



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 2 October 2008

**Interinstitutional File:
2008/0018 (COD)**

**13066/1/08
REV 1**

LIMITE

**MI 311
ENT 222
CONSOM 119
SAN 188
ECO 111
CODEC 1126**

NOTE

from :	General Secretariat of the Council
to :	Working Party on Technical Harmonisation
No. prev. doc:	11244/08 MI 230 ENT 156 CONSOM 81 SAN 132 ECO 82 CODEC 889 12520/08 MI 283 ENT 205 CONSOM 102 SAN 163 EDO 96 CODEC 1035
No. Cion prop. :	5938/08 MI 40 ENT 18 CONSOM 14 SAN 20 ECO 16 CODEC 120
Subject :	Proposal for a Directive of the European Parliament and of the Council on the safety of toys

1. The Commission submitted its Proposal to the Council and the European Parliament on 28 January 2008.
2. The European Parliament is expected to deliver its Opinion at first reading in December 2008.
3. The Czech, Danish, Maltese and United Kingdom delegations have entered Parliamentary scrutiny reservations.
4. All delegations have a general scrutiny reservation on those parts of the text on which there is not yet a tentative agreement (Compare point 6 below.)

5. The Working Party on Technical Harmonisation has examined the dossier on a number of occasions during the Slovenian and French Presidencies starting on 18 March 2008. In addition, delegations have provided written comments.
 6. This document contains Presidency proposals for changes to the text. These are indicated through underlining and ~~striketrough~~ in the legal text. Indications in bold mean that there is not yet a tentative agreement in the Working Party. These proposals are based on delegations' interventions as represented in footnotes in the documents 11244/08 and 12520/08.
 7. At the meeting of the Working Party on 22 September, some delegations asked for reinsertion of some footnotes from documents 11244/08 and 12520/08. These footnotes occur in the text, together with suggestions for changes to the text that have not been taken on board as Presidency proposals.
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2008/0018 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the safety of toys

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁴,

Whereas:

- (1) Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys⁵ was adopted in the context of establishing the internal market in order to harmonise the safety levels of toys throughout the Member States and to remove obstacles to trade in toys between Member States.

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ OJ C [...], [...], p. [...].

⁴ OJ C [...], [...], p. [...].

⁵ OJ L 187, 16.7.1988, p. 1. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

- (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 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 regulations⁶. 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.
- (3) Technological developments in the toys market have, however, raised new issues with respect to the safety of toys and have given rise to increased consumer concerns. In order to take account of those developments and to provide clarification in relation to the framework within which toys may be marketed, certain aspects of Directive 88/378/EEC should be revised and enhanced and, in the interests of clarity, that Directive should be replaced.
- (4) Toys are also subject to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety⁷, which applies in a complementary manner to specific sectoral legislation, ~~and in particular are subject to the Community Rapid Information System (RAPEX) foreseen in that Directive.~~
- (4a) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁸ lays down horizontal provisions on accreditation of conformity assessment bodies, on the CE-marking and on the Community market surveillance framework and controls of products entering the Community market, which are also applicable in the toys sector.

⁶ OJ L 204, 21.7.1998, p. 37.

⁷ OJ L 11, 15.1.2002, p. 4.

⁸ OJ L

- (5) Decision [...] No 768/2008/EC of the European Parliament and of the Council of [...] 9 July 2008 on a common framework for the marketing of products and repealing Decision 93/465/EEC⁹ provides common principles and reference provisions for the purposes of legislation based on the New Approach principles. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Directive to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations for economic operators, presumption of conformity, formal objection against harmonised standards, rules for the CE marking, requirements for conformity assessment bodies and the notification procedures as well as the provisions concerning procedures dealing with products presenting a risk should be aligned to that Decision.
- (6) In order to facilitate the application of this Directive by manufacturers and national authorities, its scope should be clarified, by completing the list of products which are not within its scope, in particular as regards certain new products, such as videogames and peripherals.
- (7) It is appropriate to provide for certain new definitions specific to the toys sector in order to facilitate the understanding and uniform application of this Directive.
- (7a) Toys that are placed on the Community market should comply with the relevant applicable Community¹⁰ legislation, and economic operators should be responsible for the compliance of toys, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of health and safety and the protection of consumers, and to guarantee fair competition on the Community market.
- (7b) All economic operators are expected to act responsibly and in full accordance with the legal requirements applicable when placing or making toys available on the market.

⁹ OJ L [...], [...], p. [...].

¹⁰ PT: add "harmonisation."

- (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.
- (9) As certain tasks can only be executed by the manufacturer, it is necessary to ~~clearly~~ distinguish clearly between the manufacturer and ~~the~~ operators further down the distribution chain. It is ~~furthermore~~ also necessary to ~~clearly~~ distinguish clearly the importer and the distributor, as the importer introduces toys from third countries ~~on~~ to the Community market. ~~He~~ The importer has thus to ~~ensure~~ make sure that ~~these~~ those toys comply with the applicable Community requirements.
- (10) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure for toys. ~~Importers and distributors perform a trading function and do not have any influence on the production process.~~ The Conformity assessment should therefore remain the obligation of the manufacturer alone.
- ~~(11) — Since importers and distributors are downstream operators they cannot in the normal course of events be obliged to ensure themselves that the design and production of the toy is in compliance with the applicable requirements. Their obligations in relation to the compliance of the toy should be limited to certain control measures to ascertain whether the manufacturer has fulfilled his obligations, such as verifying whether the toys bears the required conformity marking and whether the required documents have been supplied. However, it can be expected of both importers and distributors to act with due care in relation to the applicable requirements when placing or making available products on the market.~~

- (11a) It is necessary to ensure that toys from third countries entering the Community market comply with all applicable Community requirements, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those toys. Provision should therefore be made for importers to make sure that the toys they place on the market comply with the applicable requirements and that they do not place on the market toys which do not comply with such requirements or present a risk. For the same reason, provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.
- (11b) The distributor makes a toy available on the market after it has been placed on the market by the manufacturer or the importer and must act with due care to ensure that its handling of the toy does not adversely affect the compliance of the toy. Both importers and distributors are expected to act with due care in relation to the requirements applicable when placing or making toys available on the market.
- (11c) Is now (32a)**
- (11d) When placing a toy on the market, every importer should indicate on the product his name and the address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the product.
- (12) ~~Where an importer or a distributor~~ Any operator that either places a toy on the market under his own name or trademark or modifies a toy in such a way that compliance with applicable requirements may be affected, ~~he~~ he should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (13) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by national authorities, and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the toy concerned.

- (14) Ensuring traceability of a toy throughout the whole supply chain contributes to rendering market surveillance simpler and more efficient. An efficient traceability system facilitates the task of market surveillance authorities ~~to trace the~~ of tracing economic operators ~~responsible for supplying~~ who made non-compliant toys available on the market.
- (15) Certain essential safety requirements which were laid down in Directive 88/378/EEC should be updated to take account of technical progress since the adoption of that Directive. In particular, in the field of electrical properties, technical progress has made it possible to allow the limit of 24 volts set in Directive 88/378/EEC to be exceeded while guaranteeing the safe use of the toy concerned.

- (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 toys¹¹. 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/EC¹². 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~~¹³ Regulation (EC) No .../... of the European Parliament and of the Council of ... [on classification, labelling and packaging of substances and mixtures]¹⁴ 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.

¹¹ ES: Draws the attention to the risk for overlapping requirements/double assessments in REACH and this Directive.

¹² OJ L 396, 30.12.2006, p. 1. Regulation as amended by Council Regulation (EC) No 1354/2007 (OJ L 304, 22.11.2007, p. 1).

¹³ ~~OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).~~

¹⁴ OJ L...

- (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 waste¹⁶, 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 equipment¹⁷, in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment¹⁸, in Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste¹⁹ 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/EEC²⁰.
- (17a) Toys or their parts and their packaging that ~~could~~ can reasonably be expected to be brought in contact with food must respect the requirements of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

¹⁵ DE proposes to add the following text to recital 16:
 "If a scientific evaluation cannot determine the risk with sufficient certainty, the precautionary principle should be applied in order to ensure a high level of protection of health, especially for children.
 Since the child's organism is still developing, it responds especially sensitively to substances which are carcinogenic, mutagenic or toxic for reproduction. For this reason, the exposure of children to all practicably avoidable sources of emissions of such substances, especially from articles which are intended or likely to be placed by children in the mouth, should be reduced as far as possible.
 The evaluation of these [certain] substances shall be based on a 1 % take-up of the tolerable daily intake (TDI); in the case of a demonstrably lower background level (from other sources such as food or drinking water) a take-up of up to 10 %." (TOY 9)

¹⁶ OJ L 114, 27.4.2006, p. 9.

¹⁷ OJ L 37, 13.2.2003, p. 19.

¹⁸ OJ L 37, 13.2..2003, p. 24.

¹⁹ OJ L 365, 31.12.1994, p. 10.

