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

Consumer, Environmental and Health Technologies
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Toy Safety Directive 2009/48/EC

Technical documentation

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

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 for economic operators. However, this document does represent the opinion of the Member States and stakeholders and is a reference for ensuring consistent application of the Directive by them. The guidelines are intended to help ensure the free movement of toys in the European Union 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;
- not 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 EU territory all other relevant applicable legislation must be applied.

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

INTRODUCTION

In order to ensure compliance with the essential safety requirements, it was necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Internal production control based on the manufacturer's own responsibility for the conformity assessment has proven adequate in cases where he has followed the harmonised standards, the reference number of which has been published in the *Official Journal of the European Union (OJEU)*, covering all the safety requirements for the toy. In cases where such harmonised standards do not exist the toy should be submitted to third party verification, in this case EC-type examination[1]. The same should apply if one or more of such standards has been published with a restriction in the *Official Journal of the European Union*, or if the manufacturer has not followed such standards completely, or only in part. The manufacturer can submit the toy to EC-type examination in cases where it considers that the nature, design, construction or purpose of the toy necessitates third party verification.
To complete the legal obligations of the manufacturer which aim at ensuring the safety of toys, an explicit obligation to carry out an analysis of the various hazards that the toy may present and an assessment of the potential exposure to them, is included in the new Toy Safety Directive 2009/48/EC (TSD). With regards to chemicals, this includes in particular an assessment of the likelihood of the presence in the toy of prohibited or restricted substances. Manufacturers are obliged to keep this safety assessment in the technical documentation to allow market surveillance authorities to perform their tasks efficiently.

This guidance document aims at providing necessary information in order to elaborate an adequate technical documentation. Focus is the safety assessment to be carried out by manufacturers – including SMEs.

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 Union. It should be noted that the statements in these guidelines refer only to the application of Directive 2009/48/EC unless otherwise indicated.

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[1] For the purpose of this guide, we assume that economic operators and authorities are familiar with the content of the harmonised standards references to which are published in the OJEU.

CHANGES MADE COMPARED TO PREVIOUS VERSION

Rev 1.1	Updates of hyperlinks to websites (throughout the document)
Rev 1.1	Explanation of evidence for complying to module A
Rev 1.1	Explanation update DoC
Rev 1.1	Update of national legislation
Rev 1.2	Self-classification
Rev 1.3	Updates of hyperlinks to websites (throughout the document)
Rev 1.3	Update regarding BOM/BOS template (throughout Section 3.2)
Rev 1.3	Updates of references to Toy Safety Directive
Rev 1.3	Updates of references to harmonised standards and Toy Safety Directive
Rev 1.3	Updates of references to Toy Safety Directive
Rev 1.3	Update of Appendix I regarding BOM/BOS template
Rev 1.3	Inclusion of Appendix Ia regarding BOM/BOS template
Rev 1.3	Inclusion of Appendix Ib regarding BOM/BOS template
Rev 1.3	Updates of references to applicable EU legislation
Rev 1.3	Updates of references to national legislation
Rev 1.4	Updates of hyperlinks to websites (throughout the document)
Rev 1.4	Update of the example regarding EN 71-1
Rev 1.4	Inclusion of reference to RoHS
Rev 1.4	Inclusion of reference to non-harmonised standards
Rev 1.4	Update of the example regarding EN 71-1
Rev 1.4	Inclusion of references to RoHS and EMC
Rev 1.4	Explanation that safety assessment may lead to conclusion that no EC-type examination is required for microbiological aspects

Rev 1.4	Updates of references to harmonised standards
Rev 1.5	Update of Section 3.3 in Part I regarding safety data sheets
Rev 1.5	Update of Sections 1.3.1 and 1.3.4 in Part IV regarding formamide, bisphenol A, TCEP, PAH and DPHP

PART I TECHNICAL DOCUMENTATION

1. LEGAL FRAMEWORK

The new Toy Safety Directive 2009/48/EC contains several provisions related to the technical documentation. All economic operators have obligations, but the technical documentation is a file drawn up by the manufacturer, as this is the operator who knows the design, production, composition (materials and chemicals) … of the toy. The other economic operators (authorised representatives, importers, distributors) are obliged to make this information available.

If a manufacturer does not have the technical documentation for a certain toy, market surveillance authorities can oblige the manufacturer to have the toy tested by a notified body and have the costs paid by the manufacturer.

Section 2 of Part I of these guidelines elaborates on the different aspects of the technical documentation. Part II focuses on the safety assessment.

The applicable provisions of the Toy Safety Directive are listed below.

1.1. Article 4 Obligations of manufacturers

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.

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.

1.2. Article 5 Authorised representatives

The drawing up of technical documentation shall not form part of the authorised representative's mandate.

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.

1.3. Article 6 Obligations of importers

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).

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.

1.4. Article 7 Obligations of distributors

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.

1.5. Article 15 EC declaration of conformity

The EC declaration of conformity shall state that the fulfilment of the requirements set out in Article 10 and Annex II has been demonstrated.
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.
By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the toy.

1.6. 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.

1.7. Article 19 Applicable conformity assessment procedures

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.
If the manufacturer has applied harmonised standards, the reference number of which has been published in the *OJEU*, 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.
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 *OJEU*, 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.

1.8. Article 20 EC-type examination

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.
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.
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.
The EC-type examination certificate shall include a reference to this Directive, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference to the relevant test report.
The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.
The EC-type examination certificate shall be withdrawn if the toy fails to comply with the requirements set out in Article 10 and Annex II.
Member States shall ensure that their notified bodies do not grant an EC-type examination certificate for a toy in respect of which a certificate has been refused or withdrawn.
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.

1.9. Article 21 Technical documentation

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

1.10. Article 41 Instructions to the notified body

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.

1.11. Article 45 Formal non-compliance

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.

1.12. Annex IV Technical documentation

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

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

2. Technical documentation

New Approach directives oblige the manufacturer to draw up technical documentation containing information to demonstrate the conformity of the product to the applicable requirements. This obligation begins when the toy is placed on the EU market, whatever its geographical origin is. It is the responsibility of the manufacturer to draw up the required technical documentation. This drawing up of the technical documentation cannot form part of the authorised representative's mandate.
The technical documentation must be kept for a period of 10 years after the individual toy has been placed on the market[2]. This is the responsibility of the manufacturer or the authorised representative established within the EU. Importers shall ensure that the manufacturer has drawn up the technical documentation. All economic operators must make available all information and documentation necessary to demonstrate the conformity of the toy upon reasoned request.

As a rule, the technical documentation shall contain all relevant data or details of the means to ensure that toys comply with the requirements of the TSD; it covers the design, manufacture and operation of the toy. The details included in the documentation depend on the nature of the toy and on what is considered as necessary, from the technical point of view, for demonstrating the conformity of the toy to the essential requirements of the TSD or, if the harmonised standards references to which are published in the OJEU have been applied, to these instead by indicating the essential requirements covered by the standards. Drawing up the technical documentation by the manufacturer does not imply that the manufacturer has to draw up each document in the documentation. As mentioned above, it is a compilation of documents. The technical documentation may contain documents that are drawn up by others: e.g. the Declaration of Conformity signed by the authorised representative, an EC type certificate delivered by a Notified Body, test reports provided by labs, …. The TSD requires that the technical documentation is written in one of the official languages of the EU. Upon reasoned request, a Member States authority can ask for translation of relevant parts of the technical documentation into the language of that Member State. In order to carry out the conformity assessment procedures requiring third-party verification in a proper way, the technical documentation should always be in a language understood by the notified body.

If the market surveillance authorities have a doubt as to the conformity of toys with the essential health and safety requirements, they may request communication of the manufacturer’s technical documentation or a translation of relevant parts. These provisions have a dual purpose: on the one hand, providing the relevant elements of the technical documentation enables a manufacturer to explain the measures he has taken to deal with the risks associated with the toy in order to comply with the TSD requirements. On the other hand, the examination of these documents helps the market surveillance authorities to complete their investigation and either dispel or confirm their doubts about the conformity of the toy concerned. However, it is not necessary for the market surveillance authorities to

[2] More information can be found in the Blue Guide 2014, Section 2.3: “As for "making available",, the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.”

request these documents if they consider that they already have enough information on which to base their decision to take appropriate and proportionate measures.
The request for communication of the technical documentation or a translation of relevant parts should indicate the nature of the doubt about the conformity of the toy concerned and the parts or aspects of the toy that are subject to investigation. Only the elements of the technical documentation that are necessary for the investigation should be requested, so as not to constitute a disproportionate burden for the manufacturer. The request may indicate a deadline for the receipt of the requested documents, which shall be 30 days. A shorter deadline can be fixed if the national authority justifies the urgency on the basis of an immediate serious risk.
The manufacturer has to bear in mind that a Member State authority can oblige him to perform a test by a notified body on his own expenses if in particular he cannot present the technical documentation! In order for the notified body to carry out the examination, the manufacturer will need to provide the technical documentation anyway.
The manufacturer is obliged to provide the documentation and cannot argue that it contains confidential information (e.g. commercial confidentiality). Member State authorities are under the legal obligation to ensure that technical information they collect during market surveillance activities remains confidential, according to the principles laid down in their national legislation. Manufacturers therefore have no grounds for fearing that sensitive information they provide to national market surveillance authorities in the context of market surveillance might be disclosed.

The technical documentation will be unique to an individual toy, however much of the content may be repeated across a range of similar toys. Generic files are therefore permitted as long as the differences between toys and the documents unique to individual toys are held.

Technical documentation does not have to be single files in hard copy. Information can be stored in any format and in various locations within a company. It is important to ensure that the technical documentation is kept up to date so that it reflects any changes to the toy, legislation or standards. It is essential that the history of the product is retained.

Content of a Technical documentation

Related clauses	Directive Extract	Suggested Content
Annex IV (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.	Description of the design and manufacture
		List of components and materials
		Safety data sheets
Annex IV (b), Art 18	The safety assessment(s) carried out in accordance with Article 18.	Safety assessments
Annex IV (c) Art 4 (2) Art 6 (2) Art 19	A description of the conformity assessment procedure followed.	Conformity assessment procedure
Annex III & IV (d), Art 15	A copy of the EC declaration of conformity	EC declaration of conformity
Annex IV (e)	The addresses of the places of manufacture and storage	Addresses of manufacture and storage

Annex IV (f)	Copies of documents that the manufacturer has submitted to a notified body, if involved;	Documents submitted to a Notified Body
Annex IV (g) Art 4 (4) Art 19 (2)	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)	Test reports
		Conformity of series production details
Annex IV (h)	A copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensures conformity of the production with the product-type as described in the EC-type examination certificate and copies of the documents that the manufacturer has submitted to the notified body, if the manufacturer has followed the EC-type examination and type conformity –declaration referred to in Articles19 (3)	EC-type examination details
		Conformity of series production details

3. Detailed description of the design and manufacture

The Toy Safety Directive requires that manufacturers keep 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. This provision implies that the manufacturer must have in particular a list (of his suppliers) with an overview of the components, substances and materials he bought. He must also keep the schemes and drawings of his toy in the technical documentation.

3.1. Detailed description of design and manufacture

The detailed description should contain as a minimum following specifications:

3.1.1. a description of the toy, including the parts and components

This will most probably be included in the bill of materials (BOM, see Section 3.2 below)

3.1.2. a colour picture of the toy with high resolution

The picture should be in sufficient detail to permit reliable visual identification

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

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

3.1.5. the print of the packaging of the toy

3.1.6. the instructions or leaflet or accompanying documents

More information can be found in the explanatory guidance document to the TSD 2009/48/EC, the harmonised standards or CEN guides IEC 62079 and IEC guide 14: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

3.1.7. a description of the intended and foreseeable use

More information can be found in Guidance document No 4 on Grey zone problem: Is a specific product covered by the Toy Safety Directive 2009/48/EC or not? or other relevant guidance documents: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

3.1.8. the age suitability

It is advisable that the manufacturer keeps relevant information relating to the age suitability of the toy in the technical documentation because certain requirements in safety standards are triggered by the age grade of the toy (e.g. 10 months, 18 months, 36 months, 6 years, 8 years, etc.). An inappropriate age grade could result in inappropriate testing and incorrect conclusions on the conformity of the toy. In the event a more detailed risk assessment is required for a particular toy, it will be necessary that an appropriate age suitability is determined.

Note: more information can be found in the classification guidelines from CEN CR 14379 and other guidance documents on the Commission's website: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

Also the CPSC age determination guidelines might offer useful information which can be found on the CPSC's website: http://www.cpsc.gov/businfo/adg.pdf

Manufacturers must ensure that the packaging/advertising is consistent with the age grading. For example, the advertising should not show a child above 3 or indicate e.g. 4+ when the toy is clearly intended for children below 3 years.

3.1.9. a description of the manufacturing process, this is the description of the procedures and steps in the production (melting, cutting,…)

A possible template may be:

COMPANY: **PICTURE OF THE TOY**
PRODUCT NAME:
PRODUCT IDENTIFICATION NR:
PRODUCT DESCRIPTION:

INTENDED AND FORESEEABLE USE/DESCRIPTION OF THE USE:
AGE suitability:
checked with the CR 14379 classification guidelines and/or guidelines of COMMISSION?
justification:

CHECKLIST

	present (yes/no)
drawing/schemes	
explanation on the drawing	
BOM	
packaging	
instructions	
leaflet	

Approved by:
Date:

Description of the manufacturing process:
Address of manufacturing:
Address of storage:

3.2. List of components and materials

The Toy Safety Directive requires a list of components and materials and such a listing in manufacturing industry is more commonly known as a bill of materials (BOM).

A BOM may be defined as a list of the raw materials, subassemblies, intermediate assemblies, sub component parts, component parts and the quantities of each needed to manufacture a finished toy. An additional level of detail is known as a bill of substances (BOS). The BOM/BOS will need to be amended every time a component, product, material or supplier is changed.

Examples of BOM/BOS can be found in Appendix I.

