



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Biotechnology and Food Supply Chain

Toy Safety Directive 2009/48/EC



An explanatory guidance document

Rev 1.9 CORR

Date: 10/02/2016

GUIDANCE DOCUMENT ON THE APPLICATION OF DIRECTIVE 2009/48/EC ON THE SAFETY OF TOYS

NOTES

1. These guidelines are intended to be a manual for all parties directly or indirectly affected by Directive 2009/48/EC, commonly referred to as the TSD (Toy Safety Directive). Readers' attention is drawn to the fact that this guide is intended only to facilitate the application of Directive 2009/48/EC and it is the relevant national transposition of the text of the directive which is legally binding. However, this document does represent a reference for ensuring consistent application of the directive by all stakeholders. The guidelines are intended to help ensure the free movement of toys in the Community territory by consensus amongst Member States' government experts and other parties concerned.

2. These guidelines have been prepared by the relevant services of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs of the European Commission in consultation with Member States, European industry, European standardisation bodies, European consumer organisations and Notified Bodies.

3. The Commission accepts no responsibility or liability whatsoever with regard to the information in this guide and aims at giving advice only.

This information is:

- of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
- sometimes refers to external information over which the Commission services have no control and for which the Commission assumes no responsibility;
- a living document which will be regularly updated and subject to review;
- no legal advice.

4. All references to the CE marking and EC declaration of conformity in this Guide relate only to Directive 2009/48/EC. To place toys on the market in the Community territory all other relevant legislation must be applied.

5. Further guidance, especially concerning specific type of products, can be found on the Commission's website: http://ec.europa.eu/growth/sectors/toys/safety/index_en.htm

INTRODUCTION

The technological developments in the toys market have raised new issues with respect to the safety of toys, and made consumers express increased preoccupations in this regard. The experience made with the operation of the "old" Directive 88/378/EEC on the safety of toys led to the conclusion that there was a need to update and complete the safety requirements, in particular in areas such as noise and chemicals in toys and choking hazards presented by toys in food. At the same time, market surveillance authorities highlighted the need to ensure a coherent approach, in particular in the areas of implementation of legislation and of market surveillance, towards a very different market compared to the market existing at the time when Directive 88/378/EEC entered into force in 1988. The new Directive 2009/48/EC, therefore, needed to be adapted to those developments. According to its Better Regulation initiative, the Commission had also engaged in simplifying the legislative framework and in increasing its quality and efficiency.

Directive 2009/48/EC is the first sectoral Directive to incorporate and be aligned to the general framework for the marketing of products in the EU, the so called "goods package".

(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 339/93 and 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 Council Decision 93/465/EEC).

The objective of these guidelines is to clarify certain matters and procedures referred to in Directive 2009/48/EC on the safety of toys. The guidelines should be used in conjunction with the Directive and with the European Commission's 'Blue Guide' on the implementation of EU product rules 2014: http://ec.europa.eu/growth/single-market/goods/index_en.htm

The objective of these guidelines is to provide guidance on how to ensure that the information in instructions and warnings is accessible and can be understood by the consumers, those who buy or play with the toy, so they can use the toy safely and appropriately. The new measures are meant to improve the warnings effectiveness in the prevention of accidents. Therefore, toys should be accompanied by clearly visible, easily legible and understandable warnings in order to reduce inherent risks of their use. Bear in mind that some toys that are safe for one category of children or under certain use conditions, might be hazardous for other children or under other use circumstances.

These guidelines are not only for the use of Member States' competent authorities, but also by the main economic operators concerned, such as manufacturers, their trade associations, bodies in charge of the preparation of standards as well as those entrusted with the conformity assessment procedures.

First and foremost, this document must ensure that, when correctly applied, the directive leads to the removal of obstacles and difficulties related to the free circulation (free movement) of goods within the European Community. It should be noted that the statements in these guidelines refer only to the application of Directive 2009/48/EC unless otherwise indicated. All parties concerned should be aware of other requirements,

which may also apply (see http://ec.europa.eu/growth/sectors/toys/safety/legislation/index_en.htm)

The images appearing in this document constitute examples intended to facilitate the comprehension. They do not presuppose the conformity of the represented products.

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CHANGES MADE COMPARED TO PREVIOUS VERSION

Rev 1.1	Picture modelling clay is an example of pliable material
Rev 1.1	Picture slime is an example of sticky material
Rev 1.2	Clarification on "not possible" and "size does not allow"
Rev 1.2	Explanation of "required documents"
Rev 1.2	Clarification on "manufactured by", "imported by", "distributed by" and "represented by"
Rev 1.2	Distinction between TSD and REACH
Rev 1.2	Traces of fragrances
Rev 1.3	Definition of commercial activity
Rev 1.3	Clarification on identification number
Rev 1.3	Correct references of titles of guides
Rev 1.3	Correct use of definitions (hazard)
Rev 1.3	Better wording for warnings
Rev 1.3	Clarifications for catalogue and online selling
Rev 1.3	Correction to explanation safety assessment
Rev 1.3	Correct use of definitions (hazard)
Rev 1.3	NB versus consultancy
Rev 1.3	Guidance document relationship GPSD and REG added
Rev 1.3	Text deleted on reporting (mentioned twice)
Rev 1.3	Guidance document relationship GPSD and REG added
Rev 1.3	Clarification mechanical requirements related to toys and food (4f)
Rev 1.3	Clarification mechanical requirements related to toys and food (4h)
Rev 1.3	Activity toy and applicable standards
Rev 1.3	Scope of FCM Regulation
Rev 1.3	Traces and Good Manufacturing Process

Rev 1.3	Examples and classification of toy material
Rev 1.3	Dimensions of the pictogram warning and clarification on warnings
Rev 1.3	Update list of standards
Rev 1.3	Guidance document relationship GPSD and REG added
Rev 1.4	Clarification to obligations of distributors
Rev 1.4	Clarification on economic operators
Rev 1.4	Clarification on the visibility requirement
Rev 1.4	Clarification to wording of DoC
Rev 1.4	Clarification on labelling for hygiene
Rev 1.5	Clarification to obligation of distributor
Rev 1.6	CE marking
Rev 1.6	Distributor explanation
Rev 1.7	Deletion of reference to harmonised standards under Directive 88/378
Rev 1.7	Clarification of interpretation of Article 2(1) second subparagraph
Rev 1.7	Clarification on amusement toys
Rev 1.7	Clarification on warnings in case of online selling
Rev 1.7	Clarification on CE marking on co-packs containing both toy and “non-toy” products
Rev 1.7	Clarification of interpretation of Annex I
Rev 1.7	Updated references to Union legislation
Rev 1.7	Updated references to harmonised standards
Rev 1.7	Updated reference to Cosmetics Regulation Deletion of reference to finger paints
Rev 1.7	Updated values for certain migration limits of chemicals
Rev 1.7	Updated references to harmonised standards
Rev 1.7	Updated references to harmonised standards

Rev 1.8	Updates of hyperlinks to websites (throughout the document)
Rev 1.8	Hyperlinks to the 'Blue Guide' added (throughout the document)
Rev 1.8	Update regarding exempted uses of nickel in Appendix A
Rev 1.8	Update regarding substances included in Appendix C
Rev 1.9	Updates of hyperlinks to websites (throughout the document)
Rev 1.9	Additional clarification on CE marking on co-packs containing both toy and "non-toy" products
Rev 1.9	Update due to full applicability of CLP Regulation (EC) No 1272/2008 since 1 June 2015
Rev 1.9	Update on the role of ECHA's Committee for Risk Assessment
Rev 1.9	Update due to full applicability of CLP Regulation (EC) No 1272/2008 since 1 June 2015
Rev 1.9	Update due to full applicability of CLP Regulation (EC) No 1272/2008 since 1 June 2015
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[Rev 1.9](#)

Updated references to harmonised standards

1. CHAPTER I GENERAL PROVISIONS

1.1. Article 1 Subject-matter

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

Article 1 defines the subject matter of the Directive. The subject matter is twofold. The Directive lays down rules on the safety of toys, on the one hand, and on their free movement in the Community, on the other hand. The subject matter stems from the two main objectives of the Directive which are, first, to ensure that toys used by children are safe and, secondly, to guarantee the smooth functioning of the internal market for toys.

1.2. Article 2 Scope

1.2.1. Article 2 (1), first subparagraph

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

Article 2 (1) defines the scope of the Directive, that is the products to which it applies.

The definition in Article 2 (1), first subparagraph, provides the following criteria for deciding whether a product falls under the scope of the Directive:

- Any product designed or intended
- whether or not exclusively
- for use in play
- by children under 14 years of age.

The wording of this provision is slightly different than the definition in Directive 88/378/EEC. However, the intention has only been to codify the practice under that Directive, and not to change the material scope of the Directive from what it has been up till now. The words “whether or not exclusively” have been added to the definition to indicate that the product does not have to be exclusively intended for playing purposes in order for it to be considered as a toy, but it can have other functions as well. For example, a key-ring with a teddy bear attached to it is considered as a toy, or a sleeping bag in the shape of a soft filled toy. It was not the intention to imply that the standard for trampolines for instance needs to take into account adults using the toy-trampoline. Other examples of products with double function (door decorations, soft filled animal shaped purses or backpacks, ...) can be found in Guidance document No 11 on the classification of toys intended for children under or above 36 months of age:

http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm



The main difficulty of this definition is the concept of “use in play” or “play value”. Virtually everything has play value for a child, but this does not make every object fall into the definition of toy. To be considered as a toy for the purpose of the Directive, the play value has to be introduced in an intended way by the manufacturer. The declaration by the manufacturer of the intended use is a criterion to be considered since it figures in the wording itself. However, the words “clearly intended” which were used in Directive 88/378/EEC have been replaced and changed by deleting the word “clearly”. Namely the **reasonably foreseeable use** is considered to prevail over the declaration of intended use by the manufacturer. If the manufacturer labels the products as not being toys, he has to be able to support this claim.

Guidance document No 4 gives further indicative criteria that need to be considered for the classification of a product as a toy:
http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

Furthermore, several guidance documents have been drafted for the classification of specific products: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

Note: the definition of a toy does not refer to public or domestic use. Therefore toys used at home or in public places (schools, nurseries, kindergarten) are covered by the TSD. However, the Directive does not apply to some products for public use fulfilling the definition of toys (see Article 2(2) below).

1.2.2. Article 2 (1), second subparagraph

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

Annex I enumerates products that could be confused with toys, even if they do not fulfil the definition of a toy above in Article 2 (1), first subparagraph. The list is a list of examples and not an exhaustive list in any way. If a product does not figure in the list, it does not necessarily imply that it is a toy; in that case it needs to be assessed against the general definition in Article 2 (1) first subparagraph. See point 10 for a detailed explanation of Annex I.

1.2.3. Article 2 (2)

This Directive shall not apply to the following toys:
(a) playground equipment intended for public use;

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

This paragraph contains a list of exclusions from the scope of the Directive. It enumerates in an exhaustive manner the products that fulfil the definition of toys in Article 2 (1) first subparagraph, but are excluded from the scope of the Directive for various reasons.

(a) Playground equipment for public use is covered by the Community legislation - General Product Safety Directive (GPSD). In particular EN 1176, EN 1177, EN 1069 and EN 14960 can be used to prove compliance, if applicable.

Note: playground equipment for domestic use, known as activity toys, is addressed by the TSD (and standard EN 71-8). Domestic use is the use of toys in the family or household.

(b) The amusement toys found at hypermarkets are examples of automatic playing machines. These products might be within the scope of the Machinery Directive or other applicable Union legislation. They are also subject to the Community legislation on electromagnetic compatibility. In addition, since these products are used by consumers, certain provisions of the Community legislation on the GPSD are applicable.



(c) Examples of toy vehicles equipped with combustion engines that are not intended for road use are within the scope of the Machinery Directive. They are also subject to the Community legislation on electromagnetic compatibility. In addition, since these products are used by consumers, certain provisions of the Community legislation on the GPSD are applicable.



(d) (e) Also toy steam engines and slings and catapults are excluded from the scope of the Directive.

1.3. Article 3 Definitions

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

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

Commercial activity is understood as providing goods in a business related context. The concept of making available on the market refers to legal and natural persons carrying out such activities on a regular basis. Hence, non-profit associations can be considered as carrying out commercial activities, if the regularity of such activities is demonstrated.

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

This Article contains a number of definitions essential to the understanding of the terms used in the enacting part of the Directive.

Points 1 – 16 are horizontal definitions that are based on model provisions of Decision 768/2008. Their meaning is defined in the 'Blue Guide' on the implementation of EU product rules 2014: http://ec.europa.eu/growth/single-market/goods/index_en.htm

Definitions in point 17 to 29 are definitions specific to the toys sector and to this Directive.

1.3.1. Functional product

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

This term is used in Annex I (list of products that are in particular not considered as toys) in point 12, which specifies that following products are not considered as toys: "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". The definition in Article 3 clarifies what is meant by these products, that is, they are products which perform and are used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of them.



1.3.2. Functional toy

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

The term "functional toy" is used in Annex V which foresees specific warnings and instructions for this category of toys (Annex V, part B, point 3).

Examples of this category of toys are sewing machines, coffee machines.



1.3.3. Aquatic toy

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

The term “aquatic toy” is used in Annex II in which a specific safety requirement is laid down for aquatic toys (Annex II, part I, point 5) and in Annex V which provides for a specific warning for them (Annex V, part B, point 6). Besides this specific requirement, aquatic toys also need to fulfil the other requirements of the TSD. This definition gives as the main criteria for classifying these products as toys the intended use in shallow water. Aquatic equipment intended to be used in deep water are not considered as toys. This definition is completed by a specific guidance document on aquatic toys: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

1.3.4. Design speed

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

The term “design speed” is used in the context of the safety requirement foreseen for electrically driven ride-on vehicles in Annex II, part I point 7. Design speed is the representative potential operating speed determined by the design of the toy.

1.3.5. Activity toys

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

The term “activity toy” is used in Annex II, part I, point 11 which lays down a specific safety requirement for activity toys. Annex V also foresees specific warnings for this category of toys (Annex V, part B, point 2). Besides this specific requirement, activity toys also need to fulfil the other requirements of the TSD. Only activity toys meant for domestic use fall under the TSD. This is in line with the exclusion of playground equipment intended for public use from the scope of the Directive (Article 2 (2)). The activity toys are intended for children to perform following activities: climbing, jumping, swinging, rocking, spinning, crawling or creeping, or combination of them. The activity takes place in or on the toy. The support structure of the activity toy remains stationary while this activity takes place.

Examples of activity toys can include swings, slides, carousels, climbing frames, trampolines, paddling pools and non-aquatic inflatable toys. In contrast, ride-on vehicles are not considered as activity toys.

1.3.6. Chemical toy

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

This term is used in Annex V, part B, point 4, which foresees specific warnings for chemical toys. These toys are intended for direct handling of chemical substances and mixtures. Examples of this product are chemistry sets, crystal growing 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 (see Annex V, part B, point 4).

1.3.7. Olfactory board game, Cosmetic kit and Gustative game

- 23) "olfactory board game" means a toy the purpose of which is to assist a child to learn to recognise different odours or flavours;
- 24) "cosmetic kit" means a toy the purpose of which is to assist a child to learn to make products such as fragrances, soaps, creams, shampoos, bath foams, glosses, lipsticks, other make-up, tooth-paste and conditioners;
- 25) "gustative game" means a toy the purpose of which is to allow children to make sweets or dishes which involve the use of food ingredients such as sweets, liquids, powders and aromas;

These terms are used in Annex II, part III, point 12 which lays down a certain derogation for these kinds of toys from the requirements concerning fragrances that can be used in toys as well as in Annex V which foresees a special warning for these kinds of products (Annex V, part B, point 10). Olfactory board game does not refer to e.g. a soft filled toy with a flavour.

Picture showing an example of an olfactory board game:



Picture showing an example of a cosmetic kit:



1.3.8. Harm

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

This term is used in the definitions of hazard and risk in points 27 and 28 as well as in Article 10 (2).

1.3.9. Hazard

27) "hazard" means a potential source of harm;

This term is used in the definition of risk in point 28 and in Article 10 (2), in Article 18 and in Article 20 (3).

1.3.10. Risk

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

This term is used in Article 4, 5, 6, 7, 10, 17, 21 and 42, as well as in Annex II. As far as chemical requirements are concerned "risk" means combination of the hazard and exposure to that hazard.

1.3.11. Intended for use by

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

This term is used first in Article 10 (2) in the general safety requirement which states that "the ability of the users and where appropriate their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups". It also used Annex II, part I, point 4 (d) which lays down the prohibition of small parts for toys intended for use by children under 36 months.

This definition gives the criteria for evaluating whether a particular toy is “intended for use by” a certain age group. The definition indicates that the decisive factor is what the parent or supervisor shall reasonably assume about the intended age group by virtue of the functions, dimensions and characteristics of a toy. More information can be found in item 1.2.1. of this guide.

Remark: this definition does not relate to exemptions in Annex I such as " scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways", as the definition is only related to the age group.

2. CHAPTER II OBLIGATIONS OF ECONOMIC OPERATORS

2.1. Articles 4 to 9

Article 4 Obligations of manufacturers

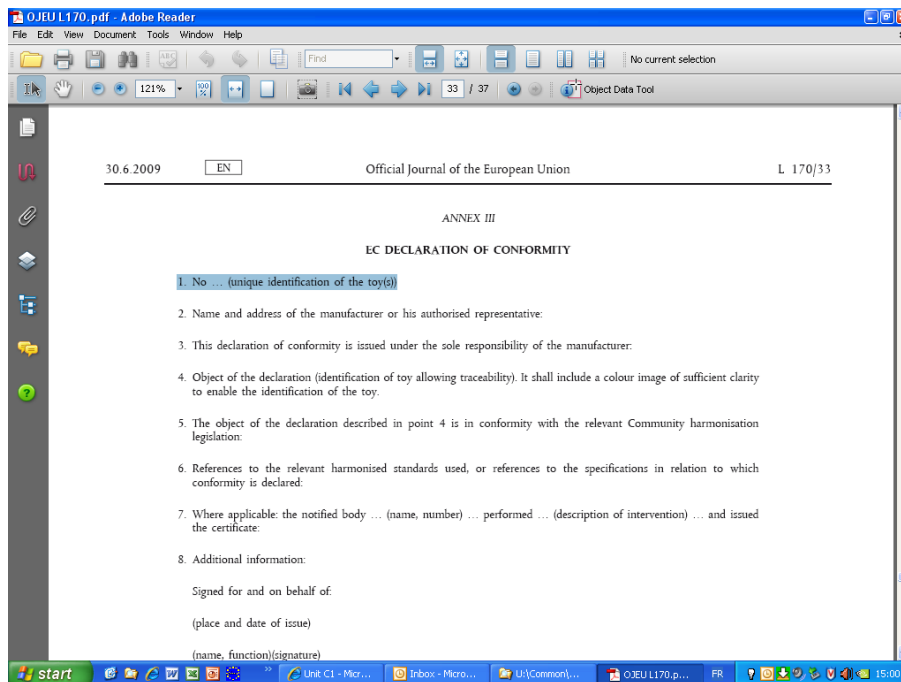
1. When placing their toys on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Article 10 and Annex II.
2. Manufacturers shall draw up the required technical documentation in accordance with Article 21 and carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19. Where compliance of a toy with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity, as referred to in Article 15, and affix the CE marking, as set out in Article 17(1).
3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market.
4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in toy design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is declared shall be adequately taken into account. When deemed appropriate with regard to the risks presented by a toy, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of any such monitoring.
5. Manufacturers shall ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.

The toy must bear a type, batch, serial or model number or other element allowing its identification.

The identification shall, as a rule, be affixed to the toy. However, it may exceptionally be moved from the toy if this rule cannot be followed. This would be justified where the size and/or the nature of the toy makes the indication illegible or technically impossible. In such cases, the identification has to be affixed to the packaging, if it exists, or to the accompanying document. The identification on the toy may neither be omitted nor be moved to the packaging or accompanying documents on purely aesthetic or economic grounds.

This provision implies that if the toy has no packaging or is not accompanied by any document, the identification must be on the toy itself.

The requirement of the TSD gives the freedom to the manufacturers to choose the element they want to use as identification of the toy, as long as traceability is ensured. This identification is a unique code for the toy, which is identical to the one used on the EC declaration of conformity.



In some cases, e.g. when a toy consists of several parts or is an assembly of several parts, its nature does not allow for the affixing of the identification code. The identification of the toy has in these cases to be affixed to the packaging (or accompanying document). In addition to the marking with an identification code on the packaging, additional marking of individual toys/parts/components can be made based on the manufacturer's internal rules and ambitions to minimise the extent of a potential recall by having an advanced system for traceability of individual items (e.g. batch codes, production dates).

According to economic operators, the established way to refer to toys is to use an item number (a so-called "SKU" - "Stock keeping unit") as identification. This item number is also typically used as the identifier on the EC Declaration of Conformity (DoC) together with a picture, the description etc.

1. The toy consists of several parts/components, such as

- Building blocks of different shape and size
- A number of animals with different colours and features
- A doll with a pair of shoes, a comb, a dress etc

Each toy above is enclosed in one packaging but typically they could/would also be sold in another packaging as separate parts/components or in other combinations of parts/components. Some of the parts/components in these packages may be possible to mark, while others may be too small or have a shape which does not allow the marking to be on the part. For these reasons, it is much more practical to give the set/packaging an item number and to use the same item number on the DoC.

The main purpose of the identification code is to enable market surveillance to identify a toy unit and to link it to a DoC. When the market surveillance takes place, the toy will still be in its packaging and it will be easy to identify the code and thus ensure that the corresponding DoC regards the toy unit in question. It would be more complicated to have to open the packaging and find codes on the individual items and then link these to a particular DoC.

2. The toy consists of one assembled item

Also when a toy consists of only one “item”, it is not uncommon that this item has been assembled by the manufacturer, using several parts (but it is not intended to be disassembled by the consumer). The parts composing the item (toy) are often used in more than one design of toy. For example, the body of a toy figurine can have a variety of different heads placed on the same body and several different toys can be created using the same body. Normally, some parts would not be large enough to bear an identification code and yet other parts might not allow marking with an identification code for technical reasons (uneven surface, spherical shaped surface etc). Also in this case it is more practical to affix an item number on the packaging and to use the same number on the DoC.

3. The toy consists of one item which has not been assembled of several parts

This is a case where it may seem simple to mark the toy itself with an identification code that is identical to the one on the DoC (i.e. an item number). However, the same toy might be sold in combination with other toys/items in a set. Since at the point of production, it is not known which of the items will be sold “alone” and which will be in a packaging together with other toys, it is therefore easier to mark the item number, corresponding to the DoC, on the packaging which will also make it easier for market surveillance authorities to link the toy to the DoC.

<p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy. The address shall indicate a single point at which the manufacturer can be contacted.</p>

Manufacturer means any natural or legal person who manufactures a toy or has a toy designed or manufactured, and markets that toy under his name or trademark. The definition contains two cumulative conditions: the person has to manufacture (or has a toy manufactured) and to market the toy under his own name or trademark. So, if the toy is marketed under another person's name or trademark, that person will be considered as the manufacturer.

The manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy, or, where that is not possible, on its packaging or in a document accompanying the toy. The name and address shall, as a rule, be affixed to the toy. However, it may exceptionally be moved from the toy if this rule cannot be followed. This would be justified where affixing it to the toy was not possible under reasonable technical or economical conditions.

The address shall indicate a single point at which the manufacturer can be contacted. The legal text obliges the manufacturer to put a single contact point on the product. This is not necessarily the address where the manufacturer is actually established. This address at which they can be contacted can be the address of their authorized representative, if accompanied by the clarification "represented by".

Nothing in this provision prevents the manufacturer from putting other addresses provided that it is clearly indicated what is the single contact point. The manufacturer cannot have a list of 10 country contact points without designating the single contact point. Designating the single contact point can be done by underscoring or highlighting the single contact point or by indicating that "the single contact point according to Directive 2009/48/EC is..."

A website is additional information, but is not enough as an address. Normally an address consists of a street and number or post-box and number and the postal code and town. Some countries may deviate from this principle (for example no street and number, but just a postal code), but then a written approval of this single point of contact from the national authority must be kept available by this manufacturer for other Member States authorities.

The manufacturer has to comply with this obligation regardless of his location (within or outside the EU). This provision implies that toys sold without packaging or any accompanying documents, must bear the name and address of the manufacturer!

Note: the wording of the provision in Directive 88/378/EEC stating that "where the said particulars are not affixed to the toy, the consumer's attention must be drawn to the advisability of keeping them" is left out of the Directive 2009/48/EC.

It is not an explicit obligation of the TSD on whether the addresses shall be preceded by the words "Manufactured by", "Imported by", "Represented by" or "Distributed by" but an implicit one, based on the aim of the Legislator to identify each economic operator and his role, when you have more than one address on the toy. If this information is not mentioned, market surveillance authorities will decide which the role of each economic operator is. Up to the economic operator to prove then that he has a different role.

There is no obligation, in the TSD or in the horizontal legislation (NLF) to translate in all necessary languages the words "manufactured by", "imported by", "represented by" or "distributed by". The translation requirements refer only to the instructions, safety information and warnings. These words are considered to be easily understandable in all languages.

Manufacturers can state "Designed and manufactured by" rather than just "Manufactured by...".

If an EU based company has a toy manufactured in- or outside the EU and sells it under its own brand name but the product also carries a logo from a license-giver, the EU based company is still the manufacturer and has to mark his address on the toy. There is no obligation to print the address of the license-owner. However, the EU based company has to have the right according to a contract to manufacture and sell products under the brand for which he obtained the license.

If an EU based company has a toy manufactured in- or outside the EU and sells it under the license brand (according to a license contract), the EU based company is still the manufacturer and has to mark his address on the toy. There is no obligation to print the address of the license-owner.

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

8. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

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

Article 5 Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.
2. The obligations laid down in Article 4(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.
3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - (a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of 10 years after the toy has been placed on the market;
 - (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy;
 - (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by toys covered by the mandate.

