Amendment 87, but with reference to PBTs and vPvBs.

Amendment 84

Proposal for a directive

Annex II – Part III – point 5

Text proposed by the Commission

Amendment

5. Substances or preparations classified as CMR category 3 according to Directive 67/548/EEC may be used in toys if use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and following a Decision as referred to in Article 45 (2) and provided that they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

deleted

Justification

See Amendment 82 and justification therefor.

Amendment 85

Proposal for a directive
Annex II – Part III – points 5 a and 5 b (new)

Text proposed by the Commission

Amendment

5a. Toys or parts of toys, irrespective of the age of the children for which they are intended, must comply with the provisions on the release of nitrosamines and nitrosatable substances from elastomer or rubber teats set out in Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.

5b. The Commission shall establish a programme aimed at systematically and regularly evaluating the occurrence of hazardous substances or materials in toys. The programme shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders. The Commission shall decide, following the opinion of the relevant Scientific Committee, to take appropriate restrictive measures, if necessary. 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 46(2).

Justification

The use of hazardous substances in toys is not limited to CMR substances, fragrances or substances containing certain elements. All hazardous substances should be subject to regular evaluation by the Commission. In case this evaluation reveals an unacceptable risk, the Commission should be empowered to take appropriate action in comitology.

Amendment 86

Proposal for a directive
Annex II –Part III – paragraph 7

Text proposed by the Commission

7. Toys shall not contain the following allergenic fragrances:

- (1) Alanroot (Inula helenium)
- (2) Allylisothiocyanate
- (3) Benzyl cyanide
- (4) 4 tert-Butylphenol
- (5) Chenopodium oil
- (6) Cyclamen alcohol
- (7) Diethyl maleate
- (8) Dihydrocoumarin
- (9) 2,4-Dihydroxy-3-methylbenzaldehyde
- (10) 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)
- (11) 4,6-Dimethyl-8-tert-butylcoumarin
- (12) Dimethyl citraconate
- (13) 7,11-Dimethyl-4,6,10-dodecatrien-3-one
- (14) 6,10-Dimethyl-3,5,9-undecatrien-2-one
- (15) Diphenylamine
- (16) Ethyl acrylate
- (17) Fig leaf, fresh and preparations
- (18) trans-2-Heptenal
- (19) trans-2-Hexenal diethyl acetal
- (20) trans-2-Hexenal dimethyl acetal
- (21) Hydroabietyl alcohol
- (22) 4-Ethoxy-phenol
- (23) 6-Isopropyl-2-decahydronaphthalenol
- (24) 7-Methoxycoumarin
- (25) 4-Methoxyphenol
- (26) 4-(p-Methoxyphenyl)-3-butene-2-one

Amendment

7. Toys shall not contain the following allergenic fragrances:

- (1) Alanroot (Inula helenium)
- (2) Allylisothiocyanate
- (3) Benzyl cyanide
- (4) 4 tert-Butylphenol
- (5) Chenopodium oil
- (6) Cyclamen alcohol
- (7) Diethyl maleate
- (8) Dihydrocoumarin
- (9) 2,4-Dihydroxy-3-methylbenzaldehyde
- (10) 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)
- (11) 4,6-Dimethyl-8-tert-butylcoumarin
- (12) Dimethyl citraconate
- (13) 7,11-Dimethyl-4,6,10-dodecatrien-3-one
- (14) 6,10-Dimethyl-3,5,9-undecatrien-2-one
- (15) Diphenylamine
- (16) Ethyl acrylate
- (17) Fig leaf, fresh and preparations
- (18) trans-2-Heptenal
- (19) trans-2-Hexenal diethyl acetal
- (20) trans-2-Hexenal dimethyl acetal
- (21) Hydroabietyl alcohol
- (22) 4-Ethoxy-phenol
- (23) 6-Isopropyl-2-decahydronaphthalenol
- (24) 7-Methoxycoumarin
- (25) 4-Methoxyphenol
- (26) 4-(p-Methoxyphenyl)-3-butene-2-one

- (27) 1-(p-Methoxyphenyl)-1-penten-3-one
- (28) Methyl trans-2-butenate
- (29) 6-Methylcoumarin
- (30) 7-Methylcoumarin
- (31) 5-Methyl-2,3-hexanedione
- (32) Costus root oil (Saussurea lappa Clarke)
- (33) 7-Ethoxy-4-methylcoumarin
- (34) Hexahydrocoumarin
- (35) Peru balsam (Myroxylonpereiarae Klotzsch)
- (36) 2-Pentylidene-cyclohexanone
- (37) 3,6,10-Trimethyl-3,5,9-undecatrien-2-one
- (38) Verbana oil (Lippia citriodora Kunth)

However, the presence of traces of these substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice.

In addition the following allergenic fragrances shall be listed if added to toys, as such, at concentrations exceeding 0,01 % by weight:

- (1) *Amyl cinnamal*
- (2) *Amylcinnamyl alcohol*
- (3) *Anisyl alcohol*
- (4) *Benzyl alcohol*
- (5) *Benzyl benzoate*
- (6) *Benzyl cinnamate*
- (7) *Benzyl salicylate*
- (8) *Cinnamal*
- (9) *Cinnamyl alcohol*

- (27) 1-(p-Methoxyphenyl)-1-penten-3-one
- (28) Methyl trans-2-butenate
- (29) 6-Methylcoumarin
- (30) 7-Methylcoumarin
- (31) 5-Methyl-2,3-hexanedione
- (32) Costus root oil (Saussurea lappa Clarke)
- (33) 7-Ethoxy-4-methylcoumarin
- (34) Hexahydrocoumarin
- (35) Peru balsam (Myroxylonpereiarae Klotzsch)
- (36) 2-Pentylidene-cyclohexanone
- (37) 3,6,10-Trimethyl-3,5,9-undecatrien-2-one
- (38) Verbana oil (Lippia citriodora Kunth)