Appendix Ia proposes an optional model letter which toy manufacturers might find useful for the purpose of communicating with their suppliers. The suggested model letter reminds the supplier about the obligations in the Toy Safety Directive relating to the content of the technical file, and in particular the need to provide a list of components and materials used in the toy as well as the safety data sheets (SDS) for chemicals used. The suggested model letter also introduces the BOM/BOS template provided as the first example (musical soft filled toy) in Appendix I. The suggested model letter strongly recommends that suppliers use the template if they do not have a workable alternative. The BOM/BOS template is intended to help ensure that toy manufacturers receive the required information from suppliers in a consistent manner.

A BOM/BOS can have many forms. This guide shows two possible formats for a bill of materials/bill of substances, however, manufacturers can use their own template, provided the key information is given.

For the first example (musical soft filled toy) in Appendix I, the following was considered:
- Coloured textile materials are sourced externally (no dyeing at the toy factory)
- Musical box (with cord and handle) is sourced externally (subassembly part)
- Label with CE marking is printed at the toy factory

For the second example (bottle with bubble solution), the following was considered:
- The bottle and the sticker are sourced externally (subassembly parts)
- The bubble solution is formulated by the manufacturer at the toy factory
- The manufacturer is moulding his own cap

3.2.1. Packaging

If the packaging of the toy is considered to be part of the toy or is a toy bag, it has to be listed in the BOM/BOS. Packaging as such does not require to be listed in the BOM/BOS, however it is part of the technical documentation (see Section 3.1). In example 1 (musical soft filled toy) in Appendix I, information related to packaging was introduced but this is optional in this case since the packaging (plastic hook to suspend the toy on shelves) is not considered to be part of the toy. More information on packaging and toy bags can be found in Guidance document No 12 on packaging: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

3.2.2. "Exploded view"

The "exploded view" given in example 1 in Appendix I may be useful to clearly identify the parts listed in the BOM/BOS but this approach is not essential. For very complex toys, e.g. including electric/electronic parts, mechanisms, etc. it is possible to handle the information in a separate document that has a format that is more convenient based on the characteristics of the toy and/or the manufacturer's practice. In this case, the parts numbering shall, as much as possible, be linked to what may appear in the BOM/BOS.

3.2.3. Level and description columns

The description column of the BOM/BOS describes all different parts of a toy. The parts can be made or assembled by the manufacturer or can be supplied as sub-assembly. If the parts are made or assembled by the manufacturer, this column will list different entries based on the components and raw materials used for manufacturing/assembling. If the part is sub-assembled, only one entry may appear in the BOM/BOS.

Frequently manufacturers use an indented bill of materials where the way the products break down is indicated by indenting the different entries. This gives rise to different levels of detail for the product and its parts. These levels can be thought of as different assembly levels which are generally identified as follows:

- Level 1 is for the finished toy
- Level 2 is for the toy parts (including packaging if appropriate)
- Level 3 is for the materials from the toy parts (and packaging if appropriate)
- Level 4 is for substances from toy materials (and packaging if appropriate)

Some intermediate levels (e.g. one additional level describing sub-assemblies, then next level describing parts of sub-assemblies) can be added and the lowest level is the level where the substances are listed.

It is quite possible for complex toys to have many levels (and indentations) in the complete BOM/BOS. When a sub-assembly is used, it will not have any further levels since it is a part that is purchased from a third party.

Examples of parts supplied as sub-assembly vs parts that can be manufactured/assembled by the manufacturer are:

- printed paper vs an ink and paper

- wooden box vs glue and wood

- purchased chemical mixture vs different substances in order to make a mixture

The first example of the BOM/BOS in Appendix I lists a musical soft filled toy with a unique code 147925. The description lists that this toy is composed of different parts, namely dyed textiles, a musical box, a label and Velcro parts.

Purchased parts (sub-assemblies), for example the musical box including the handle and the cord, which are supplied as semi-finished components, do not need further specification on the list of materials. For this part (bought as such) there is no need to give detailed information on the plastic material, the cord and the internal components of the musical box. However a detailed knowledge of the substances present would be very helpful when performing the chemical safety assessment. As can be seen from the example, the manufacturer is making his own label with two different substances.

The second example of the BOM/BOS in Appendix I lists a toy bottle bubble solution with a unique code B20A5. The description lists that this toy is composed of different parts, namely a bottle, a cap, a sticker, a wand and a bubble solution.

Purchased parts (subassemblies), for example the bottle and sticker, which are supplied as semi-finished components, do not need further specification on the list of materials. For the sticker (bought as such) there is no need to give detailed information on the ink, paper, glue, etc. used. However a detailed knowledge of the substances present would be very helpful when performing the chemical safety assessment. As can be seen from the example, the manufacturer is making his own cap out of three different materials (PVC, plasticizer and colourant) and his bubble solution out of five different substances.

3.2.4. Part number column

A column may be added listing the part numbers. These entries are not essential.

A part number is a unique identifier for the component, material, substance or sub-assembly that is incorporated into the toy.

Part numbers are very useful in order to avoid mix-ups between materials, components etc. that might look similar but are in fact different. Numbers avoid the problems of coping with different languages. For example it would be difficult for a Chinese person to spot the difference between a warning label that is in Polish and one that is in Dutch, so distinguishing them by part number helps minimise the chance of mix-ups.

Part numbers also act as the link between different production control systems (e.g. stock control and purchasing systems) and so help to ensure that the correct parts are purchased, manufactured and delivered to the production line.

3.2.5. Number used, weight of component and concentration columns

The columns with the number used, weight of component and concentration list the quantity of parts, materials and substances used in a specific toy. It can be a number (for example only one sticker needed), but also be the weight, concentration or volume. These entries are not essential but might help manufacturers during production control systems (e.g. stock control and purchasing information) and help making the necessary quantity of parts, parts, materials and substances available on the production line.

3.2.6. Material, substance, component and function columns

The column containing the material, substance or component contains a description of the material, substance or component that goes into the manufacture of the part described in the higher level of the BOM/BOS.

If the "same" material is sourced from different suppliers, then they shall appear in the BOM/BOS for the purpose of the chemical safety assessment as they may contain different substances.

The function column is a non-essential entry but provides information related to the use of the material, substance and component in the toy.

3.2.7. CAS column

The column with the CAS number is additional information which is useful to search a database for knowledge on a particular substance. This column will provide information forming part of the basis to perform the chemical safety assessment. The Chemical Abstracts

Service (CAS) provides a system whereby substances are added to the CAS Registry and are assigned a unique CAS Registry Number. Those CAS numbers are used in reference works, databases, and regulatory compliance documents throughout the world to identify substances without the ambiguity of chemical nomenclature. The safety data sheet (SDS) provided by chemical suppliers to their professional customers lists in Section 1 the product identifier, which may include the CAS number; other means of identification may also be provided. More information on the SDS can be found in Section 3.3 of this Guidance document.

Colourants are generally listed according to the widely used system of Colour Index Generic Names and Colour Index Constitution Numbers. A detailed record of products available on the market is presented under each Colour Index reference (CI). Against each product name is listed the manufacturer, physical form, principal usages and comments supplied by the manufacturer to guide prospective customers. When CI in themselves do not provide information on the purity specification for the colourant and so it is recommended that SDS are obtained where possible.

CAS numbers are more frequently used throughout the world and are preferable but if not available, EINECS or ELINCS numbers can be used. The European Inventory of Existing Commercial Chemical Substances (EINECS) lists and defines those chemical substances, which were deemed to be on the European Community market between 1 January 1971 and 18 September 1981. The EINECS list contains over 100 000 substances. Substances notified and placed on the market after 18 September 1981 are listed in the European List of Notified Chemical Substances (ELINCS).

A database to search for substances can be found on following page:

http://echa.europa.eu/information-on-chemicals

CAS number may not exist for natural substances like cotton and cellulose. In these cases a 0000-00-0 will be the default value.

3.2.8. SDS, supplier sub-declaration or test report column

The last two columns indicate whether or not a SDS, or a sub-declaration of the supplier or test reports are available.

If a manufacturer is supplied with subassemblies or intermediate assemblies, he must ensure that these products are safe to be used in the toy. In the cases in which the manufacturer has little or no control over the manufacturing process of the products he is supplied with, he needs to rely on the suppliers test data or declarations. However he can only rely on a sub-declaration of his supplier on condition that he gives the supplier the necessary information on the intended and foreseeable use. This information is crucial for the supplier as some materials, substances or components might be safe to be used in certain (inaccessible) parts of toys or other products or might be dangerous in (other parts of) toys. This has to be retrievable and can be inserted into the BOM/BOS document as it is for the musical soft filled toy example. A raw material, supplied as such, may be compliant with REACH or not subject to REACH, however once used in toys it might be subject to restrictions rendering the product non-compliant with Annex XVII to REACH (examples are certain phthalates as these substances are restricted for use in toys and childcare articles only).

Appendix Ib proposes an optional model supplier's sub-declaration which toy manufacturers might find useful for the purpose of communicating with their suppliers. The suggested model

supplier’s sub-declaration aims to obtain a guarantee that the supplied parts and components have been correctly assessed and comply with the appropriate toy safety requirements for their expected use.

A supplier's sub-declaration is also needed when the supplier does not wish to disclose the nature of the chemical ingredients used (e.g. the dyeing agent of a textile) for e.g. confidential and proprietary reasons (see blue textile and green textile parts 1c and 1d of the first example in Appendix I). This declaration can be an EC Declaration of Conformity (EC DoC) to the Toy Safety Directive only when this is a finished product (i.e. the product in question can also be placed on the market as a toy). If the product is not a toy in itself, an EC DoC cannot be issued.

Using the suggested model supplier’s sub-declaration does not release toy manufacturers from their responsibility to ensure that the sub-declaration is based on factual information.

According to the Toy Safety Directive, manufacturers must obtain the SDS on chemicals used in the manufacturing of the toy (to be obtained e.g. from the supplier of the chemical). If applicable, it will be indicated in the BOM/BOS that the SDS is present, however if no SDS needs to be obtained a "non-required" can be mentioned in the BOM/BOS. These SDS will also form part of the basis to perform the chemical safety assessment. It should be noted that the requirement applies to all manufacturers as defined in the TSD, i.e. also for chemicals that have been used e.g. by a sub-supplier to an own-brand importer during the manufacturing of the toy.

Although not part of the BOM/BOS, it is recommended that manufacturers have a system in place allowing traceability of the suppliers of materials and subassemblies/components used in the manufacturing process. This system can be a stand-alone system or a system that is linked with the BOM/BOS. This is in the own interest of manufacturers. If a subassembly is non-compliant and this subassembly has been bought from different suppliers, manufacturers who do not have such traceability (e.g. do not know which subassembly is used in what batch) will have to recall all products instead of a specific batch.

If in the listed examples of the BOM/BOS the manufacturer is supplied with a musical box (first example) or a bottle and a sticker (second example), he has to ask his supplier that these parts are compliant with the Toy Safety Directive requirements and other relevant EU legislation. In order to receive this declaration from his supplier he will have to indicate to the supplier the intended and foreseeable use of these parts. The intended and foreseeable use is important as this can have an impact on the quality of product to be supplied. For the sticker example different qualities of ink exist: one ink can be compliant to be used on packaging, however can fail the TSD requirements if it is used on a toy (for example contains a high amount of lead, as a toy is subject to a certain migration limit while packaging is not). In case the manufacturer would print his own sticker, he might need to obtain the SDS from the chemical supplier for some substances used in the inks that he purchases.

In case where the manufacturer is formulating his own mixture (e.g. the bubble solution), he might need to obtain from his chemical suppliers the SDS of the substances used. Within the EU a SDS might automatically be supplied in accordance with existing EU laws (REACH) but in other parts of the world this obligation may be different or not exist so manufacturers should ensure they request information directly from their suppliers. The listed example indicates that the manufacturer is moulding his own cap, so in principle he might need to obtain SDS for certain substances. The colourant does not meet the criteria for classification according to Regulation (EC) No 1272/2008 nor the PBT or vPvB criteria, nor does it appear on the

candidate list for authorisation, so no SDS is needed (more information on SDS can be found in Section 3.3 below).

3.2.9. Source column

This non-essential column describes how the part or material arrives when purchased by the factory. Options are:

F: Finished product. (i.e. the product in question can also be placed on the market as a toy).

P: Part, component or assembly purchased for further processing. A part/component or assembly is any item that will be used in the shape it has been purchased, for the assembly of a finished toy (except for possible physical shaping such as cutting a piece of textile to the right shape or drilling a hole in a piece of plastic or wood). Examples would be wood, textile, threads, electronics, moulded plastic, etc.

R: Raw Material. A raw material is any item that will somehow be chemically/physically processed (mixed with other materials, dried, hardened, treated with heat, subject to evaporation, etc.) during production of the finished toy. Examples of raw materials would be glue, ink, polymer resins, dye-stuff, etc.

O: Other. Where none of the above descriptions applies.

3.3. Safety data sheets (SDS)

In order to help the manufacturer perform the safety assessment it is necessary to have information on the chemicals used. The Toy Safety Directive obliges manufacturers to obtain the chemical safety data sheet (SDS) on chemicals used from the chemical suppliers, therefore making it mandatory to keep the SDS on the chemicals used. Typically this would include SDS on substances used in inks, paints, slimes, glues, adhesives and putties, etc. The Toy Safety Directive does not specify the content and criteria for elaborating SDS, so the requirements from the REACH Regulation (EC) No 1907/2006 should be used. This implies that chemical SDS can only be obtained when they are required by REACH.

SDS are an important element of hazard communication and provide a mechanism for transmitting safety information on substances and mixtures meeting the criteria for classification as hazardous and certain non-classified substances and mixtures, including information from the relevant chemical safety report(s) in accordance with Article 14 REACH down the supply chain to the immediate downstream user(s).