Article 6 Obligations of importers

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

2. Before placing a toy on the market, importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the toy bears the required conformity marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 4(5) and (6). Where an importer

considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 10 and Annex II, it shall not place the toy on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

The wording "required documents" refers to all documents which have to accompany the toy itself. According to the TSD, these documents are the safety information, instructions and the warnings.

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

An importer is always located in the Community as the definition defines an importer as any natural or legal person established within the Community who places a toy from a third country on the Community market. Importers shall also indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy, or, where that is not possible, on its packaging or in a document accompanying the toy. The provision refers to an address at which they can be contacted, so this is not necessarily the address where the importer is actually established. A website is additional information, but is not enough as contact address. Normally an address consists of a street and number or post-box and number and the postal code and town. Some countries may deviate from this principle (for example no street and number, but just a postal code), but then a written approval of this address from the national authority must be kept available by this importer for other Member States authorities.

As a rule, the identification and the address of the importer shall be indicated on the toy. Only where it is not possible, the identification and address of the importer shall be indicated on the packaging or in a document accompanying the toy. This may be the case when the importer would have to open the packaging to put his name and address. The TSD does not contain specifications on the visibility or legibility.

In conclusion: a toy normally bears one or two addresses: the manufacturer's and/or importer's address. However,

- If the manufacturer is within the Community and the toy is manufactured in the Community, it will bear only one (manufacturer's) address.
- If the manufacturer is outside the Community and the importer places the toy on the market under his own name or trademark or modifies the toy already placed on the market (in such a way that compliance with the applicable requirements may be affected), the importer is considered the manufacturer. The only address that in this case will figure on the toy (or packaging or accompanying document) is the address of the importer who is considered as the manufacturer¹. A trademark is a distinctive sign or

¹ If the importer is only affixing his name and address and leaves the trademark of the original manufacturer, he remains importer. The address of importer and manufacturer will appear on the toy (or packaging or accompanying documents).

indicator used by an individual, business organisation, or other legal entity to identify that the products or services to consumers with which the trademark appears originate from a unique source, and to distinguish its products or services from those of other entities. A trademark is a type of intellectual property, and typically a name, word, phrase, logo, symbol, design, image, or a combination of these elements.

- If the manufacturer is within the Community (a company located in the Community presents itself as being the manufacturer by allowing to having put on their trade mark, address,...) although the products are manufactured outside the Community, that company is considered to be the manufacturer who places the toys on the EU market, even if actual importation is done by another company. In this case there is no importer in the meaning of the importer's definition and it is sufficient to put only the manufacturer's address.

If the manufacturer (declaring himself as a manufacturer by putting his name and address on the toy) is outside the Community and the products are placed on the EU market by an importer, the toy will bear two addresses: the one of the manufacturer and the one of the importer.

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

5. Importers shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 10 and Annex II.

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

7. Importers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for a period of 10 years after the toy has been placed on the market, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

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

Article 7 Obligations of distributors

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

2. Before making a toy available on the market, distributors shall verify that the toy bears the required conformity marking, that it is accompanied by the required documents and by instructions and safety information in a language or languages easily understood by consumers in the Member State in which the toy is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 4(5) and (6) and Article 6(3). Where a distributor considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 10 and Annex II, it shall not make the toy available on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the distributor shall inform the manufacturer or the importer, as well as the market surveillance authorities, to that effect.

Manufacturers and importers shall ensure and distributors shall verify that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.²

- Instructions for use consist of information supplied for the safe and efficient use of the product, to enable the consumer to assemble, install, operate, store, maintain, repair, and dispose of the product.
- Instructions for assembly or installation should include the inventory parts and special skills or tools.
- Instructions on operation should include information for restriction of use, need for personal protective equipment, maintenance and cleaning, repair,
...

Instructions are an integral part of the toy. They shall allow and promote correct use of the toy. If a toy does not need any instructions or safety information (for example a soft filled bear complying with the harmonised standards), then this documentation does not need to be added. Manufacturers have to bear in mind that although no documentation is

² Note: the use of "shall" stems from the provisions of the TSD, meaning that economic operators have the duty to comply. The use of "should" indicates that economic operators have the possibility.

added to the toy, they still need to fulfil in particular the traceability and CE requirements.

If there are instructions present, the instructions should clearly relate to the toy, therefore they should repeat the information with which the toy is marked (see traceability). If the instructions comprise more than one page, the pages should be numbered.

- Safety information may include text and/or images that shall accompany or be associated with the toy. For some types of toy no safety information is relevant. The intent of safety information is to enable the consumer or user to use the toy safely and that, in addition to the warnings required by the TSD, contributes to avoiding risks to the users or damage to the product. Examples of this are: e.g. "cool only in a domestic refrigerator"; "do not place in the freezer compartment".

There are no specific requirements for the affixation of instructions and safety information. The TSD only mentions that the toy needs to be accompanied, meaning that this information can be on the packaging, in a leaflet or notice.

The TSD indicates that the information shall be in a language easily understood by consumers, as determined by the Member State concerned. These provisions stem from the Goods Package and actually concerned only the language issue: instructions and safety information do not necessarily have to be in the national language, it can be in another language "easily understood by the consumer, as determined by each Member State". This means that Member States will determine in their national law the language (s) which they will consider as easily understood by consumers. (Generally, it is the official language(s) of the Member State but they can also request other additional languages.)

More information for manufacturers on how to draw the instructions and safety information can be found in:

CEN guide 11 "product information relevant to consumers",
ISO IEC guide 14 "Purchase information on goods and services intended for consumers",
CEN TR 13387 "Child use and care articles – safety guidelines",
IEC 62079:2001 "Preparation of instructions".

What is meant by the obligations for distributors?

The distributor has no specific obligations to draw up or keep the EC declaration of conformity and technical documentation. However, when making a toy available on the market, he must ensure that the toy bears the appropriate conformity marking(s) and is accompanied by the required documents³ and instructions and safety information in the appropriate language. The conformity marking under the TSD is the CE marking; however the toy may be subject to other Community legislation requiring other conformity markings. The distributor must also ensure that the manufacturer and/or importer complied with their obligations, in other words verifying the application of the name, brand name or address to which the manufacturer and the importer can be

³ "Required documents" refers to all documents which have to accompany the toy itself. According to the TSD, these documents are the safety information, instructions and the warnings.

contacted on the toy or its packaging and the affixing by the manufacturer's batch number, serial number or other element on the toy for the identification of the toy.

As indicated above, the distributor is not required to hold the technical documentation. The obligation to act with due care and verify the presence of the required documents must be interpreted in the light of this situation.

The distributor must check the coherence between the toy and the documents received with it, by checking for example the safety information, the warnings, the CE Marking and the addresses of the manufacturer / importer. Concerning the verification of the presence of required warnings, distributors can verify their presence based on the warnings listed in Annex V of the TSD. Verification of presence of these do not require the technical documentation, e.g. warning for activity toys, functional toys, aquatic toys, chemical toys, etc... The same diligence requirement may apply, for example, if a soft filled toy bears the warning "not suitable for children under 36 months...". In the latter case, and in the absence of technical documentation, the distributor's obligation is to verify and act, as soft filled toys for holding and cuddling are considered inherently suitable for children under 36 months, and so the presence of the warning "not suitable for children under 3 years" is not appropriate.

Moreover, when in doubt for products falling in the "grey area" the distributor can always request the importer or manufacturer the explanations for the absence of any marking.

3. Distributors shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 10 and Annex II.

4. Distributors who consider or have reason to believe that a toy which they have made available on the market is not in conformity with the relevant Community harmonisation legislation shall make sure that the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the toy presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

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

Article 8 Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and be subject to the obligations of the manufacturer under Article 4 where it places a toy on the market under its name or trademark or modifies a toy already placed on the market in such a way that compliance with the applicable requirements may be affected.

Article 9 Identification of economic operators

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

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

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

The Articles dealing with the obligations of the economic operators are based on the model provisions of the horizontal Decision 768/2008. The TSD is aligned to these provisions and refers specifically to economic operators placing or making available toys on the market. The 'Blue Guide' on the implementation of EU product rules 2014 (http://ec.europa.eu/growth/single-market/goods/index_en.htm) provides further explanations.

Explanation I to this guide tries to give you more guidance in order to determine when an economic operator can be considered as manufacturer, importer or distributor. It also explains the main obligations of the economic operators. Economic operators have to be careful, when choosing their business model so that they can comply with the directive's requirements. The legal framework sets up obligations economic operators have to comply with, but does not enter into the private sphere of commercial and business related negotiations that economic operators may conduct between them.

The criteria depend, for example, on how toys are purchased, who designed (or modified) the toy, the brand under which the toy is placed on the market and the stage in the product cycle at which an operator becomes involved.

The operator roles, as defined in the TSD, may be different to what a company would consider to be their “normal trading role”. For example, there are times when an importer must adopt the role of a “manufacturer” furthermore depending on the mode of supply; companies may even adopt different operator roles when selling the same toy into different retailers. It is therefore important to note that the role adopted needs to be assessed on a case by case basis.

For each operator type there are a series of obligations that they are legally required to meet when supplying or purchasing toys. In general terms the obligations are more onerous when companies adopt the role of “manufacturer” and less onerous when adopting the role of “importer” and even less onerous when adopting the role of “distributor”. A Manufacturer can appoint by a written mandate, an “Authorised Representative”. The authorised representative shall perform all the tasks in the mandate.

3. CHAPTER III CONFORMITY OF THE TOYS

3.1. Article 10 Essential Safety requirements

3.1.1. Article 10 (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.

Article 10 (1) sets the basic principle of the Directive which is that only toys complying with the essential safety requirements of the Directive can be placed on the market, and that the Member States are required to take all the necessary measures to ensure that toys not complying with these requirements are not placed on the market.

This provision also clarifies that the Directive contains both a general safety requirement which is set in the paragraph 2 below, and particular safety requirements applying to specific risks contained in Annex II.

3.1.2. Article 10 (2), first subparagraph

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

Article 10 (2) sets the general safety requirement which applies to risks that toys may present which are not covered by any particular safety requirement. The general safety requirement may be used as legal basis for taking measures against toys which present risks that are not covered by any particular safety requirement. An example of such a risk was the recently discovered hazard presented by certain strong magnets which could present the risk of intestinal injuries if swallowed. When this risk from magnetic toys was discovered in 2007, Directive 88/378/EEC did not contain any particular safety requirement applying to this kind of risk of intestinal injury, and there were no technical requirements in the toy standard EN 71 either at that time. Therefore, the general safety requirement of Directive 88/378/EEC was used as a legal base for taking some dangerous toys with magnets out of the market. Subsequently, a standard has been developed to ensure the safety of magnetic toys (see EN 71-1:2005+A8:2009, now EN 71-1:2011).

The general safety requirement states, first, that toys, including chemicals they contain, shall not jeopardise the safety or health of users or third parties. The general safety requirement therefore covers both adverse effects to health, including long term effects, and adverse effects to safety, which include all minor and major injuries. The general safety requirement foresees that toys have to be safe both for users of the toy, and also to third parties, that is, parents or other supervisors, other children or even complete outsiders.

Secondly, the general safety requirement specifies that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer but it needs to be safe also when used in a foreseeable way. When assessing what can be

regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user. Where a hazard cannot be sufficiently minimised by design or by safeguards, the residual risk could be addressed by product-related information directed at the supervisors, taking into account their capacity to cope with the residual risk. According to acknowledged methods of risk assessment, it is not appropriate to use information directed to the supervisors or to give reference to a lack of history of accidents to be used as a substitute for design improvements. Taking into account the behaviour of children, also some degree of misuse of the toy has to be considered as foreseeable use and therefore it needs to be considered when designing and manufacturing the toy. An example is that children will use a slide not only for sliding down on their back, but also to climb up the slide, or use the slide to slide down head first. Directive 88/378/EEC used the terms “normal behaviour (of children)” in this context, but this term has been changed because it had created problems of interpretation about what can be considered as “normal”. However, it is important to underline that the purpose of eliminating this word has not been to change in substance the scope of the general safety requirement.

The general safety requirement contains a reference to the chemicals contained in toys. This reference reinforces the provision in Annex II, part III, point 1 of the Directive which states that toys shall not present any risks of adverse effects on human health due to exposure to the chemical substances or mixtures contained in the toys.

3.1.3. Article 10 (2), second subparagraph

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

Article 10 (2), second subparagraph specifies the content of the general safety requirement further. It clarifies that when designing and manufacturing the toy, the ability of the users and where appropriate their supervisors shall be taken into account when ensuring the safety of the toy. This provision clarifies the provision of Directive 88/378/EEC, which stated in Annex II (I) (1) that “the degree of risk present in the use of a toy must be commensurate with the ability of the users, and where appropriate their supervisors, to cope with it”. This means that although toys are required to be safe, it is also recognised that zero risk does not exist and an acceptable level of risk must be admitted in cases where the risk cannot in a reasonable way be completely eliminated by design or safeguards. In other words, some toys contain inherent hazards (source of harm) which cannot be completely eliminated. For instance, it is not possible to require that there is no possibility of falling from a swing but the risk needs to be minimised to an acceptable level. The manufacturer is also not able to control the design of the surface under swings in private gardens in order to avoid head injury; therefore information about suitable surfacing should be given. When evaluating what is the acceptable level of risk, the ability of the users and where appropriate their supervisors have to be taken into account.

This provision states furthermore, that the ability of users or their supervisors have to be taken into account, in particular in case of toys intended for use by children under 36 months or by other specified age groups.

3.1.4. Article 10 (2), third subparagraph

Labels affixed in accordance with Article 11(2) and instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks.

Article 10 (2), third subparagraph requires as a part of the general safety requirement that toys are accompanied by appropriate warnings and instructions about the inherent hazards and risks of harms involved in using the toys and to the ways of avoiding them. As explained above under the second subparagraph, an acceptable level of risk is allowed to be present when the toy is used, but the inherent hazards have to be indicated by warnings and instructions. The way these warnings and instructions have to be affixed is foreseen in Article 11 (2).

Instructions are an integral part of the safety conception of the toy. They provide information to avoid an unacceptable risk for the user, damage to the toy and malfunction or inefficient operation, but they are not intended to compensate for design deficiencies. Instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks. Built-in safety, which does not require any further human action, is the most effective way of preventing accidents.

Manufacturers have to bear in mind that where a hazard cannot be sufficiently minimised by design or safeguards, the residual risk could be addressed by product-related information directed at supervisors, taking into account their capacity to cope with the residual risk. According to acknowledged methods of risk assessment e.g. ISO EN 14121-1, it is not appropriate for information to supervisors or a lack of history of accidents to be used as substitute for design improvements where an unacceptable risk is judged to exist. Manufacturers shall provide consumers with the relevant information to enable them to assess hazards inherent with the use of a toy throughout the normal or reasonable foreseeable period of use, where such risks are not immediately obvious to the user or caregiver. This includes information on the precautions to be taken to avoid risks. When more than one hazard is present, at least one of the principal hazards shall be indicated.

According to Article 18 of the Toy Safety Directive a risk/hazard assessment shall be carried out to determine the risks/hazards of a toy. The toy should be designed in such a way that as many hazards as possible are eliminated or that residual risk is minimised to an acceptable level. The residual risks should be described through adequate warnings and/or instructions for use. E.g. the risk of drowning presented by aquatic toys cannot be 100% eliminated by the design of the toy. Therefore supervisors should be informed that the toy shall be used in shallow water and under supervision of an adult. For latex balloons there must be a warning that children under 8 years must be supervised and broken balloons should be discarded. Activity toys shall be provided with a warning that they are for domestic use only.

Examples of instructions and safety information can be found in the harmonised standards e.g. "cool only in a domestic refrigerator"; "do not place in the freezer compartment", "not suitable for children under 10 months due to long hair". Also

projectiles and toys with hazardous sharp functional edges and points should mention safety information.

More information on risk assessment can be found in the guidelines on the technical documentation and other relevant documents such as ISO guide 51, ISO EN 14121-1, CEN TR 13387.

Note: it is acknowledged that it is not justified to ban small parts in toys intended for children above 3 years, even if they may provoke choking accidents. Therefore the age warning "not suitable..." is accepted for the grey zone toys even if it would be in theory possible to limit the access to the hazard by not allowing small parts in any toys at all. The TSD however forbids all kinds of removable or detachable small parts in toys which are intended to be put in the mouth, regardless of the age of the child (see 11.1.6. point 4. d)).

3.1.5. Article 10 (3)

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

Article 10 (3) foresees the period during which toys have to comply with the essential safety requirements. It states that they have to be safe during their foreseeable and normal period of use. In other words, it is not enough for a toy to be safe when it is placed on the market or sold to the consumer but the safety requirements have to be fulfilled during its whole foreseeable and normal period of use.

3.2. Article 11 Warnings

3.2.1. Article 11 (1), first subparagraph

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

Article 11 (1), first subparagraph, lays down the general rule for warnings applying to all toys. It states that where appropriate for safe use warnings have to specify appropriate user limitations. This means also that these warnings have to be used only where appropriate for a safe use. If the warning has no added value with regards to the safety of the toy, it should not be used. Further specification on the ways this shall be done is laid down in part A of Annex V.

3.2.2. Article 11 (1), second subparagraph

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

Article 11 (1), second subparagraph, lays down that certain categories of toys have to have a specific warning. These warnings are listed in part B of Annex V. This list is not exhaustive, and some specific warnings required also figure in the toy standards EN 71

series or EN 62115. It is further specified that the wording of these warnings has to be exactly the one indicated in points 2 to 10 of part B of Annex V.

3.2.3. Article 11 (1), third subparagraph

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

Article 11 (1), third subparagraph, aims at preventing the misuse of warnings to circumvent the safety requirements. The misuse has occurred in the past in particular in case of warnings stating that the toy is not suitable for children under 36 months, which has been misused to escape from the small parts requirements applying to toys intended for children under 36 months. The wording of this provision is, however, general and prohibits the use of all of the specific warnings laid down in part B of Annex V that contradict the intended use of the toy. The intended use of the toy is determined by virtue of its function, dimension and characteristics.

3.2.4. Article 11 (2), first subparagraph

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

Article 11 (2) lays down the rules for the marking of the warnings. First, the warnings need to be marked in a clearly visible and easily legible, easily understandable and accurate manner. Secondly, the provision requires that warnings shall be marked on the toy, on an affixed label or on the packaging. Affixed label means labels such as the sewed label on teddy bears, a hang tag or an adhesive label. In addition to this, if appropriate the warnings shall also figure in the instructions for use which accompany the toys. If small toys are sold without packaging, the warnings need to be affixed to the toy itself. This affixing of the warning can be a marked warning on the toy or can be an affixed label to the toy. It is not enough for them to be affixed for instance on a counter display box.

Note: This is not to be confused with “permanently marked” on the toy as required by Annex V, Part B point 9. Please also see 14.2.2.



The warnings cannot be affixed only on the counter display where they are not affixed on the individual toys themselves. CE marking is correctly affixed (see Article 17).

Examples of affixed labels:




3.2.5. Article 11 (2), second subparagraph

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

This provision foresees that the warnings, whether in the form of words or in the form of a pictogram, have to be preceded by the word “warning(s)” in order for the consumer to understand the nature of the warning(s). In the past, consumers may have interpreted certain warnings as being recommendations only (for instance about the suitable age). In case there are several warnings, they do not all have to be preceded by the word “warning”, but it is sufficient to insert the word “warnings” at the beginning of the list containing all warnings. The word “warning” may be followed by e.g. an exclamation mark. Provided that the packaging already carries a compliant age warning (preceded by the word "Warning"), an age warning pictogram in another location on the packaging is considered to be additional information with the sole intention of attracting attention (rather than any adding value in terms of safety). Such an additional pictogram does therefore not need to be preceded by the word "Warning".



The symbol  does not replace "warning", it is additional. The given yellow triangular warning symbol is laid down in the US standard ASTM F 963-11 „Standard consumer safety specifications for toy safety“ and combined with the requirements in the Consumer Product Safety Improvement Act (CPSIA) makes this standard (and symbol) mandatory in the US market.

3.2.6. Article 11 (2), third subparagraph

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

This provision foresees specific rules for the marking of certain warnings which determine the decision to purchase the toy, in order to ensure that these kinds of warnings are clearly visible to the consumer before they purchase the toy. These warnings have to appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase. This also applies to purchases made online, and therefore these warnings have to be visible on the website before the purchase. Purchase includes any method of purchase that allows the purchaser to order the product without being in the physical presence of the product.

If the toy is sold via a catalogue, the warnings determining the decision to purchase have to be clearly visible in the catalogue. There is no obligation for these warnings (determining the decision to purchase) to be placed adjacent to the toy picture/description, as long as the consumer can access and read the warning(s) before ordering. The picture/description of the toy can instead have a reference to the location of the warning(s). The attention of the consumer shall be drawn to the fact that the warning(s) is available, for example, on page x under reference number y.

The warning(s) is considered to be clearly visible if they appear either near the beginning of a catalogue containing the toys to purchase, or adjacent to the ordering information or order form.

A distinction should be made between a catalogue which includes means of purchase, and a catalogue which advertises toys but does not include means to purchase the toys. The latter does not need to have the warning(s).

The visibility requirement covers only the warnings (which determine the decision to purchase). In the specific case of the warning "not suitable for children under 3", Annex V part B point 1 stipulates the warning to be accompanied by a brief indication of the specific hazard. This indication is considered to be additional information for the consumer and therefore not covered by the visibility requirement. This means that it is not necessary for this indication to be visible before purchase, neither in a shop, catalogue nor on-line. It may appear in the instructions for use accompanying the toy.

If the toy is sold on a website, the warnings determining the decision to purchase have to be clearly visible on the website. These warnings must be visible in their entirety to the buyer before the consumer is carrying out the purchase.

If a consumer orders a toy online on a website written in a certain language, the warnings have to be written in the same language of the website. If the website is written in several languages, the warnings have to be visible to the consumer in the language of the webpage he is using.

The warnings concerned by Article 11 (2) are all warnings considered as necessary to determine the decision of purchase. Considered as determining the decision of purchase are in particular warnings that specify the minimum and maximum age for users and the warnings listed in Annex V, except the warning listed under item 9. The warnings listed in Annex V have to be read in conjunction with this article, meaning that although Annex V indicates that the warning should be marked on the toy, it also has to be clearly visible before purchase. This may imply that this warning also needs to be marked on the packaging or other means (internet).

3.2.7. Article 11 (3)

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

Article 11 (3) lays down language requirements for the warnings. The warnings need to be in a language or languages easily understood by consumers which each Member State shall determine for its territory. This implies that the national transposition of the Directive by the Member States contains the reference to the language (s) easily understood by consumers.

Explanation II to this guide contains recommendations on elaborating warnings.

3.3. Article 12 Free movement

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

Article 12 lays down a basic principle of this Directive, the free movement of toys complying with the Directive. Member States are not allowed to impede the making available in their territory of toys which comply with all the provisions of the Directive.

In accordance with its definition in Article 3 “making available” covers all the transactions in the supply chain. The provisions which need to be respected in order for the toy to profit from the free movement rule include also other legislation mentioned in the Directive which needs to be complied with, in particular the chemicals legislation (see Annex II, part III, point 1), cosmetics Directive in case of cosmetic toys (see Annex II, part III, point 10) and food contact material (FCM) legislation, for instance in case of toy tea sets. The FCM legislation indicates that toys or their parts and their packaging that can reasonably be expected to be brought into contact with food should comply with Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

Furthermore, other legislation which impose safety and other requirements on toys but which are not mentioned in the Toys Directive include, in particular:

- Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment,
- Directive 2004/108/EC on Electromagnetic Compatibility
- ...

More information can be found at following webpage:

http://ec.europa.eu/growth/sectors/toys/safety/legislation/index_en.htm

If these provisions are not complied with, Member States may impede the commercialisation of the toys in question on the basis of these requirements, even if they comply with the Toys Directive itself.

Some Member States may have additional national legislation, which has to be notified to the Commission. More information can be found at following webpage:

http://ec.europa.eu/growth/single-market/barriers-to-trade/tris/index_en.htm

3.4. Article 13 Presumption of Conformity

Toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 10 and Annex II.

Article 13 which following the model Article R8 set in Decision 768/2008 sets the principle of the presumption of conformity. Presumption of conformity is given by the compliance with harmonised standards the references of which have been published in the Official Journal of European Union. If toys comply with these standards, Member states shall presume that they are in conformity with the essential requirements covered by those standards or parts of them. If a Member State considers that a toy complying with such standards is not in compliance with the essential safety requirements, it has the burden of proof to demonstrate that the toy is not complying.

The reference "the relevant national standard which transpose the harmonized standards...", is not mentioned anymore in the Directive, implying that manufacturers do no longer have to wait to comply with the harmonised standards for the national transposition of the harmonised standards.

3.5. Article 14 Formal objection 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 10 and Annex II, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.
2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.
3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

This Article is based on the model provisions of the horizontal Decision 768/2008. The meaning is defined in the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

3.6. Article 15 EC Declaration of Conformity

In accordance with Article 4 (2) and (3), manufacturers have an obligation to draw up an EC declaration of conformity and to keep it (as a part of the technical documentation) for a period of 10 years after the toy has been placed on the market. This is a new obligation for the manufacturer which was not foreseen in Directive 88/378/EEC. If the manufacturer has nominated an authorised representative, the mandate of the authorised representative shall allow him to keep the EC declaration of conformity available for this period (Article 5 (3)).

3.6.1. Article 15 (1)

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

Article 15 specifies the content of the EC declaration of conformity. Article 15 (1) foresees its main content which is to state that the fulfilment of essential safety requirements specified in Article 10 and in Annex II has been demonstrated.

3.6.2. Article 15 (2)

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

Article 15 (2) specifies in more detail the content of the EC declaration of conformity (DoC). It shall contain elements that are specified 1) in Annex III of this Directive and 2) in the relevant modules for conformity assessment of the horizontal Decision No

768/2008. The requirements of Annex III will be further dealt with in section 13. Article 15 (2) specifies that the DoC has to follow the model *structure* and must contain the *elements described* in annex III of the TSD. It does not say that it has to be an exact copy paste of the wording used in the model.