²⁰ OJ L 266, 26.9.2006, p. 1.

- (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 principle²¹, 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.
- (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 user²², **and the capacity of the supervisors²³ to cope with the residual risk. Where the available scientific evidence is too uncertain to allow an accurate risk estimation, Member States, in particular through their competent authorities, should apply the precautionary principle²⁴. Economic operators should give the precautionary principle due consideration.**²⁵
- (20) In order to further promote safe conditions for use of toys, there is a need to supplement the provisions on warnings which should accompany the toy. In order to prevent the misuse of warnings to circumvent the applicable safety requirements, which has occurred in particular in case of the warning stating that the toy is not suitable for children under 36 months, it is necessary to foresee explicitly that the warnings foreseen for certain categories of toys cannot be used if they contradict the intended use of a toy.

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²¹ ES, PL, UK: Reservation on reference to the precautionary principle.

²² SE: Add "Where a hazard can not be sufficiently minimized by design or safeguards, the residual hazard might be addressed by product related information directed at the supervisors, taking into account their capacity to cope with the residual risk. However information to supervisors should not be used as substitutes for design improvements."

²³ DK, ES, PT, FI, SE: Scrutiny reservation on reference to capacity of supervisors.

²⁴ ES, PL, UK: Reservation on reference to the precautionary principle in this recital.

²⁵ DK, DE, UK: Make clear that when a standard has been agreed, then it applies, not the precautionary principle.

²⁶ DK: Suggests addition of a recital concerning guidance on the use of warnings.

- (21) The CE marking, ~~materialising~~ indicating the conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the ~~use of~~ the CE marking are set out in Regulation (EC) No 765/2008, ~~and r~~ Rules as to its governing the affixing of the CE marking should ~~therefore~~ be ~~set~~ laid down in this Directive.
- (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 with all applicable requirements and that he takes full responsibility thereof.
- (22a) The CE marking should be the only marking of conformity indicating that the toy is in conformity with Community harmonisation legislation. However, other markings²⁷ may apply as long as they contribute to improving consumer protection and are not covered by Community harmonisation legislation.**
- (23) It is appropriate to lay down rules on the affixing of CE-marking which ensure enough visibility for the marking in order to facilitate market surveillance of toys.

²⁷ MT: Opposed to use of national markings.

- (24) In order to ensure that the essential requirements are complied with it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. To complete the legal obligations of the manufacturer which aim at ensuring the safety of toys, an explicit obligation to carry out an assessment of the various hazards that the toy may present and an assessment of the potential exposure to them should be included in this Directive, and the manufacturers should be obliged to keep this safety assessment in the technical file to allow market surveillance authorities to perform efficiently their tasks. Internal production control based on the manufacturer's own responsibility for the conformity assessment has proven adequate in cases where he has followed the harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all the safety requirements for the toy. In cases where such harmonised standards do not exist, the toy should be submitted to a third party verification (EC type examination). The same should apply if such standards or one of them has been published with a restriction in the *Official Journal of the European Union*, or the manufacturer has not followed such standards completely or in part. The manufacturer should submit the toy to the EC-type-examination in cases where he considers that the nature, design, construction or purpose of the toys necessitates third party verification.

- (25) Since it is necessary to ensure throughout the Community a uniform level of performance of bodies performing conformity assessment of toys and since all such bodies should perform their functions to the same level and under conditions of fair competition, requirements should be set for conformity assessment bodies ~~seeking~~ wishing to be notified in order to provide conformity assessment services under ~~for the purposes of this Directive. Provision should also be made for the provision of adequate information about such bodies and for their monitoring.~~
- (26) In order to ensure a coherent level of quality in the performance of conformity assessment of toys, it is ~~also~~ necessary not only to consolidate the requirements that conformity assessment bodies wishing to be notified must fulfil, but also, in parallel, to set to make provision about the requirements to be fulfilled by the ~~that notifying~~ authorities responsible for notifying conformity assessment bodies to the Commission and the other Member States and other bodies involved in the assessment, notification and monitoring of notified bodies must fulfil.
- ~~(27) — Market surveillance of toys in the Member States is subject to the provisions of Directive 2001/95/EC. In order to ensure a satisfactory level of market surveillance in all Member States, the provisions on market surveillance measures laid down in Directive 2001/95/EC should, however, be enhanced and certain other obligations and powers should be added to those already existing.~~
- (27a) Regulation (EC) No 765/2008 complements and strengthens the existing framework for the market surveillance of products covered by Community harmonisation legislation, including toys. Therefore, Member States should organise and perform market surveillance of toys in accordance with the provision of that Regulation. In accordance with those provisions, the application of the Regulation does not prevent the market surveillance authorities from taking more specific market surveillance measures available under Directive 2001/95/EC. Furthermore., some specific measures concerning the possibility for a market surveillance authority to get information from a Notified body and to give instructions to it should be adopted in this Directive, in order to strengthen the possibilities of market surveillance authorities to act in case of toys covered by an EC type examination certificate.

- (28) Directive 88/378/EEC already provides for a safeguard procedure allowing the Commission to examine the justification of a measure taken by a Member States against toys it considers to be non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with the aim of making it more efficient and of drawing on expertise available in Member States.
- (29) The existing system should be complemented by a procedure allowing interested parties to be informed of measures intended with regard to toys presenting a risk for the health and safety of persons or for other issues of public interest protection. It also allows market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.
- (30) In a case in which Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required.
- (31) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission²⁸.
- (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.

²⁸ OJ L184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L200, 22/7/2006, p.11).

(32a) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products²⁹ applies *inter alia* to toys not in conformity with Community harmonisation legislation. Manufacturers and importers who have placed non-compliant toys on the Community market are liable for damages under that Directive.³⁰

(33) Member States should provide for penalties applicable to infringements of the provisions of this Directive. Those penalties should be effective, proportionate and dissuasive.

(33a) *It has been suggested to insert a recital explaining the choice of transitional period.*

(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,

HAVE ADOPTED THIS DIRECTIVE:

²⁹ OJ L 210, 7.8.1985, p. 29. Directive as amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

³⁰ This recital used to be (11c).

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject-matter and scope

1. This Directive lays down rules on the safety of toys, and on their ~~the~~ free movement in the Community; ~~of products designed or intended, whether or not exclusively, for use in play by children under 14 years of age, hereinafter "toys".~~

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

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

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

Article 1a
Material scope

- 1. This Directive applies to products designed or intended³¹, whether or not exclusively³², for use in play by children under 14 years of age, hereinafter "toys".**

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

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

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

³¹ PL: Add "by virtue of their functions, dimensions and characteristics". DK, SE: Support.

³² PL: Delete "whether or not exclusively".

*Article 2*³³
Definitions^{34 35}

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

- (1) "making available on the market" ~~means~~ shall mean any supply of a toy for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;
- (2) "placing on the market" ~~means~~ shall mean the first making available of a toy on the Community market;
- * (3) "manufacturer" ~~means~~ shall mean any natural or legal person who ~~designs and manufactures a toy or who has such a toy designed or manufactured, and markets the toy~~ under his name or trademark;
- *(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;
- ~~*(4) "distributor" means any natural or legal person in the supply chain, who makes a toy available on the market;~~
- (5) "importer" ~~means~~ shall mean any natural or legal person established within the Community, who places a toy from a third country on the Community market;
- *(5a) "distributor" means 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;
- (6) "economic operators" ~~means~~ shall mean the manufacturer, the authorised representative, the importer, the distributor ~~and the authorised representative~~;

³³ HU: All definitions should be in Art. 2.

³⁴ HU - add a definition "CE marking", HU proposes to add definitions for "conformity assessment procedure", "market surveillance".

³⁵ HU - include definitions, not just references.

- * (7) “harmonised standard” ~~means~~ shall mean 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 of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services on the basis of a request made by the Commission in accordance with Article 6 of that Directive ~~in accordance with Article 6 of Directive 98/34/EC;~~
- *(7a) “community harmonisation” legislation means any Community harmonisation legislation harmonising conditions for the marketing of products;
- (8) “accreditation” ~~has~~ shall have the meaning assigned to it by Regulation (EC) No [...] 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 products³⁶;
- (8a) "conformity assessment" shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;
- (8b) "conformity assessment body" shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (8c) “recall” shall mean any measure aimed at achieving the return of a toy that has already been made available to the end user;
- (9) “withdrawal” shall means any measure aimed at preventing ~~the making a toy in the supply chain from being made~~ available on the market ~~of a toy in the supply chain;~~
- ~~(10) “recall” means any measure aimed at achieving the return of a toy that has already been made available to the end user;~~

³⁶ OJ L [...], [...], p. [...].