- (39) *Amyl cinnamal*
- (40) *Amylcinnamyl alcohol*
- (41) *Anisyl alcohol*
- (42) *Benzyl alcohol*
- (43) *Benzyl benzoate*
- (44) *Benzyl cinnamate*
- (45) *Benzyl salicylate*
- (46) *Cinnamal*
- (47) *Cinnamyl alcohol*

<i>(10) Citral</i>	<i>(48) Citral</i>
<i>(11) Citronellol</i>	<i>(49) Citronellol</i>
<i>(12) Coumarin</i>	<i>(50) Coumarin</i>
<i>(13) Eugenol</i>	<i>(51) Eugenol</i>
<i>(14) Farnesol</i>	<i>(52) Farnesol</i>
<i>(15) Geraniol</i>	<i>(53) Geraniol</i>
<i>(16) Hexyl cinnamaldehyde</i>	<i>(54) Hexyl cinnamaldehyde</i>
<i>(17) Hydroxy-citronellal</i>	<i>(55) Hydroxy-citronellal</i>
<i>(18) Hydroxy-methylpentylcyclohexenecarboxaldehyde</i>	<i>(56) Hydroxy-methylpentylcyclohexenecarboxaldehyde</i>
<i>(19) Isoeugenol</i>	<i>(57) Isoeugenol</i>
<i>(20) Lilial (referred to in the Cosmetics Directive in entry 83 as: 2-(4-tert-Butylbenzyl) propionaldehyde</i>	<i>(58) Lilial (referred to in the Cosmetics Directive in entry 83 as: 2-(4-tert-Butylbenzyl) propionaldehyde</i>
<i>(21) d-Limonene</i>	<i>(59) d-Limonene</i>
<i>(22) Linalool</i>	<i>(60) Linalool</i>
<i>(23) Methyl heptine carbonate</i>	<i>(61) Methyl heptine carbonate</i>
<i>(24) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one</i>	<i>(62) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one</i>
<i>(25) Oakmoss extracts</i>	<i>(63) Oakmoss extracts</i>
<i>(26) Treemoss extracts</i>	<i>(64) Treemoss extracts</i>

The Commission shall mandate the relevant Scientific Committee to evaluate the fragrances as soon as allergenic concerns arise and at the latest every 3 years from the date of entry into of the Directive, in accordance with Article 46(2) was taken.

Amendment 87

Proposal for a directive

Annex II – Part III – point 7 a (new)

Text proposed by the Commission

Amendment

7a. Toys that are designed to come into frequent contact with the skin, such as finger paints or modelling dough, shall comply with the composition and labelling requirements set out in Directive 76/768/EEC.

Justification

Toys coming into frequent contact with the skin should be subject to the stringent provisions set out in the Cosmetics Directive.

Amendment 88

Proposal for a directive

Annex II – Part III – point 7 b (new)

Text proposed by the Commission

Amendment

7b. Toys designed to come into frequent contact with the skin and containing allergenic substances, other than fragrances, that are known to be seriously harmful or even fatal to children (e.g. those which trigger anaphylactic shock) shall comply with the labelling provisions set out in Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children¹.

¹ OJ L 339, 6.12.2006. p. 16.

Justification

Same comments as for Amendment 94, but here with reference to allergenic substances other than fragrances, such as gluten, etc. Children using toys containing such allergens may put them in their mouths or put their fingers in their mouths. The presence of such substances may cause reactions of varying degrees of seriousness in children. The presence of such

allergens should therefore be indicated on the label.

Amendment 89

Proposal for a directive

Annex II – Part III – point 7 c (new)

Text proposed by the Commission

Amendment

7c. The use of allergenic fragrances is allowed in olfactory and scientific toys.

Olfactory and scientific toys must comply with the compositional requirements provided for in Directive 76/768/EEC and the provisions laid down in point 6 of Annex II, Part III.

Allergenic fragrances used in these two categories of toys must be labelled as allergenic, in a different way to the other fragrances used and in an accurate, clearly visible and easily legible manner, in order to inform consumers about the use and the presence of allergenic fragrances.

The Commission may request the relevant Scientific Committee to determine the concentration limit values for the allergenic fragrances used in both these categories of toys. The relevant Scientific Committee must give its opinion within 3 months. The Commission adopts a decision in accordance with the regulatory procedure with scrutiny referred to in Article 46(2).

Bottles containing fragrances in these two categories of toys shall be supplied with a device at their openings which require the use of a specific tool to take minimal samples of the liquid or powder substances/fragrances, avoiding a risk of swallowing those substances/fragrances in anything other than small quantities.

The toys covered by this point are forbidden for children under the age of 6.

The toys covered by this point are defined as follows:

(a) an olfactory toy is a toy whose purpose is to teach children to recognise or distinguish different smells or tastes on the basis of basic substances or perfume essences;

(b) a scientific toy is a toy whose purpose is to teach children how to make products using basic substances or perfume essences and other raw materials other than fragrances.

Amendment 90

Proposal for a directive

Annex II – Part III – point 8 – introductory part

Text proposed by the Commission

Amendment

8. The following migration limits, *from toys or components* of toys *that are accessible to children during use as specified in the first subparagraph of Article 9 (2)*, **shall not be exceeded:**

8. The following migration limits **shall not be exceeded in any of the component parts** of toys:

Justification

The migration provisions need to be stricter in order to make toys safer and ensure a high level of protection for children's health.

Amendment 91

Proposal for a directive

Annex II – Part III – point 8 – table heading – column 2

Text proposed by the Commission

Amendment

mg/kg in dry, brittle, powder-like or pliable
toy material

mg/kg in **solid**, dry, brittle, powder-like or
pliable toy material

Justification

All of the different types of materials used in the manufacture of toys should be covered in order to make toys safer and ensure a high level of protection for children's health.