Requirements concerning the criteria for establishing SDS are laid down in REACH (in particular Article 31): the supplier of chemicals must provide a SDS to his professional customer (the toy manufacturer) when supplying a hazardous substance or mixture according to Regulation (EC) No 1272/2008, substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), or substances included in the candidate list for authorisation for other reasons. If the mixture does not meet the criteria for classification but contains substances meeting conditions laid down in Article 31(3) REACH, the supplier of chemicals must provide a SDS to his professional customer (the toy manufacturer) if the latter requests it.

The Commission has adopted Regulation (EU) 2015/830 amending the REACH Annex relevant for SDS – Annex II. This revision, as well as the previous revision (Regulation (EU)

No 453/2010), bring the SDS requirements into line with the Regulation on Classification, Labelling and Packaging (CLP) (EC) No 1272/2008 and with the guidance on the preparation of SDS as laid down in the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) of the United Nations. Where Article 31 REACH contains the requirements for the SDS, Annex II contains the requirements for the compilation of the SDS, listing in particular the format and content. Please consult the following European Commission or ECHA websites for the latest information:

REACH:

http://ec.europa.eu/growth/sectors/chemicals/reach/index_en.htm

http://echa.europa.eu/reach_en.asp

CLP:

http://ec.europa.eu/growth/sectors/chemicals/classification-labelling/index_en.htm

http://echa.europa.eu/clp/clp_help_en.asp

A SDS has to be supplied in an official language of the Member State(s) in which the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. The SDS must be updated if new information becomes available on hazards or new information which may affect the risk management measures, if an authorisation is granted or refused, or if a restriction is imposed. Information for downstream users can be found at:

http://guidance.echa.europa.eu/docs/guidance_document/du_en.pdf?vers=29_01_08

Manufacturers have to be aware that the Toy Safety Directive requires SDS, while often a material safety data sheet will be delivered (MSDS). However, a MSDS is for the US market and is not what the Toy Safety Directive requires, unless the MSDS complies with the compilation requirements of REACH.

Special attention has to be paid to a case where a manufacturer buys different raw materials and mixes them in a way that causes a chemical reaction. In this case a new substance has been created. Raw materials can also be mixed creating a mixture. In these cases a new SDS might need to be drafted (the original SDSs for the individual raw materials will not be sufficient).

It should be noted that classifications should be in line with the Regulation on Classification, Labelling and Packaging (CLP). Classification for the same substance can be different, e.g., due to different impurity profiles or lack of information, however the hazardous substances listed in Annex VI of the CLP Regulation have to be classified accordingly as this classification has been established at Union level.

Some suppliers of chemicals can find SDS on the internet and claim that they are applicable to their products although the SDS might not be correct for that chemical or might be correct but be subject to intellectual property rights of the original supplier. It is therefore important that manufacturers are aware that one needs to work with “responsible” suppliers who supply the correct and necessary information.

Below are the cases in which toy manufacturers will need to obtain SDS from their suppliers:

3.3.1. Substances or Mixtures for which a SDS is required:

Under REACH, the supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a SDS compiled in accordance with Annex II:

- where a substance or mixture meets the criteria for classification as hazardous in accordance with the (CLP) Regulation (EC) No 1272/2008; or
- where a substance is Persistent, Bioaccumulative and Toxic (PBT) or Very Persistent and Very Bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII of REACH; or
- where a substance is included in the list of candidate substances to authorisation (Substances of Very High Concern – SVHC), in accordance with Article 59(1) of REACH for other reasons.

3.3.2. Mixtures for which a SDS is required at the request of a recipient:

The supplier shall provide the recipient at his request with a SDS where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008 but contains:

- at least one substance posing human health or environmental hazards in an individual concentration of ≥1% by weight for non-gaseous mixtures and ≥0,2% by volume for gaseous mixtures; or
- at least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is PBT or vPvB or has been included in the candidate list for authorisation for other reasons, in an individual concentration of ≥0,1% by weight for non-gaseous mixtures; or
- a substance for which there are Union workplace exposure limits.

3.3.3. SDS in special cases

SDS shall also be required for the special cases listed in § 1.3 of Annex I to Regulation (EC) No 1272/2008.

3.3.4. Substances or Mixtures for which a SDS is not required:

A SDS need not be supplied where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.

Remark: Of course an SDS is also not required if we are not in cases of 3.3.1, 3.3.2 or 3.3.3. 3.3.4 only applies if we are in cases of 3.3.1, 3.3.2 or 3.3.3 but there is sufficient info provided.

3.3.5. Examples of toys when SDS might be needed

Poster paint is created out of different substances and materials. However as this mixture is created, it will need a SDS on its own if it meets the criteria of Sections 3.3.1, 3.3.2 or 3.3.3.

The composition of poster paint can be: flour, water, powdered tempera paint, liquid starch and liquid detergent.

4. Description of the conformity assessment procedure followed

The essential objective of a conformity assessment procedure is to demonstrate to public authorities that toys placed on the market conforms to the requirements as expressed in the provisions of the Toy Safety Directive, in particular with regard to the health and safety of users and third parties. The assessment of the conformity of a toy is done before this toy is placed into the market and consists in demonstrating that it fulfils all the legislative requirements that apply to it. Conformity assessment is performed following technical procedures which are specified in the Toy Safety Directive and which cover both design and production phase. Carry out the conformity assessment is exclusively an obligation for the manufacturer. However, the authorised representative may carry out parts of the conformity assessment procedure. Importers have to ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer.

Conformity assessment *procedures* are composed of one or two conformity assessment *modules*. A conformity assessment procedure covers both design and production phase; while a module may cover either one of these two phases (in this case a conformity assessment procedure is composed of two modules) or both (in this case a conformity assessment procedure is composed of one module).

According to the Toy Safety Directive manufacturers have two possible conformity assessment procedures (first party conformity assessment or third party verification) to demonstrate that the toy complies with the requirements of the Toy Safety Directive. The manufacturer has to list in the technical documentation, what conformity assessment procedure he followed: first party conformity assessment or third party verification, with the explanation for the choice. This list contains as well the reference of the harmonised standards referenced in the OJEU he applied in full or in part and the descriptions of the solutions adopted to meet the requirements of the Toy Safety Directive if the harmonised standards referenced in the OJEU have not been applied.

Remark: this list of standards the toys is complying with, is identical to the standards mentioned on the DoC.

4.1. Possible template

COMPANY:	**PICTURE OF THE TOY**
PRODUCT NAME:	
PRODUCT IDENTIFICATION NR:	
PRODUCT DESCRIPTION:	
first party conformity assessment	
harmonized standards referenced in the OJEU used:	
EN 71-1:20xx (+ Ay:20xx)	
EN 71-2:20xx (+ Ay:20xx)	
EN 71-3:20xx (+ Ay:20xx)	
EN 71-4:20xx (+ Ay:20xx)	
EN 71-5:20xx (+ Ay:20xx)	
EN 71-7:20xx (+ Ay:20xx)	
EN 71-8:20xx (+ Ay:20xx)	
EN 62115:20xx (+ Ay:20xx)	
other:	
third party verification notified body used:	**justification:**
Internal production control in place:	
Approved by:	
Date:	

y = amendment number

xx = year

justification: explain why third party verification is used

4.2. First-party conformity assessment or self verification (module A)

"*First-party conformity assessment or self verification*": the manufacturer applies the harmonised standards published in the OJEU covering all relevant safety requirements and puts in place an internal production control procedure (module A). This module does not require involvement of a notified body; however a manufacturer may use the services of an external source.

4.2.1. Module A

Module A covers design and production phase. The manufacturer ensures himself the conformity of the toy to the requirements of the Toy Safety Directive and demonstrates that the

other products manufactured achieve the same level of safety. Should a manufacturer subcontract design or production, he still remains responsible for the execution of conformity assessment for both phases.

In the design phase the manufacturer:

- identifies the applicable requirements
- carries out an adequate analysis and assessment of the risk(s).

In the production phase the manufacturer:

- takes all measures necessary so that the manufacturing process ensures compliance of the manufactured products with the legislative instruments that apply to them
- carries out detailed tests and controls
- monitors the compliance of the products

According to module A the manufacturer applies the harmonised standards referenced in the OJEU covering all relevant safety requirements. These standards shall correspond to the ones mentioned on the DoC "References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared" (see Section 5.1.6 below). The manufacturer has to provide the evidence that he complies with the harmonised standards referenced in the OJEU. In most cases this is done by having test reports according to the harmonised standards referenced in the OJEU. However a manufacturer might instead have test reports according to a previous version of a particular standard, but in this case the manufacturer must, in addition to these test reports, have other documentation that verifies that he complies also with the updated requirements in the latest version of the harmonised standard referenced in the OJEU. This documentation could be an internal test report or a compliance protocol, or any other means of clear verification. The overall conclusion must be that the documentation supports that the toy complies with the harmonised standards referenced in the OJEU.

Example for EN 71-1 "Mechanical and physical properties" (see also Sections 5.1.6 and 5.2 below): the DoC has to list the references to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared. The manufacturer declares using module A as conformity assessment procedure and therefore needs to apply the harmonised standards referenced in the OJEU covering all relevant safety requirements; he will therefore list, for example, EN 71-1:2011+A3:2014[3]. In order to provide evidence that the toys are in conformity with this standard, he can either provide test reports according to EN 71-1:2011+A3:2014 or test reports according to a previous version such as EN 71-1:2011 TOGETHER WITH a report/protocol/overview showing that he complies with those clauses of EN 71-1:2011+A3:2014 which are different from EN 71-1:2011. In this specific case, the manufacturer will need to document e.g. that his toys comply with the revised requirements for toys clearly designed to emit sound, since these have changed compared to EN 71-1:2011.

[3] At the time of writing this version 1.4 of the Technical documentation guidance document, EN 71-1:2011+A3:2014 is the latest version of EN 71-1 referenced in the OJEU. Note however that CEN has published a new version EN 71-1:2014 with identical technical content.

No details are given on how a manufacturer has to ensure the internal production control. If market surveillance authorities find non-compliant toys on the market which lead to a recall of the toy, it is up to the manufacturer to be able to prove that it is an isolated case. If he cannot provide prove, he will need to recall the toy concerned. However, if he is able to demonstrate that the non-compliance is linked to a certain batch or lot; he can reduce the recall to the batch or lot concerned – if the batch or lot are traceable.

4.3. Third party verification (module B + C)

"*Third party verification*": the manufacturer submits the model of the toy to EC-type examination carried out by a notified body (module B - third party conformity assessment) and puts in place the conformity to type procedure based on internal production control (module C).

Third party examination is needed in following cases:

(a) where harmonised standards, the reference number of which has been published in the OJEU, 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.

The harmonised standards, which have been referenced in the OJEU, and their restrictions can be found on the Commission's website: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/toys/index_en.htm

The notified bodies made a document available, which lists categories of toys which have been submitted to an EC-type examination and those types of toys where EC-type examination is no longer needed, but which have been submitted to an EC-type examination in the past. This document is updated regularly, so keep informed of the latest developments: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

4.3.1. Module B

Module B covers only the design phase. EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the Toy Safety Directive by issuing an EC-type examination certificate. Module B is always followed by other modules by which the conformity of the products to the approved EC-type is demonstrated. In the case of toys this is module C.

The EC-type examination may be carried out in either of the following manners:

- examination of a specimen, representative of the production envisaged, of the complete toy (production type);
- assessment of the adequacy of the technical design of the toy through examination of the technical documentation and supporting evidence plus examination of specimens,

representative of the production envisaged, of one or more critical parts of the toy (combination of production type and design type);

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

Remark: As module B covers only the design phase, the manufacturer does not draft any declaration of conformity at this stage of the process.

4.3.2. Module C

Module C covers only the production phase and follows module B. The manufacturer ensures himself the conformity of the toys to the type described in the EC-type examination certificate and to the requirements of the legislative instrument that apply to them. Its common point with module A is that the manufacturer ensures himself the conformity of its products; however under module C this conformity is evaluated against an approved EC-type resulted under module B. This module C does not require involvement of a notified body; however a manufacturer may use the services of an external source.

No details are given on how a manufacturer has to ensure the internal production control. If market surveillance authorities find non-compliant toys on the market which lead to a recall of the toy, it is up to the manufacturer to be able to prove that it is an isolated case. If he cannot provide prove, he will need to recall the toy concerned. However, if he is able to demonstrate that the non-compliance is linked to a certain batch or lot; he can reduce the recall to the batch or lot concerned – if the batch or lot are traceable.

5. EC declaration of conformity (DoC)

The Toy Safety Directive imposes an obligation on the manufacturer (or his authorised representative) to draw up an EC declaration of conformity when the toy is placed on the market. The EC DoC shall state that the toy fulfils the essential requirements of the Toy Safety Directive.

The EC DoC must be kept for a period of ten years after the toy has been placed on the market. This is the responsibility of the manufacturer or his authorised representative and the importer[4]. The distributor must make the DoC available upon reasoned request from market surveillance authorities.

A toy is placed on the EU market when it is made available for the first time. This is considered to take place when a toy is transferred from the stage of manufacture with the intention of distribution or use on the EU market. In the case of toys manufactured outside the EU, this is when the toys physically enter the EU territory and are released for free circulation. Moreover, the concept of placing on the market refers to each individual toy, not to a type of toy, and whether it was manufactured as an individual unit or in series. The transfer of the toy takes place either from the manufacturer, or the manufacturer's authorised representative, to the importer or to the person responsible for distributing the toy on the EU market. The transfer

[4] The importer is requested only to keep a copy of the DoC.

may also take place directly from the manufacturer, or authorised representative, to the final consumer or user. The toy is considered to be transferred either when the physical hand-over or the transfer of ownership has taken place. This transfer can be for payment or free of charge[5], and it can be based on any type of legal instrument. Thus, a transfer of a toy is considered to have taken place, for instance, in the circumstances of sale, loan, hire, leasing and gift. Placing on the market is considered not to take place where a product is:

- transferred from the manufacturer in a third country to his authorised representative;
- transferred to a manufacturer for further measures (for example assembling, packaging, processing or labelling);
- not (yet) granted release for free circulation by customs, or has been placed under another customs procedure (for example transit, warehousing or temporary importation), or is in a free zone;
- manufactured in a Member State with a view to exporting it to a third country;
- in the stocks of the manufacturer, or his authorised representative, where the product is not yet made available, unless otherwise provided for in the applicable directives.