- (10a) "market surveillance" shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;
- (10b) "CE marking" shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;
- (10c) "Functional product" means a product which performs and is used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of such a product, appliance or installation;
- (10d) "aquatic toy" means a toy intended for use in shallow water which is capable of carrying or supporting a child on the water;
- (10e) "design speed" means representative potential operating speed that is determined by the design of the toy;
- (11) "activity toy" means a toy ~~which is intended~~ for domestic use, ~~which is intended for children to play on or in and designed to bear the weight of one or more children, excluding ride-on vehicles, and is intended for children to play on or in,~~ such as swings, slides, carousels, climbing frames, trampolines, paddling pools and non aquatic inflatable toys, ~~excluding ride-on vehicles;~~
- (11a) "functional toy" means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of such a product, appliance or installation;
- (11b) "chemical toys" means a toy intended for the direct handling of chemical substances and mixtures and to be used in an age-appropriate manner under the supervision of adults;

(12) ~~“suffocation” means the result of airway obstruction external to the mouth and nose or internal airway obstruction by closing off the flow of air from the mouth and nose by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.~~

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

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

(15) “risk” means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.³⁷

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³⁷ DK: Add "The risk of a chemical substance contained in a toy means that the exposure level does not exceed the appropriate DNEL as defined in REACH (Regulation (EC) No 1907/2006) Annex I, section 1, 3 and 6. For those human effects for which it is not possible to determine a DNEL it shall be shown that effects are avoided based on a qualitative assessment."

³⁸ HU: (TOY 7) add definition: “ ”functional toy” means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of such a product, appliance or installation.”

³⁹ HU: (TOY 7): add a definition "functional educational product" means a product which performs and is used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of such a product, appliance or installation. These products are sold exclusively for teaching purposes under adult supervision.

⁴⁰ DK: add the following definition: "'Chemical substance" means a chemical element its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without effecting the stability of the substance or changing its composition."

⁴¹ DK: Add definitions of "components" and "materials".

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 3

Obligations of manufacturers

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

2. Manufacturers shall draw up the required technical documentation in accordance with Article 20 and carry out or have carried out the conformity assessment procedure applicable in accordance with Article 18.

Where ~~the~~ compliance of the toy with the applicable requirements has been demonstrated by ~~such~~ that 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).

3. Manufacturers shall keep the technical documentation⁴² and the EC declaration of conformity for a period of ~~10~~ 10 years after the toy has been placed on the market.

*4. Manufacturers shall ensure that procedures are in place ~~to ensure the continued~~ for series production to remain in conformity ~~of series production~~. Changes in the ~~product~~ toy design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is ~~stated~~ declared 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.~~

⁴² IE: manufacturers should be required to provide technical documentation by electronic means or alternatively be required to supply technical file with their products.

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

5. Manufacturers shall ensure that their toys bear a type, batch or serial or model number or any other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.
- *6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible ~~the size or nature of the toy does not allow it~~, on its packaging or in a document accompanying the toy. The address must indicate a single point at which the manufacturer can be contacted.
- 6a. Manufacturers shall ensure that the toy is accompanied by instructions and safety information in a language or languages which can be easily understood by consumers and other end-users, as determined by the Member State concerned.
- *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 ~~or~~ withdraw it ~~from the market and~~ or recall it ~~from end-users~~, if appropriate. They Furthermore, where the toy presents a risk, manufactures shall immediately inform the competent national authorities of the Member States in which ~~where~~ they made the toy available to ~~this~~ that effect, giving details, in particular, of the non-compliance and of any ~~the~~ corrective measures taken.
- *8. Manufacturers shall, further to a reasoned ~~on~~ request from the competent national authorities, provide ~~them~~ it with all the information and documentation necessary to demonstrate the conformity of the toy, in a language which can be easily understood by the authority. They shall cooperate with ~~those~~ that authorities, at ~~the~~ its request ~~of the latter~~, on any action ~~to avoid~~ taken to eliminate the risks posed by toys which they have placed on the market.

**Article 4*

Authorised representatives

1. ~~A m~~Manufacturers may by a written mandate appoint, ~~by a written mandate, any natural or legal person established within the Community, ("the an authorised representative"), to act on their behalf for specified tasks with regard to the obligations of manufacturers under this Directive.~~
2. The obligations ~~under~~ in Article 3 (1) and the drawing up of technical documentation may shall not form part of the authorised representative's mandate.
3. ~~Where a manufacturer has appointed an~~ An authorised representative, shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to ~~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 after the toy has been placed on the market;
 - (b) ~~on~~ further to a reasoned request from ~~the a~~ competent national authorities, provide ~~them that authority~~ with all the information and documentation necessary to demonstrate the conformity of the toy;
 - (c) cooperate with the competent national authorities, at their request ~~of the latter~~, on any action ~~to avoid~~ taken to eliminate the risks posed by toys covered by their mandate.

*Article 5

Obligations of Importers

1. ~~When placing a toy on the market, importers shall act with due care in relation to the applicable requirements.~~ **Importers shall place only compliant toys on the Community market.**⁴³

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

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

Where an importer ~~discovers~~ considers or has reason to believe that the toy is not in conformity with the essential safety requirements set out in Article 9 and in Annex II, he ~~may~~ shall not place the toy on the market ~~only after~~ until it has been brought into conformity ~~with those requirements~~. Furthermore, where the toy presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

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

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

⁴³ UK: Reservation on this requirement.

4. Importers shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 9 and in Annex II.
- 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, of non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring.
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 harmonisation legislation applicable shall immediately take the ~~necessary~~ corrective measures necessary to bring that toy into conformity, ~~to or~~ withdraw it ~~from the market and or~~ recall it ~~from end-users~~, if appropriate. ~~They~~ Furthermore, where the toy presents a risk, importers shall immediately inform the competent national authorities of the Member States where in which they made the toy available to this that effect, giving details, in particular, of the non-compliance and of the any corrective measures taken.
6. Importers shall, for a period of [10 years] after the toy has been placed on the market, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
- *7. Importers shall, ~~on~~ further to a reasoned request from ~~the~~ a competent national authorities, provide ~~them~~ 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 ~~those that~~ authorities, at ~~the~~ its request ~~of the latter~~, on any action ~~to avoid~~ taken to eliminate the risks posed by toys which they have placed on the market.

Article 6
Obligations of distributors

1. When making a toy available on the market, distributors shall act with due care in relation to the ~~applicable~~ requirements applicable.
- *2. Before making a toy available on the market distributors shall verify that the toy bears the required conformity marking(s) or markings, that it ~~and~~ 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 toy is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 3 (5) and (6) and Article 5 (3) respectively.

Where a distributor ~~discovers~~ considers or has reason to believe that a toy is not in conformity with the essential safety requirements set out in Article 9 and in Annex II, he ~~may~~ shall not make the toy available on the market ~~only after~~ until it has been brought into conformity ~~with those requirements~~. Furthermore, where the toy presents a risk, the distributor shall inform the manufacturer or the importer to this that effect as well as the market surveillance authorities.

3. ~~A distributor~~ Distributors shall ensure that, while a toy is under ~~his~~ their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 9 and in Annex II.
- *4. Distributors who consider or have reason to believe that a toy which they have made available on the market is not in conformity with the ~~applicable~~ Community harmonisation legislation applicable shall ~~take the necessary~~ make sure that the corrective measures necessary to bring that toy into conformity, or withdraw it or recall it, from the market and recall it from end-users, if appropriate, are taken. Furthermore, where the toy presents a risk, distributors ~~They~~ shall immediately inform the competent national authorities of the Member States ~~where in which~~ they made the toy available to ~~this~~ that effect, giving details, in particular, of the non-compliance and of ~~the~~ any corrective measures taken.

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

**Article 7*

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor ~~who places a toy on the market under his name or trademark~~ shall be considered a manufacturer for the purposes of this Directive and he shall 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.~~

**Article 8*

Identification of economic operators

Economic operators shall ~~be able, on request, to~~ identify the following **to the market surveillance authorities, for a period of 10 years after the toy has been placed on the market**⁴⁴.

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

The economic operators shall be able to present this information for a period of [10 years]⁴⁵
after the toy has been placed on the market, in the case of the manufacturer, and [10 years]
after they have been supplied with the toy, in the case of other economic operators.

~~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.~~

⁴⁴ HU: - propose 5 years after last placing on the market.

⁴⁵ IE, supported by NL, documentation should be available from first placing on the market and then 7 years after a toy has ceased production.

CHAPTER III

CONFORMITY OF THE TOY

Article 9

Essential safety requirements

1. Member States shall take all measures necessary to ensure that toys may not be placed on the market unless they comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2, and, as far as the particular safety requirements are concerned, in Annex II.
2. Toys 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~~ affixed⁴⁶ in accordance with Article 10(2) and the instructions for use which accompany ~~them~~ the toys 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.

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

⁴⁶ PT: Reservation on "affixed".

Article 10

Warnings

1. Where appropriate for safe use, warnings made for the purposes of Article 9 (2) shall specify appropriate user limitations, in accordance with Part A of Annex V.

As regards the categories of toys listed in Part B of Annex V, the warnings set out therein shall be used. Toys shall not bear one or more of these specific warnings, if they contradict the intended use of the toy, as determined by virtue of their function, dimension and characteristics.