As regards the elements set in Decision No 768/2008, the following apply: if Module B (EC type examination) combined with module C (conformity to type) is used or if Module A (internal production control) has been used, Annex II of the Decision requires that the EC declaration of conformity shall identify the product model for which it has been drawn up.

Secondly, it is required that these elements contained in the EC declaration of conformity are continuously updated.

Thirdly, Article 15 (2) lays down that the model structure of the EC declaration of conformity shall be that foreseen in Annex III.

Finally, it is required that the EC declaration of conformity has to be translated into the language or languages required by the Member State in which the toy is placed or made available.

A DoC declares that a toy fulfils the essential requirements of the Directive. The question arises as to the actions that need to be taken when the “generally acknowledged state of the art” has developed.

The publication of a revised harmonised standard would be one way to recognise a development in the state of the art: in this case, the manufacturer shall determine whether the state of the art concerning the requirements has changed, and if so, in what respects.

If a revised standard has no impact on the toy in question, the DoC remains valid. The manufacturer can indicate his evaluation in a separate document. For example, when the EN71-1 standard was amended by A8 to introduce new requirements for magnets, it would be unnecessary for the manufacturer to revise DoCs for toys that obviously do not contain any magnets and his assessment of this fact could be separately documented and provided to the relevant authorities.

In such cases, if the specifications and evaluation criteria originally applied to a toy no longer ensure that it complies with the latest state of the art, the DoC is no longer valid and further action is required. Given reasonable transition periods and knowledge of current developments, it is expected that the manufacturer will have sufficient time to undertake the necessary re-evaluation so that there is a smooth transition from one set of applied specifications to another.

It should be noted, however, that the issuing of a new DoC will have no retroactive effect and, therefore, will not affect products placed on the market whilst the manufacturer was in possession, where appropriate, of a valid DoC.

It should also be re-affirmed that the overall responsibility for compliance of the toys rests with the manufacturer who, where required, must ensure that a valid DoC is in his possession, as well as that all relevant conformity documents correspond to the current state of the art.

More information on the declaration of conformity can be found in the guide on the technical documentation.

3.6.3. Article 15 (3)

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

Article 15 (3) sets the legal consequences of drawing up the EC declaration of conformity. It means that the manufacturer assumes the responsibility for the compliance of every toy with the essential safety requirements set in Article 10 and in Annex II: more information can be found in the horizontal guide ('Blue Guide' http://ec.europa.eu/growth/single-market/goods/index_en.htm).

3.7. Article 16 General principles of the CE-marking

3.7.1. Article 16 (1)

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

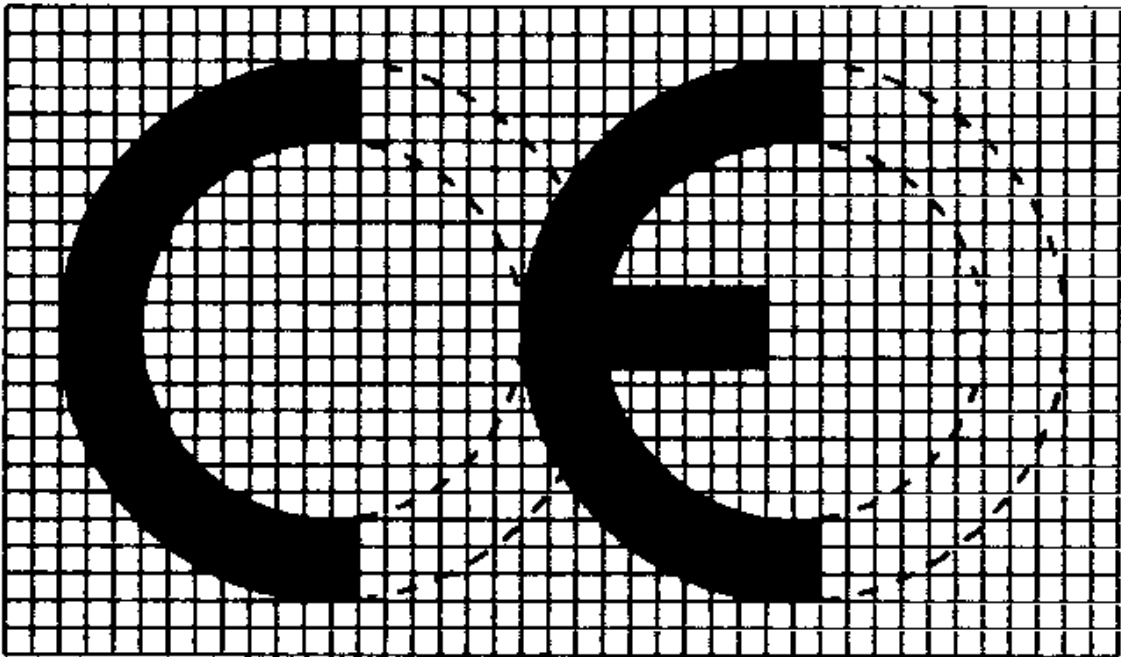
Article 16 (1) requires all toys to bear the CE marking. The CE-marking has to be fixed before the toy is placed on the market, that is, before the toy is made available on the Community market for the first time. The consequences of the non-observance of this obligation are set in Article 45. The affixing of the CE marking is mentioned in detail in Article 17 below.

3.7.2. Article 16 (2)

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

Article 16 (2) refers to the general principles set out in Article 30 of the horizontal Regulation (EC) No 765/2008 which apply. For their application please see the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

The CE marking shall consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged, the proportions given in the graduated drawing shall be respected.
The CE marking shall be at least 5 mm high.

3.7.3. Article 16 (3)

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

Article 16 (3) foresees a presumption of conformity for the toys bearing the CE-marking. This means that Member States cannot restrict the placing on the market of CE marked toys. Only substantial non-compliance demonstrated by market surveillance authorities rebuts the presumption of conformity and allows Member States to take appropriate measures. The measures shall be commensurate with the nature of risk and specify the grounds on which is based. More information about substantial non-compliance can be found in the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

3.7.4. Article 16 (4)

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

Article 16 (4) foresees a derogation from the basic rule set in paragraph 1 that all toys made available on the market have to bear the CE-marking. Namely, derogation is provided for toys that feature in trade fairs and exhibitions. It is also foreseen that such toys do not need to comply with other provisions of the Directive. This derogation is, however, subject to the following condition: a clear sign must accompany the toys indicating that they do not comply with the requirements of the Directive and they will not be made available in the European Community before being brought into conformity. This sign can take the form of a text on a label or can be a notice besides the toy. If the

sign is missing, the Member States have to take measures if the toy is not in compliance with the essential safety requirements.

3.8. Article 17 Rules and conditions for the affixing of the CE marking

3.8.1. Article 17 (1)

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

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



CE marking may be affixed only to the counter display, but NOT the warning (see art 11). Article 17 (1) first subparagraph indicates the way in which the CE-marking has to be affixed. First, the CE-marking needs to be in each case affixed visibly, legibly and indelibly. As a principle rule, it must be affixed to the toy itself, to an affixed label or to the packaging. The manufacturer has the choice between the toy, the packaging and the affixed label.

Article 17 (1), however, foresees derogations for small toys. In the case of small toys, the CE-marking can alternatively be affixed on a label or an accompanying leaflet. If that is not possible in the case of small toys sold in counter displays, the CE-marking shall be affixed on the counter display. However, it can be fixed on the counter display only on the condition that the counter display was originally used as a packaging for the toys.

Article 17 (1), second subparagraph, lays down a new rule to promote visibility of the CE-marking which was not foreseen in Directive 88/378/EEC: if the toy has a packaging and the CE-marking is not visible from the outside (the transparent) packaging, the CE-

marking has to be always affixed at least on the packaging. Affixing CE-marking on the packaging facilitate market surveillance actions, as authorities are not obliged to open the packaging in order to verify the presence of the CE marking. It is recommended, when selling toys online, to display toys in such way that the CE-marking can be visible.

CE marking on co-packs containing both toy and “non-toy” products

Toys, which are co-packed with “non-toy” product(s), shall bear the CE marking in accordance with Article 17 (see above) and warnings shall be in accordance with Article 11.

The “non-toy” product(s) in the co-pack shall comply with applicable legal requirements and shall be marked accordingly. A “non-toy” product co-packed with a toy does not need to comply with the TSD however.

When a toy is co-packed with a "non-toy" product (which is not covered by other legislation requiring CE marking), it is recommended to inform on the outer packaging that the CE marking only regards to toy, in cases where the CE marking is not visible from outside the packaging. If such information is not given, there is a risk of conflict with the legislation covering the "non-toy" product (e.g. the General Product Safety Directive under which CE marking is not permitted).

More information on the affixing of the CE marking can be found in Explanation III.

3.8.2. Article 17 (2)

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

Article 17 (2) foresees explicitly what already flows from Article 16 (1) also: The CE marking needs to be affixed before the toy is placed on the market. This paragraph further specifies that it is possible for the CE-marking to be followed by a pictogram or other mark indicating a special risk or use.

4. CHAPTER IV CONFORMITY ASSESSMENT

4.1. Article 18 Safety assessments

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

Article 18 foresees an explicit new obligation for manufacturers to draw up a safety assessment for the purposes of conformity assessment. Safety assessment consists of an analysis of the chemical, physical, mechanical, electrical, flammability, radioactivity and hygiene hazards that the toy may present as well as an assessment of the potential exposure to them. The safety assessment is often drawn before submitting the toy to the conformity assessment but it may be completed at a later stage as well, but in any case at the latest before placing the toy on the market. In this framework, manufacturers may perform an assessment of the likelihood of the presence in the toy of in particular prohibited or restricted substances. The scope of possible testing can be based on the assessment. Testing only needs to be considered for those substances that can reasonably be expected to appear in the toy in question. If the assessment tells that there is no risk for certain fragrances, manufacturers do not need to test for these fragrances. If there is no electrical hazard, manufacturers do not have to test for it.

In accordance with Annex IV, the safety assessment has to be kept in the technical documentation and therefore made available for inspection to the market surveillance authorities during 10 years after the toy has been placed on the market (Article 4 (3)).

Detailed guidance on the drafting of a safety assessment will be given in a separate guidance document on the technical documentation.

4.2. Article 19 The applicable conformity assessment procedures

4.2.1. Article 19 (1)

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

Article 4 (2) of the Directive foresees an obligation for the manufacturer to carry or have carried out a conformity assessment procedure in accordance with Article 19. Article 19 (1) repeats this obligation which is carried out with a view of demonstrating that the toys comply with the essential safety requirements set out in the Directive. It has to be carried out before placing the toy on the market.

4.2.2. Article 19 (2)

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

Article 19 (2) foresees the conditions for the use of internal production control (Module A). It shall be used if the manufacturer has applied the harmonised standards the references of which have been published in the Official Journal of the European Union. These harmonised standards need to cover the relevant safety requirements for the toy, or in other words cover all the hazards that the toy may present. If such harmonised standards do not exist, or they do not cover all requirements of the TSD, the internal production control (module A) cannot be used.

The internal production control shall be carried out using the procedure set out in Module A of Annex II to Decision No 768/2008/EC. See also the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

It is important to note in this context that point 2 of the Module A includes a provision on the technical documentation when this module is applied. One of the points include “a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied.” However, since Module A for toys can only be used when harmonised standards have been applied, the last part of the sentence “descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied” is not applicable in case of toys, but the harmonised standards need to be included and applied fully.

4.2.3. Article 19 (3)

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

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

Article 19 (3) foresees in which cases the toy has to be submitted for a certification by a third party, which consists of EC-type examination combined with the conformity to type procedure.

The first is the case when harmonised standards the references of which have been published in the Official Journal of the EU, covering all the safety requirements for the toy, do not exist.

The second case is when such standards exist but the manufacturer has not applied them or has applied them only in part.

The third case is when such standards or any of them have been published with restriction which applies to the toy in question.

Finally, the toy shall be submitted to the EC-type examination when the manufacturer considers that the nature, design, construction or purpose of the toy necessitates third party verification. This last case is a novelty, since under Directive 88/378/EEC this possibility did not exist. Under the new Directive, manufacturers have this obligation if they consider that the toy necessitates third party verification.

The EC-type examination shall be carried out using the procedures specified in Article 20. EC-type examination always needs to be combined with the conformity to type procedure which has to be carried out using the procedure set out in Module C of Annex II to the Decision No 768/2008/EC.

4.3. Article 20 EC type examination

4.3.1. Article 20 (1)

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

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

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

Article 20 (1) specifies the provisions to be used for the concrete application of the EC-type examination. The application for EC-type examination, performance of that examination and issue of the EC-type examination certificate are carried out in accordance with the procedures set out in Module B laid down in Annex II to Decision 768/2008/EC. Since that Module foresees three possibilities for carrying out the EC type examination, it is further specified that the combination of production type and design type is used in accordance with the second indent of point 2 of that module.

Furthermore, it is stated that in addition to these provisions of Module B, the provisions in paragraphs 2 to 5 of this Article have to be applied. These paragraphs contain specific rules for the purposes of the Toys sector.

4.3.2. Article 20 (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.

Paragraph 2 foresees additional documents to be submitted in the application for an EC-type examination. The application has to always contain a description of the toy and an indication of the place of manufacture, including the address.

4.3.3. Article 20 (3)

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

Article 20 (3) contains a requirement for the performance of the EC-type examination. The Notified body shall evaluate the safety assessment that the manufacturer has performed in accordance with Article 18. This is done if necessary together with the manufacturer.

4.3.4. Article 20 (4), first subparagraph

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

Article 20 (4) lays down requirements for the EC-type examination certificate. The first subparagraph includes a requirement that the certification needs to include a reference to the Toys Directive, a colour image and clear description of the toy, which includes dimensions. Furthermore, the EC-type examination certificate has to describe the tests performed with a reference to the relevant test report.

The dimensions referred to by this paragraph refer to the dimensions of a toy, not to the component parts of a toy. The aim was to distinguish a toy in an assortment of identical toys with different sizes. When considering the dimensions of the toy it would be sufficient to state for example "brown bear with embroidered features 45 cm in height" so as to distinguish from a 25cm and 35cm version in an assortment (family) of toys. The aim was not to refer to the component parts of construction sets, nor should the general dimensions of the assembled toy of a construction set be given.

4.3.5. Article 20 (4), second subparagraph

The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.

This provision foresees a review of the EC-type examination certificate. The EC-type examination certificate has to be reviewed when it is considered necessary. It is the manufacturer alone that is responsible for ensuring that the review is carried out.

The provision mentions as examples of the situations in which the review of the EC-type examination certificate is necessary: modification in the manufacturing process and modification in the raw materials or the components. In any case, the EC-type examination has to be reviewed every 5 years. Article 41 (3) foresees a power and an obligation for the market surveillance authorities to instruct the notified body to review the EC-type examination certificate where necessary and in particular in the cases mentioned in Article 20 (4), second subparagraph.

4.3.6. Article 20 (4), third subparagraph

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

This provision foresees an obligation for a notified body to withdraw the EC type examination certificate it has granted. The EC-type examination certificate shall be withdrawn if the toy fails to comply with the essential safety requirements of the Directive. According to Article 41 (2), the market surveillance authority has the power and obligation to instruct the notified body to withdraw the certificate if it finds that the toy is not in conformity with the essential safety requirements of the Directive.

4.3.7. Article 20 (4), fourth subparagraph

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

This provision foresees an obligation for the Member States. They have to ensure that their notified bodies do not grant an EC-type examination certificate for a toy for which it has already been refused or withdrawn.

4.3.8. Article 20 (5)

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

Article 20 (5) sets the language requirements for the technical documentation and correspondence to be drafted for the purposes of the EC-type examination. This documentation and correspondence must be drawn up in an official language of the Member State in which the Notified body is established. If the body accepts another language, the technical documentation can be also drawn up in that language.

4.4. Article 21 Technical documentation

4.4.1. Article 21 (1)

The technical documentation referred to in Article 4(2) shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements set out in Article 10 and Annex II. It shall, in particular, contain the documents listed in Annex IV.

Article 21 contains requirements on the technical documentation that the manufacturer is obliged to draw up under Article 4 (2), and which the manufacturer or his authorised representative shall keep available for inspection by the market surveillance authorities in accordance with Article 4 (3) and 5 (3). Article 21 (1) specifies the content of the technical documentation. It must contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the relevant essential safety requirements of the Directive. It must at least contain the documents listed in Annex IV.

More information on the technical documentation can be found in a separate guidance document on the technical documentation.

4.4.2. Article 21 (2)

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

Article 21 (2) sets the language requirements for the technical documentation. The technical documentation must be drafted in one of the official languages of the European Community. As regards, the technical documentation drawn up for the EC type examination, the language requirement is laid down in Article 20 (5).

4.4.3. Article 21 (3)

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

When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may fix a deadline for receipt of such file or translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

Article 21 (3) lays down the translation obligations regarding the technical documentation. If the market surveillance authority of a MS makes a reasoned request, the manufacturer shall provide for a translation of the relevant parts of the technical documentation into the language of that Member State. This provision requires the request to be reasoned. It does not however, prevent random checks of a toy and its technical documentation.

The second paragraph lays down rules on the deadline for providing the translation of the technical documentation or parts of it. The market surveillance authority may fix a deadline for producing the documentation. This deadline must in principle be fixed at 30 days. Fixing a shorter deadline is possible if it is justified because of a serious and immediate risk.

4.4.4. Article 21 (4)

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

Article 21 (4) fixes the consequences for the case when the manufacturer does not observe his obligations foreseen in the previous paragraphs, that is, if he has not drawn up the technical documentation with the required content (for example if there is no link between the toy and the technical documentation in question), if he has not drawn it in one of the official languages of the Community, or if he is not providing the translation of it within the required timeframe. If the manufacturer does not observe these obligations, the market surveillance authority may require him to have a test performed by a notified body within a specified period in order to verify compliance with the harmonised

standards and the essential safety requirements. This shall be done at the expense of the manufacturer. If the non-compliance persists, the authority has the possibility in accordance with Article 45 to take all the appropriate measures to restrict or prohibit the toys being made available on the market or ensure that it is recalled or withdrawn from the market.

This paragraph refers to tests performed by a notified body. Notified bodies deliver EC-type certificates according to the procedure described in module B annex II of Decision 768/2008/EC. According to this procedure, the technical documentation is part of the manufacturer's application and can be examined by the notified body. It is therefore expected for the manufacturer to be in possession of a technical documentation after the product has been tested by a notified body and to keep it for 10 years.

The scope of the notified body intervention is to demonstrate the compliance of the toy with the TSD requirements.

5. CHAPTER V NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

5.1. Articles 22 to 38

This Chapter comes in its entirety from the horizontal Decision 768/2008/EC. Therefore please see the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

The EA guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes contains horizontal criteria for conformity assessment bodies seeking accreditation for the purpose of notification, to carry out as notified bodies, third-party conformity assessment tasks under Community harmonisation legislation.

Article 22 Notification

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

Article 23 Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of this Directive, and for the monitoring of notified bodies, including compliance with Article 29.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 24(1) to (5). In addition, that body shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 24 Requirements relating to notifying authorities

1. Notifying authorities shall be established in such a way that no conflict of interest with a conformity assessment body occurs.
2. Notifying authorities shall be organised and operated so as to safeguard the objectivity and impartiality of their activities.
3. Notifying authorities shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform, nor shall they offer or provide consultancy services on a commercial or competitive basis.
5. Notifying authorities shall safeguard the confidentiality of the information they obtain.
6. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.

Article 25 Information obligation of notifying authorities

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

The Commission shall make that information publicly available.

Article 26 Requirements relating to notified bodies

1. For the purposes of notification under this Directive, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
2. Conformity assessment bodies shall be established under national law and shall have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the toy it assesses.

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

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

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design or manufacture, the marketing, installation, use or maintenance of those toys, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

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

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
6. Conformity assessment bodies shall be capable of carrying out the conformity assessment tasks assigned to them by the provisions of Article 20 and in relation to which they have been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

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

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

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

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

7. The personnel responsible for carrying out the conformity assessment activities shall have:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant Community harmonisation legislation and of its implementing regulations;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

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

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

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 38, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Conformity assessment bodies often combine activities as Notified Body (issuing EC-type certificates) and regular testing to standards. The two mentioned activities are operated as separate activities and the requirements mentioned above and below relate only to the NB activities.

Meant by a "NB cannot perform consultancy activities for the products for which they perform EC-type examination" (Article 26.4 of the new TSD) is the fact that the NB can offer 'consultancy services', seen as interpreting the requirements of the legislation for the manufacturer, only in connection with the certification it is in fact carrying out. This

would be a natural extension of the certification process, with added value for the manufacturer. For example, the NB would need to explain exactly why it is refusing to issue a certificate. Consultancy can be an activity offered by a test house (even if the test house is also a notified body) provided the two activities are well identified and separated.

The NB is not allowed to support manufacturers to create the technical documentation, the EC declaration of conformity or to make the safety assessment (as defined in article 18) as in this case the NB would be confirming its own work.

Article 27 Presumption of conformity

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 26 insofar as the applicable harmonised standards cover those requirements.

Article 28 Formal objection to a harmonised standard

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

Article 29 Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 26, and shall inform the notifying authority accordingly.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 20.

Article 30 Application for notification

1. A conformity assessment body shall submit an application for notification under this Directive to the notifying authority of the Member State in which it is established.
2. The application referred to in paragraph 1 shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the toy or toys for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

Article 31 Notification procedure

1. Notifying authorities may only notify conformity assessment bodies which have satisfied the requirements laid down in Article 26.
2. Notifying authorities shall notify conformity assessment bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules, toy or toys concerned and the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate as referred to in Article 30(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26.
5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

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

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

Article 32 Identification numbers and lists of notified bodies

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

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

Article 33 Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying and market surveillance authorities, at their request.

Article 34 Challenge to the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued

fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 35 Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 20.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

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

3. Where a notified body finds that the requirements set out in Article 10 and Annex II or in corresponding harmonised standards have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue the EC-type examination certificate as referred to in Article 20(4).
4. Where, in the course of the monitoring of conformity following the issue of a EC-type examination certificate, a notified body finds that a toy is no longer in compliance, it shall require the manufacturer to take appropriate corrective measures, and shall suspend or withdraw the EC-type examination certificate if necessary.
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EC-type examination certificates, as appropriate.

Article 36 Information obligation of notified bodies

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

with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 37 Exchange of experience

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

Article 38 Coordination of notified bodies

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

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

6. CHAPTER VI OBLIGATIONS AND POWERS OF THE MEMBER STATES

6.1. Article 39 Precautionary Principle

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

Article 39 foresees an obligation and a power for the Member States to take due account of the precautionary principle. The competent authorities of the Member States shall take the precautionary principle into account when they take measures under this Directive. These measures include in particular the market surveillance measures referred to in Article 40.

The precautionary principle is applied in situations where the available scientific evidence is too uncertain to allow accurate risk estimation. The precautionary principle is a general principle of Community law that has been developed in the case law of the Court of Justice⁴ on the basis of a Treaty provision applying in the environmental field (Article 191 TFEU). Its content is specified in the Communication of the Commission on the precautionary principle of 2 February 2000 (see COM (2000)1 or <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1453135971943&uri=CELEX:52000DC0001>).

In accordance with the Communication, recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a toy have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty. In other words Member States authorities are faced with an unacceptable potential risk which cannot be determined with sufficient certainty in spite of a scientific evaluation carried out.

In the field of safety of toys, when the risks of a toy are fully covered by harmonised standards, the references of which have been published in the Official Journal, there is no room for the application of the precautionary principle, unless a formal objection is raised against the standard or parts of it. If the toy is connected to serious incidents, the principle may however be applied even before the formal objection is officially raised.

It should be noted - as mentioned in the Commission Communication - that where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review*, in the light of new scientific data, and

⁴ See i.a. Judgement of the Court of Justice of 26 May 2005 in Case C-132/03 *Codacons and Federconsommatori* [2005] ECR I-4167.

- *capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.*

It is also clear that the precautionary principle should be applied taking into account the other rules and principles of the Directive. Clear rules naturally take precedence over a principle. As for other principles contained in the Directive such as the free movement of toys (Article 12) and presumption of conformity (Article 13), they have to be considered when applying the precautionary principle and weighed against the precautionary principle.

6.2. Article 40 General obligation to organise market surveillance

Member States shall organise and perform surveillance of toys placed on the market in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008. In addition to those Articles, Article 41 of this Directive shall apply.

This Article lays down a general obligation for the Member States to organise and perform market surveillance. Market surveillance is performed in accordance with Articles 15 to 29 of Regulation 765/2008. For their application please see the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

In addition to this, the Toys Directive foresees certain specific powers and obligations for the market surveillance authorities in Article 41.

Note: the more specific market surveillance measures provided in the General Product Safety Directive will also apply in the toys sector (see Article 15 (3) of the horizontal Regulation). The applicable measures are described in the guidance document outlining the relationship between the GPSD and Regulation (EC) No 765/2008 which is enclosed to these guidelines.

6.3. Article 41 Instructions to the Notified body

Article 41 lays down specific obligations and powers for the market surveillance authorities in relation to Notified bodies.

6.3.1. Article 41 (1)

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

Article 41 (1) gives the market surveillance authorities the power to ask a notified body to provide information to it. It can ask information relating to an EC-type examination certificate which the body has issued or withdrawn. It can also ask information relating to a refusal of a notified body to issue such a certificate. The information requested may include the test reports and technical documentation relating to the certificate in question.

6.3.2. Article 41 (2)

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

Article 41 (2) foresees an obligation for the market surveillance authorities to act if it finds that a particular toy is not in conformity with the essential safety requirements of the Directive. If the toy is covered by an EC-type examination certificate it shall instruct the notified body to withdraw the EC-type-examination certificate in respect of such toys.

6.3.3. Article 41 (3)

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

Article 41 (3) foresees a power and an obligation for the market surveillance authorities to instruct the notified body to review the EC-type examination certificate. This should be done in particular in cases specified in Article 20 (4) second subparagraph, that is, when there has been a modification in the manufacturing process and modification in the raw materials or the components. In any case, the EC-type examination has to be reviewed every 5 years.