Amendment 92

Proposal for a directive

Annex II – Part III – point 8 – table

Text proposed by the Commission

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material
Aluminium	5625	1406
Antimony	45	11.3
Arsenic	7.5	1.9
Barium	4500	1125
Boron	1200	300
Cadmium	3.8	0.9
Chromium (III)	37.5	9.4
Chromium (VI)	0.04	0.01
Cobalt	10.5	2.6
Copper	622.5	156
Lead	27	6.8
Manganese	1200	300
Mercury	15	3.8
Nickel	75	18.8
Selenium	37.5	9.4
Strontium	4500	1125
Tin	15000	3750
Organic tin	1.9	0.5
Zinc	3750	938

Amendment by Parliament

Element	mg/kg in solid , dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material
Aluminium	5625	1406
Antimony	45	11.3
deleted	deleted	deleted
Barium	4500	1125
Boron	1200	300
deleted	deleted	deleted
Chromium (III)	37.5	9.4
deleted	deleted	deleted
Cobalt	10.5	2.6

Copper	622.5	156
<i>deleted</i>	<i>deleted</i>	<i>deleted</i>
Manganese	1200	300
<i>deleted</i>	<i>deleted</i>	<i>deleted</i>
Nickel	75	18.8
Selenium	37.5	9.4
Strontium	4500	1125
Tin	15000	3750
<i>deleted</i>	<i>deleted</i>	<i>deleted</i>
Zinc	3750	938

Justification

Arsenic, cadmium, lead, chromium (VI), mercury and organic tin are highly toxic. Cadmium, lead, chromium (VI), and mercury are already banned in cars and electrical and electronic devices. Chromium (VI) in cement needs to be reduced to a harmless form by the addition of ferrous sulfate. Arsenic is banned in paint and in wood treatment, organotins are banned as biocides. Clearly, substances based on these elements should not be used in toys.

All of the different types of materials used in the manufacture of toys should be covered in order to make toys safer and ensure a high level of protection for children's health.

Amendment 93

Proposal for a directive

Annex II – Part III – table (para 2) - under the table

Text proposed by the Commission

Amendment

These limit values do not apply to 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 9 (2).

deleted

Justification

The last paragraph needs to be deleted as it allows too wide exemptions from the CMR ban.

Amendment 94

Proposal for a directive
Annex II – Part III – point 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

Substances or preparations based on any of the following elements shall be prohibited for use in toys or components of toys:

(1) Arsenic

(2) Cadmium

(3) Chromium (V)

(4) Lead

(5) Mercury

(6) Organic tin

Justification

Arsenic, cadmium, lead, chromium (VI), mercury and organic tin are highly toxic. Cadmium, lead, chromium (VI), and mercury are already banned in cars and electrical and electronic devices. Chromium (VI) in cement needs to be reduced to a harmless form by the addition of ferrous sulfate. Arsenic is banned in paint and in wood treatment, organotins are banned as biocides. Clearly, substances or preparations based on these elements should not be used in toys.

Amendment 95

Proposal for a directive
Annex II, Part III, point 8 a (new)

Text proposed by the Commission

Amendment

8a. Toys or parts of toys which are intended to be put in the mouth must comply with the provisions for migration limit values for food packaging, irrespective of the age of the children for which they are intended, as set out in 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.

Amendment 96

Proposal for a directive Annex II – Part V

Text proposed by the Commission

1. Toys must be so designed and manufactured as to meet the requirements of hygiene and cleanliness in order to avoid any risk of infection, sickness and contamination.
2. Textile toys for children under 36 months shall be washable and shall fulfil the safety requirements also after washing.

Amendment

1. Toys must be so designed and manufactured as to meet the requirements of hygiene and cleanliness in order to avoid any risk of infection, sickness and contamination. ***Toys must be able to be washed, scrubbed and disinfected without impairing their functions or their safety.***
2. Textile toys for children under 36 months shall be washable and shall ***function and*** fulfil the safety requirements also after washing.

Justification

It should be possible to ensure high standards of hygiene while still having a toy that works and is safe.

Amendment 97

Proposal for a directive Annex IV – point (a)

Text proposed by the Commission

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

Amendment

- (a) a detailed description of the design and manufacture, including a list of components, materials ***and raw materials*** used in toys as well as ***detailed information*** on chemicals used ***in the toys and their component parts, and the quantities used;***

Justification

This is an addition to amendment 100 by the rapporteur to also include information about raw materials. The findings of tests of chemicals can vary significantly from batch to batch due to the use of different raw materials. It is therefore important that information about raw

materials is also provided.

Amendment 98

Proposal for a directive

Annex V – Part B – point 1 – subparagraph 2

Text proposed by the Commission

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

Amendment

These warnings shall be accompanied with a brief indication of the specific ***hazards*** calling for this restriction. ***This indication shall be marked in a clearly visible and legible manner on the toy or, where this is impossible for technical reasons, on an affixed label or on the packaging and on the instructions for use. Small toys that are sold without packaging shall have such indications affixed to them.***

Justification

The initial provisions are insufficiently specific and binding. The amendment seeks to make them clearer and easier to understand.

Amendment 99

Proposal for a directive

Annex V – Part B – point 2 – subparagraph 2

Text proposed by the Commission

Such toys shall bear a marking “Warning: only for domestic use”.

Amendment

Such toys shall bear a marking ***such as*** “Warning: only for domestic use ***and requiring the presence and assistance of an adult***” or “Warning: only for domestic use and not suitable for children under six years without the supervision of an adolescent or an adult”.

Justification

The provisions are not sufficiently specific. The initial wording proposed is in keeping with the scope of the directive but does not provide a clear warning against possible risks.

Amendment 100

Proposal for a directive

Annex V – Part B – point 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

A clear, visible, easy-to-read and understandable warning distinct from all other wording shall appear on the packaging or, where this is impossible, on the label affixed to the toy, drawing attention to the need to read the instructions, as referred to in the following subparagraph, prior to assembly.