2. The manufacturer shall mark the warnings⁴⁷ in a ~~visible~~, clearly **visible and easily** 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 **clearly** visible, **easily** legible and conspicuously displayed at the point of sale.

3. In accordance with Article 3(6a), Member States may require warnings and safety instructions, or some of them, in a language or languages which can be easily understood by consumers in their territory to be presented in their own official language or languages when the toys are placed on the market in their territory.

⁴⁷ SE, supported by DE, DK, FI, NL, MT, RO: need to define form and minimum size of the letters used in warnings.

SE (TOY 17): amend paragraph 2 as follows

"The manufacturer shall mark the warnings in an accurate, clearly visible, and easily ~~clearly~~ legible ~~and accurate~~ manner, so that they are conspicuously displayed on the toy, on an affixed label or on the consumer 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." COM: current wording attends to these preoccupations.

Warnings that are necessary for a choice of toy that is safe in connection with the intended use or user, shall appear on the consumer packaging or on the Internet web page or otherwise attached to the toy in such a way that the consumer can read it before purchase.

Warning of hazards that occur every time the toy is used or of unsafe behaviour that is likely to occur after some time of use, shall be permanently marked on the toy.

Article 11

Free movement

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

Article 12

Presumption of conformity

Toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in Article 9 and in Annex II.

Article 13

Formal objection ~~against~~ to harmonised standards

- *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, having consulted the relevant European standardisation bodies, deliver its opinion without delay.
2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.
3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

**Article 14*

EC declaration of conformity⁴⁸

1. The EC declaration of conformity shall state that the fulfilment of the requirements specified in Article 9 and in Annex II has been demonstrated.
2. The EC declaration of conformity shall as a minimum contain the elements specified in **Annex III the relevant modules of Decision N°768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC⁴⁹** and shall continuously be updated. The EC declaration of conformity shall have the model structure set out in Annex III. It shall be translated into the language or languages required by the Member State in which market the toy is placed or made available.
3. By drawing up the EC declaration of conformity, the manufacturer shall assume the responsibility for the compliance of the toy.

**Article 15*

General principles of the CE marking

1. Toys made available on the market shall bear the CE marking.
2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008 of the European Parliament and of the Council, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ~~may only be affixed by the manufacturer or his authorised representative.~~

~~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.~~

⁴⁸ IE: Add a provision that economic operators should be have the power to access technical information that they are asked to provide to the Member State Authorities.

⁴⁹ IE: Opposes this change.

3. Member States shall presume that toys bearing the CE marking comply with the provisions of this Directive.
- ~~4. The CE marking shall be the only marking which attests conformity of the toy with the applicable requirements.~~
- ~~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.~~
- ~~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.~~
7. Toys not bearing a CE-marking ~~and~~ 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.

**Article 16*

Rules and conditions for the affixing of the CE marking

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

[Deleted figure.]

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

If the CE-marking is not visible from outside the packaging, if any, it shall at least be affixed on the packaging.

- ~~*2. If the CE marking is reduced or enlarged the proportions given in the graduated drawing in paragraph 1 must be respected.~~
- ~~*3. Where specific legislation does not impose specific dimensions, the CE marking shall have a height of at least 5 mm.~~
- ~~*4. The CE marking shall be marked visibly, legibly and indelibly either on the toy, on an affixed label, or on the packaging.~~
- ~~*5. In the case of small toys and toys consisting of small parts the CE marking may alternatively be affixed on a label or an accompanying leaflet. If that is not technically possible in the case of toys sold in counter displays, the information shall be affixed to the counter display.~~
- ~~*6. If the CE marking is not visible from outside the packaging, if any, it shall at least be affixed on the packaging.~~
- *7. The CE marking shall be affixed before the toy is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

CHAPTER IV

CONFORMITY ASSESSMENT

Article 17

Safety assessments

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

Article 18

The applicable conformity assessment procedures

1. Before placing the toys on the market, manufacturers shall use the conformity assessment procedures identified in paragraphs 2 and 3 to demonstrate that the toys comply with the essential safety requirements set out in Article 9 and Annex II.
2. If the manufacturer has applied the harmonised standards the reference number of which has been published in the *Official Journal of the European Union* covering all the relevant safety requirements for the toy, the manufacturer shall use the procedure of internal production control as set out in Module A⁵⁰ of Annex I to Decision [~~---~~ **768/2008/EC**].
3. The toy shall be submitted for EC-type-examination as referred to in Article 19 combined with the conformity to type procedure set out in Module C of Annex I to Decision [~~---~~ **768/2008/EC**] in the following cases:
 - (a) when harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, do not exist;
 - (b) when standards as referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;

⁵⁰ DE: Requests use of module A2. See TOY-39 and TOY-40. GR, NL, RO, SE: Positive scrutiny reservation. DK, MT, PL, PT, FI, UK: Point to the work needed to define module A2 and therefore reserve their position.

- (c) when standards as referred to in point (a) or any of them have been published with a restriction.;
- (d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

Article 19

EC type-examination

1. Application for EC type-examination, performance of that examination and issue of the EC type-examination certificate shall be carried out in accordance with the procedures set out in Module B laid down in Annex I II to Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [...].

The EC type-examination shall be carried out in the manner specified in paragraph 2, second indent, of Module B (combination of production type and design type).

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

2. The application for an EC type-examination shall include a description of the toy and an indication of the place of manufacture, including the address.
3. When a conformity assessment body notified under Article 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.

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

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.

It shall be withdrawn if the toy fails to comply with the essential safety requirements set out in Article 9 and Annex II.

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

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

Article 20

Technical documentation⁵¹

1. The technical documentation referred to in Article 3 (2) shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the relevant essential requirements set out in Article 9 and in Annex II and, in particular, it shall contain the documents listed in Annex IV.
2. The technical documentation shall be drafted in one of the official languages of the Community, subject to the requirement laid down in Article 19 (5).

⁵¹ RO: - The title “technical documentation” is used in art 20. for the set of documents that is set up by a manufacturer for a market surveillance body and in annex IV for the set of documents necessary for the conformity assessment. The two sets of documents differ in content, as one includes the other. RO suggests to maintain the title „technical documentation” only for the set of documents as mentioned in module A and which accompany the request for conformity assessment according to module B and to use another title for the set of documents that have to be made available to the control bodies. A possibility might be “product file”. (art.20) (TOY-15)

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

When a market surveillance authority requests the technical documentation or a translation of parts 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.

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.

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⁵² BE: Add "As long as this test has not been performed and the compliance verified, the market surveillance authority may presume that the toy does not comply with the relevant essential requirements set out in Article 9 and in Annex II, and may act accordingly". IE: support.

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 21

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under article 19 of this Directive.

~~Bodies which were notified according to Directive 88/378/EEC shall be presumed notified for the purposes of this Directive.~~

**Article 22*

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of this Directive and for the monitoring of notified bodies, including compliance with the provisions of Article 27.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by ~~their~~ a national accreditation ~~bodies~~ body within the meaning of and in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [...].
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~~ 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 from its activities.
- 3a. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

**Article 23*

Requirements relating to notifying authorities

- (1) ~~The notifying authority shall meet the requirements set out in paragraphs 2 to 7.~~
- (2) ~~The~~ A notifying authority shall be established in such a way that no conflicts of interest with conformity assessment bodies occurs.
- (3) ~~The~~ A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities
- (4) ~~The~~ A notifying authority shall be organised in such a way that each decision relating to notification of the conformity assessment body is taken by competent persons different from those who carried out the assessment;
- (5) ~~The~~ A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.
- (6) ~~The~~ A notifying authority shall ~~have adequate arrangements to~~ safeguard the confidentiality of the information it obtains ~~obtained~~.
- (7) ~~The~~ A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

**Article 24*

Information obligation for the notifying authorities

Member States shall inform the Commission ~~and the other Member States~~ of their ~~national~~ procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto ~~to that information~~.

The Commission shall make that information publicly available.

Article 25

Requirements ~~for~~ relating to notified bodies

1. For the purposes of notification under this Directive, a conformity assessment body shall meet the requirements set out in paragraphs 2 to 11.
2. ~~The~~ A conformity assessment body shall be established under national law and have legal personality.
- *3. ~~The~~ A conformity assessment body shall be a third-party body independent from the organisation or the ~~product~~ toy it assesses.

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

- *4. ~~The~~ A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the ~~products~~ toys which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed toys that are necessary for the operations of the conformity assessment body or the use of such toys for personal purposes.

~~Not~~ A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall ~~they become~~ not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those ~~products~~ toys, nor represent the parties engaged in those activities.

~~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.~~

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.

~~The e~~Conformity assessment body bodies shall ensure that ~~the~~ their activities of ~~its~~ their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of ~~its~~ their conformity assessment activities.

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

- *6. ~~The A~~ a conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to ~~such a body~~ it by the provisions of Article 19 and ~~for~~ 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 for each kind or category of ~~products~~ toys for which it is notified, ~~the a~~ a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and 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 technology of the toy 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.