A toy offered in a catalogue or by means of electronic commerce is deemed not to have been placed on the EU market until it is actually made available for the first time. In order to respect the rules and principles aiming to prohibit misleading advertising, a non-compliance of a toy intended for the EU market should be clearly indicated.

The Toy Safety Directive only indicates that the DoC has to be made available; it does not have to accompany the toy. Manufacturers can distribute or make publicly available their DoC on the web.

5.1. Layout of the DoC

The contents of the EC DoC are laid down in Annex III of the Toy Safety Directive and the relevant modules set out in Annex II to Decision 768/2008/EC.

5.1.1. No … (unique identification of the toy(s)).

The unique identification of the toy which refers to the traceability of the toy shall be added.

The purpose of this information is to enable both the manufacturer and the market surveillance authorities to identify the toy covered by the declaration without ambiguity.

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

The address of the manufacturer or authorised representative shall be added (see TSD explanatory guidance document):
http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

[5] The transfer, either for payment or free of charge, is always made in the course of a commercial activity.

The address is the postal address of the manufacturer/authorised representative where he can be contacted. Normally an address consists of a street and number or post-box and number and the postal code and town.

5.1.3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

The name of the manufacturer shall be added and is identical to point 2 if the authorised representative is not mentioned in point 2.

5.1.4. 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.

The "object" should be unequivocally described so that the declaration of conformity may be related to the object in question. This item contains a description of the toy, meaning the sizes, colours, … and shall include a colour image of high resolution. The picture should be in sufficient detail to permit reliable visual identification.

5.1.5. The object of the declaration described in point 4 is in conformity with the relevant EU harmonisation legislation:

This item contains the reference to the Toy Safety Directive 2009/48/EC and other relevant EU harmonisation legislation the toy fulfils. The other relevant EU harmonisation legislation are the directives based on the principle of the New Approach which provide for CE marking, e.g. EMC and RoHS for electrical toys, … Where several New Approach directives apply to a product, the manufacturer (or authorised representative) shall, basically, merge all the declarations into a single document. However, this is not possible if the directive provides for a specific form of the declaration.

http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

Other directives may be added under item 8 - additional information, if the toy complies with their requirements. However, this is not possible if those directives provides for a specific form of the declaration.

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

This item contains the reference to the relevant harmonized standards of the Toy Safety Directive 2009/48/EC and other relevant EU harmonisation legislation the toy fulfils, if applicable. The list of standards is specifically those standards harmonised and published in the OJEU for the purposes of the TSD (EN 71-z:20xx + Ay:20xx series and EN 62115:20xx + Ay:20xx), if applicable. The particular version of each standard should be identified together with the relevant clauses or parts if it has not been applied in full.

Under Module A, manufacturers have to list the applicable harmonised standards published in the OJEU. The way to provide evidence to comply with these applicable harmonised standards published in the OJEU is described in module A in this guidance document (Section 4.2.1).

Under Module B+C, manufacturers have to list all applicable harmonised standards or the manufacturer may indicate the references of other technical documents used to design and

construct the toy. It should be borne in mind that the application of such documents does not confer a presumption of conformity.

Where the reference of a harmonised standard is indicated in the EC Declaration of Conformity, the market surveillance authorities are entitled to consider that the manufacturer has applied the specifications of the standard in full. If the manufacturer has not applied all of the specifications of a harmonised standard, he may still indicate the reference of the standard in the EC Declaration of Conformity, but, in that case, he must indicate which specifications of the standard he has applied.

Other standards, not harmonised or referenced under any of the listed directives, regulations and specifications may be added under item 8 - additional information, if the toy complies with their applicable requirements.

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

This item lists the details of the notified body if the toy was subject to an EC type examination. It shall be filled in only if the manufacturer applied the third part certification procedure.

5.1.8. Additional information:

This item lists any additional information the manufacturer wants to share.

Signed for and on behalf of:

(place and date of issue)

(name, function)(signature)

The indication of the place and date of the declaration are customary requirements for a signed legal document. The place to be indicated is usually the town where the premises of the manufacturer or his authorised representative are established. Since the EC Declaration of Conformity must be drawn up before the toy is placed on the market the date indicated in the EC Declaration of Conformity must be no later than the placing on the market of the toy. The identity of the person empowered by the manufacturer or his authorised representative to draw up the EC Declaration of Conformity must be indicated adjacent to his or her signature. The identity of the person is understood as comprising his or her name and position. The EC Declaration of Conformity can be signed by the Managing Director of the Company concerned or by another representative of the Company to whom this responsibility has been delegated.

5.2. Updating of the DoC

A DoC declares that a toy fulfils the essential requirements of the Directive. However the TSD indicates that the DoC needs to be updated. 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 EN

71-1:2011 standard was amended by A2:2013 to introduce new requirements for toys that are clearly designed to emit sound, it would have been unnecessary for the manufacturer to revise DoCs for toys that obviously do not contain any function clearly designed to emit sound 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. Meaning that if a manufacturer placed a product on the market (as understood by the definition of placing on the market), having a valid DoC, it can stay on the market. However, if an update to the DoC is needed (due to changes of standard or other reasons), the new products placed on the market shall have this updated DoC. The manufacturer does not have to withdraw or recall all his products placed on the market having a valid DoC at that time. The way to provide evidence to comply with the applicable harmonised standards published in the OJEU is described in module A in this guidance document (Section 4.2.1).

5.3. DoC in all 23 languages

The DoC shall be translated into the language(s) required by the Member State in whose market the toy is placed or made available.

The DoC in all 23 languages of the EU Member States can be found on the Commission's website: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm.

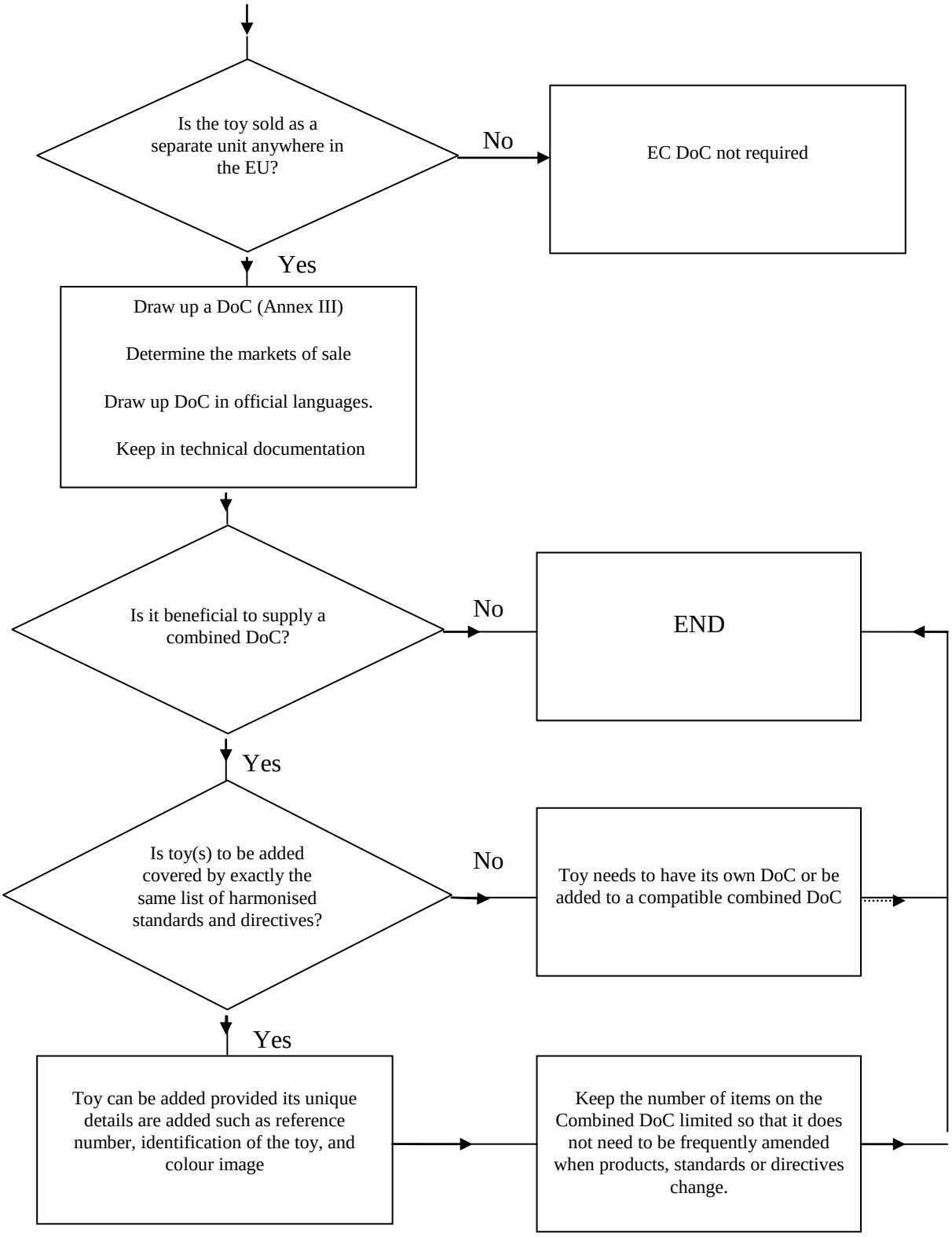
5.4. Combining DoC

Some toys come in an assortment of identical toys with different sizes, e.g. brown bear with embroidered features 25, 35 and 45 cm in height or bricks with 2 nods in different colors. Different toys (with each their identification code and corresponding color picture) can be listed on one DoC if they all comply with the same EU harmonised legislation and the same standards.

A toy can consists of different parts (a doll, clothes and the doll electrical car) having one unique identification code. This will imply that one DoC will be elaborated mentioning the TSD, the RoHS and EMC Directives and the harmonised standards referenced in the OJEU e.g. EN 71-1:20xx + Ay:20xx, EN 71-2:20xx + Ay:20xx, EN 71-3:20xx + Ay:20xx, EN62115:20xx + Ay:20xx, and other referenced standards supporting the RoHS and EMC Directives. However, the manufacturer may decide to place on the market the different parts separately (with their own unique identification code). In this case, he will need to draw up at least one additional DoC: one for the doll and clothes with each their unique code and colour picture, referring to the TSD and harmonised standards referenced in the OJEU e.g. EN 71-1:20xx + Ay:20xx, EN 71-2:20xx + Ay:20xx, EN 71-3:20xx + Ay:20xx. A DoC for the electrical car, referring to the TSD, RoHS and EMC Directives and the supporting harmonised standards referenced in the OJEU e.g. EN 71-1:20xx + Ay:20xx, EN 71-2:20xx + Ay:20xx, EN

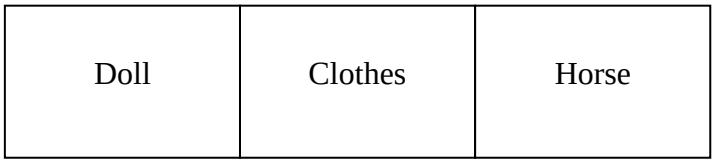
71-3:20xx + Ay:20xx, EN62115:20xx + Ay:20xx and other referenced standards supporting the RoHS and EMC Directives, may be added to the existing original DoC, as it complies with the same Directives and standards. The following scheme will try to illustrate:

Flow Chart:

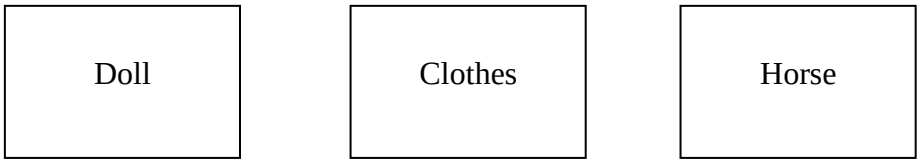

Is the toy sold as a separate unit anywhere in the EU?
No
EC DoC not required
Yes
Draw up a DoC (Annex III)
Determine the markets of sale
Draw up DoC in official languages.
Keep in technical documentation
Is it beneficial to supply a combined DoC?
No
END
Yes
Is toy(s) to be added covered by exactly the same list of harmonised standards and directives?
No
Toy needs to have its own DoC or be added to a compatible combined DoC
Yes
Toy can be added provided its unique details are added such as reference number, identification of the toy, and colour image
Keep the number of items on the Combined DoC limited so that it does not need to be frequently amended when products, standards or directives change.

Illustrative Example:

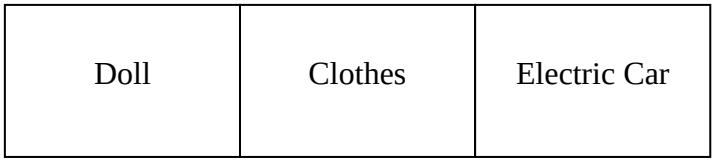
A1. Sold as a playset: 1 DoC



A2. Sold individually: Individual DoCs for all 3 components or 1 combined DoC



B1. Sold as a play set: 1 DoC



B2. Sold individually: Individual DoCs for all 3 components or a combined DoC for clothes and doll and an individual DoC for the electric car (different standard covered).

In conclusion, according to the Toy Safety Directive, a DoC is required for each toy that is placed on the EU market. There is nothing in the Toy Safety Directive that prevents a DoC from referring to more than one toy (a combined declaration). However, if a combined declaration is made then all the toys referenced on the DoC must conform with the same set of harmonised standards and legislation. It is not allowable to list harmonised standards or legislation of which are not applicable and state “as applicable".

6. Addresses of the places of manufacture and storage

Addresses where the product has been manufactured and stored should be recorded, even if these addresses are located outside of the EU.