Justification

Users must be given a clear warning to the effect that they must read the assembly instructions before assembling the toy, so as to ensure that they know how to do so safely.

Amendment 101

Proposal for a directive

Annex V – Part B – point 7 – subparagraph 2

Text proposed by the Commission

Amendment

“Adult supervision recommended”

“Contains a toy for use under adult supervision”

Justification

The proposed wording does not warn against any specific risk. The precautions to be taken must be clearly spelled out to users.

PROCEDURE

Title	Safety of toys
References	COM(2008)0009 – C6-0039/2008 – 2008/0018(COD)
Committee responsible	IMCO
Opinion by Date announced in plenary	ENVI 11.3.2008
Drafts(wo)man Date appointed	Anne Ferreira 7.3.2008
Discussed in committee	15.7.2008 8.9.2008
Date adopted	7.10.2008
Result of final vote	+: 45 -: 6 0: 2
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Liam Aylward, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Avril Doyle, Mojca Drčar Murko, Jill Evans, Anne Ferreira, Elisabetta Gardini, Matthias Groote, Satu Hassi, Gyula Hegyi, Jens Holm, Marie Anne Isler Béguin, Dan Jørgensen, Christa Kläß, Urszula Krupa, Marie-Noëlle Lienemann, Peter Liese, Jules Maaten, Marios Matsakis, Linda McAvan, Roberto Musacchio, Riitta Myller, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Guido Sacconi, Daciana Octavia Sârbu, Amalia Sartori, Bogusław Sonik, María Sornosa Martínez, Salvatore Tatarella, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Glenis Willmott
Substitute(s) present for the final vote	Iles Braghetto, Antonio De Blasio, Bairbre de Brún, Caroline Lucas, Miroslav Mikolášik
Substitute(s) under Rule 178(2) present for the final vote	Pervenche Berès, Dieter-Lebrecht Koch

9.10.2008

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Internal Market and Consumer Protection

on the proposal for a directive of the European Parliament and of the Council on the safety of toys
(COM(2008)0009 – C6-0039/2008 – 2008/0018(COD))

Draftsman: David Hammerstein

SHORT JUSTIFICATION

The toy industry in Europe, standing at approximately € 13 billion in retail sales, 2.000 manufacturers with some 100.000 employees may not be one of the largest European industries in terms of turnover, yet with roughly 80 million children below 15 years of age across EU-27 it has perhaps the widest base within this most vulnerable consumer group.

The need for special regulation of this specific industry resulted in the Directive on Toy Safety adopted in May 1988. Undisputedly, the Directive served the industry well since its inception. However, the 2007 worldwide recalls of millions of toys by leading producers made it clear that the provisions of the 1988 directive have fallen behind the dynamic and fast-evolving development of the toy industry thus rendering the existing legislation inadequate to address the emerging issues in that sphere.

In a response to these developments and the rising wave of consumer concern about the level of safety of toys marketed throughout Europe, the Commission presented in January 2008 a proposal for an improved directive on the safety of toys that seeks to address three main priority points:

- I. *Enhanced safety requirements* - dealing with bans on the use of cancer-provoking carcinogenic, mutagenic and toxic for reproduction (CMR) chemical substances and allergenic fragrances; reduction in the legal limits of certain dangerous substances; stricter measures on warnings, physical and mechanical properties of toys; new provisions for toys in food;
- II. *More coherent and efficient enforcement of the Directive* - seeking to step up market surveillance in Member States; improve and strengthen the rules on the CE marking and the safety assessment procedure;

III. *Clarified scope and concepts of the Directive* - regarding the list of products not covered by the directive; a list with definitions of terms used in the directive;

Your draftsman welcomes the initiative for a much needed revised version of the Toy Safety Directive. The proposal goes in the right direction by strengthening current and introducing new measures that cover all contested fields with regards to regulating the safety of toys in Europe.

However, in view of ensuring the highest level of protection for children, not the scope but the depth of certain categories of measures does require further consideration:

Chemical properties of toys: Cancer-provoking substances (all CMR categories 1, 2 and 3) as well as dangerous elements present a very potent risk to children's health. Results of irreversibly and adversely affected health may not be manifested overnight but over a prolonged period of exposure to such substances. Similarly, it is widely recognised that certain fragrances lead to allergies that are rather difficult to treat. In this respect, your draftsman is of the opinion that as strict as possible measures should be taken to minimise the health risks by introducing a general prohibition for CMR substances categories 1 and 2 and a ban with possibility for exemptions for category 3. All fragrances and a list of six dangerous elements (arsenic, mercury, lead, organic tin, cadmium and chromium IV) should also be respectively banned.

Safety assessment procedure: The safety assessment procedure is a key element in the process of ensuring a high level of safety of toys placed on the market and as such it should be further strengthened. Without overburdening the industry, there is a need to introduce the EC-type examination for at least those of most dangerous categories of toys as well as conduct annual sample checks on these groups of toys in order to guarantee consistent checks on safety in the production beyond the initial prototype testing.

Flexibility of Directive's provisions: The toy industry has proven to be highly dynamic and fast evolving in terms of new products and new product designs, materials used, etc. The new provisions in the revised directive should be so designed as to make it flexible enough to quickly respond to unforeseen risks and developments and thus avoid fatalities that could be prevented with quick action (rather than reaction) on behalf of manufacturers, legislators and enforcement authorities. Consequently, the regulatory procedure with scrutiny should be extended and have a prominent role to play in the following areas - amending limits on physical characteristics of toys (speed, noise, temperature), amending the list of products not considered toys under the directive as well as the list with toys within the four categories of most dangerous toys to be subjected to EC-type examination.

In addition, the pre-cautionary principle with regards toy safety will allow for measures to be taken when there is a potential risk to health but there is insufficient accident history to warrant the instigation of such protective measures.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) Another important objective of the new system to be established by this Directive is to encourage and in certain cases to 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.