7. The personnel responsible for carrying out the conformity assessment activities shall have the following:
 - (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;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out ~~such operations~~ those assessments;
 - ~~*(c)~~ appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of the relevant Community harmonisation legislation and ~~relevant of its~~ implementing regulations;
 - (d) the ability required to draw up the certificates, records and reports ~~to demonstrate~~ demonstrating that ~~the~~ assessments have been carried out.
8. The impartiality of the conformity assessment ~~body~~ bodies, ~~its~~ their top level of the management and assessment personnel shall be guaranteed.

The remuneration of the ~~conformity assessment body's~~ top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of ~~such~~ those assessments.
9. ~~The~~ a Conformity assessment ~~body~~ bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of ~~the~~ a conformity assessment body shall ~~be bound to~~ observe professional secrecy with regard to all information ~~gained~~ obtained in carrying out ~~its~~ their tasks under Article 19 or any provision of national law giving effect to it, except in relation to the competent ~~administrative~~ authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

- *11. ~~The e~~Conformity assessment ~~body~~ bodies shall participate in, or ensure that ~~its~~ their assessment personnel ~~is~~ are 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 decisions and documents produced as a work result of that group.

**Article 26*

Presumption of conformity

Where a conformity assessment body ~~can~~ demonstrates its conformity with the criteria laid down in the 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.

**Article 26a*

Formal objection against harmonised standards

Where a Member State or the Commission has a formal objection to the harmonised standards referred to in Article 25, the provisions of Article 13 shall be apply.

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DK: add **New Article 26b**, *Precautionary principle*

"If there is no applicable standard for the type of toy being assessed or if the standard do not cover all risks of the toy, then it is the obligation of the conformity assessment body to use the precautionary principle when assessing the toy or the part of the toy that is not covered by the requirements in the harmonised standards."

**Article 27*

Subsidiaries of and subcontracting by ~~of~~ notified bodies

1. Where ~~the conformity assessment~~ a notified body subcontracts specific tasks connected with the conformity ~~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, and shall inform the notifying authority accordingly.
2. ~~The conformity assessment~~ Notified bodied ~~body~~ shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
4. ~~The conformity assessment~~ Notified bodies ~~body~~ shall keep at the disposal of the ~~national notifying authority~~ authorities the relevant documents concerning the assessment of the ~~subcontractor's or subsidiary's~~ qualifications of the subcontractor or the subsidiary and the work carried out by ~~the subcontractor or the subsidiary~~ them under Article 19.

Article 28

Application for notification

1. A conformity assessment body shall submit an application for notification under this Directive to the notifying authority of the Member State in which it is established.
2. The application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module ~~or modules~~ and the ~~product or products~~ toy or toys for which the body claims to be competent, as well as by an accreditation certificate, where ~~it~~ one exists, ~~delivered~~ issued by a national accreditation body ~~within the meaning of Regulation (EC) No [...]~~, attesting that the conformity assessment body ~~meets~~ fulfils the requirements laid down in Article 25 of this Directive.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 25.

Article 29

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 25.
2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module ~~or modules~~ and ~~product or products~~ toy or toys concerned and the relevant attestation of competence.
- *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~~ 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.
- *5. The body concerned may perform the activities of a notified body only where no objections ~~have been~~ are raised by the Commission and or the other Member States within ~~two months following that~~ 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 as a notified body for the purpose of this Directive.
6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 30

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.
It shall assign a single such number even where the body is notified under several Community acts.
2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been ~~assigned~~ allocated to them and the activities for which they have been notified.

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

Article 31

Changes to the notification

- *1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements ~~set out~~ laid down in Article 25, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the 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 ~~thereof~~ accordingly.
2. In the ~~case~~ event of ~~withdrawal~~, restriction, ~~or~~ suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State ~~concerned~~ shall take ~~the~~ appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities ~~on~~ at their request.

Article 32

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts or doubt is brought to its attention ~~as to~~ regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities ~~placed on it~~ to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all information ~~related~~ relating to the basis for the notification or the maintenance of the competence of the body concerned.
- *3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State ~~thereof~~ accordingly and request it to take the necessary corrective measures, including de-notification, if necessary.

Article 33

Operational obligations for notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 19.
- *2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators, ~~in particular taking into consideration the size of companies and the relative complexity of the technology used by the toys.~~
Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the toy with the provisions of this Directive.

3. Where a notified body finds that the requirements laid down in Article 9 and in Annex II or corresponding harmonised standards or technical specifications have not been met by the manufacturer, it shall require ~~the~~ that manufacturer to take appropriate corrective measures and it shall not ~~deliver~~ issue the EC type-examination certificate as referred to in Article 19(4).
4. Where, in the course of the monitoring of conformity following the ~~delivery~~ issue of a certificate, a notified body finds that a toy no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 34

Information obligation for notified bodies

1. Notified bodies shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of EC type-examination certificates;
 - (b) any circumstances affecting the scope of and conditions for notification;
 - *(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - (d) on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting.
2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities ~~and~~ covering the same ~~products~~ toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35

Exchange of experience

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

**Article 36*

Coordination of notified bodies

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

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

CHAPTER VI

MARKET SURVEILLANCE

**Article 37*

General obligation to organise market surveillance

Member States shall organise and perform surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008 of the European Parliament and of the Council, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ~~6, 8 and 9 of Directive 2001/95/EC~~ of toys placed on the market. In addition to those provisions, Articles ~~38, 39 and 40~~ of this Directive shall apply.

*~~*Article 38~~*

~~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.~~

**Article 39*

Instructions to the notified body

- 0a. 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.
1. If the market surveillance authority finds that a particular toy is not in conformity with the essential safety requirements set out in Article 9 and Annex II, it shall, where appropriate, instruct the notified body to withdraw the EC type-examination certificate in respect of such ~~products~~ toys.
2. Where necessary, and in particular in cases specified in the second subparagraph of Article 19 (4), the market surveillance authority shall instruct the notified body to review the EC type-examination certificate.

*~~*Article 40~~*

~~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.~~

CHAPTER VII

SAFEGUARD PROCEDURES

Article 41

Safeguard clause

Procedure to deal with toys presenting a risk at national level

- *1. Where the market surveillance authorities of one Member State have taken action ~~referred~~ pursuant to in Article 12 of Directive 2001/95/EC 20 of Regulation (EC) No 765/2008 of the European Parliament and of the Council, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 or where they have sufficient reason to believe that a toy covered by this Directive presents a risk ~~for~~ to the health or safety of persons they shall, ~~together with the relevant economic operators, perform~~ carry out an evaluation in relation to the toy concerned covering all the requirements laid down ~~by~~ 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 ~~by~~ in this Directive, they shall without delay 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 to recall it within ~~such a~~ 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... shall apply to the measures referred in the second subparagraph.

2. Where the market surveillance authorities consider that the non-compliance is not ~~limited~~ restricted to ~~the~~ their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

- *3. The economic operator shall ensure that ~~any~~ all appropriate corrective actions ~~are~~ is taken in respect of all the toys concerned ~~which~~ that it he has made available on the market throughout the Community.
4. Where the relevant economic operator ~~does not take adequate corrective actions,~~ 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's~~ being made available on their national markets, ~~or~~ to withdraw the toy from that market or to recall it.
- They shall inform the Commission and the other Member States, without delay, of such measures.
- *5. The information referred to in paragraph 4 shall ~~provide~~ include all available details, in particular ~~as regards the necessary~~ 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 ~~of the following~~:
- (a) failure of the toy to meet the requirements related to the health or safety of persons or;
 - * (b) shortcomings in the harmonised standards referred to in Article 12 ~~(1)~~ as conferring a presumption of conformity.
6. Member States other than the Member State ~~which initiated~~ initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the toy concerned ~~at their disposal~~, and, in the event of disagreement with the notified national measure, of their objections.
7. Where, within three months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State ~~in relation to the toy concerned, the~~ that measure shall be deemed justified.

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

**Article 42*

Community safeguard procedure

1. Where, on completion of the procedure set out in Article 41 (3) and (4), objections are raised against a ~~national measure of taken by~~ a Member State or where the Commission considers ~~the~~ a national measure to be contrary to Community legislation the Commission shall without delay enter into consultation with the Member States and the relevant economic operator(s) or operators and shall ~~proceed to the evaluation of~~ evaluate the national measure.

On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not ~~take a decision, indicating whether the measure is justified or not.~~

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

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

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

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~~ shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay.

**Article 43*

~~RAPEX notifications~~ Exchange of information - Community Rapid Information System

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 22 of Regulation (EC) No 765/2008 of the European Parliament and of the Council, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 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:

- (a) the Community Rapid Information Exchange ~~RAPEX~~ notification indicates that the notification of the measure is also required by this Directive;
- (b) the supporting evidence referred to in Article 41 (5) is enclosed with the Community Rapid Information Exchange ~~RAPEX~~ notification.