6.4. Article 42 Procedure for dealing with toys presenting a risk at national level

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

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take appropriate corrective action to bring the toy into compliance with those requirements, to withdraw the toy from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

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

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

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

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

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

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

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant toy, the origin of the toy, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either:

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

(b) shortcomings in the harmonised standards referred to in Article 13 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the toy concerned, and, in the event of disagreement with the notified national measure, of their objections.

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

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

Procedure to deal with toys presenting a risk at national level.

6.5. Article 43 Community safeguard procedure

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

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

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

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

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

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

Article 42 and 43 stem from the horizontal Decision 768/2008. Please see the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

6.6. Article 44 Exchange of information – Community Rapid Information System

If a measure referred to in Article 42(4) is a type of measure which is required under Article 22 of Regulation (EC) No 765/2008 to be notified through the Community Rapid Information Exchange System, it shall not be necessary to make a separate notification under Article 42(4) of this Directive, provided that the following conditions are met:

(a) the Community Rapid Information Exchange notification indicates that the notification of the measure is also required by this Directive;

(b) the supporting evidence referred to in Article 42(5) is enclosed with the Community Rapid Information Exchange notification.

This Article foresees a simplification of procedures in cases where both notification under Article 22 of Regulation (EC) No 765/2008 and a safeguard clause notification have to be done. In that case it is not necessary to make a separate safeguard clause notification under the following conditions:

a) the Article 22 of Regulation (EC) No 765/2008 notification indicates that the notification is also required under the toys directive

b) The evidence mentioned in Article 42 (5) is enclosed with the notification according to Article 22 of Regulation (EC) No 765/2008

6.7. Article 45 Formal non compliance

1. Without prejudice to Article 42, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
 - (a) that the CE marking has been affixed in violation of Article 16 or 17;
 - (b) that the CE marking has not been affixed;
 - (c) that the EC declaration of conformity has not been drawn up;
 - (d) that the EC declaration of conformity has not been drawn up correctly;
 - (e) that technical documentation is either not available or not complete.
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take appropriate measures to restrict or prohibit the toy being made available on the market, or shall ensure that it is recalled or withdrawn from the market.

Article 45 stem from the horizontal Decision 768/2008. Please see the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm).

7. CHAPTER VII COMMITTEE PROCEDURES

7.1. Article 46 Amendments and implementing measures

7.1.1. Article 46 (1), first subparagraph

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

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

Article 46 (1), first subparagraph, foresees which provisions of the Directive can be amended by the Commission by using the comitology procedure.

First of all, the comitology procedure may be used to amend Annex I containing the list of examples of products that are not considered as toys. This can be useful in particular in order to add to the list new products that appear on the market and which could be confused with toys.

Secondly, point 11 of the chemical safety requirements may be amended by comitology, that is, the list of prohibited fragrances or fragrances that have to be labelled if used in toys. This could in particular be done when new substances are added to the list of prohibited fragrances or to the list of fragrances subject to labelling in the cosmetics directive.

Thirdly, point 13 of the chemical safety requirements may be amended by comitology, that is, the list of migration limits for certain elements. New limits could be set if new scientific evidence is gained or new substances could be added to this list if appropriate.

Finally, comitology can be used to amend and complete Annex V which contains the specific warnings for certain categories of products.

7.1.2. Article 46 (1), second subparagraph

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

Article 46 (1), second subparagraph foresees which procedure of the Comitology Decision 1999/468/EC is used to amend the above mentioned provisions. The procedure to be used by the Commission is the regulatory procedure with scrutiny.

7.1.3. Article 46 (2)

The Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food. The

Commission shall amend Appendix C to Annex II to this Directive accordingly. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2) of this Directive.

Article 46 (2) foresees a possibility to ensure protection of the particularly vulnerable subgroup of children by adopting specific limit values for chemicals. These toys are toys intended for children under 36 months and other toys intended to be put in the mouth (such as toy instruments). The specific limit values shall be set taking into account the Food Contact Material legislation, on the one hand, and the differences between toys and material which come into contact with food, on the other hand. In particular the differences in exposure scenarios (dynamic for toys due to mouthing and static for food contact materials) have to be taken into account in the analytical procedure in order to simulate the contact conditions with toys.

Also these limit values are adopted by the Commission under the regulatory procedure with scrutiny.

7.1.4. Article 46 (3)

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

Article 46 (3) foresees the use of the comitology procedure for granting exemptions from the ban of CMRs for such CMRs substances that have been evaluated by the Scientific committee. When these exemptions are granted, the substances and their permitted uses shall be listed in Appendix A to Annex II of the Directive. The conditions for granting the exemptions are laid down in Annex II, part 3, points 4 and 5.

Also these measures are adopted by the Commission under the regulatory procedure with scrutiny.

7.2. Article 47 Committee

7.2.1. Article 47 (1)

The Commission shall be assisted by a committee.

Article 47 creates a Committee to assist the Commission in the implementation of the Toys Directive.

7.2.2. Article 47 (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.

Article 47(2) specifies the applicable provisions of the Comitology Decision (1999/468/EEC) when this paragraph is referred to. The reference to this paragraph is made in the previous Article 46, in its paragraphs 1, 2 and 3.

8. CHAPTER VIII SPECIFIC ADMINISTRATIVE PROVISIONS

8.1. Article 48 Reporting

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

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

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

This Article sets an obligation for the Member States to draw up a report on the application of the Directive. This report has to be sent to the Commission five years after the date of entry into force of the Directive which means by 20 July 2014 and every five years thereafter.

As regards the content of the report, it has to contain the following elements 1) an evaluation of situation concerning the safety of toys, 2) an evaluation of the effectiveness of this Directive, and 3) presentation of the market surveillance activities that the Member State has performed.

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

The Commission declared for the Council minutes for the adoption of the Directive of the European Parliament and of the Council on the safety of toys that:

"Following the entry into force of the revised Toys Safety Directive, the Commission will monitor closely all developments relating to its implementation in order to assess whether it provides for an adequate level of toys safety, notably as concerns the application of the conformity assessment procedures as laid down in Chapter IV.

The revised Toys Safety Directive provides for a reporting obligation of Member States on the situation concerning the safety of toys, the effectiveness of the Directive and market surveillance performed by Member States.

The evaluation by the Commission will *inter alia* be based on the Member States reports to be submitted three years following the date of application of the Directive with a particular focus on market surveillance in the European Union and its external borders.

The Commission will report back to the European Parliament at the latest one year after submission of Member States reports."

8.2. Article 49 Transparency and confidentiality

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

As regards the transparency and confidentiality to be respected by the Member States when they take measures under the Directive, a reference is made to the provisions of Article 16 of the General Product Safety Directive. This Article foresees the following:

"Article 16

1. Information available to the authorities of the Member States or the Commission relating to risks to consumer health and safety posed by products shall in general be available to the public, in accordance with the requirements of transparency and without prejudice to the restrictions required for monitoring and investigation activities. In particular the public shall have access to information on product identification, the nature of the risk and the measures taken.

However, Member States and the Commission shall take the steps necessary to ensure that their officials and agents are required not to disclose information obtained for the purposes of this Directive which, by its nature, is covered by professional secrecy in duly justified cases, except for information relating to the safety properties of products which must be made public if circumstances so require, in order to protect the health and safety of consumers.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant for ensuring the effectiveness of market monitoring and surveillance activities. The authorities receiving information covered by professional secrecy shall ensure its protection."

The applicable measures are described in the guidance document outlining the relationship between the GPSD Directive and Regulation (EC) No 765/2008 enclosed to these guidelines.

8.3. Article 50 Motivation of measures

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

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

This Article foresees an obligation for Member states authorities to give the grounds for any Decision they take under the Directive which prohibits or restricts the placing on the market of a toy or which orders its withdrawal or recall from the market.

These measures and their grounds have to be notified to the economic operator concerned. This notification shall also contain information about the remedies, that is, about the possibilities of redress, available to him in the Member State concerned and about the time limits that need to be respected for such remedies.

8.4. Article 51 Penalties

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

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

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

Article 51 contains an obligation for the Member States to lay down rules on penalties for economic operators in case of infringements of the national provisions adopted to transpose the Directive. These penalties may include criminal sanctions in case of serious infringements. Member States also need to ensure that these sanctions are implemented in practise.

The Article further requires that these sanctions are effective, proportionate to the infringement and dissuasive. They may be increased if the economic operators have already committed a similar infringement of the Directive.

The Member States have an obligation to notify the Commission of the provisions laying down the sanctions in question by 20 July 2011. Any amendments to these provisions need to be notified without delay.

9. CHAPTER IX FINAL AND TRANSITIONAL PROVISIONS

9.1. Article 52 Application of Directive 85/374/EEC and 2001/95/EC

9.1.1. Article 52(1)

This Directive is without prejudice to Directive 85/374/EEC.

Article 52 (1) foresees that this Directive does not affect the application of the Product Liability Directive which foresees the liability and compensation obligations for economic operators in case of a damage caused by products including toys, based on strict liability for defective toys. It is in particular important to note that under the Product liability Directive, the liable person can be

- manufacturer of a finished product,
- the producer of any raw material or
- the manufacturer of a component part
- any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer, and
- any person who imports into the Community a product for any form of distribution in the course of his business.

This article means that the compliance with all obligations and safety requirements set by the TSD does not exempt the manufacturer from the defective product liability in accordance to Directive 85/374. In order to evaluate if a product is “defective” in accordance to Article 6 of Directive 85/374, the safety requirements of the TSD should be used.

9.1.2. Article 52 (2)

Directive 2001/95/EC shall apply to toys in accordance with Article 1(2) thereof.

Article 52 (2) foresees how the General Product Safety Directive is applied in the toys field. The General Product Safety Directive applies to toys in accordance with its Article 1 (2) which lays down that each of its provisions apply in so far as there are not specific provisions with the same objective in rules of Community law governing the safety of the product.

See also article 40 in order to have an overview on the more specific provisions.

9.2. Article 53 Transitional periods

9.2.1. Article 53 (1)

Member States shall not impede the making available on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before 20 July 2011.

Article 53 (1) lays down the general transitional period which applies to toys except for the chemical requirements for which a longer transitional period is foreseen in paragraph

2. The transitional period means that toys complying with Directive 88/378/EEC can be made available on the market if they have been placed on the market before and during a period of 2 years from the entry into force of the Directive, that is before 20 July 2011. Making available covers any supply of the toy for distribution, consumption or use in the Community in the course of commercial activity. It is therefore possible for toys complying with the old Directive to stay on the market and be supplied in any stage of the supply chain as long as the toys have been placed on the market (= first making available in the European Community) before 20 July 2011.

9.2.2. Article 53 (2)

In addition to the requirement of paragraph 1, Member States shall not impede the making available on the market of toys which are in accordance with the requirements of this Directive, except those set out in Part III of Annex II, provided that such toys meet the requirements set out in Part 3 of Annex II to Directive 88/378/EEC and were placed on the market before 20 July 2013.

Article 53 (2) lays down a specific, longer transitional period for complying with the chemical requirements. This transitional period is two years longer than the general one, and it ends 20 July 2013. Therefore toys which do not comply with the new chemical requirements can be made available on the market if they comply with the chemical requirements of Directive 88/378/EEC and they have been placed on the market before 20 July 2013. If they were placed on the market after the end of the general transitional period that is 20 July 2013, they have to comply with the other requirements of the Directive.

Remark: placed on the market is defined in art 3

9.3. Article 54 Transposition

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

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

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

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

Member States have 18 months, that is, until 20 January 2011 to transpose the Directive into their national law. They have to inform the Commission therefore and communicate to the Commission the provisions of national law that they adopt in the field covered by the Directive.

Member States shall all apply the provisions transposing the Directive at the same time. This is from 20 July 2011.

When Member States adopt provisions transposing the Directive, they have to contain a reference to the Directive or be accompanied by such a reference when the provisions are published. Member States must determine how such references are made.

If a Member State fails to transpose the Directive within this period, the provisions of the Directive may in accordance with the case law of the European Court of Justice be relied upon as against any national provision which is incompatible with the directive or insofar as the provisions define rights which individuals are able to assert against the State if they are unconditional and sufficiently precise (this is called the direct effect of Directive). However, directives cannot have horizontal effect (against another private individual or company), as this is adjudged contrary to the principles of equality. As such, Directives are currently only vertically directly effective (i.e. against the state).

9.4. Article 55 Repeal

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

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

Article 55 repeals Directive 88/378/EEC from 20 July 2011, that is, when the transitional period ends. The chemicals part is, however, repealed from 20 July 2013 due to the longer transitional period applying to chemical requirements.

The references in other pieces of legislation that have been made to Directive 88/378/EEC shall be considered as being made to the new Directive or to its corresponding provision.

9.5. Article 56 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*.

The Directive entered into force on the 20th July 2009

9.6. Article 57 Addressees

This Directive is addressed to the Member States.

The addressees of the Directive are the Member States who are obliged to ensure the implementation of the Directive by transposing it into national law.

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

This Annex enumerates examples of products that are not considered as toys but could be confused with toys. Since it would be impossible to enumerate all the products that are not considered as toys, the list is naturally not exhaustive. A contrario interpretation should not be drawn from the list, that is, if a particular product is not mentioned in the list, it does not mean that it is automatically a toy. Each of the exceptions needs to be considered separately. The wording for some of the exceptions in the list of Annex I is straightforward, leaving little margin for appreciation when assessing whether a product falls within the scope of the exception or not. That is the case, for example, for Points 3, 4, 8 or 9. For some other exceptions, the wording would still require a certain assessment to establish whether the conditions for the exception are met and a product is therefore not to be considered as a toy. This would be for example the case for Points 1, 14 or 19 where it may need to be assessed whether the product has a play value of its own. In the latter cases, the definition of toy in Article 2 (1) first subparagraph has to always be the basis for deciding whether a product is a toy or not. The reasonable foreseeable use will prevail over the declaration of intention of the manufacturer. If a product falls under the scope of art.2, it will be qualified as a toy and submitted to the directive's requirements (with the exception of toys listed in art. 2.2). In addition to that, the guidance documents mentioned under that Article above (point 1.2.1) give useful criteria which should always be considered in case of grey zone products.

Please note that if a consumer product does not fall under the Toys Directive, it still needs to be safe as regards the health and safety of consumers according to Directive 2001/95/EC on general product safety or any other applicable Community legislation containing specific health and safety requirements.

10.1.1. Point 1

Decorative objects for festivities and celebrations

This category of products includes a variety of decorative objects, for example for Christmas or birthdays. They can be child appealing, such as a decorative Santa Claus for Christmas. However, it is important to note that a child appealing product which is not considered as a toy, still needs to be safe for children in accordance with the provisions of the General Product Safety Directive. More information and guidance can be found in the guidance document 11 "toys intended for children under and above 36 months".

10.1.2. Point 2

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

- (a) detailed and faithful scale models;
- (b) kits for the assembly of detailed scale models;
- (c) folk dolls and decorative dolls and other similar articles;
- (d) historical replicas of toys; and
- (e) reproductions of real fire arms.

This category of products for adult collectors includes a variety of products, some of which are specifically mentioned in this point as examples.

10.1.2.1. Detailed and faithful scale models

These can be for example cars, boats, aeroplanes, trains, historical buildings.

10.1.2.2. Kits for the assembly of detailed scale models

These are the same kind of products as under point 10.1.2.1. but they are to be assembled by the consumer himself.

10.1.2.3. Folk dolls and decorative dolls and other similar articles

A specific guidance document has been drafted to give criteria to make a distinction between dolls which should be considered as toys and articles which should be regarded as products for adult collectors (Guidance document No 6 "Criteria for differentiating dolls for adult collectors from toys"):

http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

10.1.2.4. Historical replicas of toys

Examples of these products are tin soldiers.

10.1.2.5. Reproductions of real fire arms

Replicas of firearms are not considered as toys. A distinction between them and toy guns intended for playing should be done on the basis of the general criteria for classification (price, place for selling, target audience etc) as well as degree of detail.

10.1.3. Point 3

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

Equipment intended for sports and not for play by children under 14 is not considered as a toy. Since grey zone products exist, this point clarifies the classification by foreseeing as criteria whether the product is intended for children with a body mass of more than 20 kilos.

10.1.4. Point 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

This point clarifies which bicycles are considered as toys intended for playing and which do not fall under the Toys Directive. The decisive criterion is the maximum saddle height. The bicycle is not a toy if the maximum saddle height is more than 435 mm measured as the vertical distance from the ground to the top on the seat surface with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark.

This point has changed from what was foreseen in Directive 88/378. In that Directive the decisive criteria was whether the bicycle was designed for sport or for travel on the public highway. In that case it was not considered as a toy. Because of the general nature of this definition it, however, led to differences in the classification of bicycles in different Member States.

Bicycles with a saddle height of more than 435 mm and less than 635 mm fall under the General Product Safety Directive and comply preferably to standard EN 14765.

10.1.5. Point 5

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

This point covers means of transport, in particular scooters. It is stated that they are not toys when they are designed for sport or intended to be used for travel on public roads or public pathways. Other examples include roller skis, kick sledges and kick bikes and roller-skates (which also follows from point 3). Although bicycles are means of transport, they are not considered under this point, because they are dealt with specifically in point 4. Also electrically driven vehicles are treated separately in point 6.

In contrast, some means of transport can be considered as toys, if they have a play value and are intended for children under 14 years of age, for instance some scooters with play value which are not intended to be used for travel on public roads or public pathways.

10.1.6. Point 6

Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof

This point covers electrically driven vehicles. It is clarified that they are not toys when intended to be used for travel on public roads, public pathways, or on the pavement of these. In contrast, electrically driven ride on toys, that is electrically driven vehicles for children under 14 years of age with play value which are not intended for travel on public roads, pathways, on the pavement of these, are considered as toys.

10.1.7. Point 7

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

This point covers, first, aquatic equipment which is used in deep water, and secondly swimming learning devices, such as swim seats and swimming aids. The classification of aquatic equipment is dealt with specifically in Guidance document No 7 "Are certain aquatic devices/equipment covered by the Safety of Toys Directive (88/378/CEE) or not?": http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

10.1.8. Point 8

Puzzles with more than 500 pieces

This point gives a clear cut criterion for deciding which puzzles are not toys. Puzzles with more than 500 pieces are not considered as toys.

10.1.9. Point 9

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

This point deals first with some type of guns that could be confused with toys. It clarifies that guns and pistols using compressed gas, for instance airguns, are not toys. However, water guns are considered as toys. Secondly, bows for archery over 120 cm long are never considered as toys.

10.1.10. Point 10

Fireworks, including percussion caps which are not specifically designed for toys

This point clarifies that fireworks are not considered as toys. Percussion caps are not considered as toys, except when specifically designed for toys.

10.1.11. Point 11

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

This point specifies that if a product or game includes sharp pointed missiles it is not considered as a toy. Examples of these products include sets of darts with sharp-pointed metallic tips. Therefore, toy darts can never include metallic points.

10.1.12. Point 12

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

This point excludes functional educational products. As the definition in Article 3 indicates, 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 product, appliance or installation. Point 12 mentions as examples electric ovens, irons. These products cannot be considered as toys when operated at a nominal voltage exceeding 24 volts and are sold exclusively for teaching purposes under adult supervision.

10.1.13. Point 13

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

This point excludes products intended for educational purpose. They are excluded if for use in schools or other pedagogical framework under the surveillance of an adult instructor. As example is mentioned science equipment.

10.1.14. Point 14

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

This point clarifies which kind of electronic equipment cannot be considered as toys. First, electronic equipment, such as personal computers and game consoles which are used to access interactive software are not considered as toys. However, they shall be considered as toys if specifically designed and targeted at children and have a play value, such as specifically designed personal toy computers. Secondly the associated peripherals of the electronic equipment which is used to access interactive software are not considered as toys either. However, they shall be considered as toys if they are specifically designed and targeted at children and have a play value on their own, such as key boards, joy stick or steering wheels.

Example of a toy personal computer:



10.1.15. Point 15

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

This point clarifies that interactive software intended for leisure and entertainment, and their storage media should not be considered as toys. As examples are mentioned computer games and (music)CD's.

10.1.16. Point 16

Babies' soothers

This point specifies that babies' soothers are not toys. They are childcare articles which fall under the General Product Safety Directive.

10.1.17. Point 17

Child-appealing luminaires

This point clarifies that child-appealing luminaries, that is lamps and lightings, are not considered as toys. They do not have the play value to be classified as toys. However lamps used in a doll house are considered as toys.

The Low Voltage Directive is applicable to these products. More information on child appealing luminaries can be found on following page:

<http://ec.europa.eu/DocsRoom/documents/8765/attachments/1/translations/en/renditions/native>

10.1.18. Point 18

Electrical transformers for toys

This point specifies that electrical transformers for toys are not considered as toy. In this context it is important to note the requirement in Annex II, part IV, point 9, which foresees that electrical transformers for toys shall not be integral part of the toy.

10.1.19. Point 19

Fashion accessories for children which are not for use in play

This point clarifies that fashion accessories, in particular jewellery for children, which are not for use in play are not considered as toys. Jewellery with play value, in contrast, is a toy, for instance jewellery sold with toy disguise costumes and (imitation) jewellery to be assembled by the child himself.

11. ANNEX II PARTICULAR SAFETY REQUIREMENTS

11.1. I PHYSICAL AND MECHANICAL PROPERTIES

11.1.1. Point 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.

This requirement concerns mechanical strength of toys which have to be such that the toy does not cause injury by breaking or by distortion. This requirement is dealt with in the EN 71-1:2011 (see annex ZA) and in EN 71-8:2011 (see annex ZA)

11.1.2. Point 2

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

This requirement, first, concerns any accessible edges and protrusions which should not present injury from contact with them, such as contain sharp edges or protrusions. Secondly, it also requires that cords, cables and fastenings do not present risk of injury. This requirement is dealt with in the EN 71-1:2011 (see annex ZA) and in EN 71-8:2011 (see annex ZA).

11.1.3. Point 3

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

This requirement concerns the risk presented by moving parts of the toy. They should not present any risk of injury or only the minimum risks inherent with the toys use. For example, scooters which can be folded could cause injury by entrapment of fingers but this risk needs to be covered so that it is reduced to the minimum possible. This requirement is dealt with in the EN 71-1:2011 (see annex ZA) . Also some strength tests refer to “crushing, e.g. 4.15.1.3. EN 71-8:2011(see annex ZA) .

11.1.4. Point 4 (a)

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

This safety requirement states that toys should not present the risk of strangulation. This is in particularly important in case of toys with cords or strings which could present the risk of strangulation.

It is important to note that since there is no age group specified, this requirement applies to all toys, irrespective of the intended age group, whereas point 4 (d) only applies to toys

specified in that point. This requirement is dealt with in the EN 71-1:2011 (see annex ZA) and in EN 71-8:2011 (see annex ZA).

11.1.5. Point 4 (b)

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

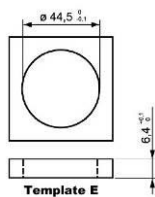
This requirement concerns the risk of external airway obstruction which could cause asphyxiation. This could happen if the flow of air from the mouth and nose is closed by the toy or its parts. In Directive 88/378/EEC the same risk was covered by the term “the suffocation” risk. For instance, a thin plastic sheet put over the mouth and nose could cause this risk of external airway obstruction. Since there is no age group specified, this requirement applies to all toys, irrespective of the intended age group. Warnings are not sufficient to address this hazard. Another example is a hemispherical shaped toy that forms an airtight seal over mouth and nose. For such toys intended for children above 3 years, a warning is at present considered to be sufficient to minimize the hazard. This requirement is dealt with in the EN 71-1:2011 (see annex ZA).

11.1.6. Point 4 (c)

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

This requirement concerns the risk of internal airway obstruction which could also cause asphyxiation. This could result from the closing of the flow of air by objects wedged in the mouth or pharynx or lodged over the entrance of the lower airways. This requirement which did not exist in the Directive 88/378 covers such products as suction cups, balloons and small balls. This requirement is dealt with in the EN 71-1:2011 (see annex ZA).

Since there is no age group specified, this requirement applies to all toys, irrespective of the intended age group. They should fulfil the small ball test, template E. It is important to note that this risk is different from the risk of choking dealt with under d)



For small balls, marbles and similar objects, warnings are at present considered to be sufficient to minimize the hazard if the toy is intended for children above 3 years. For balloons, the warning should address children under 8 years.

11.1.7. Point 4 (d)

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

intended to be put in the mouth, and to their component parts and any of their detachable parts.

This requirement concerns the risk of choking presented by small toys and small parts. It only applies to two types of toys: 1) toys clearly intended for use by children under 36 months and their component parts and any of their detachable parts, and 2) other toys which are intended to be put in the mouth, such as toy instruments, and their component parts and any of their detachable parts. Component parts and detachable parts refer to any small part that might be present on the whole toy, not only to the mouthpiece of the toy. If the toy to be placed in the mouth is sold together with other toys (whistle with ball, trumpet with drum), than only the toy intended to be put in the mouth is envisaged. These kinds of toys should be of such dimension as to prevent their being swallowed or inhaled. This risk has generally been called “choking” risk. This requirement is dealt with in the EN 71-1:2011 (see annex ZA).

For small parts in general warnings are considered to be sufficient to deal with the hazard if the toy is intended for children above 3 years. For other toys intended to be put in the mouth, a warning is not sufficient.

11.1.8. Point 4 (e)

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

This requirement lays down requirements applicable to all kinds of toy packaging. The packaging in which toys are contained for retail sale, that is, the consumer packaging, must not present any of the following risks:

- 1) Strangulation, or
- 2) Asphyxiation caused by airway obstruction external to the mouth and nose (see under 4 b for the explanation of this hazard).

Packaging requirements are dealt with in the EN 71-1:2011 (see annex ZA).

11.1.9. Point 4 (f)

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

This provision sets specific requirement for the packaging of toys in food, i.e. for toys contained within food or co-mingled with a food. Toys within or co-mingled with food always must be in their own packaging, separating the toy from the food. Examples are toys in surprise eggs, toys in cereals, toys in chips,...