Justification

This amendment is an adaptation to the REACH Regulation (recital 12).

Amendment 2

Proposal for a directive Recital 8

Text proposed by the Commission

Amendment

(8) All economic operators intervening in the supply and distribution chain should take the appropriate measures to ensure that they make available on the market only toys which are in conformity with the applicable legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.

(8) This Directive is based on the principle that all economic operators intervening in the supply and distribution chain should manufacture, import or place toys on the market with such responsibility and care as may be required to ensure that, under normal and reasonably foreseeable conditions of use, children's health and safety and the environment are not adversely affected. Economic operators should take the appropriate measures to ensure that they make available on the market only toys which are in conformity with the applicable legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.

Justification

This amendment introduces a duty of care for economic operators. It is an adaptation inspired from the provisions of the REACH Regulation (recital 16).

Amendment 3

Proposal for a directive

Recital 16

Text proposed by the Commission

(16) In order to ensure protection of children against **recently discovered** risks, **it** is also necessary to adopt new essential safety requirements. In particular, it is necessary to complete and update provisions on chemical substances in toys. These provisions should specify that toys should comply with the 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹⁶. These provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to 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 substances¹⁷ and fragrances in toys should be provided for on account of the special risks that these substances may entail for human health.

Amendment

(16) In order to ensure **a high level of** protection of children **and the environment** against risks, **dangerous substances, in particular carcinogenic, mutagenic or toxic for reproduction (CMR) and allergenic substances and elements, should, in accordance with the precautionary principle, be subject to careful attention.** **It** is also necessary to adopt new essential safety requirements. In particular, it is necessary to complete and update provisions on chemical substances in toys. These provisions should specify that toys should comply with the 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹⁶. These provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on substances that are classified as **CMR** according to Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and

The specific limit values laid down in Directive 88/378/EEC for certain substances should be updated to take into account of the development of scientific knowledge.

administrative provisions relating to the classification, packaging and labelling of dangerous substances¹⁷ and fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. The specific limit values laid down in Directive 88/378/EEC for certain substances should be updated to take into account of the development of scientific knowledge.

Justification

This amendment draws the attention to the importance to address substances of very high concern. It is an adaptation from the REACH Regulation (recital 69).

Amendment 4

Proposal for a directive Recital 16 a (new)

Text proposed by the Commission

Amendment

(16a) In order to avoid any possible duplication of evaluation under this Directive and Regulation (EC) No 1907/2006 (REACH), CMRs that have been evaluated and have not been prohibited under this Directive should not be made subject to proposals for restriction under Regulation (EC) No 1907/2006 on the grounds of risks to human health and should not be made subject to authorisation under Regulation (EC) No 1907/2006 on the grounds of risks to human health according to Article 58(2) of that Regulation. In order to avoid similar duplication, CMRs which have been evaluated for use in toys and which have not been prohibited under Regulation (EC) No 1907/2006 should not be made subject to restrictions or evaluation under this Directive.

Justification

Any duplication of evaluation by different EU bodies for the use of the same substance in toys

must be avoided. Once a substance is evaluated where it is contained in toys under this Directive, it should not subsequently become subject to restrictions or to the Authorisation procedure under Reach (Article 58(2) of Reach). Similarly, if a substance is not prohibited under REACH for use in a toy subsequent to a relevant evaluation, it should not be made subject to the provisions of this Directive.

Amendment 5

Proposal for a directive Recital 16 b (new)

Text proposed by the Commission

Amendment

(16b) It is necessary to apply a harmonised transition period of two years after the entry into force of this Directive for compliance with its provisions and a further transition period of three years to allow toy manufacturers and economic operators the time needed to comply with the new technical requirements on chemicals, and to ensure consistent application of this Directive throughout the European Union.

Justification

The proposal provides that Member States shall not restrict the placing on the market of toys that comply with the current Toy Safety Directive 88/378/EEC "at the latest two years after the Directive enters into force." This means that Member States may decide to apply the new provisions of the Directive right after entry into force. For reasons of legal certainty, it is important to avoid such a situation.

Amendment 6

Proposal for a directive Article 2 – point 3 a (new)

Text proposed by the Commission

Amendment

(3a) "authorised representative" means any natural or legal person established within the Community who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the obligations of

manufacturers under this Directive;

Justification

A definition for 'authorised representative' needs to be added to Article 2.

Amendment 7

**Proposal for a directive
Article 3 – paragraph 7**

Text proposed by the Commission

7. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that toy into conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the toy available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.

Amendment

7. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that toy into conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the toy available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken. ***Manufacturers shall immediately suspend the placing on the market of these toys until they comply with the applicable Community legislation.***

Amendment 8

**Proposal for a directive
Article 4 – title and paragraph 1**

Text proposed by the Commission

Authorised representatives

1. ***Manufacturers*** may appoint, by a written mandate, ***any natural or legal person established within the Community, ("the authorised representative"), to act on their behalf for specified tasks with regard to the obligations of manufacturers under***

Amendment

Obligations of authorised representatives

1. ***A Manufacturer*** may appoint, by a written mandate, ***an*** authorised representative ***as defined in Article 2, point (3a).***

this Directive.

Justification

In order to be consistent with the titles of Articles 3 and 5. A definition for 'authorised representative' has been added to Article 2.

Amendment 9

Proposal for a directive
Article 10 – paragraph 3

Text proposed by the Commission

3. Member States **may** require warnings and safety instructions, **or some of them**, to be presented in their own official language or languages when the toys are placed on the market in their territory.

Amendment

3. Member States **shall** require **all** warnings and safety instructions to be presented in their own official language or languages when the toys are placed on the market in their territory.

Justification

It is not admissible that such important safety information for consumers may be displayed in a language that is not the official one for the market where the toy is placed.

Amendment 10

Proposal for a directive
Article 45 – Paragraph 1

Text proposed by the Commission

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

- (a) Points 7 and 8 in Part III of Annex II;
- (b) Annex V.