The address is the postal address of the manufacturing site or storage site. Normally an address consists of a street and number or post-box and number and the postal code and town.

Remark: The Toy Ssafety Directive is applicable only to toys placed on the EU market. If a manufacturer stores also toys for other markets (US, etc, …) he only has to mention the storage addresses of toys to be placed on the EU market.

7. Copies of documents that the manufacturer has submitted to a notified body

Copies of documents that a manufacturer has submitted to a notified body when carrying out an EC type examination are required to be retained. It is considered good practice to keep copies of all documents used to request testing.

The application made by the manufacturer to the notified body shall include:

- the name and address of the manufacturer and, if the application is lodged by his authorised representative, his name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;
- the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

8. Test reports

The manufacturer has to subject each toy design to compliance tests. The results of these tests should be recorded in a or several test report(s). This may be done by the manufacturer himself or by an external source. It is advisable that test reports are drawn up in accordance with clause 5.10 of the standard ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories”.

If the manufacturer has used first party conformity assessment (Module A) he must keep copies of the test reports in the technical documentation together with a list containing the reference of the harmonized standards referenced in the OJEU he applied. The reference to standards needs to include the issuing date of the standards used.

Remark: this list is identical to the standards mentioned on the DoC

Manufacturers shall ensure that procedures are in place for ongoing/series production to remain in conformity. Details of how the manufacturer has ensured that the toy remains in conformity after any changes in the toy’s design or characteristics or changes in the harmonised standards should be documented.

9. Copy of the EC-type examination certificate

If the manufacturer has used Module B and C, he must keep copies of documents sent to the notified body and a copy of the EC-type examination certificate in the technical documentation.

Manufacturers shall ensure that procedures are in place for ongoing/series production to remain in conformity. Details of how the manufacture has ensured that the toy remains in conformity after any changes in the toy's design or characteristics or changes in the harmonised standards (e.g. publications of notes in the OJEU restricting the presumption of conformity) should be documented.

The notified bodies created several recommendation sheets: in particular a recommendation on the format of the EC-type examination certificate and a recommendation on the list of the technical documentation provided by the applicant for to the EC-type examination carried out on the model of the toy reference (reference of the toy) on (date). http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm

It is common practice for original manufacturers to sell their toy to different importers who wish to place them on market as their own. According to the Toy Safety Directive, in this situation the importer becomes "own brand manufacturer" and, amongst other, he has to draw up the technical documentation. It then follows that the own brand manufacturer must make an application for an EC-type examination in their own name and be issued with an EC-type examination certificate that supports the CE marking of the toy. There will be no identifiable link back to the original manufacturer in the market place. However, the original manufacturer has in most cases a technical documentation which can be used by the own brand manufacturers. The toy offered for sale by the own brand manufacturer will be identical to the original toy except for marking and probably user instructions. All other elements of the technical documentation can be applied to the own brand toy. The own brand manufacturer is legally responsible for ensuring that the toy(s) meet the requirements of the Directive.

10. Safety assessment

Article 18 foresees an explicit new obligation for manufacturers to draw up a safety assessment. Safety assessment consists of an analysis of the hazards that the toy may present such as chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity, 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.

For the purpose of this guidance document, we will divide the safety assessment into different parts:

- mechanical, physical, flammability and electrical hazards for which standards exist;

- hygiene and radioactivity hazards for which currently there are no (harmonised) standards available;

- chemical hazards for which some standards exist but have a different approach on risk assessment.

PART II MECHANICAL, PHYSICAL, FLAMMABILITY AND ELECTRICAL ASSESSMENT

1. MECHANICAL, PHYSICAL, FLAMMABILITY AND ELECTRICAL HAZARDS

The harmonised standards references to which are published in the OJEU under the TSD aim at reducing as far as possible the hazards which are not evident to users. Harmonised standards referenced in the OJEU cover mechanical, physical, flammability and electrical requirements of the TSD. The correspondence between the clauses of the harmonised standard referenced in the OJEU and the requirements of the TSD are listed in Annex ZA/ZZ of the standard. As mentioned above, this guide assumes that economic operators have knowledge of the harmonised standards referenced in the OJEU.

If the toy satisfies the harmonised standards which have been referenced in the OJEU, it has presumption of conformity and normally no further mechanical, physical, flammability and electrical assessment has to be performed. If toys do not comply with these harmonised standards or only comply in part or if a hazard is present that is not covered by these harmonised standards, third party verification is applied (see previous section for explanation on the conformity assessment procedures). This implies that the main purpose of a safety assessment for mechanical, physical, flammability or electrical hazards is to ascertain that no hazards are present that are not covered by these harmonised standards. This is important in particular when designing innovative toys. New innovative toys are toys that differ from established toys in design, material or construction such that this difference could influence safety.

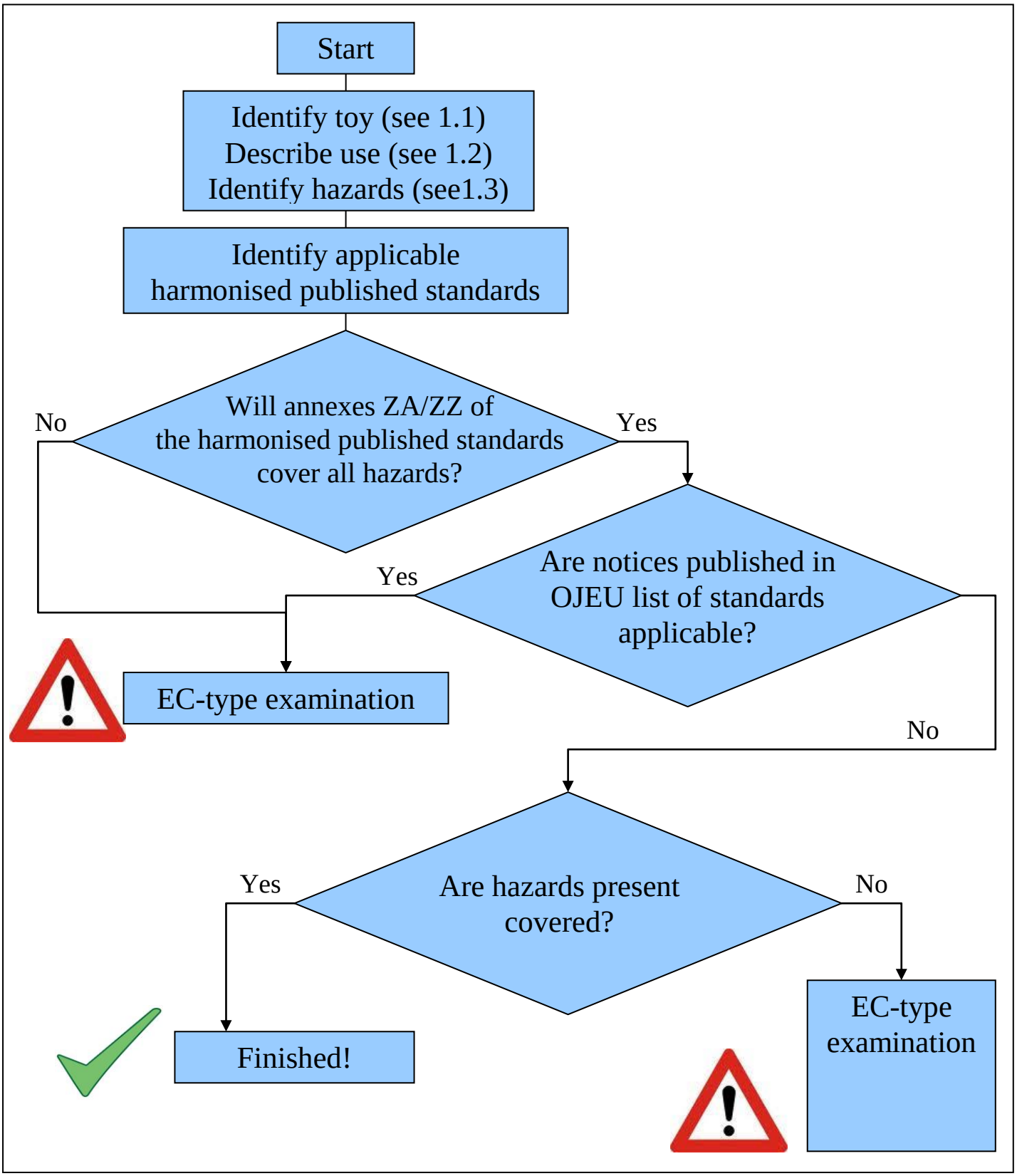
The safety assessment is defined as an analysis of the hazards that the toy may present and an assessment of the potential exposure to such hazards. A risk is defined as the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm. The safety assessment is therefore a form of risk assessment.

The aim of performing a safety assessment is to identify and minimise risks before the toy is placed on the market. However, in some cases all hazards cannot be minimised and some inherent risks remain: toys may cause harm when used, such as a swing that can cause injury if a child runs into it or a skateboard that can cause bruises if a child falls when riding on it. In most cases, such injury does not occur because the manufacturer minimised the hazard by design or appropriate use instructions teach how to use toys safely. Nevertheless, a risk of injury remains.

Taking the above into consideration, different steps need to be followed prior to the placing a toy on the market. As a first step, the manufacturer has to describe his product and identify the intended and foreseeable use in order to determine the hazards present. A second step is to verify if these hazards are or are not covered by harmonised and referenced standards. The conclusion may be either that the manufacturer needs to submit the toy to an EC-type examination, or that the hazards are covered by a harmonised and referenced standard and therefore the manufacturer benefits from the presumption of conformity.

A new safety assessment shall be performed whenever a design is revised if such design revisions result in creating reasonably foreseeable hazards and/or risk factors that were not previously present. Colour changes to toys are not considered as new innovative knowledge. If the safety assessment shows that the toy still complies fully with the harmonised standards referenced in the OJEU and that all hazards are still covered, manufacturers benefit from the presumption of conformity. Manufacturers could as part of the safety assessment also consider

if the toy presents risks that could be lowered. A risk assessment is very helpful in this process and whatever the result is (high, medium or low risk) the manufacturer shall take an internal decision on any design changes or perhaps submit an application for third party verification to ensure that the toy is safe.



1.1. Description of the toy

In order to be able to identify the hazards in a following step, manufacturers should describe the toy and should identify unambiguously.

The description of the toy includes the drawings and schemes, a picture of the toy, the packaging and the markings (if appropriate). Also the instructions for use may contain relevant information as they might be the result of reducing the hazards, e.g. by use of personal protective equipment (PPE). An example for the latter is a warning to use PPE marked on a skateboard.

1.2. The use

In order to be able to identify the hazards in a following step, manufacturers should indicate the use of the toy.

Factors that should be considered include who uses the toy and under which conditions it is to be used. The abilities and behaviour of the user and exposure may strongly influence the level of risk. Also the foreseeable use has to be taken into consideration. Using the toy in a way other than intended, in particular by (older or younger) children is a common phenomenon. The environment the toy will be used in, is also important. This does not only cover in- or outdoor use, but also the use under supervision (or not).

Consideration should also be given to people who are not actually using the toy, but who may be affected by the vicinity of the user (third parties).

1.2.1. Intended user:

The intended user of a product may use the product without difficulties because he takes all instructions of use well into account or because he has used the kind of product since long and is therefore familiar with its handling and use, including any apparent or non-apparent hazard(s). The hazard of the product may then not come into effect, and the product risk could be minor.

The consumer's cultural background and the way a product is used in his home country may influence the risk of a product. Manufacturers in particular have to take account of such cultural differences when launching a new product onto a market, in order to ensure that the product can indeed be used safely.

1.2.2. Vulnerable consumers:

Several categories of vulnerable consumers can be distinguished: Children 0 to 36 months, >36 months, <8 years, 8 to 14 years. They all have reduced capacities to recognise a hazard, for example children who, when touching a hot surface, notice the heat only after some 8 seconds (and then are already burnt), whereas adults notice heat immediately.

Vulnerable consumers may also have difficulties to take account of warning labels, or may have particular difficulties when using a product they have never used before. They may also exhibit specific behaviour that affects their exposure, for example crawling and mouthing of young children.

Furthermore, consumers who are normally not vulnerable may become vulnerable in specific situations, for example when the use instructions or the warnings on a product are in a foreign language that the consumer does not understand.

1.2.3. Intended and reasonably foreseeable use:

Consumers may use a product for other purposes than the product is intended for, although the use instructions are clearly understandable including possible warnings. Therefore, and because warnings may be of limited effectiveness, other uses than the intended ones have to be considered. This aspect is particularly important for the manufacturer of a product since he has to ensure that his product is safe under any reasonably foreseeable conditions of use. Such reasonably foreseeable uses may have to be derived on the basis of experience, because there may be no information available in official accident statistics or other sources of information.

1.2.4. Frequency and duration of use:

Different consumers may use a product more or less often, and for longer or shorter periods of time. This depends also on the attractiveness of the product and the ease with which it can be used. Daily or long-time use could make a consumer entirely familiar with a product and its specificities, including its hazards, its use instructions and warning labels, and the risk would be minor. On the other hand, daily or long-time use may make the consumer feel too much accustomed to the product and may lead to user fatigue, and he may recklessly ignore use instructions and warning labels because he considers mastering the product entirely.

1.3. Identify the hazards

Based on the above mentioned description (warnings, instructions, etc.) and the foreseeable usage, the manufacturer has to identify the hazards present. Hazard is the intrinsic property of the toy that may cause a physical injury or any other damage to health to the user of the toy. It can appear in different forms:

- Hazards causing entrapment of e.g. head and neck, fingers, limbs, feet and hands
- Hazards from moving parts causing e.g. crushing
- Hazards due to presence of cords etc. causing strangulation
- Hazards due to presence of e.g. small parts causing choking
- Hazards of protruding parts of the toy causing choking
- Hazards due to presence of sheeting or packaging causing suffocation
- Hazards of design of the toys presenting edges and projections causing cuts and injuries
- Hazards due to electrical parts causing electric shock
- Hazard due to presence of heat or cold surfaces causing burns
- Hazard due to noise, causing hearing impairment
- Etc…

All potential hazards associated to the toy should be identified. A non-exhaustive overview of hazards can be found in the table enclosed to this guide. This does not imply that a list has to be maintained in the technical documentation, as hazards covered by the harmonised and referenced standard will be subject to a test report and those not covered will be subject to the EC-type examination. However a manufacturer might list, in the technical documentation, hazards he has reduced or which he has covered by appropriate warnings or redesign.