The aim of the “co-mingled requirement” is to minimize the risk of choking due to confusion between the food and the toy. This risk arises when the toy is mixed up with the food and the handling of the toy and the food is similar. The child will have access in the same way to the toy as to the food, while not having any visibility of the content (food) and the toy item if the toy has no own packaging. The separate packaging increases the possibility for the child to discover the toy and to distinguish it from the food. An example is a flippo (round toy disc that has the same dimensions as chips) which is co-mingled in a bag of crisps and for which the consumer will not notice the difference with the flippo when eating crisps from the bag.

The aim of the “toy contained within food” requirement is also to minimize the risk of choking. However, in this case it is due to the fact that the toy is not visible when the foodstuff is eaten. An example is a chocolate egg with a toy inside.

Some toys can be sold together with food without falling under the scope of this article. For example, a toy attached to the outside or inside packaging of a box of biscuits. The toy is not co-mingled or contained in the food, as it is attached to the packaging of the food and not mixed up with food. Another example would be a box containing food stuffs and a toy, each one separated from the other. In these cases, when opening the box/package, the child will see the content and handle the different items differently. The risk of confusion is therefore minimized.

The packaging must not present any choking risk, that is it has to be of such dimensions as to prevent it being swallowed and/or inhaled. This means that like the toys under point 4 (d), the packaging needs to pass the small parts test cylinder test 8.2 in EN 71-1:2011.

11.1.10. Point 4 (g)

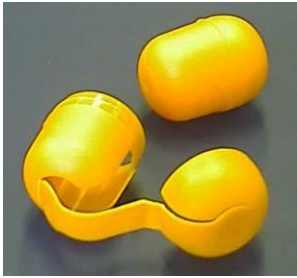
(g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx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

This provision sets specific requirements for certain shapes of toy packaging. First of all, spherical, egg-shaped or ellipsoidal packaging and any detachable part of it must be of such dimension as to prevent it from causing internal airway obstruction. It must pass the small ball test, template E, of the standard EN 71-1. Secondly, the same requirement applies to the detachable parts of a cylindrical toy packaging with rounded ends, meaning that a cylindrical toy packaging with rounded ends that can be separated in two individual parts is addressed by the requirement.

Picture showing examples of non-compliant packaging, as the detachable parts of the cylindrical toy packaging with rounded ends fail the small ball test, template E:



Picture showing examples of compliant packaging as the cylindrical toy packaging with rounded ends has no detachable parts after testing according to the tests mentioned in clause 5.1 of EN 71-1:2011:



The requirements apply to all toys packaging, irrespective of the intended age group. Small plastic bags are not addressed as they are not spherical, egg-shaped or ellipsoidal. Small parts are allowed in packaging to toys, except for the separate packaging to toys in food or comingled with food.

11.1.11. Point 4 (h)

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

This first sentence prohibits certain kinds of products composed of a toy and food, that is, toys which are *firmly* attached to the food-stuff at the moment of consumption. Firmly attached means that the food products need to be actually consumed – and not only removed- to get direct access to the entire toy (no part of the toy is accessible before consuming the food). Three criteria need to be fulfilled for this requirement to be applicable: the toy is inside the food, is attached to the food **and** is not accessible without consuming the food first. An example would be a toy completely covered by candy. In order to access the toy inside the candy, the child will need to eat the candy.

In contrast to the toy requirement above, the second sentence foresees requirements for parts of toys otherwise directly attached to a food product; that is to part of toys that are attached to the food-stuff of a food product but are accessible without consuming the food product. Meaning parts of the toy are accessible, without eating the food first or parts can be accessible by taking of the food with your hands, as the food is not firmly attached. In aforementioned conditions, the toy and its parts cannot have small parts, causing choking or cannot create internal airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways. Examples of these products are toy candy lipsticks, some party lollipops. These parts of toys are when applicable required to fulfil the requirements of 4 (c) (internal airway obstruction – small ball test, template E) and 4 (d) (small parts prohibition, irrespective of the age category they are intended to). As explained above, 4 (c) applies to all toys, and therefore, this point is mentioned here only for reasons of clarity. It is not allowed to use the age warning "not suitable..." in these cases.

Examples of parts of toys otherwise directly attached to a food can be found in Explanation IV.

11.1.12. Point 5

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

This point foresees a safety requirement for aquatic toys. Aquatic toys are defined in Article 3 as toys intended for use in shallow water which is capable of carrying or supporting a child on the water (see also Guidance document No 7 on aquatic toys http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm). These toys must be designed and manufactured so as to reduce as far as possible, any risk of loss of buoyancy of the toy and loss of support afforded to the child. Recommended use of the toy must be considered when evaluating whether the risk in question has been reduced as far as possible. This requirement is dealt with in the EN 71-1:2011 (see annex ZA). Aquatic toys need also to fulfil the other applicable requirements of the TSD (small parts,...).

11.1.13. Point 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.

This point sets requirements for toys which it is possible to get inside, such as tents and some activity toys. They need to have a means of exit, and this exit must be designed and manufactured so that the intended user can open easily from the inside. This requirement is dealt with in the EN 71-1:2011 (see annex ZA).

11.1.14. Point 7

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

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

This point lays down, first, requirements for all toys conferring mobility, such as bicycles, scooters, electrically driven toys and roller skates. They should contain, as far as possible, a braking system. This braking system needs to be compatible with the type of a toy and commensurate with the kinetic energy that the toy develops. Furthermore, the child must be able to operate the system easily, and a risk of ejection or physical injury to the user or to the outsiders should be covered. This requirement is dealt with in the EN 71-1:2011 (see annex ZA).

Secondly, this point contains a requirement for electrically driven ride-on-toys. Their maximum design speed must be limited so as to minimise the risk of injury. “Design speed” is defined in Article 3 (20).

11.1.15. Point 8

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

This point lays down requirement for the kinetic energy of toy projectiles. Their form and composition must be such that there is no risk of physical injury to the user or to the third parties when the projectiles are fired from a toy designed for that purpose and taking into account the nature of the toy. This requirement is dealt with in the EN 71-1:2011 (see annex ZA).

11.1.16. Point 9 (a)

Toys must be manufactured so as to ensure that:

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

This point contains first, in point a) a requirement concerning the maximum and minimum temperature of any accessible surface of a toy. The minimum and maximum temperature of the surfaces must not cause injury when touched. In other words, toys may not contain heating or burning elements which could cause injury when touched. As far as the minimum temperature is concerned, toys have to be made of materials in such a way that the cold surface could not cause injury. For instance, compressed gas that creates a cold surface when expanding may not cause injuries when touched. This requirement is partly dealt with in the EN 71-1:2011 (see annex ZA).

An example of a toy where minimum temperatures should be assessed is a science experiment kit that would allow children to discover the effect on temperature of a compressed gas allowed to come back to the atmospheric pressure (the temperature of the container would decrease).

11.1.17. Point 9 (b)

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

Point b) foresees requirements for liquids and gases contained within toys. They should not reach temperatures or pressures which are such that their escape from the toy might cause burns, scalds or other physical injury. However, an exemption from this requirement is foreseen for toys which for reasons essential to their proper functioning contain liquids or gases that reach high temperatures.

11.1.18. Point 10

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

This point foresees a requirement for toys that are designed to emit noise. Thus, it does not apply to the noise that could come out of a toy which is clearly not designed to emit a

sound such as a balloon which bursts or a balloon which a child could make to "whistle" without any helping device, but to toys that are constructed with the intention to emit noise. These toys should be designed and manufactured so that the sound of them is not able to impair children's hearing. This applies to both impulse and continuous noise. The peak (maximum) values to be respected are found in EN 71-1:2011 (see annex ZA).

11.1.19. Point 11

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

This point concerns activity toys, which are defined in Article 3, point 21. First, they must be designed and manufactured in such a way as to reduce the following risks to the minimum: crushing or trapping of body parts or trapping of clothing and the risk of falls, impacts and drowning. Secondly, it is required in particular that any surface to which one or more children have access to play on must be designed to bear their load during static and dynamic use. This requirement is dealt with in the EN 71-8. Activity toys need also to comply with the other applicable requirements of the TSD, meaning that activity toys shall fulfill also other applicable requirements in the EN 71-series of standards.

11.2. II FLAMMABILITY

11.2.1. Point 1

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

- (a) they do not burn if directly exposed to a flame or spark or other potential source of fire;
- (b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);
- (c) if they do ignite, they burn slowly and present a low rate of spread of the flame;
- (d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

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

Paragraph 1 sets the basic rule for flammability: toys must not constitute a dangerous flammable element in the child's environment. This means that toys must be composed of materials which fulfil one or more of the conditions enumerated in points a to d.

The first possibility to fulfil the flammability-requirement is that the toy does not burn if directly exposed to a potential source of fire, such as flame or spark (point a).

The second possibility is that the toy is not readily flammable. This means that the flame goes out as soon as the fire cause disappears (point b).

Third possibility to fulfil the flammability requirement is that if the toy ignites, it burns slowly and the flame spreads slowly (point c).

The fourth possibility to fulfil the flammability requirement is to design the toy so as to mechanically delay the combustion process. Therefore, the use of chemical flame retardants to delay the combustion process is in this case not possible.

The first, second and third possibility do not exclude the use of flame-retardants, provided of course that they are not banned or chemically unsafe and that the (chemical) provisions laid down in this Directive are fulfilled.

Furthermore, it is required that the combustible materials if present must not constitute a risk of ignition of other materials used in toys. This requirement is dealt with in the EN 71-2.

11.2.2. Point 2

Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down in Section 1 of Appendix B, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.

This paragraph lays down a specific rule for toys which by way of exemption and for reasons essential to their functioning contain classified substances or mixtures. The applicable classification criteria are specified in section 1 of Appendix B to Annex II. This provision concerns in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, photography or similar activities. These kinds of toys are not allowed to contain substances or mixtures which may become flammable due to the loss of non-flammable volatile components.

11.2.3. Point 3

Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in the first subparagraph of Article 10(2).

This paragraph requires that toys should not be explosive or contain elements or substances likely to explode when the toy is used as foreseen in Article 10 (2), first subparagraph. However, an exemption is foreseen for toy percussion caps.

11.2.4. Point 4

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

- (a) which, when mixed together, may explode through chemical reaction or through heating;
- (b) which may explode when mixed with oxidizing substances; or
- (c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

This paragraph also concerns explosion and flammability and in particular such toys as chemical games and toys. Point a) requires that they should not explode when mixed with oxidizing substances, either through chemical reaction or through heating. Point b) requires that the substances or mixtures in toys should not contain volatile components which are flammable in air or which are liable to form a flammable or explosive vapour/air mixture.

11.3. III CHEMICAL PROPERTIES

11.3.1. Point 1

Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first subparagraph of Article 10(2).

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

This paragraph sets the general safety requirement concerning chemical substances or mixtures in toys. It must always be respected by manufacturers, and national enforcement authorities can take action against toys that do not respect this requirement even if it complies with the more specific provisions in the rest of this section on chemical properties.

This provision requires that toys are so designed and manufactured that there are no risks of adverse effects on human health because of the chemical substances or mixtures of which the toys are composed of or which they contain through exposure to them. This provision is thus risk based in the sense that if toys contain hazardous chemicals that cannot in any circumstances come out, in other words that there is no exposure to them, their use is not prohibited (unless any other restriction/prohibition in the Toy Safety Directive or other pieces of legislation apply (see second part of this paragraph)). Furthermore, it concerns situations where toys are used as specified in Article 10 (2), first subparagraph, that is, when toys are used as intended or in a foreseeable way bearing in mind the behaviour of children.

The second part of this paragraph clarifies that all toys have to comply with Community's general chemicals legislation, that is, with the legislation relating to certain products or laying down restrictions for certain substances or mixtures.

Information on relevant Community legislation can be found at following webpage http://ec.europa.eu/growth/sectors/toys/safety/legislation/index_en.htm

This legislation is wide-ranging, and is not exhaustively enumerated in the provision. An important piece of legislation is Regulation (EC) No 1907/2006 (REACH). This means that amongst others, the requirements concerning phthalates, benzene, azo colorants, nickel ... have to be fulfilled. The European Chemicals Agency's (ECHA) Committee for Risk Assessment prepares scientific opinions on the hazards and risks of chemical substances under REACH and CLP, whereas the DG SANTE scientific committees will provide scientific advice on sector specific issues.

Other acts of importance are those adopted in the environmental field. The general and specific chemical requirements laid down by this Directive should aim at protecting the health of children from certain substances in toys, while the environmental concerns presented by toys are addressed by horizontal environmental legislation applying to electrical and electronic toys, namely Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (recast) and Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste

electrical and electronic equipment. In addition, environmental issues on waste are regulated by Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008, those on packaging and packaging waste by Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 and those on batteries and accumulators and waste batteries and accumulators by Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006.

11.3.2. Point 2

Toys that are themselves substances or mixtures must comply also with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁵, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations⁶ and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures⁷, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures.

This paragraph foresees for toys that are themselves substances or mixtures that they must comply with Directive 67/548/EEC (Dangerous Substances Directive, DSD) and Directive 1999/45/EEC (Dangerous Preparations Directive, DPD) and with Regulation (EC) No 1272/2008 (CLP). The latter has replaced DSD and DPD since 1 June 2015.

In accordance with the transitional provision laid down in Article 61(4) second subparagraph CLP, where a toy that is itself a mixture is already classified, labelled and packaged according to the DPD rules and placed on the market before 1 June 2015, i.e. it is already in the supply chain by that date, its re-labelling and re-packaging according to the CLP rules may be postponed until 1 June 2017. This means that the toy can be sold further in the supply chain with the DPD label until 1 June 2017. However, in cases where a toy mixture is re-filled into another packaging on its way through the supply chain and the respective supplier (re-filler) changes the packaging such that other labelling elements become necessary, he must adapt the label to the CLP requirements and no longer use the DPD labelling as far as the relevant CLP classifications are made available to him, e.g. through a Safety Data Sheet⁸. As from 1 June 2017, all labels and packaging of toys which are themselves mixtures will have to comply with CLP.

⁵ OJ 196, 16.8.1967, p. 1.

⁶ OJ L 200, 30.7.1999, p. 1.

⁷ OJ L 353, 31.12.2008, p. 1.

⁸ Cf. ECHA, Guidance on Labelling and Packaging under the CLP Regulation, 2011, http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf, p. 4.

11.3.3. Point 3

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

Point 3 concerns the use of CMR substances in toys. These are substances that are classified as carcinogenic, mutagenic or toxic for reproduction category 1A, 1B or 2 according to Regulation (EC) No 1272/2008. CMR substances of all of these categories are in principle prohibited in toys or in microstructurally distinct parts of toys. This prohibition, however, does not affect the application of the restrictions in accordance with the general chemicals legislation as foreseen in the second paragraph of point 1.

The term “microstructurally distinct parts” of toys may be regarded as similar in meaning to the term “homogeneous material” mentioned in Commission Decision 2005/618/EC amending the RoHS Directive 2002/95/EC. These definitions capture a situation where for example, a paint coating is present on a base material, even if the paint coating is microscopically thin.

"Structurally distinct" means having a well-defined boundary. A "structurally distinct" part is one that can be visually delineated from its surroundings; it is a term that has a wider meaning than that of "part". The term "part" normally means something that can be assembled into, or separated from, a manufactured article, such as a toy. For example, a bicycle is composed of the following parts: frame, saddle, wheels, handle bars, chain, brakes etc. However, many of those parts are not homogeneous substances. For example, a bicycle saddle may contain both metals and plastics which cannot be easily separated. Nevertheless, the metal and plastic areas within that part would be visibly distinct (even if the part has to be cut in two to see them) and the metal and plastic regions within that part are considered to be the "structurally distinct parts" of that "part" of the toy.

The purpose of the term "microstructurally distinct parts" is to ensure that the concentration limits for the restricted chemical substances in the TSD apply to all areas of the toy that could be of relevance for the safety of children.

11.3.4. Point 4

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

- (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
- (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);
- (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

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

- (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;
- (ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and
- (iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

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

Paragraph 4 foresees the conditions for the exemptions from the prohibition laid down in point 3 for two categories of CMRs i.e. categories 1A and 1B under CLP. These CMR categories are specified in section 3 of Appendix B to Annex II (see below for explanation of the categories).

The conditions for exempting the above mentioned categories from the prohibition are that one of the following conditions is met:

Point a) lays down the first possibility to use CMR substances or mixtures in toys. This is the case when they are contained in toys or microstructurally distinct parts of toys in individual concentrations equal to or smaller than the relevant concentration limits established for the classification of mixtures containing these substances. These concentration limits are established in the legal act referred to in Section 2 of Appendix B to Annex II (see pages below for the explanation).

Point b) lays down a second possibility to use the CMR substances or mixtures of the categories concerned. This is when the substance or mixture is inaccessible to children in any form, including inhalation. The inaccessibility is assessed when the toy is used as intended or foreseeable bearing mind the behaviour of children. Clauses 8.3; 8.4; 8.5; 8.7; 8.8; 8.9; 8.10 of EN 71-1:2011 have to be performed in order to ensure inaccessibility. These criteria are not exhaustive since they do not cover inhalation exposure.

Point c) lays down the third case when CMRs of the concerned categories may be used in toys. This is when they have been exempted by a Decision of the Commission taken in the comitology procedure in accordance with Article 46 (3). In addition to that, the substance or the mixture and its permitted use must be listed in Appendix A to Annex II. This decision to allow the use of the CMRs of the concerned categories can be taken if all of 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 for children. The safety is assessed in particular in view of the exposure to the substance or mixture concerned in the toy concerned.
- ii) there are no suitable alternative substances or mixtures available. This fact needs to be documented in the analysis of alternatives by the applicant; and
- iii) The substance or mixture concerned is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 (REACH).

Finally, the Commission must mandate the Scientific Committee to re-evaluate the allowed CMR substances as soon as safety concerns arise, and in any case every 5 years starting from the date of adoption of the Decision allowing the substance or mixture and its use.

11.3.5. Point 5

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

- (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
- (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); or
- (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

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

- (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure; and
- (ii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

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

Point 5 foresees the conditions for the exemptions from the prohibition laid down in point 3 for one category of CMRs i.e. category 2 under CLP. This CMR category is specified in section 4 of Appendix B to Annex II (see below for explanation of the category).

The conditions for exempting the above mentioned categories from the prohibition are that one of the following conditions is met.

Point a) lays down the first possibility to use CMR substances or mixtures in toys. This is the case when they are contained in toys or microstructurally distinct parts of toys in individual concentrations equal to or smaller than the relevant concentrations limits established for the classification of mixtures containing these substances. These concentration limits are established in the legal act referred to in Section 2 of Appendix B to Annex II (see pages below for the explanation). This possibility to use CMR substances or mixtures is foreseen because they are considered as safe below this limit.

Point b) lays down a second possibility to use the CMR substances or mixtures of the categories concerned. This is when the substance or mixture is inaccessible to children in any form, including inhalation. The inaccessibility is assessed when the toy is used as intended or foreseeable bearing mind the behaviour of children. Clauses 8.3; 8.4; 8.5; 8.7;

8.8; 8.9; 8.10 of EN 71-1:2011 have to be performed in order to ensure inaccessibility. These criteria are not exhaustive since they do not cover inhalation exposure.

Point c) lays down the third case when CMRs of the concerned category may be used in toys. This is when they have been exempted by a Decision of the Commission taken in the comitology procedure in accordance with Article 46 (3). In addition to that, the substance or the mixture and its permitted use must be listed in Appendix A to Annex II. This decision to allow the use of the CMRs of the concerned categories can be taken if all of 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 for children. The safety is assessed in particular in view of the exposure to the substance or mixture concerned in the toy concerned.
- ii) The substance or mixture concerned is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 (REACH).

Compared to the conditions for the exemption under point 4, the absence of a suitable alternative is not a condition for allowing the CMR in question under this paragraph.

Finally, the Commission must mandate the Scientific Committee to re-evaluate the allowed CMR substances as soon as safety concerns arise, and in any case every 5 years starting from the date of adoption of the Decision allowing the substance or mixture and its use.

11.3.6. Point 6

Points 3, 4 and 5 shall not apply to nickel in stainless steel

This point lays down a specific exemption from the CMR provisions of points 3, 4 and 5 for nickel in stainless steel, because its safety has been proven.

Note: This derogation for nickel in stainless steel does not apply to nickel in coatings.

11.3.7. Point 7

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

This point lays down an exemption from the CMR provision for materials that comply with the specific limit values set in Appendix C. These values are set by a Decision of the Commission under the comitology procedure of Article 46 (2).

The chemicals listed in Appendix C are chemicals that comply with stricter limit values and can be used in toys intended for children under 36 months and toys to be placed in the mouth. Setting stricter limits is justified by the high degree of exposure related to

these two specific categories of toys. Therefore, these specific limits are mandatory for the above mentioned toys, but can be also used for all other categories of toys.

The Regulation on Food Contact Materials establishes which materials it covers in its Article 1.2:

"This Regulation shall apply to materials and articles (...) which in their finished state:

- (a) are intended to be brought into contact with food; or
- (b) are already in contact with food and were intended for that purpose; or
- (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use."

Until such specific provisions are adopted but no longer than until 20 July 2017 the same exemption applies to materials covered by and complying with the Food Contact Material legislation, that is, with Regulation (EC) No 1935/2004 and the relevant specific measures for particular materials. Therefore, these materials are allowed in toys without further testing of them during this period limited in time. More information can be found at following web page

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

11.3.8. Point 8

Without prejudice to the application of points 3 and 4, nitrosamines and nitrosatable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosatable substances.

This point lays down specific limit values for N-nitrosamines and for N-nitrosatable substances in toys for children under 36 months or in other toys intended to be put in the mouth. These values have to be complied with in addition to what is laid down in points 3 and 4. These limit values are 0,05 mg/kg for N-nitrosamines and 1 mg/kg for N-nitrosatable substances.

For nitrosamines, the "intended to be placed in the mouth" limits the application to such toys as balloons, which are of real concern, and excludes bicycle tyres, which are not. As for other materials, they are relevant in particular for rubber or finger paints. Plastics such as polyethylene and PVC do not normally contain amines, and therefore, they would not normally contain nitrosamines. In the latter, testing would not be necessary.

11.3.9. Point 9

The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.

Point 9 lays down an obligation for the Commission to re-evaluate systematically and regularly the occurrence of hazardous substances in toys. This evaluation, which can also be carried out within the framework of REACH if the scope is broader than toys, shall take into account the reports of market surveillance and concerns expressed by Member States and stakeholders (industry and consumers, Notified bodies, standardisation organisations).

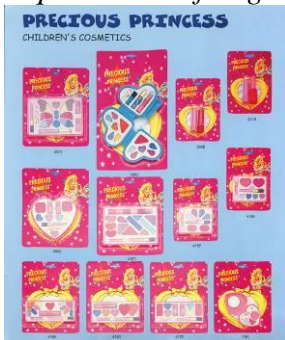
11.3.10. Point 10

Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁹.

This point clarifies that the Cosmetics Directive is applicable to cosmetic toys, such as play cosmetics, as regards the compositional and labelling requirements laid down in that directive. These toys must also comply with all the relevant provisions of the Toys Directive. Note that the Cosmetics Regulation (EC) No 1223/2009 repealed and replaced the Cosmetics Directive as from 11 July 2013.

According to the Cosmetics Regulation, a ‘cosmetic product’ shall mean any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

Note: cosmetic products for children are cosmetic products and need to fulfil the requirements of Regulation (EC) No 1223/2009.



It can be foreseen that there could be some ways of packaging and presenting a child's cosmetic that will give rise to intended play value, for example a shampoo container in the shape of figures. Here the container is a toy (when rinsed and emptied), but the shampoo is a cosmetic.



In situations where the cosmetic is not being used as a cosmetic in such applications, then the whole product can be treated as a toy. The cosmetic must however comply with the Cosmetics Regulation.

Several guidelines and opinions have been issued on various aspects of the Cosmetics Directive. In order to consult these guidelines, please refer to the website:

⁹ OJ L 262, 27.9.1976, p. 169.

http://ec.europa.eu/growth/sectors/cosmetics/index_en.htm
http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out152_en.pdf
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_169.pdf
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_03j.pdf

11.3.11. Point 11

Toys shall not contain the following allergenic fragrances:

No	Name of the allergenic fragrance	CAS number
(1)	Alanroot oil (Inula helenium)	97676-35-2
(2)	Allylisothiocyanate	57-06-7
(3)	Benzyl cyanide	140-29-4
(4)	4 tert-Butylphenol	98-54-4
(5)	Chenopodium oil	8006-99-3
(6)	Cyclamen alcohol	4756-19-8
(7)	Diethyl maleate	141-05-9
(8)	Dihydrocoumarin	119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4,6,10-dodecatrien-3-one	26651-96-7

No	Name of the allergenic fragrance	CAS number
(14)	6,10-Dimethyl-3,5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2-Hexenal diethyl acetal	67746-30-9
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8
(23)	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenoate	623-43-8
(29)	6-Methylcoumarin	92-48-8
(30)	7-Methylcoumarin	2445-83-2

No	Name of the allergenic fragrance	CAS number
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke)	8023-88-9
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1
(37)	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil (Lippia citriodora Kunth)	8024-12-2
(39)	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
(40)	4-Phenyl-3-buten-2-one	122-57-6
(41)	Amyl cinnamal	122-40-7
(42)	Amylcinnamyl alcohol	101-85-9
(43)	Benzyl alcohol	100-51-6
(44)	Benzyl salicylate	118-58-1
(45)	Cinnamyl alcohol	104-54-1
(46)	Cinnamal	104-55-2

No	Name of the allergenic fragrance	CAS number
(47)	Citral	5392-40-5
(48)	Coumarin	91-64-5
(49)	Eugenol	97-53-0
(50)	Geraniol	106-24-1
(51)	Hydroxy-citronellal	107-75-5
(52)	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
(53)	Isoeugenol	97-54-1
(54)	Oakmoss extracts	90028-68-5
(55)	Treemoss extracts	90028-67-4

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

This first point lists the allergenic fragrances that are prohibited in toys. The list contains altogether 55 substances. These are first, the same allergenic fragrances that were prohibited under the Cosmetics Directive (those numbered 1 – 40). Secondly, some further allergenic fragrances are prohibited in toys, even if they were only subject to labelling in cosmetics (numbers 41-55).