Those measures, designed to amend non-essential elements of this *Regulation* shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 46(2).

Amendment

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

- (a) Points 7 and 8 in Part III of Annex II;
- (b) 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 46(2) **and according to the assessment of the relevant Scientific Committee.**

Justification

I consider the Scientific committee has to be involved in the revision of the Annex II and V, in order to give scientific and technical advice in light of the scientific progress.

Amendment 11

Proposal for a directive Article 45 - Paragraph 2

Text proposed by the Commission

2. The Commission may decide upon the **use in toys** of substances or preparations classified as carcinogenic, mutagenic or toxic to reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC.

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 46(2).

Amendment

2. The Commission may decide upon the **content** of substances or preparations classified as carcinogenic, mutagenic or toxic to reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC **in toys**.

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 46(2) **and according to the assessment of the relevant Scientific Committee**.

Justification

I consider the Scientific committee has to be involved in the revision of the Annex II and V, in order to give scientific and technical advice in light of the scientific progress.

Amendment 12

Proposal for a directive Article 52

Text proposed by the Commission

Member States shall not impede the placing on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before this Directive entered into force or **at the latest 2 years** after this Directive entered into force.

Amendment

Member States shall not impede the placing on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before this Directive entered into force or **for two years** after this Directive enters into force.

With regard to Articles 3(1) and 9(1) and

part III of Annex II on chemical properties, Member States shall not impede the placing on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market either before this Directive entered into force or during the three year period after its entry into force.

Justification

It is important that this directive enters into force at same time in all Member States. An additional period is necessary to give time both central bodies to develop new tests and industry to comply with the new technical requirements on chemicals.

Amendment 13

**Proposal for a directive
Annex I – point 17 a (new)**

Text proposed by the Commission

Amendment

17a. Books that do not contain any additional elements or objects (except those made of paper or cardboard).

Justification

Following the implementation of the 1988 Toy Safety Directive, some Member States have considered children's books as toys. This has led to considerable difficulties for the children's book publishing industry in several EU Member States. Due to the crucial importance of books, especially at the youngest age, for improving reading skills, it is important that encouragement of books' reading continues to be promoted. So for the purpose of the Directive, it should be considered that a book is not a toy unless it has evident game-related elements.

Amendment 14

**Proposal for a directive
Annex II – part I – paragraph 4 – subparagraph 2**

Text proposed by the Commission

Amendment

The packaging in which toys are contained for retail sale must not present risk of strangulation or asphyxiation caused by

The packaging in which toys are contained for retail sale must not present risk of strangulation or asphyxiation caused by

airway obstruction external to the mouth and nose.

airway obstruction ***internal and*** external to the mouth and nose.

Amendment 15

Proposal for a directive Annex II – part III – paragraph 3

Text proposed by the Commission

3. Without prejudice to the application of the restrictions under the first sentence of point 2, ***the use in toys of substances*** that are classified as carcinogenic, mutagenic or toxic for reproduction (***CMR***) according to Directive 67/548/EEC in individual concentrations equal to or greater than the relevant concentrations established for the classification of preparations containing the substances in accordance with the provisions of Directive 1999/45/EC ***shall be prohibited***, except if the substances are contained in components ***of toys*** or ***micro-structurally distinct*** parts of ***toys*** that are not accessible ***to any physical contact*** by children.

Amendment

3. Without prejudice to the application of the restrictions under the first sentence of point 2, ***toys shall not contain substances*** that are classified as carcinogenic, mutagenic or toxic for reproduction ***categories 1 or 2*** according to ***Annex I of*** Directive 67/548/EEC in individual concentrations equal to or greater than the relevant concentrations established for the classification of preparations containing the substances in accordance with the provisions of Directive 1999/45/EC except if the substances are contained in components or parts of ***the toy*** that are not accessible by children ***as defined in standard EN 71***.

Justification

If CMR 1 and 2 substances are not accessible (that means non exposure) there is no risk in the use of toys. Safety will not be enhanced by extending the restriction to the non accessible components of a toy. To better define this concept I consider important to introduce the definition of accessibility as established by the EU Standard EN 71.

Amendment 16

Proposal for a directive Annex II – part III – paragraph 4

Text proposed by the Commission

4. Substances ***or preparations*** classified as CMR category 1 and 2 according to Directive 67/548/EEC may be used in toys provided that the following conditions are met:

Amendment

4. Substances classified as CMR category 1 and 2 according to ***Annex I of*** Directive 67/548/EEC may be used in toys provided that the following conditions are met:

Justification

The deletion of the word preparations and the Annex I specification is needed for legal clarity.

Amendment 17

Proposal for a directive

Annex II – part III – paragraph 4 – subparagraph 4.1

Text proposed by the Commission

4.1 use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and a Decision as referred to in Article 45(2) has been taken;

Amendment

4.1 the relevant Scientific Committee has concluded that the substances classified as CMR category 1 and 2 according to Annex I of Directive 67/548/EEC contained in accessible components or parts of toys above the concentration limits in paragraph 3 does not pose an unacceptable risk to human health, in particular in relation to exposure;

To that end, manufacturers may, prior to the end of the transition period in Article 52, apply to the Commission for an evaluation by the relevant Scientific Committee of the risk posed by substances classified as CMR category 1 and 2 according to Annex I of Directive 67/548/EEC. That application shall be accompanied by relevant information in particular on exposure. Upon the receipt of an application, the Commission shall without delay mandate the Scientific Committee to provide its opinion.

Manufacturers are allowed to place on the market toys containing the substances classified as CMR category 1 and 2 according to Annex I of Directive 67/548/EEC for which an application has been submitted and until a decision is adopted.

Justification

There is no benefit to the safety by apply the restrictions to the internal components of a toy. It is in the standard that all the technical details of toy safety are worked out, including the

likelihood of breakages. It is for this reason that we recommend that the definition of accessibility is that established by the standard. When there is no exposure to these components there is no risk for children's health.