1.4. Identify applicable standards

As the manufacturer has a clear view on the possible hazards, he has to check if these hazards are covered by the harmonised standards.

The harmonised standards references to which are published in the OJEU are made public on the website of the European Commission: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/toys/index_en.htm

The harmonised standards can be purchased via a national standardisation body: http://standards.cen.eu/dyn/www/f?p=CENWEB:5

In order to check if the harmonised standards referenced in the OJEU cover the hazards, verify using Annexes ZA or ZZ of the concerned harmonised standards which lists the correspondence between the European standard and the Toy Safety Directive's requirements. Be careful that more than one standard is often required in order to address all requirements in the Toy Safety Directive.

Verify if any notices are published with the harmonised standards referenced in the OJEU. Harmonised standards provide a presumption of conformity with the essential requirements of the Toy Safety Directive, if their reference has been published in the Official Journal. However if these standards are published with a notice, meaning that the standard does not fully address the general and particular safety requirements of the Toy Safety Directive, then this standard does not give presumption of conformity of the mentioned clause. If this is the case and the toy falls in this category, an EC-type certificate elaborated by a notified body is needed. In addition, the notified bodies elaborated a recommendation document, listing the toys which need an EC-type certificate. More information can be found on the European Commission’s website:

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

If hazards are present which are not covered by the harmonised referenced standard, a manufacturer may also decide to redesign his toy, prior to proceed with an EC-type examination. The previous steps need to be reassessed.

If the toy does not (need to be) subjected to an EC-type examination, the manufacturers may still assess if the toy presents any new features that includes risks that are possibly not covered by the harmonised referenced standard. If new risks are present, manufacturers can proceed with a risk assessment as described in relevant publications, e.g. CEN TC 13387, ISO/IEC Guide 50, CEN/CENELEC Guide 14 and ISO/IEC Guide 51.

In the past, manufacturers placed toys containing magnets on the market, complying with the harmonised standards referenced in the OJEU and presuming complying with the requirements of the Toy Safety Directive. However, as toy industry is very innovative, some manufacturers brought very strong magnets on the market, in the assumption they still complied with these harmonised standards and Toy Safety Directive. However accidents started to be reported with

magnets creating serious risks for children. This proves that hazards can be present, which are not covered by a harmonised standard referenced in the OJEU, which were not known from the start. Seen the accidents, the Commission published a decision which is now obsolete due the fact that an amendment to the standard has been published in the Official Journal.

Yoyo balls are another example for which hazards were revealed during its placing on the market. Possible strangulation hazards were revealed during use, causing serious injuries. Several Member States took national measures in order to ban these products.

Both examples show that manufacturers have to perform an assessment – especially for new innovative products – taking into account the foreseeable use and behaviour of children. After identification of the hazards, manufacturers should remove the hazards preferably by design wherever possible and for those hazards that cannot be removed, taking action to reduce the risks associated with them to an acceptable level before placing the toy on the market. Measures to remove hazards and reduce risks at the manufacturing stage can include the following:

1) remove the identified hazard as much as possible;

2) limit the access to the hazard by design;

3) limit or prevent the access to the hazard by barriers etc.

4) or inform the user about the residual risk which cannot be removed by design of safeguarding techniques.

The result of this risk assessment elaborated by the manufacturer is to be able to place a safe toy on the market, compliant to the requirements of the Toy Safety Directive. The necessary information is retained and made available to the authorities upon request. This information will help to prove that the hazards have been reduced by design or, where this is not possible, by appropriate information and instructions.

The test reports and EC-type certificates have also to be kept in the technical documentation (see previous sections) and made available to the authorities upon request.

Hazards and their typical injury scenario and typical injury

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Size, shape and surface	Product is obstacle	Person trips over product, falls and hits the floor; or person bumps into product	Bruising; fracture
	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child), or covers internal airway	Suffocation
	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Choking, internal airway obstruction
	Possibility to bite off small part from product	Person (child) swallows small part; the part gets stuck in the digestive tract	Digestive tract obstruction
	Sharp corner or point	Person hits sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Puncture; blinding, foreign body in eye; hearing, foreign body in ear
	Sharp edge	Person touches sharp edge; this lacerates skin or cuts through tissues	Laceration, cut; amputation
	Slippery surface	Person walks on surface, slips and falls hitting the floor	Bruising; fracture
	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
	Gap or opening between elements	Person puts a limb or body in opening and is trapped with finger, arm, neck, head, body or clothing; injury occurs due to gravity or movement	Crushing, fracture, amputation, strangulation
Potential energy	Low mechanical stability	Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; sprain; fracture; crushing; electric shock; burns
	Low mechanical strength	Product collapses by overloading; person on top of product falls from height, or person near product is hit by the product;	Bruising; dislocation; fracture; crushing;

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
		electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces	electric shock; burns
	High position of user	Person at high position on the product loses balance, has no support to hold on to and falls from height	Bruising; dislocation; fracture; crushing
	Elastic element or spring	Elastic element or spring under tension is suddenly released; person in the line of movement is hit by the product	Bruising; dislocation; fracture; crushing
	Pressurised liquid or gas, or vacuum	Liquid or gas under pressure is suddenly released; person in the vicinity is hit; or implosion of the product produces flying objects	Dislocation; fracture; crushing; cuts (see also under fire and explosion)
Kinetic energy	Moving product	Person in the line of movement of the product is being hit by the product or run over	Bruising; sprain; fracture; crushing
	Parts moving against one another	Person puts a body part between the moving parts while they move together; the body part gets trapped and put under pressure (crushed)	Bruising; dislocation; fracture; crushing
	Parts moving past one another	Person puts a body part between the moving parts while they move close by (scissor movement); the body part gets trapped between the moving parts and put under pressure (shearing)	Laceration, cut; amputation
	Rotating parts	A body part, hair or clothing of a person is entangled by the rotating part; this causes a pulling force	Bruising; fracture; laceration (skin of the head); strangulation
	Rotating parts close to one another	A body part, hair or clothing of a person is drawn in by the rotating parts; this causes a pulling force and pressure on the body part	Crushing, fracture, amputation, strangulation
	Acceleration	Person on the accelerating product loses balance, has no support to hold on to and falls with some speed	Dislocation; fracture; crushing
	Flying objects	Person is hit by the flying object and depending on the energy sustains injuries	Bruising; dislocation; fracture; crushing

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
	Vibration	Person holding the product loses balance and falls; or prolonged contact with vibrating product causes neurological disorders, osteo-articular disorder, trauma of the spine, vascular disorder	Bruising; dislocation; fracture; crushing
	Noise	Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance	Hearing injury
Electrical energy	High/low voltage	Person can touch part of the product that is at high voltage; the person receives an electric shock and may be electrocuted	Electric shock
	Heat production	Product becomes hot; a person touching it may sustain burns; or the product may emit molten particles, steam etc. that hits a person	Burn, scald
	Live parts too close	Electric arc or sparks occur between the live parts. This may cause a fire and intense radiation	Eye injury; burn, scald
Extreme temperatures	Open flames	A person near the flames may sustain burns, possibly after clothing catches fire	Burn, scald
	Hot surfaces	Person does not recognise the hot surface and touches it; the person sustains burns	Burn
	Hot liquids	Person handling a container of liquid spills some of it; the liquid falls on the skin and causes scalds	Scald
	Hot gases	Person breathes in the hot gases emitted from a product; this causes lung burn; or prolonged exposure to hot air causes dehydration	Burn
	Cold surfaces	Person does not recognise the cold surface and touches it; the person sustains frostbite	Burn
Radiation	Ultraviolet radiation, laser	Skin or eyes of a person are exposed to radiation emitted by the product	Burn, scald; neurological disorders; eye injury; skin cancer, mutation

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
	High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)	Person is close to the electromagnetic field (EMF) source, body (central nervous system) is exposed	Neurological (brain) damage, Leukaemia (children)
Fire and explosion	Flammable substances	Person is near the flammable substance; an ignition source sets the substance to fire; this causes injuries to the person	Burn
	Explosive mixtures	Person is near the explosive mixture; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear
	Ignition sources	The ignition source causes a fire; a person is injured by flames, or intoxicated by gases from the house fire	Burn; poisoning
	Overheating	Product overheats; fire, explosion	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Product operating hazards	Unhealthy posture	Design causes unhealthy posture of person when operating the product	Strain; musculoskeletal disorder
	Overexertion	Design requires use of considerable force when operating the product	Sprain or strain; musculoskeletal disorder
	Anatomical unsuitability	Design is not adapted to human anatomy which makes it difficult or impossible to operate	Sprain or strain
	Ignoring personal protection	Design makes it difficult for a person wearing protection to handle or operate the product	Various injuries
	Inadvertent (de)activation	Person can easily (de)activate product which leads to unwanted operation	Various injuries
	Operational inadequacy	Design provokes faulty operation by a person; or product with a protective function does not provide expected protection	Various injuries
	Failure to stop	Person wants to stop the product, but it continues to operate in situation where this is unwanted	Various injuries
	Unexpected start	Product shuts down during a power failure, but resumes operation in a hazardous way	Various injuries
	Inability to stop	In an emergency situation, person is not able to stop operation of the product	Various injuries
	Inadequately fitting parts	Person tries to fit a part, needs too much force to fit, product breaks; or part is too loosely fitted and gets loose during use	Sprain or strain; laceration, cut; bruising; entrapment
	Missing or incorrectly fitted protection	Hazardous parts are reachable for a person	Various injuries
	Insufficient warning texts and symbols	User does not notice warning texts and/or does not understand symbols	Various injuries

Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
	Insufficient warning signals	User does not see or hear warning signal (optical or auditive) causing dangerous operation	Various injuries

PART III HYGIENE AND RADIOACTIVITY ASSESSMENT

1. HYGIENE AND RADIOACTIVITY

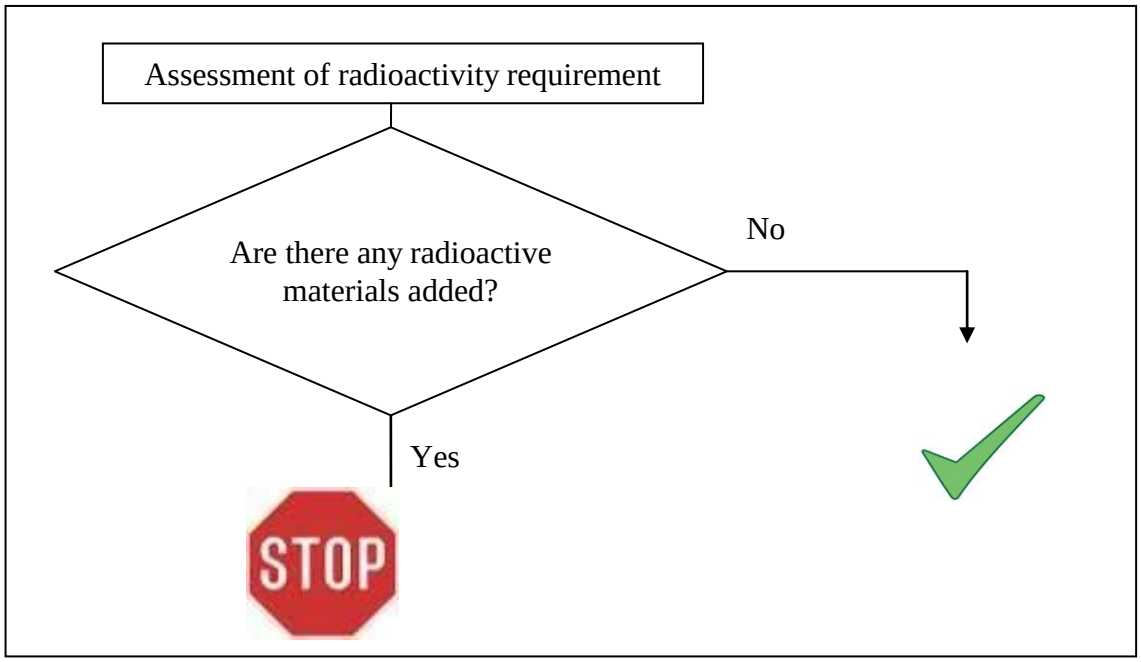
There are no harmonised standards available for the hygiene and radioactivity requirements, therefore an assessment is needed to evaluate the compliance. In order to assess the toy, the composition of the toy and the materials used in the toy need to be known.