However, traces of these substances are allowed on the following conditions: their presence is technically unavoidable in good manufacturing practise (GMP) and does not exceed 100 mg/kg. The 100 mg/kg limit is per fragrance substance. The manufacturer should not intentionally use these prohibited fragrances. The limit of 100 mg/kg has been set for market surveillance purposes. Trace can be defined as a small quantity of an impurity in the finished product, while the impurity is unintended constituents in raw materials. More information on GMP can be found in EN ISO 22716.

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

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

Secondly, point 11 enumerates those allergenic fragrances that need to be labelled. The labelling is obligatory when these substances are added in toys at concentrations exceeding 100 mg/kg of the toy or components of it.

The substances shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet.

It is to be noted that this point (both lists) can be amended by a Decision of the Commission taken under the Comitology procedure as foreseen in Article 46.

Several guidelines have been issued on various aspects of the Cosmetics Directive. In order to consult these guidelines, please refer to the website:

http://ec.europa.eu/growth/sectors/cosmetics/index_en.htm

11.3.12. Point 12

The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- (i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- (ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC; and
- (iii) if applicable, those fragrances comply with the relevant legislation on food.

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

This point foresees exemptions for certain types of toys from the prohibition of certain of the allergenic fragrances listed in point 11. These exemptions concern three categories of toys: olfactory board games, gustative games and cosmetic kits as defined in Article 3. These categories of toys may contain the allergenic fragrances listed in points 41-55 of the prohibition list (the first list in point 11), if the following conditions are all met:

- i) clear labelling of those fragrances on the packaging. A warning as foreseen in point 10 of part b of Annex V: “contains fragrances that may cause allergies”
- ii) the resulting products that the child has made in accordance with the instructions comply with the requirements of Cosmetics directive if applicable.
- iii) The fragrances comply with the relevant legislation on food, if applicable.

Furthermore, such categories of products that profit from the exemptions must not be permitted to be used by children under 36 months. Therefore, they have to contain the warning as foreseen in point 1 of Part B of Annex V (not suitable for children under 36 months etc).

11.3.13. Point 13

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

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47

Barium	1 500	375	18 750
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	13,5	3,4	160
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2).

This point lays down specific migration limits for certain chemical substances in toys. These limits have to be respected in addition to those laid down in points 3, 4 and 5 of the same Annex, which is in addition to the provisions on the CMRs in toys. The migration limits apply to toys or components of toys that are accessible to children when the toys are used as intended or in a foreseeable way taken into account the behaviour of children.

"without prejudice" means that two requirements can exist and apply independently and additionally. When a conflict appears between these two requirements, the one which we are not prejudicing prevails.

Applied to point 13 of the chemical part of the TSD, this definition means that the values set out in point 13 exist and apply in addition to points 3, 4 and 5. Point 3, 4 and 5 refer to the ban of CMRs and certain exemptions based on concentration limits, and point 13 refers to migration limits.

Migration limits set out in point 13 will apply to the listed substances as long as these substances will not be subject to a general ban or stricter restriction under the general horizontal legislation. In this case, there would be a conflict between the two requirements and point 13 will no longer apply. The final result is that the stricter or safer limits will prevail. Point 13 is not an exemption allowing us to maintain higher limits or to stray from a general ban.

The limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, are set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.

The migration limit values are different depending on the material of the toy or the component in question. The materials in question are a) Dry, brittle, powder-like or pliable toy materials; b) Liquid and sticky toy materials, and c) Scraped-off toy materials. More information on the toy material can be found in the RIVM study "Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements". <http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf>

a) Dry, brittle, powder-like or pliable toy materials

By these materials are meant solid toy material from which powder-like material is released during playing. The material can be ingested. Contamination of the hands with powder contributes to enhanced oral exposure. The assumed ingestion is 100 mg per day.



b) Liquid and sticky toy materials

By these materials are meant fluid or viscous toy material which can be ingested and/or to which dermal exposure occurs during playing. The assumed ingestion is 400 mg per day.



c) Scraped-off toy materials

By these materials are meant solid toy material with or without a coating which can be ingested as a result of biting, tooth scraping, sucking or licking. The assumed ingestion is 8 mg per day.



Examples of different toy materials are listed in the table below

1. Dry, brittle, powder-like or pliable toy material

Dry	Brittle	Powder-like	Pliable
Compressed paint tablets	Chalk	Plaster of Paris	Magic sand
	Crayons		Modelling compounds
			Plasticine
			Oven hardened PVC modelling compounds
			Bouncing putty

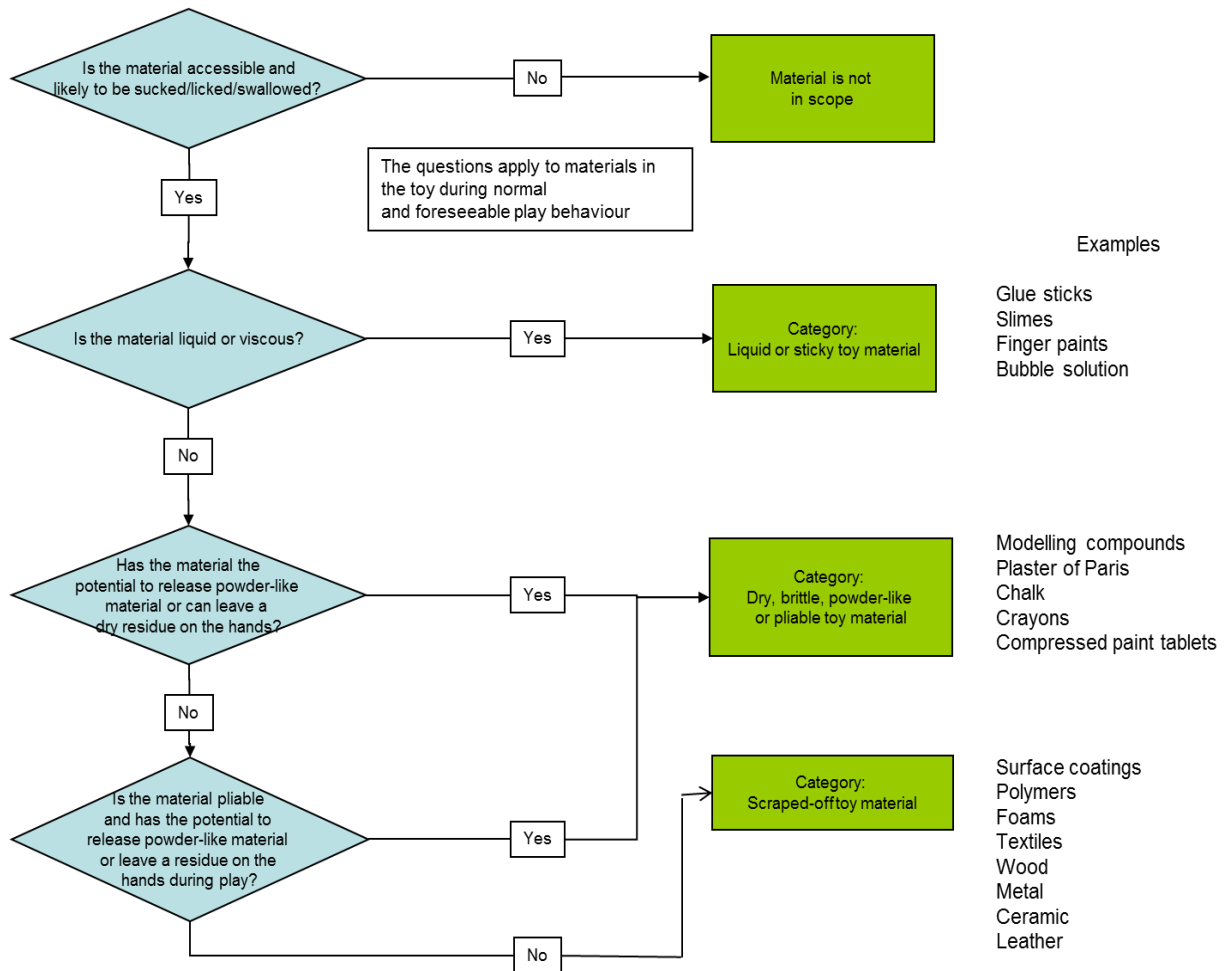
2. Liquid or sticky toy material

Liquid	Sticky
Bubble solution	Liquid adhesives
Poster paints	Glue sticks
Finger paints	Slimes

3. Scraped off toy material

Material	Examples
Surface coatings	Paints, varnish
	Electroplating
	Vacuum deposited metals
Polymers (hard)	Polystyrene
	ABS
	uPVC
	Polypropylene
Polymers (soft)	EVA foam (closed cell foams)
	Rubber
	PVC
	Elastomers
	Leatherette
Other materials	Leather
	Bone
	Natural sponge
	Paper/card
Wood	Fibreboards
	Chipboard
	Plywood
Textiles	Fuzzy felts
	Cotton wool
	Polyester staple fibres
	Plush fabrics
Glass, ceramics	Marbles
	Fibre glass
Metals and alloys	Steel
	Nickel-silver

The flowchart below provides help how to classify a toy material.



There is, however, an exemption from these requirements regarding certain types of toys. These are toys which clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when the toy is used as intended or in a foreseeable way taking into account the behaviour of children. The hazards may be clearly excluded because of the accessibility, function, volume or mass of the toy.

Excluded because of function: This could be a bicycle where the chain, tyres or brake blocks are accessible but unlikely to be sucked chewed or ingested.

Excluded because of accessibility: This could be a swing where the top suspension bar is accessible, but cannot realistically be mouthed. This is an example of where the part is accessible according to EN71-1 but in a real life situation it is highly improbable that mouthing would take place because the part is large, immovable and difficult to reach with the mouth.

Note: bear in mind that other Community legislation (in particular REACH) can also be applicable, like the requirements on cadmium, organic tin compounds, nickel... The nickel requirements apply to any article intended for direct and prolonged contact with the skin. Toys that fall into that category would be covered by the nickel Directive (currently the restrictions in Annex XVII of REACH). There is no duplication as the nickel Directive addresses contact allergy whereas the TSD addresses ingestion.

The heading of the table refers to "element", however not all "elements" listed are elements, but some are compounds. The migration limit should apply to the sum of all organotin substances, as they are all toxic and have an additive effect (although some are more potent than others).

11.4. IV ELECTRICAL PROPERTIES

11.4.1. Point 1, first paragraph

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

This provision sets the basic rule concerning the maximum voltages allowed to power the toys and in accessible parts of toys. Toys should not be powered by electricity exceeding 24 nominal volts direct current or equivalent alternative current. The accessible parts of toys should not exceed 24 volts direct current or equivalent alternative current.

11.4.2. Point 1, second paragraph

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

This paragraph lays down the requirements for internal voltages in toys. In principle, internal voltages should not exceed the 24 voltage direct current or equivalent alternative current. However, there is an exemption from this requirement for internal voltages if it is ensured that the voltage and the current combination generated do not lead to any harmful electric shock, even when the toy is broken. The requirement is applicable regardless of the age of the child.

The definition of “accessible” and the “foreseeable use tests” in clause 5.1 in EN 71 part 1 can be used as a minimum requirement to assess what is meant by broken.

11.4.3. Point 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.

This paragraph lays down a requirement to properly insulate and mechanically protect parts of toys in order to prevent the risk of electric shock. This applies, first, to parts of toys which are connected to or liable to come into contact with a source of electricity capable of causing electric shock. Secondly, it applies to cables or other conductors through which electricity is conveyed to such parts.

11.4.4. Point 3

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

This point repeats specifically for electric toys what is foreseen for all toys in point 9 of part 1 of this Annex. Namely, it lays down that electric toys must be designed and manufactured as to ensure that the maximum temperature reached by any accessible surface does not cause burns when touched.

11.4.5. Point 4

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

This point requires that toys must provide protection against all electrical hazards such as electric shock or burns, also under fault conditions when they are foreseeable.

11.4.6. Point 5

Electric toys must provide adequate protection against fire hazards.

Point 5 requires specifically that electronic toys must provide protection against fire hazards. It is important to note that the flammability requirements in part 2 of the annex of the TSD (particular safety requirements) also concern electronic toys.

11.4.7. Point 6

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

This point concerns electric, magnetic and electromagnetic fields and other radiation that electric toys may generate. Electric toys must be designed and manufactured in such a way that this radiation is limited to the extent necessary for its operation and is safe. The compliance with this requirement is evaluated against the generally acknowledged state of art, taking account of specific Community measures.

This means in particular that the EMC Directive 2004/108 needs to be respected.

11.4.8. Point 7

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

Point 7 concerns toys which have an electronic control system, such as toys with remote control. These kinds of toys must operate safely, also in case the electronic system starts malfunctioning or fails, whatever reason that is the failure of the system itself or an outside factor.

11.4.9. Point 8

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

Point 8 concerns toys with lasers, light-emitting diodes (LEDs) or any other type of radiation. These kind of toys must designed and manufactured so that they do not present

any health hazards or risk of injury to eyes from lasers, LEDs or any other type of radiation.

Technical requirements for lasers and LEDs in toys are found in international standard IEC 608251-1 and its amendments. CENELEC is currently working on this item in order to make separate standard requirements for toys.

11.4.10. Point 9

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

This point requires that the electrical transformer for toys must not be integral part of the toy. This is in line with Annex I, point 18 which states that electrical transformers for toys are not considered as toys, and therefore do not have to respect the requirements of the toys Directive.

CENELEC standard EN 62115:2005 + A2:2011 + A11:2012 + their corrigenda lays down technical requirements for the electrical properties of toys.

11.5. V HYGIENE

11.5.1. Point 1

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

Point 1 sets the basic rule for hygiene that all kinds of toys have to respect. All toys must be designed and manufactured so that there is no risk of infection, sickness and contamination from them due to deficiencies in hygiene or cleanliness.

11.5.2. Point 2

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

This point sets specific requirements for toys intended for children under 36 months. These toys have to be designed and manufactured in such a way that they can be cleaned. Cleaning here means removing impurities or dirt from the toy in general.

Note: Some types of toys for children under 3 years are formulated with preservative systems and so may be considered to be “self-cleaning”. However they must comply with point 1 of the hygiene requirements.

As regards textile toys for children under 36 months, this point specifies that they have to be washable, which means possibility to soak wash them. However, if the textile toy contains a mechanism that may be damaged if soak washed, it is possible to only provide for a surface cleaning. Soak washing means immersing the toy in water or other liquid; this handling does not necessarily imply machine washing, it can be hand wash.

A textile toy is a toy made of textile, like soft filled toys aimed at cuddling/holding. The aim is to have washing requirements covered for those textile toys that in particular a child takes with him in a cot/playpen. Therefore textile toys are toys entirely made of textile with exception for materials inside the toy and minor features or decorations sewed/adhered to the outside (e.g. eyes and nose). They can have a mechanical non textile component (mechanism) on the inside. A mechanism means a component or multiple interconnected components that are designed to deliver at least one additional function to the textile toy such as light, sound, retention of form, movement ...

Examples of textile toys are included in Explanation V to this guide.

Furthermore, this point requires that the toys needs to fulfil all the safety requirements also after it has been cleaned in accordance with the provisions of this point and the manufacturer's instructions. The manufacturer should, if applicable, provide instructions on how the toy has to be cleaned. In view of complying with all the safety requirements after cleaning, article 18 of the TSD is used. Meaning the manufacturer shall carry out an analysis of all hazards mentioned in article 18, among them also hygiene hazards as well as an assessment of the potential exposure to all such hazards. For example small parts hazards that appear after cleaning or soak washing need to be assessed.

These textile toys for children under 36 months which are able to be soak washed and need to comply after soak washing, cannot be labelled "surface washing":

- if the toy is labelled "surface washing", then "surface washing" is considered to be the manufacturers instruction. The requirements of the TSD say that the toy has to comply with the requirements after cleaning, in accordance with the manufacturer's instructions. However the manufacturer's instructions say surface wash, while the toy is a textile toy without mechanism and needs to be soak washable. So there is a contradiction to the TSD.

- with this sentence "surface washing", manufacturers might try to circumvent the requirements of the TSD, similar to the warning "not suitable for children under 36 months". Manufacturers placing a toy on the market for children under 36 months and complying (or not) with the requirements of small parts, still added the warning "not suitable for children under 36 months - small parts". In order to make clear that there was a conflict adding this warning, the regulator inserted a sentence in the new TSD so that that warning may not be placed on those kinds of toys (toys under 36 months). It cannot be placed on toys above 36 months if they are not dangerous for under 36months, this in order not to dilute the impact of properly used warnings (instructions in this case).

In conclusion, the manufacturer shall not label "surface washing" on textile toys which, under the TSD, need to be soak washable.

11.6. VI RADIOACTIVITY

Toys shall comply with all relevant measures adopted under Chapter III of the Treaty establishing the European Atomic Community.
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Chapter III of the Euratom Treaty concerns health protection from radiation.

11.7. Appendix A

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

Substance	Classification	Permitted use
Nickel	CMR 2	In toys and toy components made of stainless steel. In toy components which are intended to conduct an electric current.

This appendix contains a list of CMRs and their permitted uses. They contain both the exemptions granted under the exemption procedure of points 4 and 5 of Annex II, Part III, but also the use of nickel in stainless steel that has been found safe by point 6 of Annex II, Part III.

The exemption for the use of nickel in stainless steel applies since 20 July 2013. The exemption for the use of nickel in toy components intended to conduct an electric current will apply from 1 July 2015.

11.8. Appendix B

The objective of Appendix B is to clarify, for the purposes of classification of substances and mixtures, which classification rules apply at a given time. This is due to the timing of the Regulation (EC) No 1272/2008 (CLP) whose classification rules started applying in a stepwise manner, first for substances (as from 1 December 2010) and then for mixtures (as from 1 June 2015). As from 1 June 2015, classification of substances as well as mixtures is to be performed according to CLP rules only.

11.8.1. Point 1

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

A. Criteria to be applied from 20 July 2011 until 31 May 2015:

Substances

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

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

Mixtures

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

B. Criteria to be applied from 1 June 2015:

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

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

This point explains which classification rules apply in case of toys that are themselves substances or mixtures (point 2 of Annex II part III) as well as in case of the special warning required for chemical toys in Annex V, part b, point 4. As from 1 June 2015, point A became obsolete and only the criteria of point B apply.

11.8.2. Point 2

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

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

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

This point explains which concentrations apply for the purposes of the derogation from the prohibition of CMR substances in points 4(a) and 5(a) of Annex II, part III. As from 1 June 2015, the first paragraph became obsolete and only the concentrations of CLP apply.

11.8.3. Point 3

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

Substances

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

Mixtures

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

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

This point explains which CMR classifications are concerned by the derogation from the CMR prohibition in point 4 of part III of Annex II. As from 1 June 2015, that derogation applies only for substances and mixtures classified as CMR category 1A and 1B under CLP.

11.8.4. Point 4

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

Substances

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

Mixtures

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

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

This point explains which CMR classifications are concerned by the derogation from the CMR prohibition in point 5 of part III of Annex II. As from 1 June 2015, that derogation applies only for substances and mixtures classified as CMR category 2 under CLP.

11.8.5. Point 5

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

Substances

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

Mixtures

From 20 July 2011 until 31 May 2015, Article 46(3) concerns mixtures classified as CMR category 1, 2 and 3 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

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

This point explains for which CMR classifications exemptions from the CMR prohibition can be granted under the comitology procedure in accordance with Article 46(3). As from 1 June 2015, such exemptions can only be granted for substances or mixtures classified as CMR category 1A, 1B or 2 under CLP. The exemptions actually granted appear in Appendix A.

11.9. Appendix C

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

Substance	CAS No	Limit value
TCEP	115-96-8	5 mg/kg (content limit)
TCPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Bisphenol A	80-05-7	0,1 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005

Appendix C contains specific limit values for chemicals used in toys intended for children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46 (2).

Regarding the substances included it should be noted that:

- Tris(2-chloroethyl) phosphate (**TCEP**), CAS No 115-96-8, is a phosphate ester used as a flame-retardant plasticiser in polymers. Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (**TDCP**), CAS No 13674-87-8, and tris(2-chloro-1-methylethyl) phosphate (**TCPP**), CAS No 13674-84-5 are TCEP's halogenated alternatives;
 - The specific limit values for TCEP, TCPP and TDCP will apply from 21 December 2015.
- **Bisphenol A** residual monomer is normally found at trace levels only in polycarbonate and epoxy resins. It can also be present as an additive (polymerisation aid) in certain PVC materials;
 - The specific limit value for bisphenol A will apply from 21 December 2015.

12. ANNEX III

12.1. EC declaration of conformity

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

This Annex sets the model structure for the EC declaration of conformity which has to be established in accordance with Article 15 as well as the information that needs to be contained in it. More information can be found in the guide on technical documentation.

13. ANNEX IV

13.1. Technical documentation

The technical documentation referred to in Article 21 shall contain, in particular, so far as relevant for assessment:

- (a) a detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;
- (b) the safety assessment(s) carried out in accordance with Article 18;
- (c) a description of the conformity assessment procedure followed;
- (d) a copy of the EC declaration of conformity;
- (e) the addresses of the places of manufacture and storage;
- (f) copies of documents that the manufacturer has submitted to a notified body, if involved;
- (g) test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in Article 19(2); and
- (h) a copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in Article 19(3).

This Annex sets in a non-exhaustive manner the documents that the technical documentation needs to contain. These documents have to be in the technical documentation if they are relevant for the assessment of the compliance of the toy with the Directive. However, also other data and details can be needed if relevant.

A specific guidance document is elaborated on the technical documentation, including the safety assessment.

14. ANNEX V WARNINGS

14.1. PART A general warnings

The user limitations referred to in Article 11(1) shall include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

Part A sets general rules applicable to warnings for all categories of toys. It specifies what is laid down in Article 11 (1). The user limitations required under that Article must contain at least the minimum or maximum age of the user. If appropriate they shall also contain the ability of the users of toys that is needed to use the toy safely, for instance ability to sit up unaided, the maximum or minimum weight of the users as well as the possible need to use the toy under adult supervision. These warnings specifying user limitations shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks.

This provision does not imply that all toys need to have a reference to the age of the user. These user limitations only have to be mentioned for a safe use of the toy. Manufacturers may indicate an age grading (2+, 6+,...), but this cannot be confused with or have the same legal meaning as a warning.

Examples of toys needing to specify the user limitations are:

- Chemistry set (will need a minimum age and the reference to adult supervision)
- Scooters (have to mention the weight of the child intended for)
- Functional toys (have to mention that supervision is needed)

14.2. PART B specific warnings and indications of precautions to be taken when using certain categories of toys

14.2.1. Point 1

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



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

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

This provision is applicable to all toys which are not intended for children under 36 months because they might be dangerous for them. These toys have to bear a warning stating clearly that they are not suitable for children under 3 years (or 36 months) of age. Economic operators can choose between the use of "not suitable for children under 36 months", "not suitable for children under 3 years" or the pictogram



The details of the design of the pictogram are: the circle and the stroke should be red, the background should be white, the age range and the face should be black and the size should not be less than 10mm diameter. This symbol should be used to indicate only "0 to 3" years and not for any other age-grade warning to avoid misinterpretation of the symbol.

The age warning alone is not sufficient. It needs to be accompanied by a short indication of the specific hazard involved if the toy is used by children under 36 months.

Hazard is defined in the TSD as the potential source of harm. Harm means physical injury or any other damage to health, including long term health effects.

Note: According to CEN guide 11 the term hazard can be qualified in order to define its origin (e.g. mechanical hazard, electrical hazard) or the nature of the potential harm (e.g. electric shock hazard, cutting hazard, toxic hazard, fire hazard).

The most commonly quoted indication of a specific hazard for children under 36 months is that due to small parts. The hazard is the small parts, and the harm is choking. The age restriction warning must be given in accordance with Article 11(3). The hazard indication may, however, appear in the instructions for use where appropriate.

Some hazards, and the harm they might cause, are generally well understood by consumers. For example small parts and sharp points are understood to cause choking and skin puncture respectively. However in some cases, this is not the case. For example, consumers may not always be aware that a long cord might cause strangulation or that the shape and size of some toys might cause harm if the child, too young to sit up unaided, were to fall or turn onto their belly without being able to turn back whilst the toy was being chewed or sucked. Article 11 (2) of the TSD requires that warnings have to be understandable. Therefore, if the hazard is not obvious to consumers, the hazard indication should be supplemented by a clear description of the harm in order to explain the warning as a whole (e.g. strangulation hazard due to long cord or choking hazard due to small balls). The harm may be referred to using e.g. the terms "Choking hazard" and "Strangulation hazard" since this is well established. However, it is never sufficient to indicate the harm alone (choking, strangulation etc.). In cases where it is well known which harm a product characteristic can cause (for example that "small parts" can cause choking) it is sufficient to indicate the hazard alone. It is, however, always permitted to mention both the hazard and the harm (e.g. "Small parts. Choking hazard"). When more than one hazard is present, at least one of the principal hazards shall be indicated.

Examples of hazards that can be mentioned:

The words between brackets may be added, but are not mandatory by the TSD.

- Small parts (choking)
- Long Cord - strangulation (hazard)
- Small balls - choking

It may happen that some kind of toys would require bearing more than one of the warnings in annex V that contain an age limitation. This is for example the case of a chemical toy that contains small parts. In this case only the strictest age limitation and the corresponding warning should be mentioned.

Some toys are clearly not intended for children under 3 years. This may be because of their functions, dimensions, characteristics, properties or other cogent grounds. For example some bicycles or roller skates, remote controlled toys with advanced functions, toy disguise costumes in large sizes and strategy based board games are obviously aimed at older children and it is obvious to the consumer that they are clearly not intended for children under 36 months. In these instances the requirement to provide a warning is not mandatory. These toys which clearly cannot be intended for children under 36 months do not need to carry a warning. Even if the use of a voluntary warning against use by children under 36 months is not prohibited by the TSD, manufacturers should consider carefully the use of warnings when they are not really necessary. Over-use of warnings may dilute the impact of properly used warnings in the long term. Therefore, it is recommended not to misuse this warning by affixing it on all toys (i.e. all toys intended for children above 3 years), so that the added value of the warning for the consumer remains fully efficient.