**Article 44*

Formal non-compliance

1. Without prejudice to Article 41, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
 - (a) the conformity marking has been affixed in violation of Article 15 or Article 16,
 - (b) the conformity marking has not been affixed;
 - (c) the EC declaration of conformity has not been drawn up;
 - (d) the EC declaration of conformity has not been drawn up correctly;
 - (e) technical documentation is either not available or not complete.
2. Where the non-compliance referred to in paragraph 1 ~~persists~~ continues, the Member State concerned shall take all appropriate measures to restrict or prohibit the ~~making toy's being made~~ made available on the market ~~of the toy~~ or ensure that it is recalled or withdrawn from the market.

CHAPTER VIII

COMMITTEE PROCEDURES

**Article 45*

Amendments and implementing measures

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~~ Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 46 (2).

2. The Commission may decide upon the use in toys of substances or ~~preparations~~ mixtures⁵⁴ classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3⁵⁵, under ~~Annex I to Directive 67/548/EEC~~ Part 3 of Annex VI to Regulation (EC) No .../... of the European Parliament and of the Council of ... [on classification, labelling and packaging of substances and mixtures] and amend Appendix A to Annex II accordingly.⁵⁶

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).

⁵⁴ DK: delete "or mixtures".

⁵⁵ DK: Replace "category 1, 2 and 3" by "category 1A, 1B and 2".

⁵⁶ DK: Add "The Commission may also decide upon the use in toys of other substances that fulfil the criteria for being hazardous according to Regulation (EC) No. ... or give raise to concern, if justification is provided demonstrating the need for such action at Community level."

Article 46

Committee

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

CHAPTER IX

SPECIFIC ADMINISTRATIVE PROVISIONS

Article 47

Reporting

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.

Article 48

Transparency and confidentiality

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

Article 49

Motivation of measures

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

Such measures shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits applying to such remedies.

Article 50

Penalties

Member States shall lay down ~~the~~ rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements ~~to~~ of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of this Directive.

The Member States shall notify the Commission of those provisions ~~to the Commission~~ by the date specified in Article 53 at the latest and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER X

FINAL AND TRANSITIONAL PROVISIONS

Article 51

Application of Directives 85/374/EEC and 2001/95/EC

1. This Directive is without prejudice to the application of Directive 85/374/EEC.
- *2. Directive 2001/95/EC shall apply to toys in accordance with Article 1(2) thereof. ~~The applicable Articles of Directive 2001/95/EC are those mentioned in Articles 37, 43 and 48 of this Directive as well as Articles 10, 11 and 13 of Directive 2001/95/EC.~~

Article 52

Transitional period

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]**⁵⁷ after this Directive entered into force.

Article 53

Transposition

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by **[...]** at the latest. They shall forthwith inform the Commission thereof.

They shall apply those provisions with effect from [...]

⁵⁷ **DK:** Should different transitional periods be used for different requirements?

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

Article 54

Repeal

Directive 88/378/EEC is repealed from the date set out in the second paragraph of Article 53. References to the repealed Directive shall be construed as references to this Directive.

Article 55

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 56

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

LIST OF PRODUCTS THAT, IN PARTICULAR, ARE NOT CONSIDERED AS TOYS WITHIN THE MEANING OF THIS DIRECTIVE (ARTICLE 2 (1))

1. Decorative objects for festivities and celebrations;
2. Products for adult collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above. Examples of this category are:
 - (a) detailed and faithful scale models,
 - (b) kits for the assembly of detailed scale models,
 - (c) folk dolls and decorative dolls and other similar articles,
 - (d) historical replicas of toys,
 - (e) reproductions of real fire arms;
3. Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg;
4. Bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark;
- ~~4a.~~ Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;
5. Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or on the pavement of these.
6. Aquatic equipment intended to be used in deep water and swimming learning devices for children, such as swim seats and swimming aids;
7. Puzzles with more than 500 pieces;

8. Guns and pistols using compressed gas, with the exception of water guns, and bows for archery over 120 cm long;
9. Fireworks, including percussion caps which are not specifically designed for toys;
10. Products and games using sharp-pointed missiles, such as sets of darts with metallic points;
11. Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision;

~~“Functional product” means a product which performs and is used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of such a product, appliance or installation.~~
12. Products intended for use for educational purposes in schools and in other pedagogical framework under the surveillance of an adult instructor, such as science equipment;
13. Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels;
14. Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CD;
15. Babies' soothers;
16. Child-appealing luminaires;
17. Electrical transformers for toys.
18. Fashion accessories for children, including jewellery, which are not for use in play.

ANNEX II
PARTICULAR SAFETY REQUIREMENTS

I. PHYSICAL AND MECHANICAL PROPERTIES

1. Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.
2. Accessible edges, protrusions, cords, cables and fastenings on toys must be so designed and constructed⁵⁸ that the risks of physical injury from contact with them are reduced as far as possible.
3. Toys must be so designed and constructed as to **not present any risk or only the minimum risks inherent with the toy's use which could be caused by the movement of their parts** ~~minimize the risk of physical injury which could be caused by the movement of their parts~~ **minimum risks inherent with the toy's use which could be caused by the movement of their parts, considered to be acceptable and consistent with a high level of protection of the safety and health of the users.**

⁵⁸ RO: Clarify whether "constructed" is not the same as "manufactured".

4. **a)** Toys and their parts must not present risk of ~~asphyxiation caused, in particular, by strangulation or suffocation.~~
- b)** Toys and their parts must not present risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.
- c)** Toys and their parts must be of such dimensions as not to present risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
- ~~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.~~
- d)** Toys, which, by virtue of their function, dimension or characteristics, are clearly⁵⁹ 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/or⁶⁰ inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.
- e)** The packaging in which toys are contained for retail sale must not present risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.
- f)** 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.

⁵⁹ SE: Delete "clearly".

⁶⁰ SE: Reinsert "and".

g) Toy packaging, as referred to in 4e and 4f, which is spherical, egg-shaped or ellipsoidal and any detachable parts of this, or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, shall be prohibited.⁶¹

5. ~~Toys intended for use in shallow water which are capable of carrying or supporting a child on the water~~ **Aquatic toys** 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.

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

7. Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy 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.

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

~~"Design speed" means representative potential operating speed that is determined by the design and correlation of the physical features.~~

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

⁶¹ SE: Add "Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in 4c and 4d." or explain in a recital that this requirement must be met.

9. Toys must be so constructed as to ensure that:
- (a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched;
 - (b) liquids and gases contained within toys do not reach temperatures or pressures which are such that their escape from a toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.
10. Toys which are designed to emit a sound should be so designed and constructed so that the sound from them is not able to impair children's hearing.
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.
In particular, any surface thereof accessible for one or more children to play on shall be designed to bear their weight.

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II. FLAMMABILITY

1. Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:
- (a) they do not burn if directly exposed to a flame or spark or other potential seat of fire;
 - (b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);
 - (c) if they do ignite, they burn slowly and present a low rate of spread of the flame;

⁶² HU: particular safety requirements for magnetic toys and hazards arising from them should be defined (toys with magnets should have such mechanical properties that the magnets should not be detached during life time of toy) and required warnings should be included in Annex V.

HU: add new paragraph: "Magnetic toys must be so designed and constructed as to prevent their magnetic parts being swallowed or inhaled" or "Magnetic toys and their parts must not present risk, in particular, by strangulation or suffocation." (TOY 7)

- (d) irrespective of the toy's chemical composition, they are ~~treated~~ **designed** mechanically so as to delay the combustion process
 - (e) Such combustible materials must not constitute a risk of ignition for other materials used in the toy.
2. Toys which, for reasons essential to their functioning, contain ~~dangerous~~ substances or ~~preparations~~ **mixtures that are dangerous according to the classification criteria laid down in Appendix B to this Annex**⁶³ ~~as defined in Council Directive 67/548/EEC~~, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or ~~preparations~~ **mixtures** which may become flammable due to the loss of non-flammable volatile components.
 3. Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in the first subparagraph of Article 9(2).
 4. Toys and, in particular, chemical games and toys, must not contain as such substances or ~~preparations~~ **mixtures**:
 - (a) which, when mixed, may explode:- through chemical reaction, or through heating,- when mixed with oxidizing substances;
 - (b) which contain volatile components which are flammable in air and liable to form flammable or explosive vapour/air mixture.