Amendment 18

Proposal for a directive

Annex II – part III – paragraph 4 – subparagraph 4.2

Text proposed by the Commission

Amendment

**4.2 there are no suitable substances
available, as documented in an analysis of
alternatives,** **deleted**

Justification

We ask that the requirement to replace a chemical simply because an alternative exists be deleted in the interest of child safety. If a risk assessment demonstrates that the substance poses no risk to a child, there is no reason to require to experiment with new chemical formulations that risk changing the performance of the material that contains it. A child's safety depends first and foremost upon the safety of the materials used to construct a toy, e.g. whether a plastic will crack or splinter. Safety is therefore enhanced when materials which meet established performance tests are used.

Amendment 19

Proposal for a directive

Annex II – part III – paragraph 5

Text proposed by the Commission

Amendment

5. Substances or preparations classified as CMR category 3 according to Directive 67/548/EEC may be used in toys if use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and following a Decision as referred to in Article 45(2) and provided that they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

5. Without prejudice to the application of the restrictions under the first sentence of paragraph 2, toys shall not contain substances that are classified as carcinogenic, mutagenic or toxic for reproduction category 3 according to Annex I of Directive 67/548/EEC if:

(i) they *have been* prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH); or

(ii) the CMR category 3 substance is contained in components or parts of toys that are accessible, as defined in standard EN71, by children and the relevant Scientific Committee has evaluated in accordance with Article 45(2) that the content of the substance in the toy poses an unacceptable risk to human health, in particular in relation to exposure.

Justification

The difference between CMRs 1-2 and CMRs 3 is clear: the large number of CMR 3 substances are not subject to the same legal restrictions as CMR 1 and 2. Several hundred chemicals are categorized as CMR 3s and are found in materials used to produce other consumer products as well as toys. For the sake of children's health and the EU's commitment to better regulation, a common approach is needed for all consumer products. CMR3s that are banned should be listed in a new annex IIb.

Amendment 20

Proposal for a directive

Annex II – part III – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Manufacturers may continue placing on the market toys which contain the substances classified as CMR according to Directive 67/548/EEC for which a request has been submitted, until a decision has been adopted.

Amendment 21

Proposal for a directive

Annex II – part III – paragraph 7 – first list of fragrances – new points after point 38

Text proposed by the Commission

Amendment

- (39) Musk ambrette***
- (40) 4-Phenyl-3-buten-2-one***
- (41) Amyl cinnamal***
- (42) Amylcinnamyl alcohol***

- (43) Benzyl alcohol*
- (44) Benzyl salicylate*
- (45) Cinnamyl alcohol*
- (46) Cinnamal*
- (47) Citral*
- (48) Coumarin*
- (49) Eugenol*
- (50) Geraniol*
- (51) Hydroxycitronellal*
- (52)*
Hydroxymethylpentylcyclohexenecarboxaldehyde
- (53) Isoeugenol*

Justification

Scientific reports show that there are 40 forbidden fragrances. These are contained in the list of banned fragrances in the Proposal on the safety of toys with the exception of 2 substances. These 2 substances (= musk ambrette and 4 phenyl-3-buten-2-one) which have been considered as allergenic by the SCCNFP in 2003 were not included in the list of the TSD and need to be added. It is also appropriate to ban 13 fragrances that are subject to labelling in the Commission's Proposal because Scientific reports indicated that these 13 fragrance chemicals are most frequently reported as contact allergens.

Amendment 22

Proposal for a directive

Annex II – part III – paragraph 7 – second list of fragrances

Text proposed by the Commission

Amendment

- (1) Amyl cinnamal*
- (2) Amylcinnamyl alcohol*
- (3) Anisyl alcohol*
- (4) Benzyl alcohol*
- (5) Benzyl benzoate*
- (6) Benzyl cinnamate*
- (7) Benzyl salicylate*
- (8) Cinnamal*

- (3) Anisyl alcohol*
- (5) Benzyl benzoate*
- (6) Benzyl cinnamate*

(9) Cinnamyl alcohol

(10) Citral

(11) Citronellol

(11) Citronellol

(12) Coumarin

(13) Eugenol

(14) Farnesol

(14) Farnesol

(15) Geraniol

(16) Hexyl cinnamaldehyde

(16) Hexyl cinnamaldehyde

(17) Hydroxy-citronellal

(18) Hydroxy-methylpentylcyclohexenecarboxaldehyde

(19) Isoeugenol

(20) Lilial

(20) Lilial

(21) d-Limonene

(21) d-Limonene

(22) Linalool

(22) Linalool

(23) Methyl heptine carbonate

(23) Methyl heptine carbonate

(24) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one

(24) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one

(25) Oakmoss extracts

(25) Oakmoss extracts

(26) Treemoss extracts

(26) Treemoss extracts

Justification

The Commission failed to include a number of important substances in the list of allergenic fragrances. These must be added.

Amendment 23

Proposal for a directive

Annex II – part III – paragraph 8 – Introductory wording and table

Text proposed by the Commission

The following migration limits, from toys or components of toys that are accessible to children during use as specified in the first subparagraph of Article 9 (2), shall not be exceeded:

<i>Element</i>	<i>mg/kg in dry, brittle, powder-like or</i>	<i>mg/kg in liquid or sticky</i>
----------------	--	----------------------------------