It is important to note that the provision of Article 11 (1) par 3 prohibits the misuse of a warning in cases where the warning conflicts with the intended use of the toys as determined by virtue of its function, dimension and characteristics. If a toy is clearly intended for children under 3 according to the functions, dimensions, etc (for example rattles, soft-filled toys, baby toys), the use of an age warning is prohibited by art.11 (1) par 3. If it is reasonable to assume that parents or other supervisors would consider the toy to be intended for children under 36 months because of its functions, dimensions or characteristics (as described in article 3, point 29), it is not permissible to use the warning “not suitable for children under 36 months” etc. In other words it is not permissible to circumvent safety requirements for these toys simply by the use of a warning.

Detailed requirements for the age warning symbol (size, colour etc) can be found in EN 71-1.

14.2.2. Points 2 to 10

These points lay down specific warnings for other categories of toys than those based on the age of the child. All these warnings have to be used as worded in these points (Article 11 (1)).

Activity toys (point 2), Functional toys (point 3), chemical toys (point 4), Aquatic toys (point 6), olfactory board games, cosmetic kits and gustative games (point 10) are defined in Article 3.

Although the word "Warning" is not present in the wordings of Annex V part B, the warnings and the pictogram shall be preceded by the word "warning(s)" (see article 11).

Note: the harmonized standards can contain additional warnings that might be applicable to these categories of toys.

2. Activity toys

Activity toys shall bear the following warning:

"Only for domestic use".

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

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

This means that the instructions must contain these indications. A CD accompanying the toy with the instructions is not sufficient as not all consumers have a computer to consult the instructions and assembly information. The information must accompany the activity toy in a paper format (notice or leaflet or on the packaging).

3. Functional toys

Functional toys shall bear the following warning:

"To be used under the direct supervision of an adult".

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

4. Chemical toys

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

"Not suitable for children under (*) years. For use under adult supervision".

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

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

Where these toys are offered for sale as toys, they shall bear the following warning:

"Protective equipment should be worn. Not to be used in traffic".

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

This means that the instructions must contain these indications!

6. Aquatic toys

Aquatic toys shall bear the following warning:

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

7. Toys in food

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

"Toy inside. Adult supervision recommended".

8. Imitations of protective masks and helmets

Imitations of protective masks and helmets shall bear the following warning:

"This toy does not provide protection".

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

Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps shall carry the following warning on the packaging, which shall also be permanently marked on the toy:

"To prevent possible injury by entanglement, remove this toy when the child starts trying to get up on its hands and knees in a crawling position".

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

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part III of Annex II and of the fragrances set out in points 1 to 11 of the list set out in third paragraph of that point shall contain the following warning:

"Contains fragrances that may cause allergies".

* Age to be specified by the manufacturer.

Note: equipment designed to be worn by children to protect them against one or more risks falls within the scope of the PPE Directive e.g. bicycle or ski helmets, ski goggles etc. However, imitations of PPE (such as imitations of firemen's helmets, doctor's protective clothing) fall under the Toys Directive. Where there may be doubt as to the real intended use of such a product, it has been agreed with the Member States that such products should be supplied with a warning to the effect that they are toys and not PPE. Care needs to be taken by the manufacturer if it appears that imitation PPE might be reasonably assumed to protect against hazards. In such cases the manufacturer may not be able to derogate from his liability even with such a warning.

Without prejudice to the above on 5 November 2008 the PPE WG further clarified the borderline between the two directives by agreeing distinguishing three categories of products. This was approved by the Expert Group on the Safety of Toys on 13 April 2010:

a) Toys which imitate PPEs and which remain toys

They are only acceptable if it is clear that no protection at all can be expected from them. For example: a fireman's or motorcyclist's helmet in a fancy dress outfit can constitute a toy.

b) PPEs sold with toys

Insofar as each product has its specific destination (respectively protection function and game function), each element falls within the scope of the regulations connected with its destination and which is specific to it.

c) Products for children, even decorated in an infantile manner, which have a protection function and remain PPEs

These products only have a single destination: protection. They remain PPEs.

It is the case, for example, of a child's cycle helmet. Even decorated with naïve motifs, it remains a PPE because protection is awaited from it, irrespective of its appearance.

15. OVERVIEW OF STANDARDS AND GUIDELINES

15.1. Harmonised standards under Directive 2009/48/EC

EN 71-1:2014 Safety of toys — Part 1: Mechanical and physical properties

EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability

EN 71-3:2013+A1:2014 Safety of toys — Part 3: Migration of certain elements

EN 71-4:2013 Safety of toys — Part 4: Experimental sets for chemistry and related activities

EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets

EN 71-7:2014 Safety of toys — Part 7: Finger paints — Requirements and test methods

EN 71-8:2011 Safety of toys — Part 8: Activity toys for domestic use

EN 71-12:2013 Safety of toys- Part 12 N-Nitrosamines and N-nitrosatable substances

EN 71-13:2014 Safety of toys – Part 13: Olfactory board games, cosmetic kits and gustative games

EN 71-14:2014 Safety of toys – Part 14: Trampolines for domestic use

EN 62115:2005 Electric toys — Safety - IEC 62115:2003 (Modified) + A1:2004

EN 62115:2005/A2:2011 - IEC 62115:2003/A2:2010

EN 62115:2005/A2:2011/AC:2011

EN 62115:2005/A11:2012

EN 62115:2005/A11:2012/AC:2013

EN 62115:2005/A12:2015

15.2. Non-harmonised standards under Directive 2009/48/EC

EN 71-9:2005+A1:2007 Safety of toys - Part 9: Organic chemical compounds – Requirements

EN 71-10:2005 Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction

EN 71-11:2005 Safety of toys - Part 11: Organic chemical compounds - Methods of analysis

15.3. Other relevant standards and guidelines

CEN CR 14379 Classification of toys – Guidelines

CEN Guide 11 Product information relevant to consumers Guidelines for standard developers

CEN Guide 12 Child Safety Guidance for its Inclusion in Standards

CEN TR 13387 Child use and care articles - Safety guidelines

CEN TR 15071 Safety of toys - National translations of warnings and instructions for use in EN 71

CEN TR 15371 Safety of toys - Replies to requests for interpretation of EN 71-1, EN 71-2, and EN 71-8

CEN/CENELEC Guide 6 Guidelines for standards developers to address the needs of older persons and persons with disabilities

CENELEC Guide 29: Temperatures of hot surfaces likely to be touched. Guidance document for Technical Committees and manufacturers

EN 14362-1 Textiles - Methods for the determination of certain aromatic amines derived from azo colorants - Part 1: Detection of the use of certain azo colorants accessible without extraction

EN 14362-2 Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 2: Detection of the use of certain azo colorants accessible by extracting the fibres

EN 14372 Child use and care articles - Cutlery and feeding utensils - Safety requirements and tests (phthalates test method)

EN 14682 Safety of children's clothing - Cords and drawstrings on children's clothing – Specifications (disguise costumes)

EN 60825-1 Safety of laser products

EN 61558-2-7 Safety of power transformers, power supplies, reactors and similar products -- Part 2-7: Particular requirements and tests for transformers and power supplies for toys

IEC 62079 preparation of instructions – structuring, content and presentation

ISO IEC guide 14 purchase information on goods and services intended for consumers

16. EXPLANATION I OBLIGATIONS OF ECONOMIC OPERATORS

Table 1: How to identify your Operator type



The 'Manufacturer' as defined by the new TSD



The 'Importer' as defined by the new TSD



The 'Distributor' as defined by the new TSD

Conditional Notes:

1. A *Manufacturer* may, by written mandate, appoint an *Authorised Representative* to meet the obligations of the *Manufacture* (but NOT the drawing up of the technical documentation).
2. An *Importer* or *Distributor* who modifies the product and by doing so alters its compliance, assumes the responsibilities of the *Manufacturer*.
3. The addition of legal labels to the retail pack does not constitute *modified product*. *Modifications* which may affect compliance are changes in materials, colour, age grading etc.
4. The same product may be sold according to a number of different business models which may in turn alter the responsibilities of the parties involved.
5. Where an EU entity presents itself as the manufacturer (by affixing their name, address etc) they are considered to place the product on the market even if they do not physically import the product. In this case there is no importer.

Typical Business Model

a	Type	Description	b Product Cycle				
			Design & Development	Production	(Bring in to EU)	Storage & Transport	Retail
1	EU Production	Product developed, produced and sold entirely within the EU.	manufacturer		distributor		
2	Developed & Domestic	Product developed and sold within the EU by an EU Operator, but produced outside the EU.	manufacturer		distributor		
3	3rd Party & Domestic (without product alteration)	Unaltered product developed by a supplier, then sold within the EU by an EU Operator	manufacturer		importe	distributor	
4	3rd Party & Domestic (with product alterations)	Supplier product specifically modified (see point 3 below) for or by an EU Operator and sold within the EU.	manufacturer		distributor		
5	Direct Import / FOB	Developed product (by a Non-EU Operator) sold outside of the EU for Direct Import by an EU Operator.	manufacturer		importe		
6	Direct Import/FOB - manufacturer is an EU entity	Developed product (by EU Operator) sold outside of the EU for Direct Import by an EU Operator. *5	manufacturer		distributor		
7	3rd Party (Sales Commission) FOB	Developed product (by EU or Non-EU Operator) sold outside of the EU by an EU or Non-EU sales agent, for Direct Import by an EU Operator.	manufacturer		importe		
8	Manufacturers Authorised Representative in EU	Product sold by a contracted representative of a Non-EU Operator to hold (but not draw up) Technical File.	manufacturer		Authorised representative	distributor	
9	Retailer own Brand Product	Product developed exclusively for EU retailer and bought outside the EU.	manufacturer				

Obligation	Manufacturer		Authorized representative		Importer		Distributor	
	Article 4	Ensure toys comply with essential safety requirements	Article 5	Not allowed	Article 6	Place only compliant toys on the market	Article 7	act with due care
Draw up technical documentation and carry out the conformity & safety assessments	A4(2),A21,A18,A19	Yes	A5(2)	Not allowed Can carry out parts of the conformity assessment procedures according to decision 768/2008/EC	A6(2)	Ensure its done		NO OBLIGATION
Keep the technical documentation	A4(3)	10 years after placing on the market	A5(3)	10 years after placing on the market		NO OBLIGATION		NO OBLIGATION
Make available the technical documentation, upon request	A4(9)	Upon reasoned request	A5(3)	Upon reasoned request	A6(8)	10 years after placing on the market	A7(5)	Upon reasoned request
Draw up EC declaration of conformity	A4(2)	Yes	A5(3)	Yes		NO OBLIGATION		NO OBLIGATION

Keep a DoC and make it available	A4(3)	10 years after placing on the market	A5(3)	10 years after placing on the market	A6(8)	10 years after placing on the market	A7(5)	Upon reasoned request
Affix conformity marking (CE); Affix identification: type, batch, serial or model number	A4(2),A4(5)	Yes	A30 Reg, A5(2)	Yes	A6(2)	Ensure its done	A7(2)	verify it's done
Ensure conformity of series production	A4(4),A19(2)	Yes		NO OBLIGATION		NO OBLIGATION		NO OBLIGATION
Add name and address	A4(6)	Yes		Only his address if manufacturer outside EU	A6(2),A6(3)	Yes	A7(2)	verify it's done
Ensure the required documents accompany the toy in the correct languages	A4(7)	Yes	A5(3)	Depends on the written mandate	A6(4)	Yes	A7(2)	yes
Bring non conforming toys into compliance. Inform authorities if there is a safety risk. Recall or withdraw Provide information to	A4(8),A4(9)	Yes	A5(3)	Depends on the written mandate	A6(2),A6(7),A6(9)	Yes	A7(2),A7(4),A7(5)	Yes (make sure it's done)

authorities on request								
Sample test marketed toys (taking into account risk)	A4(4)	Yes	A5(3)	Depends on the written mandate	A6(6)	Yes		NO OBLIGATION
Keep register of complaints, non-conforming toys and recalls. Inform Distributors of this monitoring.	A4(4)	Yes	A5(3)	Depends on the written mandate	A6(6)	Yes		NO OBLIGATION
Don't jeopardise compliance during storage or transport		NO OBLIGATION			A6(7)	Yes	A7(3)	Yes
Identify the other Economic Operators in each toy's supply chain.	A9	Yes			A9	Yes	A9	Yes

Manufacturers obligations

(1) Draw up Technical Documentation and carry out Safety & Conformity Assessments

Articles 4(2), 18, 19 & 21

(2) Draw up EC Declaration of Conformity and retain for 10 years. Retain technical documentation for 10 years after the toy has been placed on the market

Article 4(2)

Where compliance with the applicable requirements Article 10 & Annex II has been demonstrated, Manufacturers shall draw up an EC Declaration of Conformity and keep it updated (Article 15).

Article 4(3)

The Declaration of Conformity and technical documentation should be retained for 10 years after the toy has been placed on the market. NB. It is advisable that Declaration of Conformity and technical documentation be kept for 10 years after the last toy has been supplied.

(3) Affix conformity marking, batch or model number to the toy or its packaging

Article 4(2)

Affix the CE marking as per Article 17(1). CE Marking shall be fixed to the toy, a label or to the packaging. It is sufficient for the CE marking to be on the packaging if it is visible at the point of sale.

Article 4(5)

Manufacturers shall ensure that their toys bear a type or batch or serial or model number. If the size or nature of the toy does not allow it, this can be on the packaging or document accompanying the toys.

(4) Ensure conformity of series production

Article 4(4) & 19(2)

Add name and address onto toy or, if not possible, on the packaging

Article 4(6)

The address shall indicate a single point at which the Manufacturer can be contacted. A website is additional information, but is not enough as an address. Normally an address consists of a street and number or post-box and number and the postal code and town.

On packages and products that have several contact addresses it is suggested that the address of the office holding the technical documentation is underlined.

(5) Ensure the required documents are in the correct languages

Article 4(7)

Instructions and safety information should be in a language or languages easily understood by consumers, as determined by the member state concerned.

More information can be found <http://ec.europa.eu/DocsRoom/documents/7030/attachments/1/translations/en/renditions/native>

(6) Bring non-conforming toys into compliance and inform authorities if there is a safety risk. Recall or withdraw. Provide information to competent authorities on request

Article 4(8)

This directive states that toys being made available on the EU market must be brought immediately into conformity. For toys that are already on the market that are found not to be in conformity it is advisable that actions taken are commensurate with the risk posed.

Note: Although the directive requires that all Economic Operators inform authorities if there is a safety risk, it is strongly recommended that the Economic Operators co-operate to put together a comprehensive information package ensuring a coordinated response.

Article 4(8)

Manufacturers should contact their “Authority” where they have reason to believe that a toy presents a safety risk

Article 4(9)

Manufacturers should be able to supply documentation relevant to the nature of the enquiry.

These documents must be supplied in a language “easily understood” so obviously Chinese documents are not acceptable. It may be necessary to translate certain parts of the technical documentation into the language of the requesting authority if English is not acceptable.

(7) Sample test marketed toys (taking into account risk)

Article 4

This does not require that each marketed product be sample tested. It is advisable that a targeted risk based approach be used. As this is also an obligation of Importers some co-operation is recommended to prevent duplication.

(8) Keep register of complaints, non-conforming toys and recalls and inform Distributors of this monitoring

Article 4(4)

It is considered sufficient to inform Distributors of the systems that a Manufacturer has in place to do such monitoring. It is not necessary to inform Distributors of each and every complaint.

Obviously if a non-conforming toy is such that it presents a risk such that a recall is required, other parties in the supply chain should be informed.

Don't jeopardise compliance during storage or transport

This is not a specific obligation for Manufacturers however they should be mindful of this requirement and ensure that compliance is not jeopardised during storage and transit while the toy is under their control.

(9) Identify the other Economic Operators in each toy's supply chain

Article 9

The supply chain should be traceable meaning that manufacturers should be able to identify any Economic Operator who has supplied them with a toy and any Economic Operator to whom they have supplied a toy.

It is advisable to ensure you are aware of and record the complete supply chain for each toy.

Records must be retained as this information needs to be available for a period of 10 years after the toy was placed on the market. It is advisable that these records are kept for 10 years after the toy was last supplied.

Importers obligations

(1) Draw up Technical Documentation and carry out Conformity and Safety Assessments

Article 6(2)

The requirement is for the Importer to check if the appropriate conformity assessment has been carried out by the Manufacturers. It is important to note that the requirement is not to obtain and retain such documentation themselves, just to ensure that it will be available.

It is considered sufficient that an Importer check that the Manufacturer has systems and procedures in place to do this rather than requesting evidence on a product by product basis.

NB: It should be noted that there will be a time limit given to supply such documents to enforcement. If Importers are not confident that they will be able to get such documentation within the time limit from a Manufacturer, they should obtain and hold it themselves

(2) Draw up EC Declaration of Conformity and retain for 10 years

Article 6(8)

An Importer shall keep a copy of the EC Declaration of Conformity with in the EC. However with regards to other technical documentation an importer must ensure that it “can be made available” to authorities for 10 years after the toy has been placed on the market. It important to note that the requirement for Importers is not to obtain and retain such documentation themselves (except for EC Declaration of Conformity), just to ensure that it will be available. However, if Importers are not confident that they will be able to get such documentation within the time limit or that it will not be retained for 10 years by the Manufacturer, they should obtain and hold it themselves.

Note: It is mandatory that Declaration of Conformity and technical documentation be kept available for 10 years after the last toy has been supplied.

(3) Affix conformity marking, batch or model number to the toy or its packaging

Article 6(2)

Importers need only to ensure that type or batch or serial or model number, and CE marking is present

It is not considered necessary for Importers to check each product individually only to ensure that Manufacturers have procedures and systems in place to ensure that this is present.

Importers who carry out pre-shipment inspections may wish to add this check point

(4) Add name and address onto toy or packaging

Article 6(2) & (3)

Importers should add their name and address to the toy or, if not possible, to its packaging. This means that it is acceptable to have these details only on the retail packaging if the Importers would have to open the packaging to put their name and address onto the product.

Note: Importers should ensure that the Manufacturers address is also present on the toy or its packaging.

A website is additional information, but is not enough as contact address. Normally an address consists of a street and number or post-box and number and the postal code and town.

If the Manufacturer is outside the EU Community and the Importer places the toy on the market under his own name or trademark or modifies the toy already placed on the market, the Importer is considered to be the Manufacturer. In this case the only address required on the toy (or packaging or accompanying document) is the address of the Importer who is considered to be the Manufacturer.

If the Manufacturer is within the EU, although the products are manufactured outside the EU, they are considered to be the entity who places the toys on the EU market - even if they do not import in reality - it can be done by another company on their behalf. In this case there is no Importer in the meaning of the Importer's definition and it is sufficient to apply only the Manufacturer's address.

(5) Ensure the required documents are in the correct languages

Article 6(4)

Instructions and safety information should be in a language or languages easily understood by consumers, as determined by the member state concerned.

More information can be found <http://ec.europa.eu/DocsRoom/documents/7030/attachments/1/translations/en/renditions/native>

(6) Bring non-conforming toys into compliance. Inform authorities if there is a safety risk. Recall or withdraw. Provide information to competent authorities on request

Articles 6(2) & 6(7)

Importers should stop supplying non compliant product and immediately consult with the Manufacturer. It is advisable that any actions taken are commensurate with the risk.

Note: Although the directive requires that all Economic Operators inform authorities if there is a safety risk, it is strongly recommended that the Economic Operators co-operate to put together a comprehensive information package ensuring a coordinated response.

Importers should contact their “Authority” where they have reason to believe that a toy presents a safety risk

It should be noted that each Economic Operator may have a different Home Authority.

Article 6 (9)

These documents must be supplied in a language “easily understood” so obviously Chinese documents are not acceptable. It may be necessary to translate certain parts of the technical documentation into the language of the requesting authority if English is not acceptable

(7) Sample test marketed toys (taking into account risk)

Article 6 (6)

This does not require that each marketed product be sample tested. It is advisable that a targeted risk based approach be used. As this is also an obligation of Manufacturers co-operation is recommended to prevent duplication. Keep register of complaints, non-conforming toys and recalls and inform Distributors of this monitoring

It is considered sufficient to inform Distributors of the systems that a Manufacturer has in place to do such monitoring. It is not necessary to inform Distributors of each and every complaint.

Obviously if a non-conforming toy is such that it presents a risk such that a recall is required, other parties in the supply chain should be informed.

(8) Don’t jeopardise compliance during storage or transport

This could include careless handling or inappropriate storage conditions (e.g. storing wooden or plush toys stored in damp conditions).

(9) Identify the other Economic Operators in each toy’s supply chain.

Article 9

The supply chain should be traceable meaning that Importers should be able to identify any Economic Operator who has supplied them with a toy and any Economic Operator to whom they have supplied a toy.

It is advisable to ensure you are aware of and record the complete supply chain for each toy.

Records must be retained as this information needs to be available for a period of 10 years after the toy was placed on the market. It is advisable that these records are kept for 10 years after the toy was last supplied.

Distributors

(1) Affix conformity marking, batch or model number to the toy or its packaging

Article 7(2)

Distributors are required to ensure that the required conformity markings are present. It is not considered necessary for Distributors to check each product individually only to have confidence that Manufacturers have procedures and systems in place to ensure that these are applied.

(2) Add name and address onto toy or packaging

Article 7(2)

Distributors are only to verify that the address is present. This should be the address of the Importer and/or the Manufacturer.

(3) Ensure instructions and safety information are in the correct languages.

Article 7(2)

Instructions and safety information should be in a language or languages easily understood by consumers, as determined by the member state concerned.

More information can be found <http://ec.europa.eu/DocsRoom/documents/7030/attachments/1/translations/en/renditions/native>

(4) Bring non-conforming toys into compliance. Inform authorities if there is a safety risk. Recall or withdraw. Provide information to competent authorities on request

Article 7(2) & (4)

Where a Distributor has reason to believe that the toy is not in conformance with the essential safety requirements (Article 10) and the particular requirements (Annex II) it shall not make the toy available on the market until it has been brought into compliance

The Distributor's responsibility is to stop selling the non-complaint product and immediately consult with the Manufacturer or Importer with regards to bringing the toy back in to compliance. It is advisable that actions taken are commensurate with the risk.

Article 7 (5)

Although the directive requires that all Economic Operators inform authorities if there is a safety risk, it is strongly recommended that the Economic Operators co-operate to put together a comprehensive information package ensuring a coordinated response.

Distributors should contact their “Home Authority” trading standards office where they have reason to believe that a toy presents a safety risk

It should be noted that each Economic Operator may have a different Home Authority.

(5) Keep register of complaints, non-conforming toys and recalls and inform Distributors of this monitoring

It is not a requirement of Distributors to keep a register of complaints; however it is recommended that Distributors inform other Economic Operators in the supply chain of any safety related complaints.

(6) Don’t jeopardise compliance during storage or transport

Article 7 (3)

This could include careless handling or inappropriate storage conditions (e.g. storing wooden or plush toys stored in damp conditions).

(7) Identify the other Economic Operators in each toy’s supply chain

Article 9

The supply chain should be traceable meaning that Distributors should be able to identify any Economic Operator who has supplied them with a toy and any Economic Operator to whom they have supplied a toy.

It is advisable to ensure you are aware of and record the complete supply chain for each toy.

Records must be retained as this information needs to be available for a period of 10 years after the toy was placed on the market. It is advisable that these records are kept for 10 years after the toy was last supplied.

Authorised Representative

1. A manufacturer may, by a written mandate, appoint an authorised representative.
2. The obligations laid down in Article 4(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.
3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - (a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of 10 years after the toy has been placed on the market;
 - (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy;
 - (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by toys covered by the mandate.

17. EXPLANATION II CLEARLY VISIBLE AND EASILY LEGIBLE WARNINGS

The bodies in charge of the preparation of standards under directive 2009/48/EC are expected to revisit the present standard requirements regarding visibility and legibility of warnings. During this work, the standard developers should, when relevant, consult available guides and standards such as CEN Guide 11 – Product information relevant to consumers, IEC Guide 14 – Purchase information on goods and services intended for consumers, CEN TR 13387 Safety Guidelines for child use and care articles and IEC 62079 – Preparation of instructions.

When considering these guidelines, the standard developers must also acknowledge that the legibility should always depend on a concrete evaluation of the individual product and the size of the packaging.

The above mentioned guides and standards include, for example, the following recommendations and statements that should be considered in the standardisation work (the below text is included for information only). The requirements are given in the TSD and relevant harmonised standards.

According to the TSD, the word “Warning” and accompanying text shall be easily legible. To achieve this several factors must be considered. Understandable warnings consist of comprehensible, readable and legible warnings. The following aspects are relevant for legibility:


- Lay-out;
- letter size, type and font;
- colours and contrast;
- illustrations;
- physical elements.

Layout of the warning

Warnings are not intended to be directed to children, but to adults supervising the child. Warning sentences should describe the nature and the consequences of the hazard and should give guidance on what to do and what to avoid.

They should comply with the following grammar: instruction part/hazard part/consequence part. In some cases these parts do not need to be positioned in direct connection to each other. Hazards and consequences should be specified if they are not obvious.

Warnings have to be preceded by the word "Warning(s)".


The age warning symbol, if present,  or the warning should be placed in a prominent position on the toy, on an affixed label or its packaging. The indication of the specific hazard that calls for the warning/restriction "not suitable for children under 3 years" may however be placed in the instructions for use. Warnings should be marked on the toy in cases of safety information that requires extra attention (where for example the hazards involved are severe) or because the hazards occurs every time the toy is used or because unsafe behaviour is likely to occur after some time of use. E.g. the warning for toys

intended to be strung across a cot. Warnings which determine the decision to purchase the toy shall be clearly seen prior to purchase or shall appear on the consumer packaging.

Letter size, type and font – criteria and guidelines for safety sentences

The x-height of letters in on-product text is at least 3 mm when anticipating optimum reading conditions, e.g. viewing distance 0.5 m and good lighting, or 8 mm when anticipating difficult reading conditions, e.g. viewing distance 2 m and poor lighting. The x-height of letters in continuous text in manuals etc. is at least 1.5 mm. Even if the above guidelines regarding x-heights are taken into account, the legibility of the resulting product information should be checked in realistic purchase and use conditions and within the target population.