⁶³ **Please note that the text in bold underline together with Apeendix B should be equivalent to the bold underlined text used in document 13066/08.**

III. CHEMICAL PROPERTIES

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~~ **mixtures** 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).
2. Toys shall comply with⁶⁴ relevant Community legislation relating to certain categories of products or to the prohibition of use of certain dangerous substances and ~~preparations~~ **mixtures**. Toys that are themselves substances or ~~preparations~~ **mixtures** must comply also with ~~Directives 67/548/EEC and 1999/45/EC~~ **Regulation (EC) No .../... of the European Parliament and of the Council of ... [on classification, labelling and packaging of substances and mixtures]** relating to the classification, packaging and labelling of dangerous substances and dangerous ~~preparations~~ **mixtures**.
3. Without prejudice to the application of the restrictions under the first sentence of point 2, the use in toys⁶⁵ **, in components of toys or micro structurally distinct parts of toys**⁶⁶, of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR)⁶⁷ according to ~~Directive 67/548/EEC~~ **Regulation (EC) No .../... of the European Parliament and of the Council of ... [on classification, labelling and packaging of substances and mixtures]** in individual concentrations equal to or greater than the relevant concentrations established for the classification of ~~preparations~~ **mixtures** containing the substances in accordance with the provisions of ~~Directive 1999/45/EC~~ **Regulation (EC) No .../... of the European Parliament and of the Council of ... [on classification, labelling and packaging of substances and mixtures]** 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.~~⁶⁸

⁶⁴ DK: add "the REACH-Regulation (Regulation (EC) No 1907/2006) and other" (TOY-45).

⁶⁵ DK. Delete "the use in toys". (TOY-45)

⁶⁶ DK: add "must not contain". (TOY-45)

⁶⁷ HU: suggests general ban of CMR substances with scientifically justified exceptions.

⁶⁸ HU: suggests inclusion in this point of substances having endocrine disrupting properties, PBT substances and other substances that need authorisation according to REACH.

4⁶⁹. Substances or ~~preparations~~ mixtures classified as CMR category 1 and 2⁷⁰ according to Directive 67/548/EEC Regulation (EC) No .../... of the European Parliament and of the Council of ... [on classification, labelling and packaging of substances and mixtures] may be used in toys in concentrations greater than those following from the provisions in Paragraph 3 provided that: ~~the following conditions are met~~

a) they are physically inaccessible to children and are not released in any form that could be accessible to children when the toy is used according to the provisions of Article 9 paragraph 2 or the following conditions are met:

or

b) a Decision as referred to in Article 45 (2) has been taken to allow the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A to this Annex.

This Decision may be taken if the following conditions are met:

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

~~4.2. ii)~~ there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives, and

~~4.3. iii)~~ the substance or mixture is ~~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~~ mixtures 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.

⁶⁹ DK: Suggests rewording of point 4. Most notably, add a new subparagraph that requires that "the manufacturer or the importer can demonstrate that the presence or the addition of a substance or a mixture are technically necessary for the production of the toy, and submits a request to the relevant Scientific Committee to evaluate if the use of such a substance or mixture is safe." (TOY-45).

⁷⁰ DK: Replace "category 1 and 2" by "category 1A, 1B and 2". (TOY-45)

5. Substances or ~~preparations~~ mixtures classified as CMR category 3 according to ~~Directive 67/548/EEC~~ Regulation (EC) No .../... of the European Parliament and of the Council of ... [on classification, labelling and packaging of substances and mixtures] may be used in toys if in concentrations greater than those following from the provisions in Paragraph 3 provided that:

a) they are physically inaccessible to children and are not released in any form that could be accessible to children when the toy is used according to the provisions of article 9 paragraph 2,

or

b) a Decision as referred to in Article 45 (2) has been taken to allow the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A to this Annex.

This Decision may be taken if the following conditions are met:

- i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, ~~and following a Decision as referred to in Article 45 (2)~~ and⁷¹
- ii) the substance or mixture is ~~provided that 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 mixtures 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.

⁷¹ GR: Replace "and following a Decision ...and;" by "and following a Decision as referred to in Article 45(2) has been taken and the substance and its permitted uses have been listed in Appendix .. to this Annex and;".(TOY-44).

5a. Without prejudice to points 3 and 4, nitrosamines and nitrosable substances are prohibited for use in toys which are intended to be placed in the mouth if the migration of the substances is equal to or higher than [0.05 mg/kg] for nitrosamines and [...] mg/kg for nitrosable substances.

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6. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements provided for in Directive 76/768/EEC.

7. Toys shall not contain the following allergenic fragrances⁷³:

- | | |
|--|------------------------------|
| (1) Alanroot (Inula helenium) | <u>CAS 97676-35-2</u> |
| (2) Allylisothiocyanate | <u>CAS 57-06-7</u> |
| (3) Benzyl cyanide | <u>CAS 140-29-4</u> |
| (4) 4 tert-Butylphenol | <u>CAS 98-54-4</u> |
| (5) Chenopodium oil | <u>CAS 8006-99-3</u> |
| (6) Cyclamen alcohol | <u>CAS 4756-19-8</u> |
| (7) Diethyl maleate | <u>CAS 141-05-9</u> |
| (8) Dihydrocoumarin | <u>CAS 119-84-6</u> |
| (9) 2,4-Dihydroxy-3-methylbenzaldehyde | <u>CAS 6248-20-0</u> |
| (10) 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) | <u>CAS 40607-48-5</u> |

⁷² DK: Add a new point "Substances that are classified with R48; "Danger of serious damage to health by prolonged exposure" 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." (TOY-45)

⁷³ DK: suggests a full ban on fragrances in toys. (TOY-45)

(11) 4,6-Dimethyl-8-tert-butylcoumarin	<u>CAS 17874-34-9</u>
(12) Dimethyl citraconate	<u>CAS 617-54-9</u>
(13) 7,11-Dimethyl-4,6,10-dodecatrien-3-one	<u>CAS 26651-96-7</u>
(14) 6,10-Dimethyl-3,5,9-undecatrien-2-one	<u>CAS 141-10-6</u>
(15) Diphenylamine	<u>CAS 122-39-4</u>
(16) Ethyl acrylate	<u>CAS 140-88-5</u>
(17) Fig leaf, fresh and preparations	<u>CAS 68916-52-9</u>
(18) trans-2-Heptenal	<u>CAS 18829-55-5</u>
(19) trans-2-Hexenal diethyl acetal	<u>CAS 67746-30-9</u>
(20) trans-2-Hexenal dimethyl acetal	<u>CAS 18318-83-7</u>
(21) Hydroabietyl alcohol	<u>CAS 13393-93-6</u>
(22) 4-Ethoxy-phenol	<u>CAS 622-62-8</u>
(23) 6-Isopropyl-2-decahydronaphthalenol	<u>CAS 34131-99-2</u>
(24) 7-Methoxycoumarin	<u>CAS 531-59-9</u>
(25) 4-Methoxyphenol	<u>CAS 150-76-5</u>
(26) 4-(p-Methoxyphenyl)-3-butene-2-one	<u>CAS 943-88-4</u>
(27) 1-(p-Methoxyphenyl)-1-penten-3-one	<u>CAS 104-27-8</u>
(28) Methyl trans-2-butenolate	<u>CAS 623-43-8</u>
(29) 6-Methylcoumarin	<u>CAS 92-48-8</u>
(30) 7-Methylcoumarin	<u>CAS 2445-83-2</u>
(31) 5-Methyl-2,3-hexanedione	<u>CAS 13706-86-0</u>
(32) Costus root oil (Saussurea lappa Clarke)	<u>CAS 8023-88-9</u>

(33) 7-Ethoxy-4-methylcoumarin	<u>CAS 87-05-8</u>
(34) Hexahydrocoumarin	<u>CAS 700-82-3</u>
(35) Peru balsam (Myroxylonpereirae Klotzsch)	<u>CAS 8007-00-9</u>
(36) 2-Pentylidene-cyclohexanone	<u>CAS 25677-40-1</u>
(37) 3,6,10-Trimethyl-3,5,9-undecatrien-2-one	<u>CAS 1117-41-5</u>
(38) Verbana oil (Lippia citriodora Kunth).	<u>CAS 8024-12-2</u>
<u>(39) Musk ambrette</u> <u>(4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)</u>	<u>CAS 83-66-9</u>
<u>(40) 4-Phenyl-3-buten-2-one</u>	<u>CAS 122-57-6</u>

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	<u>CAS 122-40-7</u>
(2) Amylcinnamyl alcohol	<u>CAS 101-85-9</u>
(3) Anisyl alcohol	
(4) Benzyl alcohol	<u>CAS 100-51-6</u>
(5) Benzyl benzoate	
(6) Benzyl cinnamate	
(7) Benzyl salicylate	<u>CAS 118-58-1</u>
(8) Cinnamal	
(9) Cinnamyl alcohol	<u>CAS 104-54-1</u>