	<i>pliable toy material</i>	<i>toy material</i>
<i>Aluminium</i>	<i>5625</i>	<i>1406</i>
<i>Antimony</i>	<i>45</i>	<i>11.3</i>
<i>Arsenic</i>	<i>7.5</i>	<i>1.9</i>
<i>Barium</i>	<i>4500</i>	<i>1125</i>
<i>Boron</i>	<i>1200</i>	<i>300</i>
<i>Cadmium</i>	<i>3.8</i>	<i>0.9</i>
<i>Chromium (III)</i>	<i>37.5</i>	<i>9.4</i>
<i>Chromium (VI)</i>	<i>0.04</i>	<i>0.01</i>
<i>Cobalt</i>	<i>10.5</i>	<i>2.6</i>
<i>Copper</i>	<i>622.5</i>	<i>156</i>
<i>Lead</i>	<i>27</i>	<i>6.8</i>
<i>Manganese</i>	<i>1200</i>	<i>300</i>
<i>Mercury</i>	<i>15</i>	<i>3.8</i>
<i>Nickel</i>	<i>75</i>	<i>18.8</i>
<i>Selenium</i>	<i>37.5</i>	<i>9.4</i>
<i>Strontium</i>	<i>4500</i>	<i>1125</i>
<i>Tin</i>	<i>15000</i>	<i>3750</i>
<i>Organic tin</i>	<i>1.9</i>	<i>0.5</i>
<i>Zinc</i>	<i>3750</i>	<i>938</i>

Amendment

In order to protect children's health, no more than the following maximum daily amounts of the substances listed below may be bioavailable as a result of handling toys:

0.2 µg Antimony
0.01 µg Arsenic
0.85 µg Barium
5.0 µg Boron
0.25 µg Cadmium
0.25 µg Chromium (derived from Cr III)*
0.35 µg Lead
0.2 µg Mercury
1.25 µg Selenium

In addition, only the following amounts may be bioavailable from organic tin compounds:

0.025 µg Tin or
0.075 µg Sum of organic tin compounds.

For oral exposure via toys, a maximum of 10% of the respective tolerable daily intake for children (TDI value) may be bioavailable as a result of handling any toy.

Justification

Substances such as strontium that do not occur during the manufacture of toys should be deleted from the directive and monitored in accordance with the usual toxicological processes. The limit values for other substances are far too high and must be reduced. In particular, a lower limit value should be set for lead. The measurement of the listed substances should be based on the tolerable daily intake for children.

Amendment 24

Proposal for a directive

Annex V – part B – paragraph 7 – subparagraph 2

Text proposed by the Commission

Amendment

“Adult supervision recommended”.

“Adult supervision **strongly** recommended”.

Justification

This wording offers better guarantees for the safety of children.

PROCEDURE

Title	Safety of toys
References	COM(2008)0009 – C6-0039/2008 – 2008/0018(COD)
Committee responsible	IMCO
Opinion by Date announced in plenary	ITRE 11.3.2008
Drafts(wo)man Date appointed	David Hammerstein 27.5.2008
Discussed in committee	27.5.2008 16.7.2008 7.10.2008
Date adopted	7.10.2008
Result of final vote	+: 29 -: 2 0: 11
Members present for the final vote	Jan Březina, Jerzy Buzek, Jorgo Chatzimarkakis, Giles Chichester, Dragoş Florin David, Pilar del Castillo Vera, Den Dover, Nicole Fontaine, Norbert Glante, András Gyürk, David Hammerstein, Erna Hennicot-Schoepges, Mary Honeyball, Ján Hudacký, Romana Jordan Cizelj, Werner Langen, Pia Elda Locatelli, Eluned Morgan, Angelika Niebler, Reino Paasilinna, Atanas Paparizov, Francisca Pleguezuelos Aguilar, Miloslav Ransdorf, Herbert Reul, Teresa Riera Madurell, Paul Rübig, Britta Thomsen, Patrizia Toia, Claude Turmes, Nikolaos Vakalis, Adina-Ioana Vălean
Substitute(s) present for the final vote	Gabriele Albertini, Etelka Barsi-Pataky, Manuel António dos Santos, Juan Fraile Cantón, Neena Gill, Pierre Pribetich, Silvia-Adriana Țicău, Vladimir Urutchev
Substitute(s) under Rule 178(2) present for the final vote	Domenico Antonio Basile, José Javier Pomés Ruiz, Stefano Zappalà

PROCEDURE

Title	Safety of toys			
References	COM(2008)0009 – C6-0039/2008 – 2008/0018(COD)			
Date submitted to Parliament	25.1.2008			
Committee responsible Date announced in plenary	IMCO 11.3.2008			
Committee(s) asked for opinion(s) Date announced in plenary	ENVI 11.3.2008	ITRE 11.3.2008		
Rapporteur(s) Date appointed	Marianne Thyssen 28.2.2008			
Discussed in committee	7.4.2008	27.5.2008	23.6.2008	24.6.2008
	6.10.2008			
Date adopted	6.11.2008			
Result of final vote	+: –: 0:	40 0 0		
Members present for the final vote	Mia De Vits, Janelly Fourtou, Evelyne Gebhardt, Martí Grau i Segú, Małgorzata Handzlik, Malcolm Harbour, Anna Hedh, Iliana Malinova Iotova, Pierre Jonckheer, Alexander Graf Lambsdorff, Kurt Lechner, Lasse Lehtinen, Toine Manders, Catiuscia Marini, Arlene McCarthy, Nickolay Mladenov, Zita Pleštinská, Giovanni Rivera, Zuzana Roithová, Heide Rühle, Leopold Józef Rutowicz, Salvador Domingo Sanz Palacio, Christel Schaldemose, Andreas Schwab, Marianne Thyssen, Jacques Toubon, Bernadette Vergnaud, Barbara Weiler, Marian Złotea			
Substitute(s) present for the final vote	Emmanouil Angelakas, Wolfgang Bulfon, Colm Burke, Joel Hasse Ferreira, Filip Kaczmarek, Guntars Krasts, Marine Le Pen, Andrea Losco, Manuel Medina Ortega, José Javier Pomés Ruiz, Olle Schmidt, Francesco Enrico Speroni, Anja Weisgerber			
Substitute(s) under Rule 178(2) present for the final vote	Maddalena Calia, Francesco Ferrari, Mario Mauro, Willem Schuth, Csaba Öry			