Lay-out, Size – criteria and guidelines for safety symbols

According to harmonized standard EN 71-1 the details of the design of the pictogram  are: the circle and the stroke should be red, the background should be white, the age range and the face should be black. This symbol shall be used to indicate only "0 to 3" years and not for any other age-grade warning to avoid misinterpretation of the symbol. This symbol shall have a diameter of at least 10 mm.

According to TR 13387 other safety symbols should have a height of at least 12 mm, and in CEN guide 11 20 mm is recommended for safety symbols in general.

Colours and contrast

Contrast between the text and the background is important. Too little contrast between the text and the background adversely affects the accessibility of the information. Therefore, background images should in principle not be placed behind the text since they may interfere with the clarity of the information making it harder to read.

The relationship between the colours used is as important as the colours themselves. As a general rule dark text should be printed on a light background. But there may be occasions when reverse type (light text on a dark background) could be considered to highlight for instance particular warnings. In such circumstances the quality of the print will need careful consideration and may require the use of a larger type size or bold text. Similar colours (like white text on yellow background) and red-green and blue-yellow colour combinations should not be used for the text and background as legibility is impaired.

Illustrations: use of symbols and pictograms

Symbols and pictograms can be useful provided the meaning of the symbol is clear and the size of the graphic makes it easily legible. They should only be used to aid navigation, clarify or highlight certain aspects of the text and should in principle not replace the actual text. Evidence may be required to ensure that their meaning is generally understood and not misleading or confusing. If there is any doubt about the meaning of a particular pictogram it will be considered inappropriate. Symbols should be developed according to recognised standards, they should be fully developed and tested across consumers from all social, economic and cultural groups throughout Europe.

Physical elements

The paper weight chosen should be such that the paper is sufficiently thick to reduce transparency which makes reading difficult.

Glossy paper reflects light making the information difficult to read, so the use of uncoated paper should be considered.

Make sure that when the leaflet is folded the creases do not interfere with the readability of the information.

18. EXPLANATION III CE MARKING

Principles of the CE marking

The CE marking symbolises the conformity of the toy. The CE marking affixed to the toy is a declaration by the manufacturer that:

- the toy conforms with all applicable requirements, and
- he takes full responsibility therefore.

General principles governing the CE marking are set out in article 30 of Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking are laid down in article 17 of the TSD. Since all products covered by New Approach directives bear CE marking, this marking is not intended to serve commercial purposes. Neither is the CE marking a mark of origin, as it does not indicate that the product was manufactured in the Community.

The CE marking is mandatory and must be affixed before any toy is placed on the market. Where toys are subject to several directives, which all provide for the affixing of the CE marking, the marking indicates that the toys are presumed to conform to the provisions of all these directives. This means that if a toy is subject to another Directive (e.g. EMC) providing to affix the CE marking, the toy can only bear the CE marking if the toy conforms to the provisions of all these directives (TSD and e.g. EMC).

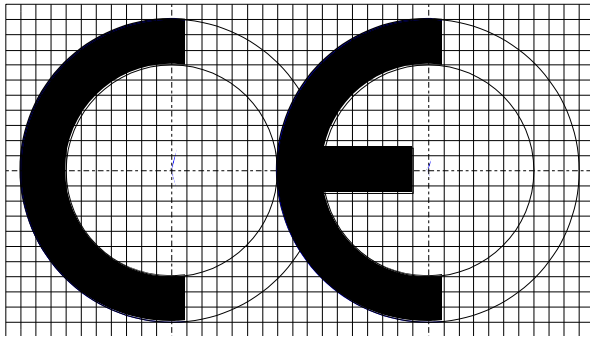
The CE marking should be the only marking of conformity indicating that the toy is in conformity with Community harmonisation legislation. However, other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation.

Affixing of the CE marking

The CE marking shall be affixed only by the manufacturer or his authorised representative. The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the toy complies with all the provisions of the relevant directives.

The CE marking symbolises conformity to essential public interests covered by the directives in question. Therefore, it is to be considered as essential information to Member States' authorities as well as other relevant parties (for example distributors, consumers and other users). Accordingly, the requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible. It shall also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards use a rub test with water and petroleum spirits). However, this does not mean that the CE marking must form an integral part of the product.

The CE marking shall consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged, the proportions given in the graduated drawing shall be respected. However, the CE marking shall be at least 5 mm high.

The manufacturer may choose to affix the CE marking visibly, legibly and indelibly to the toy, to an affixed label or to the packaging.

However, in the case of small toys and toys consisting of small parts, the CE marking may be affixed to a label or an accompanying leaflet.

Where, in the case of toys sold in counter displays, that is not technically possible, and on condition that the counter display was originally used as packaging for the toy, the CE marking may be affixed to the counter display.

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

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.



CORRECT for the affixing of the CE marking

CE marking and other marks (see also 3.8.1)

CE marking is the only marking which symbolises conformity to all the obligations incumbent on manufacturers for the toy. Member States shall refrain from introducing any reference to another conformity marking into their national regulations, which would signify conformity with objectives that relate to the CE marking.

A toy may bear additional markings and marks, provided that they:

- fulfil a different function from that of the CE marking,
- are not liable to cause confusion with it, and
- do not reduce its legibility and visibility.

The affixing to a toy of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. The affixing of legal marking (such as a protected trademark of a manufacturer), or of acceptable certification and other marks additional to the CE marking, is allowed to the extent that such markings or marks do not create confusion with the CE marking, and that they do not reduce the legibility and visibility of the CE marking. This confusion may either refer to the meaning or form of the CE marking. Whether or not a marking or mark is confusing should be decided from the point of view of all relevant parties likely to come into contact with it.

More information on the CE marking can be found on following pages:

<http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/>

http://ec.europa.eu/growth/single-market/ce-marking/index_en.htm

Conclusion

This table gives an overview for marking the necessary information according to Directive 2009/48/EC

	Identification	Identification (if size/nature of toy does not allow it)	Address	Address (if not possible on the toy)	CE marking	CE marking (small toy)	CE marking (toys in counter display)	Warning	Warning (small toy without packaging)
Toy	X		X		X			X	
OR									
Packaging		X		X	X	X	X	X	
Document (leaflet/instructions)		X		X		X	X	X (if appropriate)	
Affixed label		X		X	X	X	X	X	X
Counter display							X (if display is used as		

							packaging)		
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Remark: CE marking has always to be visible from outside the packaging

Remark: warnings which determine the decision to purchase shall be visible to the consumer before the purchase (including on-line purchase)

This table gives an overview for marking the necessary information according to Directive 88/378/EEC

	Address	Address (small toys)	CE marking	CE marking (small toy)	Warning
Toy	X		X		X
Packaging	X*	X*	X*	X*	X
Document (leaflet/instructions/label)		X*		X*	X

Remark: * consumer's attention must be drawn to the advisability to keep the information

19. EXPLANATION IV PARTS OF TOYS OTHERWISE DIRECTLY ATTACHED TO A FOOD

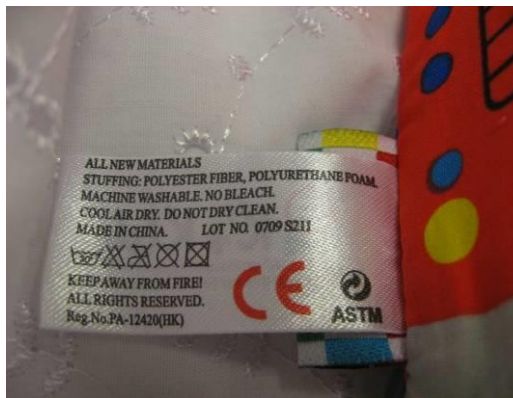


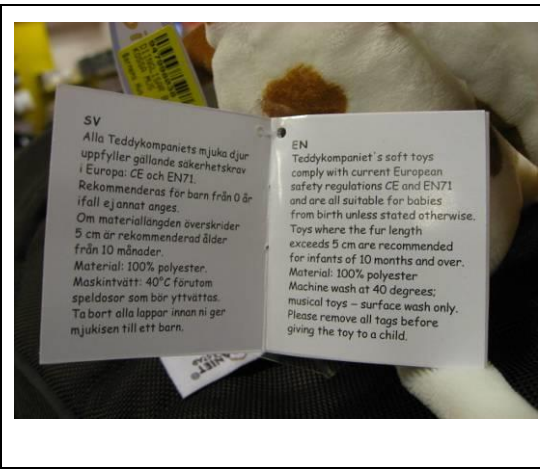


20. EXPLANATION V OVERVIEW OF TEXTILE TOYS

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

Toys intended for use by children under 36 months – able to be cleaned





Textile toys intended for use by children under 36 months – able to be soak washed









Textile toys intended for use by children under 36 months, containing a mechanism – able to be cleaned



Contains a rattle-mechanism that may be damaged



Contains a rattle-mechanism that may be damaged

21. GUIDANCE DOCUMENT OUTLINING THE RELATIONSHIP BETWEEN THE GPSD DIRECTIVE AND REGULATION (EC) No 765/2008

Working paper on the relationship between the General product Safety Directive 2001/95/EC and the market surveillance provisions of Regulation (EC) No 765/2008

1. OBJECTIVE AND SCOPE OF THIS DOCUMENT

The objective of this paper is to clarify the relationship between the Directive 2001/95/EC on general product safety (the "GPSD")¹⁰ and Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance (the "Regulation").¹¹ It should help Member States to properly implement the Community legal framework on market surveillance of products.¹²

This paper only addresses the relationship between the two horizontal regimes on market surveillance, i.e. the GPSD and the Regulation. It does not deal with the relationship between these two pieces of Community legislation and sector specific Community legislation which contains specific market surveillance obligations for certain product sectors (e.g. the Medical Devices Directives¹³ or Cosmetics Directive¹⁴). The relationship with sector-specific legislation will be clarified in a separate step.

Chapter 2.2 of this document is not relevant for carrying out market surveillance with respect to legislation that does not have the objective of protecting the health and safety of consumers, but other objectives, e.g. the protection of health and safety at the work place, the protection of the environment or energy efficiency aspects. The measures listed in this chapter only concern market surveillance measures relating to products which present a risk to the health and safety of consumers. Chapter 2.3 however clarifies certain aspects of the use of the RAPEX system which are relevant for all areas of Community harmonisation legislation.

¹⁰ OJ L 11, 15.1.2002, p. 4

¹¹ OJ L 218, 13.8.2008, p. 30

¹² This document sets out the interpretation of the responsible Commission services. It does not in any way prejudice a possible formal position of the European Commission. Furthermore a binding interpretation of Community law is the sole competence of the European Court of Justice.

¹³ Directive 90/385/EEC relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), Directive 93/42/EEC concerning medical devices (OJ L 169, 12.7.1993, p. 1) and Directive 98/79/EC on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1)

¹⁴ Directive 76/768/EEC relating to cosmetic products (OJ L 262, 27.9.1976, p. 169) (to be replaced as of 11 July 2013 by Regulation (EC) No 1223/2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59)

2. RELATIONSHIP BETWEEN THE GPSD AND THE REGULATION

2.1. The scope of application of the GPSD and the Regulation

The GPSD first introduced requirements on the organisation and performance of market surveillance of health and safety aspects of (non-food) consumer products at the Community level. Since the adoption of the Regulation, there are two horizontal pieces of Community law containing requirements for market surveillance as regards the safety of products. The scope of application of the GPSD is, however, different from that of the Regulation.

The GPSD applies to all consumer products¹⁵ - regardless of whether they are covered by Community harmonisation legislation - provided that there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned; within this scope, it aims to protect the health and safety of consumers.

The Regulation applies to all products subject to Community harmonisation legislation (the "harmonised products")¹⁶ - regardless of whether they are consumer or non-consumer products – in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Community harmonisation legislation; within this scope, it protects not only the health and safety of consumers, but also other public interests, such as health and safety of users in the workplace, the environment, the sustainable use of energy, etc.

Hence, there are clearly defined areas with no overlap between the GPSD and the Regulation: the area of non-harmonised consumer products is subject to the rules of the GPSD, the area of harmonised non-consumer products is subject to the Regulation, and the area of non-harmonised non-consumer products is not subject to either of these two horizontal instruments. As regards the protection of the health and safety of consumers, however, the area of harmonised consumer products comes under the market surveillance provisions of both, the GPSD and the Regulation. This relationship between the GPSD and the Regulation is illustrated by Table 1.

¹⁵ Article 2(a) of the GPSD defines (consumer) product as "any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned." This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect;

¹⁶ Community harmonisation legislation is defined in Article 2 (21) of Regulation 765/2008 as "any Community legislation harmonising the conditions for the marketing of products". Examples of such legislation are the Toys Directive (Directive 88/378/EEC on the safety of toys, as amended (to be replaced by Directive 2009/48/EC on the safety of toys), the Low Voltage Directive (Directive 2006/95/EC on the electrical equipment designed for use within certain voltage limits), the Electromagnetic Compatibility Directive (Directive 2004/108/EC on electromagnetic compatibility), etc.

Table 1:

Products	Consumer	Non-consumer
Harmonised	Regulation GPSD	Regulation
Non-harmonised	GPSD	No horizontal Community rules on market surveillance

In order to clarify which market surveillance provisions of the GPSD and the Regulation are applicable to harmonised consumer products, Article 15 (3) has been integrated into the Regulation. It states that “[t]he application of Regulation 765/2008 shall not prevent market surveillance authorities from taking more specific measures as provided for in the GPSD”.

This means that all the market surveillance provisions of the Regulation, i.e. Articles 16 to 26, apply to harmonised consumer goods. In addition, the market surveillance provisions of the GPSD which contain "more specific measures" – when compared to the aforementioned market surveillance provisions of the Regulation – also apply to harmonised consumer products. Other market surveillance provisions of the GPSD, which do not entail "more specific measures", no longer apply to harmonised consumer products.

The market surveillance provisions of the GPSD which may entail such "more specific measures" are included in the Directive under *Chapter IV – Specific obligations and powers of the Member States* (Articles 6 to 9 of the GPSD), *Chapter V – Exchanges of information and rapid intervention situations* (Articles 11 and 12 of the GPSD) and *Chapter VII – Final provisions* (Articles 16 and 18 of the GPSD).

To determine which market surveillance measures contained in these Articles of the GPSD are more specific, they need to be compared in detail to the corresponding measures of the Regulation.

On the basis of such a comparison carried out by the Commission services, the market surveillance measures of the GPSD described in the following chapter have been identified to be more specific than those foreseen in the Regulation.

The consequences of Article 15 (3) of the Regulation for the exchange of information and the operation of the RAPEX system (Articles 11 and 12 of the GPSD) are explained in a specific chapter (chapter 2.3).

2.2. More specific GPSD measures which apply in addition to the Regulation

The market surveillance measures of the GPSD described in the following sections (2.2.1 – 2.2.8) have been identified as being more specific than those foreseen in the Regulation. As provided for in Article 15 (3) of the Regulation, they therefore apply, in addition to the provisions of the Regulation, to harmonised consumer products. The legal basis for their adoption is the GPSD that is, the legal acts transposing the GPSD into national law.

2.2.1. Measures under Article 8 (1) (b) GPSD (warnings and imposing prior conditions for marketing)

Article 8 (1) (b) of the GPSD foresees that for any products that could pose a risk in certain conditions, market surveillance authorities can require such products to be marked with specific warnings or make their marketing subject to prior conditions. The Regulation does not contain such a provision. Therefore, measures under Article 8 (1) (b) of the GPSD are more specific to those laid down in the Regulation and, consequently, they should be applied in the area of harmonised consumer products.

2.2.2. Measures under Article 8 (1) (c) of the GPSD (warnings for certain persons at risk)

According to Article 8 (1) (c) of the GPSD, market surveillance authorities can order that warnings be given to certain persons for whom products could pose risks. The provision in the Regulation on warnings (Article 19 (2)) is more general. Therefore, measures under Article 8 (1) (c) of the GPSD are more specific to those laid down in the Regulation, and, consequently, they should be applied in the area of harmonised consumer products in addition to Article 19 (2) of the Regulation.

2.2.3. Measures under Article 8 (1) (d) of the GPSD (temporary ban for period of evaluation)

Article 8 (1) (d) of the GPSD enables market surveillance authorities to impose a temporary ban on potentially dangerous products for the period needed for evaluation. The Regulation does not specifically foresee a temporary ban. Therefore, measures under Article 8 (1) (d) of the GPSD are more specific to those laid down in the Regulation, and consequently, they should be applied in the area of harmonised consumer products.

2.2.4. Accompanying measures required to ensure that a marketing ban is complied with, as provided for under Article 8 (1) (e) GPSD other than informing the public, the Commission and the other Member States

Article 8 (1) (e) GPSD foresees the possibility to adopt accompanying measures, alongside a marketing ban, which are required to ensure that the ban is complied with. The Regulation foresees that the public, the Commission and the other Member States must be informed of marketing bans (Articles 19 (2), 22 and 23) but it does not contain any other specific provisions on accompanying measures to ensure that the ban is respected. Hence, any other accompanying measure ensuring that a marketing ban is complied with is a more specific measure of the GPSD and should, consequently, be applied in the area of harmonised consumer goods.

2.2.5. Measures under Article 8 (1) (f) (ii) of the GPSD (recall and destruction of products that are dangerous but do not present a serious risk)

Article 8 (1) (f) (ii) of the GPSD enables market surveillance authorities to order, coordinate or organise the recall of all dangerous products and their destruction. The Regulation only foresees recalls of products presenting *a serious risk* (Article 20) and enables authorities to destroy products which present a *serious risk* (Article 19 (1)).

Recalls and destruction of products which are dangerous but do not present a serious risk as foreseen under Article 8 (1) (f) (ii) GPSD are more specific measures than those foreseen in the Regulation and should, consequently, be applied in the area of harmonised consumer products.

2.2.6. Encouragement and promotion of voluntary action as provided for under Article 8(2), second sub-paragraph of the GPSD

The second subparagraph of Article 8 (2) of the GPSD requires market surveillance authorities to encourage and promote voluntary action, including the development of codes of good conduct. Such a requirement is not foreseen in the Regulation. Since this requirement is a more specific measure under the GPSD, it should consequently be applied, as appropriate, also in the area of harmonised consumer products.

2.2.7. Information for consumers on complaint procedures, as provided for under Article 9(2) of the GPSD

Article 18 (2) of the Regulation requires Member States to establish procedures to follow up complaints or reports on issues relating to risks arising in connection with products. Article 9 (2) GPSD contains a similar requirement on allowing consumers and other interested parties to submit complaints on product safety. Furthermore, it obliges authorities to actively inform consumers and interested parties about the procedures established to that end. This obligation to "*actively inform consumers and interested parties about the procedures established to that end*" goes beyond the Regulation and is therefore a specific measure of the GPSD which should be applied in the area of harmonised consumer products in addition to Article 18 (2) of the Regulation.

2.2.8. Information for consumers on products posing a risk as provided for under Article 16 (1) of the GPSD

Article 19 (5) of the Regulation stipulates that information must be made public to the fullest extent necessary in order to protect the interests of users in the Community. Article 16 (1) GPSD sets out the same principle. However, the first subparagraph of Art. 16 (1) of the GPSD further specifies that the public shall have access to information on product identification, the nature of the risk and the measures taken. Since this obligation to allow the public to have access to information on product identification, the nature of the risk and the measures taken is not spelled out in the Regulation, it is a more specific measure under the GPSD which applies in the area of harmonised consumer products in addition to Article 19 (5) of the Regulation.

2.2.9. *General principles of the law of the European Union and good administration, as provided for under Articles 8 (2) and 18 of the GPSD*

Articles 8 (2) and 18 of the GPSD make reference to a number of principles to be observed when carrying out market surveillance activities. The Regulation contains similar provisions in its Articles 19 and 21. The relevant GPSD provisions do not foresee any specific measures, which would apply in addition to the measures set out in the Regulation. These provisions are an expression of the general principles of the law of the European Union. In Article 8 (2), the GPSD explicitly mentions that recall shall take place as a last resort. This principle is an important expression of the proportionality principle in the market surveillance context and it is fully applicable also to recalls adopted on the basis of the Regulation.

2.3. **Consequences for the operation of the RAPEX system**

Both the GPSD and the Regulation will use the RAPEX system for the notification of products presenting a serious risk. RAPEX will thus continue to function as a single system, and will operate as the rapid information exchange system for both the GPSD and the Regulation.

Article 22 (4) of the Regulation provides that paragraphs 2, 3 and 4 of Article 12 of the GPSD shall apply “*mutatis mutandis*” under the Regulation. The *mutatis mutandis* application means that the conditions of the GPSD also apply, in principle, to the functioning of RAPEX under the Regulation subject to certain adaptations necessary or inherent to the intention that RAPEX is to be used for notifications under the Regulation.

This means, inter alia, that:

- (a) the procedures for the functioning of RAPEX set out in Annex II of the GPSD and in the RAPEX Management Guidelines (Commission Decision 2010/15/EU¹⁷) also apply, *mutatis mutandis*, to notifications based on the Regulation;
- (b) the GPSD Committee has an advisory role in the adoption of any guidelines for notifications based on Article 22 of the Regulation; and
- (c) access of third countries to the RAPEX system is determined on the basis of, and under the conditions set out in, Article 12 (4) of the GPSD, also with regard to notifications made on the basis of the Regulation.

2.3.1. *Notifications of measures concerning harmonised consumer products which present a serious risk to health and safety*

Article 22 (1) of the Regulation obliges Member States to notify to the Commission through the RAPEX system measures taken in accordance with Article 20, i.e. *withdrawals, recalls and prohibitions of the marketing* of harmonised products presenting a serious risk, when it is considered that the reasons which prompted the measure or the effects of the measure go beyond the territory of the notifying Member State. This

¹⁷ OJ L 22, 26.1.2010, p. 1

obligation also includes notifications of measures recommended or agreed with economic operators. Furthermore voluntary measures taken by economic operators with respect to products presenting a serious risk have to be notified.

Article 12 (1) of the GPSD requires Member States to submit a RAPEX notification when they adopt or decide to adopt measures or actions to *prevent, restrict or impose specific conditions on the possible marketing or use* of harmonised consumer products presenting a serious risk and when it is considered that the effects of the risk are not limited to the national territory.

Hence, from the date of applicability of the Regulation on 1 January 2010, the legal basis for RAPEX notifications of *recalls, withdrawals and marketing prohibitions* of harmonised consumer products presenting a serious risk, including the accompanying measures, is no longer Article 12 of the GPSD but Article 22 of the Regulation. This means that the notification conditions set out in Article 22 (1) of the Regulation must be fulfilled and the information provided for in Article 22 (3) of the Regulation has to be provided with the notification.

However, Article 12 of the GPSD will still remain the legal basis for RAPEX notifications of *measures restricting or imposing specific conditions on the possible marketing or use of harmonised consumer products by reason of serious risk not amounting to a recall, withdrawal or prohibition*. Therefore, whenever market surveillance authorities adopt one of the more specific GPSD measures mentioned under points 2.2.1., 2.2.2 or 2.2.3 by reason of a serious risk they must notify them in accordance with Article 12 of the GPSD through the RAPEX system which determines the notification conditions and the information to be provided with the notification.

2.3.2. Notifications of measures concerning harmonised consumer products which present a non-serious risk to health and safety

Article 11 of the GPSD requires Member States to notify the Commission of measures taken which restrict the placing on the market of products, or require their withdrawal or recall unless a notification under Article 12 of the GPSD or any specific Community legislation is needed. Article 23 (2) of the Regulation obliges Member States to provide the Commission with information concerning products not already provided under Article 22. Hence, Article 23 of the Regulation serves as a basis for notification of any information on harmonised products posing a non-serious risk, including the measures adopted on the basis of the GPSD mentioned under points 2.2.1 - 2.2.5

2.3.3. Notification of measures concerning non-harmonised consumer products which present a risk to the health and safety of consumers

The applicability of the Regulation will not lead to any changes for RAPEX notifications concerning non-harmonised consumer products which present a risk to health and safety. Any market surveillance measures aimed at non-harmonised consumer products, i.e. all the measures listed in Article 8 (1) (b) – (f) (as well as other measures), continue to be notified on the basis of, and in accordance with, Article 11, in the case of a non-serious risk to the health and safety of consumers, or on the basis of and in accordance with Article 12, in the case of a serious risk to the health and safety of consumers.

2.3.4. Notification of measures concerning harmonised products which present other risks than a risk to the health and safety of consumers

For the sake of clarity and completeness it should be mentioned that measures taken against harmonised consumer and non-consumer products, which pose other risks than those affecting the health and safety of consumers, have to be notified on the basis of Article 22 of the Regulation through the RAPEX system. This concerns, for example, measures taken in view of a serious risk to the environment or to security.

NB: For an interim period pending the availability of the necessary informatics solutions notifications in this area should be made in accordance with the guidance issued on 14 December 2009 on "Interim lines of communication between the national authorities and the European Commission under Regulation No. 765/2008/EC".

3. GPSD PROVISIONS WHICH ARE NOT RELATED TO MARKET SURVEILLANCE

For the sake of clarity, it should be mentioned that the GPSD contains several provisions which do not concern market surveillance but other product safety related aspects, e.g. a general safety requirement in Article 3 or other obligations for economic operators in Article 5. These GPSD provisions are not affected by the Regulation and continue to apply to harmonised as well as non-harmonised consumer products in accordance with Article 1 (2) of the GPSD:

- Article 1: Objective and scope;
- Article 2: Definitions;
- Article 3: General safety requirement, conformity assessment criteria;
- Article 4: Procedure for mandating and drawing up European standards;
- Article 5: Other obligations for producers and obligations of distributors;
- Article 10: Network of the authorities promoted by the Commission¹⁸;
- Article 13: Specific decision-making procedure allowing the Commission to adopt decisions in urgent situations;
- Articles 14, 15: Comitology provisions;
- Article 17: Relationship to the Directive 85/374/EEC on liability for defective products¹⁹;
- Articles 19, 20: Reporting requirements for the Commission; and
- Articles 21-24: Final provisions.

¹⁸ This measure cannot be regarded as a market surveillance measure in the meaning of Article 15 (3) of the Regulation.

¹⁹ Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7.8.1985, p. 29