<u>(9a) Cinnamal</u>	<u>CAS 104-55-2</u>
(10) Citral	<u>CAS 5392-40-5</u>
(11) Citronellol	
(12) Coumarin	<u>CAS 91-64-5</u>
(13) Eugenol	<u>CAS 97-53-0</u>
(14) Farnesol	
(15) Geraniol	<u>CAS 106-24-1</u>
(16) Hexyl cinnamaldehyde	
(17) Hydroxy-citronellal	<u>CAS 107-75-5</u>
(18) Hydroxy-methylpentylcyclohexenecarboxaldehyde	<u>CAS 31906-04-4</u>
(19) Isoeugenol	<u>CAS 97-54-1</u>
<u>(19a) Anisyl alcohol</u>	<u>CAS 105-13-5</u>
<u>(19b) Benzyl benzoate</u>	<u>CAS 120-51-4</u>
<u>(19c) Benzyl cinnamate</u>	<u>CAS 103-41-3</u>
<u>(19d) Citronellol</u>	<u>CAS 106-22-9</u>
<u>(19e) Farnesol</u>	<u>CAS 4602-84-0</u>
<u>(19f) Hexyl cinnamaldehyde</u>	<u>CAS 101-86-0</u>
(20) Lilial (referred to in the Cosmetics Directive in entry 83 as: 2-(4-tert-Butylbenzyl) propionaldehyde	<u>CAS 80-54-6</u>
(21) d-Limonene	<u>CAS 5989-27-5</u>
(22) Linalool	<u>CAS 78-70-6</u>

- (23) Methyl heptine carbonate **CAS 111-12-6**
- (24) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)
-3-buten-2-one **CAS 127-51-5**
- (25) Oakmoss extracts **CAS 90028-68-5**
- (26) Treemoss extracts **CAS 90028-67-4**

8. **Without prejudice to other provisions of Annexe II Part 3, the** ~~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:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	<u>mg/kg in scraped off toy material</u>
Aluminium	5625	1406	<u>70000</u>
Antimony	45	11.3	<u>560</u>
Arsenic	7.5	1.9	<u>93</u>
Barium	4500	1125	<u>56000</u>
Boron	1200	300	<u>15000</u>
Cadmium	3.8	0.9	<u>46</u>
Chromium (III)	37.5	9.4	<u>460</u>
Chromium (VI)	0.04	0.01	<u>0.5</u>
Cobalt	10.5	2.6	<u>130</u>
Copper	622.5	156	<u>7700</u>
Lead	27	6.8	<u>330</u>
Manganese	1200	300	<u>15000</u>
Mercury	15	3.8	<u>180</u>
Nickel	75	18.8	<u>930</u>
Selenium	37.5	9.4	<u>460</u>
Strontium	4500	1125	<u>56000</u>
Tin	15000	3750	<u>180000</u>
Organic tin	1.9	0.5	<u>23</u>
Zinc	3750	938	<u>46000</u>

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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).

⁷⁴ DK: Add Silver (TOY-45).

IV. ELECTRICAL PROPERTIES

1. Toys shall not be powered by electricity exceeding 24 volts direct current or equivalent alternative current and their accessible parts shall not exceed 24 volts direct current or equivalent alternative current.

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

2. Parts of toys which are connected to, or liable to come into contact with a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock.
3. Electric toys must be so designed and constructed as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.
4. Under foreseeable fault conditions, toys must provide protection against electrical hazards arising from an electrical power source.
5. Electric toys must provide adequate protection against fire hazards.
6. Electric toys must be designed and manufactured in such a way that electric, magnetic, and electromagnetic fields and other radiations generated by the equipment are limited to the extent necessary for its operation, and operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Community measures.
7. Toys which have an electronic control system shall be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to the failure in the system itself or due to an outside factor.
8. Toys must be so designed and constructed that they do not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation.
9. The electrical transformer for toys shall not be integral part of the toy.

V. HYGIENE

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. A toy intended for children under 36 months must be designed and manufactured in such a way that it can be cleaned. A Textile toys shall, to this aim, be washable, except if it contains a mechanism that may be damaged if soak washed for children under 36 months. The toy shall be washable and shall fulfil the safety requirements also after cleaning in accordance with the provisions of this paragraph and the manufacturer's instructions washing.

VI. RADIOACTIVITY

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

Appendix A

List of CMR substances evaluated by the Scientific Committee and their permitted uses in accordance with Annex II Part III Point 4

Appendix B

Criteria for classifying substances and mixtures as dangerous for the purposes of Annex II, Part II, Point 2 and Annex V, Point 4⁷⁵

As a result of the timing of the implementation of the Globally Harmonised System of Classification and Labelling of Chemicals in the European Union, there are three equivalent sets of criteria for classifying a substance or a mixture as dangerous for the purposes of Annex II, Part II, Point 2 and Annex V, Point 4.

1. Criterion to be applied from the date set out in the second paragraph of Article 53 until 30 November 2010:

The substance or mixture is dangerous as defined in Council Directive 67/548/EEC.

2. Criteria to be applied from 1 December 2010 until 31 May 2015:

Dangerous substances

The substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No ... of the European Parliament and of the Council of ... on Classification, Labelling and Packaging of Substances and Mixtures⁷⁶:

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

Dangerous mixtures

The mixture is dangerous as defined in Council Directive 67/548/EEC.

⁷⁵ DK: Suggests that the hazard concept shall be the extended to all hazard categories. (TOY-45)

⁷⁶ OJ L....

3) Criteria to be applied from 1 June 2015:

The substance or mixture fulfils the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No ... of the European Parliament and of the Council of ... on Classification, Labelling and Packaging of Substances and Mixtures⁷⁷:

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

⁷⁷

ANNEX III
EC DECLARATION OF CONFORMITY

1. No xxxxxx (unique identification of the toy(s))
- *2. Name and address of ~~(authorised representative of the)~~ manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
- *4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy.
5. The object of the declaration described above is in conformity with the relevant Community harmonisation legislation.....
6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
- *7. Where applicable the ~~The~~ notified body ... (name, number)... performed ... (description of intervention)... and issued the certificate:
8. Additional information:

Signed for and on behalf of:.....

(place and date of issue)

(name, function)(signature)

ANNEX IV
TECHNICAL DOCUMENTATION

The technical documentation referred to in Article 20 shall contain, in particular, so far as relevant for assessment:

- a) a detailed description of the design and manufacture, including a list of components and materials used in toys as well as the safety data sheets on chemicals used to be obtained from chemical suppliers;
- b) the safety assessment(s) carried out in accordance with Article 17;
- c) a description of the conformity assessment procedure followed;
- d) a copy of the EC declaration of conformity;
- e) the addresses of the places of manufacture and storage;
- f) copies of documents that the manufacturer has submitted to a notified body if involved;
- g) test reports and description of the means whereby the manufacturer ensures conformity of production with the harmonised standards if the manufacturer has followed the internal production control referred to in Article 18 (2).
- h) a copy of the EC type-examination certificate, a description of the means whereby the manufacturer ensures conformity of the production with the product-type as described in the EC type-examination certificate and copies of the documents that the manufacturer has submitted to the notified body, if the manufacturer has followed the EC type-examination and type conformity –declaration referred to in Articles 18 (3).
- i) ~~Colour image of the toy.~~

ANNEX V
WARNINGS
(Article 10)

PART A – GENERAL WARNINGS

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

**PART B – SPECIFIC WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE
TAKEN WHEN USING CERTAIN CATEGORIES OF TOYS**

**Toys shall not bear one or more of the specific warnings listed in annex V part B
contradicting their intended use, as determined by virtue of their function, dimension and
characteristics.**

1. Toys not intended for children under 36 months

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.

2. ~~Slides, suspended swings and rings, trapezes, ropes and similar toys attached to a crossbeam~~ **Activity toys**

~~Such~~ **Activity** toys **or their packaging** shall bear a marking “Warning: only for domestic use”.

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

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

3. **Functional toys**

~~“Functional toy” means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of such a product, appliance or installation.~~

Functional toys or their packaging shall bear the marking 'Warning: to be used under the direct supervision of an adult'.

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

4. **Toys containing inherently dangerous substances or ~~preparations~~ mixtures. Chemical toys**

Without prejudice to the application of the provisions laid down in **applicable** Community **directives law** on the classification, packaging and labelling of dangerous substances or **preparations mixtures**, the instructions for use of toys containing **substances or mixtures that are** inherently dangerous **substances or preparations according to the classification criteria laid down in Appendix B to Annex II**⁷⁸ shall bear a warning of the dangerous nature of these substances or **preparations mixtures** and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toys must be kept out of reach of ~~very young~~ children **under a certain age - to be specified.**

In addition to the instructions provided for in **the previous** subparagraph, chemical toys shall bear the following marking on their packaging:

‘Warning: Not suitable for children under (¹) years. For use under adult supervision

(¹) Age to be decided by the manufacturer.’

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

⁷⁸ **Please note that the text in bold underline together with Appendix B of Annex II should be equivalent to the bold underlined text used in document 13066/08.**

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

If these toys are offered for sale as toys they shall bear the following markings:

'Warning: protective equipment should be worn. Not to be used in traffic'.

Moreover, the instructions for use shall contain a reminder that the toy must be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user and third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

6. **Toys intended for use in water**

The toys intended for use in water defined in Section 1 (5) of Annex II shall contain the warning:

'Warning! Only to be used in water in which the child is within its depth and under adult supervision'.

~~(1) Age to be decided by the manufacturer.~~

7. **Toys in food**

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

“Adult supervision recommended”.