1.1. Radioactivity

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

Information can be found on following website:
http://europa.eu/legislation_summaries/institutional_affairs/treaties/treaties_euratom_en.htm

The full text is available on http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012A/TXT



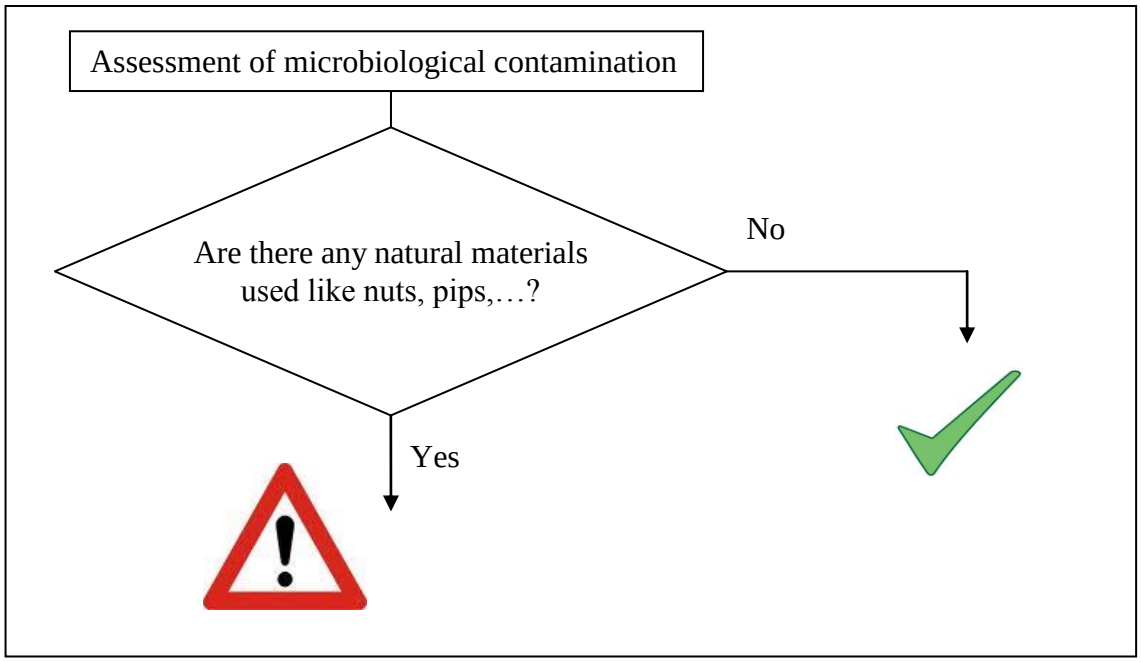
1.2. Hygiene

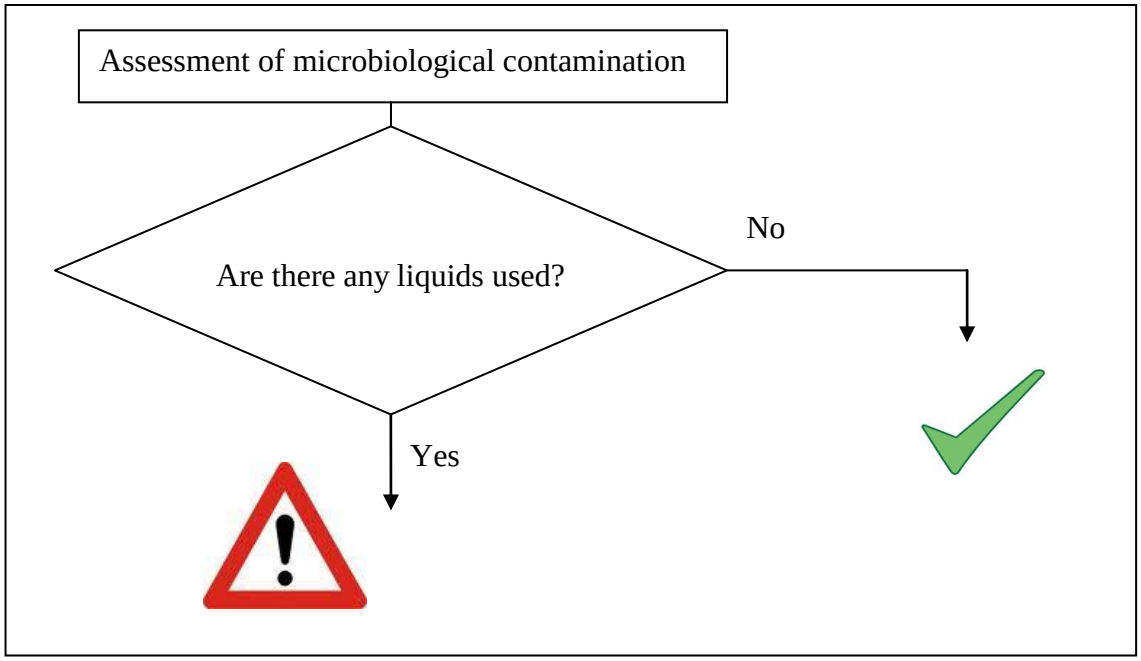
The Toy Safety Directive requires that all toys must be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination.

Specific cases apply for a toy intended for use by children under 36 months which 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

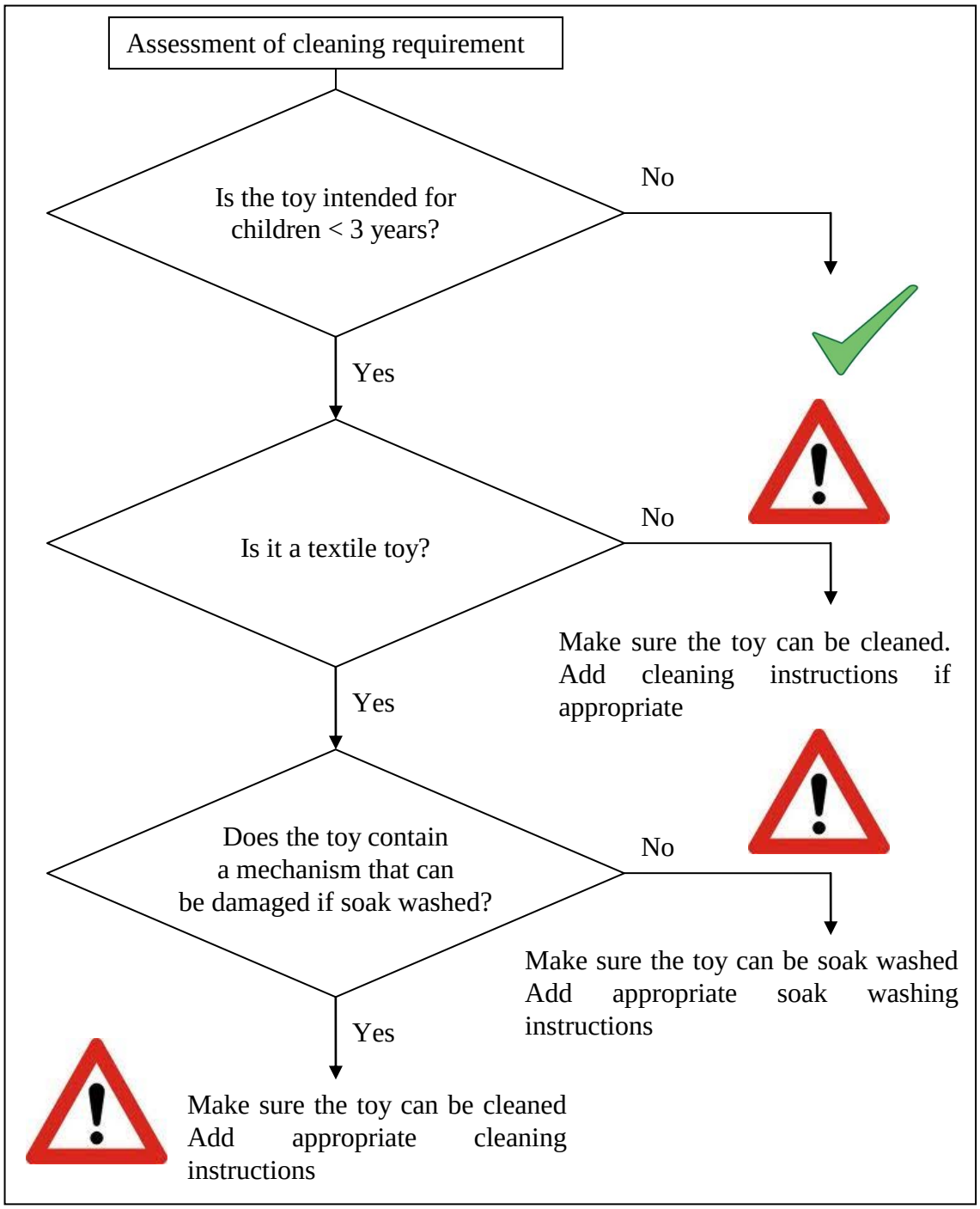
point and the manufacturer's instructions. Some types of toys for children under 3 years are formulated with preservative systems and so may be considered to be “self-cleaning”.

1.2.1. Assessment





Remark: The notified bodies adopted a protocol on "Microbiological safety of toys containing aqueous media". http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm



As regards textile toys for children under 36 months, above 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 of the Toy Safety Directive was 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 …

Furthermore, the Toy Safety Directive requires that the toys needs to fulfil all the safety requirements also after it has been cleaned in accordance with 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, meaning the manufacturer shall ensure that in particular no small parts become present after cleaning or soak washing or that no water can accumulate or that the flammability requirements are still complied with after cleaning/washing.

1.2.2. Microbiological hazards, infection and sickness

Microbiological contamination refers to the presence of one or more various bacteria, yeasts, mould, fungi, protozoa or their toxins and by-products, which could adversely affect the product or a consumer's health and safety. Test methods described in the European Pharmacopeia can be used. Following standards are used under the Cosmetics legislation, but might contain relevant parts for toys:

EN ISO 18416:2009 Detection of Candida albicans (ISO 18416:2007)
EN ISO 21148:2009 General instruction for microbiological examination (ISO 21148:2005)
EN ISO 21149:2009 Enumeration and detection of aerobic mesophilic bacteria (ISO 21149:2006)
EN ISO 21150:2009 Detection of Escherichia coli (ISO 21150:2006)
EN ISO 22716:2007 Guidelines on Good Manufacturing Practices (ISO 22716:2007)
EN ISO 22717:2009 Detection of pseudomonas aeruginosa (ISO 22717:2006)
EN ISO 22718:2009 Detection of Staphylococcus aureus (ISO 22718:2006)

If the mandatory safety assessment performed in accordance with Article 18 of the Toy Safety Directive finds that there are no microbiological risks, then EC-type examination is not required in respect of the microbiological aspects of toys.

Toxicity of natural materials or substances will be dealt with in the chemical safety assessment.

1.2.3. Update of the safety assessment

A safety assessment might need to be updated if for example:

- new information becomes available
- changes are made to the product (design, raw materials, additives, paints etc) that will affect the safety aspects
- legal requirements change
- consumer complaints suggest that the product presents a risk (e.g. allergic reactions)
- products were withdrawn from the market due to a risk

PART IV CHEMICAL REQUIREMENTS

1. CHEMICAL REQUIREMENTS

1.1. The Toy Safety Directive and chemical safety assessment

The Toy Safety Directive 2009/48/EC sets out various chemical requirements in Annex II, Part III and it should be noted that these took legal effect as of 20th July 2013. The chemical requirements of the old Toy Safety Directive 88/378/EEC applied until July 2013. However, carrying out a safety assessment, meaning the evaluation of the chemical hazards a toy may present and the potential exposure to such hazards, is required by the Toy Safety Directive 2009/48/EC since July 2011.

The chemical requirements in the Toy Safety Directive, includes a general safety requirement and particular requirements for certain categories of toys and substances. The Toy Safety Directive also requires that toys comply with relevant EU legislation regarding certain categories of products or restrictions for certain substances and mixtures as well as rules for classification, labelling and packaging of certain substances and mixtures.

In addition, the Toy Safety Directive requires that a safety assessment is carried out, i.e. an analysis of the various hazards that the toy may present and an assessment of the potential exposure to them. For chemicals, a major part of this is the assessment of the likelihood of the presence in the toy of prohibited or restricted substances (i.e. those covered by the references made in the paragraph above). However, the assessment should also cover other chemical hazards (and the exposure to these) that might be presented by substances that are presently not prohibited or restricted but are commonly known as undesirable for use in toys. This is important in relation to the general safety requirement for chemicals in the Toy Safety Directive.
A chemical safety assessment shall therefore take into consideration all applicable regulations and directives and additional relevant information on other substances that children may be exposed to when playing with toys. Such additional information is often supplied to toy manufacturers through their industry associations but can also be found from other sources.

In short, the basis for a good chemical safety assessment is **knowledge**; knowledge about the toy, how it is used, the materials used, the substances used; knowledge about the restrictions imposed on certain substances, their scope and emerging issues.

A safety assessment might need to be updated if for example:

- new toxicological information becomes available for the chemicals used
- changes are made to the product (design, raw materials, additives, paints etc) that will affect the presence of chemicals and/or the exposure to these
- legal requirements change
- consumer complaints suggest that the product presents a chemical risk (e.g. allergic reactions)
- products were withdrawn from the market due to a chemical risk

1.2. The Role of chemical standards

Several of the requirements in the Toy Safety Directive are fully or partly supported by harmonised standards, the references of which have been published in the OJEU. Such standards give presumption of conformity to the directive, meaning that if a toy complies with such standards the manufacturer has no obligation to carry out further assessment or testing with regard to the chemical hazards covered by these standards.

The route of EC-type examination can be used as a means of assessing whether the toy is in conformity with the Toy Safety Directive, particularly if there is a concern that a chemical hazard exists that is not covered by harmonised standards. However, this route does not release the manufacturer from his obligation to perform the safety assessment. Also, the mandatory safety assessment is considered to be an alternative to EC-type examination for chemical hazards that are not covered by harmonised standards.
Presently, the following harmonised standards, relevant to chemicals in toys, have been referenced in the OJEU:

- EN 71-3 Migration of certain elements
- EN 71-4 Experimental Sets for Chemistry and Related Activities
- EN 71-5 Chemical toys (sets) other than experimental sets
- EN 71-7 Finger paints – Requirements and test methods
- EN 71-12 N-Nitrosamines and N-nitrosatable substances
- EN 71-13 Olfactory board games, cosmetic kits and gustative games
- EN 12472 Method for the simulation of wear and corrosion for the detection of nickel release from coated items
- EN 1811 Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin
- ISO/TS 17234 Leather - Chemical tests -Determination of certain azo-colorants in dyed leathers
- 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

Testing for conformity to the above standards is frequently used as a means of establishing compliance with the Toy Safety Directive 2009/48/EC or relevant parts of Annex XVII of the REACH Regulation (which includes restrictions for e.g. nickel and azo-colourants). There is however no explicit obligation to test to these standards and there are cases where such testing would be superfluous. If the chemical safety assessment e.g. results in a conclusion that certain heavy elements covered by EN 71-3 cannot be present in the toy material, there is no obligation to test to the harmonised standard to confirm this (for the elements in question). Testing may also be superfluous in the case where the safety assessment concludes that due to the accessibility, function, volume or mass of the toy or toy material, there is no chemical hazard due to sucking, licking, swallowing or prolonged contact with skin.

For several of the chemical requirements of the Toy Safety Directive 2009/48/EC, there are at present no supporting harmonised standards, the references of which have been published in the OJEU. The safety assessment process must therefore cover for example:

- Substances classified as CMR (Carcinogenic, Mutagenic or Repro-toxic)
- Fragrances
- Substances included in Appendix C of the Toy Safety Directive
- Chemical substances prohibited or restricted in other directives/regulations (e.g. REACH)
- Undesirable chemical substances that are not yet prohibited or restricted

Harmonised standards, the reference of which has been published in the OJEU under the REACH Regulation (EC) No 1907/2006, are available for nickel and azo-colorants (mentioned above). For certain other substances (CMRs and among those certain phthalates) harmonised standards, the references of which have not been published in the OJEU, are available and are of great help during a chemical safety assessment although the application of them does not give presumption of conformity with the Directive. More information related to these standards is given in the following section.

1.3. Additional information on the substance-categories to be covered in the safety assessment

1.3.1. CMRs

CMRs are prohibited according to the new Toy Safety Directive but may, however, be used if they are inaccessible to children in any form, including by inhalation, or if they are present in concentrations equal to or smaller than the relevant concentrations for classification of mixtures containing the substances, in accordance with Directive 1999/45/EC on Dangerous Preparations (DPD) (until 31 May 2015) or in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) (from 1 June 2015).

The Toy Safety Directive contains an exemption from the CMR restrictions for materials that are covered by and comply with the provisions on food contact materials (Regulation (EC) No 1935/2004) and the related specific measures for particular materials. This exemption does not have any effect on other legal restrictions that may impose prohibitions or restrictions on CMR substances in toys, e.g. REACH restrictions.

It is therefore necessary as part of a chemical safety assessment, to determine whether or not a substance of interest has the formal classification of CMR. This is carried out in the characterisation stage of the chemical safety assessment (see Section 1.5.3).

The number of substances classified as CMRs is very high and it is therefore not feasible to test for the presence of all these. Instead, the safety assessment is used. Many CMRs of particular relevance to toys are covered by standards, the references of which have so far not been published in the OJEU:

EN 71-9	Organic chemical compounds – Requirements
EN 71-10	Organic chemical compounds – Sample preparation and extraction

EN 71-11 Organic chemical compounds – Methods of analysis

As explained above, these standards do not give presumption of conformity with the Toy Safety Directive but they cover many hazardous substances that are known to have been found in toy materials and the standards are therefore valuable tools in a chemical safety assessment.

CMR substances not covered by these standards could be present in toys and there could also be cases where the generic or specific classification limit is not considered appropriate for toy materials. An example is benzo(a)pyrene, a polycyclic aromatic hydrocarbon (carcinogenic category 1B), which can sometimes be present in e.g. rubber and black colourants, and is considered as undesirable in accessible toy materials.

Commission Regulation (EU) No 1272/2013 therefore amended Annex XVII of the REACH Regulation regarding Polycyclic Aromatic Hydrocarbons (PAHs). According to this Regulation, toys shall not be placed on the market if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005% by weight of this component) of any of the listed PAHs. It started applying on 27 December 2015. Entry 50 to Annex XVII of REACH lists 8 PAHs.

1.3.2. Fragrances

The Toy Safety Directive lists a number of allergenic fragrances, defined by CAS numbers, that are prohibited for use in toys and also a number of fragrances that when used require special labelling of the toy. The safety assessment should check that the toy complies with these requirements.
Traces of a fragrance are allowed provided that 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, where the impurity is an unintended contaminant in raw materials. More information on GMP can be found in the standard EN-ISO 22716.

In the safety assessment process it should be noted that the Toy Safety Directive does not provide any automatic allowance to use fragrances just because they are "natural". Natural fragrances may potentially contain one or more of the prohibited fragrance substances listed in the new TSD in which case they will be subject to restrictions.

1.3.3. Other prohibited/restricted substances

The Toy Safety Directive is not the only legal instrument that sets out restrictions and prohibitions on certain chemical substances in toys. Regulations like REACH contain a variety of chemical provisions for toys and must be taken into consideration during a chemical safety assessment. Sometimes there are national regulations that affect toys and these too must be considered if the toy enters these national markets. A list of legal instruments possibly affecting toys is given in Appendix II of these guidelines.

For example REACH, Annex XVII, restrictions 51 and 52, prohibits 6 named phthalates. Test methods for determination of the presence of these 6 phthalates are given in the standard EN 14372, the reference of which has so far not been published in the OJEU.

1.3.4. Undesirable chemicals (not prohibited/restricted)

Some substances, although not restricted because they do not have a CMR classification, are still potentially unacceptable in toy materials because they have other health effect classifications (see 1.3.1 above for identifying classifications). Acute toxicity, corrosive properties, the ability to trigger allergic reactions, are examples of intrinsic properties that can be hazardous to health.

For example if a toy contained a powder paint and the powder contained a substance that was a skin irritant, the safety assessment would need to consider the concentration and potential exposure of the child to this substance during intended or foreseeable use.

The safety assessment process must also take into consideration that whilst a law may restrict or prohibit a named substance, it is not allowable for it to be replaced with an alternative that has a similar toxicological profile unless it can be shown that the exposure is different and the risks have become acceptably low. For example, possible replacement for restricted phthalates could be other phthalates which are not classified. However, for some phthalates authorities do have intentions to propose harmonised classifications or restrictions and they are therefore not the best choice of substitution. Information on intentions to proposals for classifications or restrictions is notified on http://echa.europa.eu/uk/addressing-chemicals-of-concern/registry-of-intentions.

Some substances, although not CMRs according to CLP Annex VI (and not covered by EN 71-9), are under review due to their suspected or known adverse health effects. Information about Member States' and ECHA's intentions to prepare dossiers for the identification of substances of very high concern (SVHCs), proposing restrictions or proposing harmonised classification and labelling of substances could be relevant information in a chemical safety assessment and should be taken into account (http://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions). In other cases substances are classified for health effects other than CMR classifications. For example, acetophenone is a classified substance (irritating to eyes) and although not a CMR, there have been indications that this substance might create undesirable health effects if present at high enough concentrations in toys like EVA puzzle mats.

1.4. The basis for chemical safety assessment

The starting point for a chemical safety assessment is the gathering of information on the materials and chemicals used in the manufacture of the toy. The more comprehensive this information is, the better the safety assessment will be. It is invaluable to have comprehensive information in the form of a bill of materials, a bill of substances and in support of these, safety data sheets where applicable, and finally the results of any analytical testing.

Incorrect or incomplete information could invalidate the findings of a chemical safety assessment. In contrast to mechanical and physical hazards, chemical hazards in toys are less

obvious. Apart from colourants, chemicals cannot be "seen" and only in some cases will their odour indicate that they are present. The presence of chemical hazards in toys therefore needs to be determined using one or both of the following:

a) the manufacturer's or supplier's knowledge about the materials and/or the substances used in the manufacturing process, or
b) by chemical analysis (testing)

Both options have benefits and drawbacks and it is for the user of this guide to determine which approach suits them best in order to minimise the chemical risk.

In relation to analytical testing, validated test methods are not always available for qualitative and quantitative determination of the substances of interest. Furthermore, chemical analysis is often very expensive and this precludes the notion of testing every toy material for every chemical of interest. Therefore, the chemical safety assessment is an important alternative tool for determining which substances might be of toxicological significance in a given toy material and also to determine the exposure to these chemicals. This leads on to the determination of appropriate risk management measures in order to minimise or eliminate the risk. The decision as to which risk management measures might be appropriate are outside the scope of this guidance document but typical options include substitution of the material affected, elimination of the substance, replacement of the substance with a suitable alternative, etc.

The following sections of this guidance document outline a basic generic process for the chemical safety assessment of a toy. It is important to recognise that the process is tailored to an article, i.e. a toy, and thus not comparable to the chemical safety assessment of a chemical substance. The overall aim of the chemical safety assessment process is to ensure that a manufacturer carefully considers the chemical hazards that the toy, its materials and contained substances might present to the health of the child. It is a logical consequence of the chemical safety assessment that the manufacturer would consider appropriate risk management measures where an unacceptable risk has been identified.

The guide presents one process but also other accepted and/or effective models can be applied when performing chemical safety assessment of toys.

To summarise, the available experience in the toy sector together with the available standards (referenced or not referenced) provides a very good basis for the chemical safety assessment. If it can be excluded that the toy materials contain excessive amounts of any of the substances covered by the standards, or of substances that are prohibited/restricted, or of substances that are well known and under suspicion to be hazardous (examples have been given above), there is a high probability that the toy can be considered to be chemically safe. If any of the mentioned substances are present in excessive levels, exposure to the substances must be considered: if the substances are contained in parts of the toy that are inaccessible under reasonably foreseeable use or if the substances do not migrate or emit from the toy material under reasonably foreseeable use, then there is no exposure and the chemical risk may be regarded as acceptably low. However care should be taken to avoid contravening any limits for **total** content of certain substances that are set out in legal instruments (see 1.3.3 above).

1.5. The chemical safety assessment process

1.5.1. General Outline

The chemical safety assessment process described in this guide comprises 3 major stages: Identification, Characterisation and Assessment.

Identification relates to the examination of information contained in documentation to identify materials and substances contained in the toy together with amounts (if known). Each identified material or substance then goes through the characterisation stage.

Characterisation is the process by which a material or substance is reviewed against known prohibitions/restrictions, to determine whether it falls within scope, and reviewed against scientific knowledge on potentially hazardous substances. The outcome of the characterisation is to place the material or substance into one of two groups:

i) Materials or substances subject to legal restrictions or restrictions in safety standards.

ii) Materials or substances not subject to restrictions

Once a material or substance is characterised it is put through the appropriate assessment process (see 1.5.4.1 and 1.5.4.2)

Assessment is concerned with establishing the likelihood of a given material containing an undesirable substance in amounts that are high enough to present an unacceptable risk taking into consideration the hazard and the exposure of the user.

1.5.2. Identification stage

A suitably detailed bill of materials (BOM) will enable all the various material types used in the toy to be identified. For example it will identify that a named part is made of ABS plastic or that a textile is brushed polyester. Without a bill of materials, the chemical safety assessment process described in the guide cannot proceed.

A bill of substances (BOS) is the most detailed level of a BOM where information on individual substances is given. This level of detail is normally associated with a formulation of a chemical mixture within a toy, e.g. a poster paint, a slime, a liquid ink etc., but can on occasion be present in relation to a polymer. For substances that are identified on the BOM it is necessary for the manufacturer to keep SDSs in the technical documentation, subject to the rules governing the availability of an SDS (see previous sections of this guide). This requirement applies also to the chemicals that have been used in the manufacturing process. SDSs provide valuable information for the chemical safety assessment.

The BOM does not necessarily list where in the toy the various materials are used but for the purpose of the safety assessment, this knowledge is essential whenever it is necessary to assess the potential exposures of the user. The use/location of the material should be described in a way that makes it possible to assess if it is e.g. inaccessible, or accessible for sucking/licking, accessible for ingestion, accessible for dermal contact etc. A prototype of the toy, if available, would also be sufficient to provide this same information.

1.5.2.1.Barriers to the flow of information [Confidentiality of Information]

Importers that fall within the definition of a manufacturer (see 2009/48/EC, e.g. an importer who imports toys under his own brand) may find it difficult to obtain the necessary level of information from the actual producer of the toy. The most frequent obstacle encountered is that of confidential and proprietary information. In some cases reluctance or even refusal to supply BOM information may well be justified from the supplier's point of view but this does not remove the obligation of the own-brand importer to conduct a chemical safety assessment. In situations where limited information is available, there are still ways to undertake a chemical safety assessment but these typically include more dialogue with the producer, making worst-case assumptions and additional chemical testing. Some of the options are explained in more detail below.

1.5.2.2.How to proceed with limited information

- The chemical safety assessment can be conducted on the basis of a series of "worst-case" assumptions. Some materials are known to have a possibility of containing certain substances some of which may be either restricted or considered undesirable. For example if soft PVC is present, then it should be assumed that it is plasticised with a restricted phthalate. Such assumptions can facilitate the dialogue with the supplier since it can then be focussed on ascertaining that the original "worst-case assumption" was incorrect. See Appendix III of these guidelines for further information.
- In the case of "own-brand importers", the original producer of the toy (e.g. factory) can provide the chemical safety assessment on condition it respects the principles set out in this guide, it should be acceptable. However the manufacturer, as defined in the new TSD, remains responsible for any shortcomings with the chemical safety assessment.
- In order to facilitate the conduct of a chemical safety assessment by the manufacturer, the supplier may be willing to sign a declaration of conformity (or a non-use declaration) declaring that the item is in conformity with certain EU legislation or that certain substances have not been used.
- The manufacturer may need to conduct a range of chemical testing aimed at ensuring that the toy he is going to produce or import is in conformity with relevant EU regulations. Whilst it is common practice to test toys for the absence of certain heavy elements like lead, cadmium, chromium etc it is not so common to test for the presence of flame retardants, wood preservatives etc. The option of testing in order to check for the absence of a long list of substances can be far more costly than the time and effort it takes to obtain reliable information from the original producer of the item. Nonetheless it is possible to target testing so that it is focussed on finding prohibited/restricted or undesirable substances that have the possibility of being present in a given material. For example it is not worthwhile to test an unpainted wooden toy for the presence of restricted phthalates but may be worthwhile to test for the presence of certain preservatives. These types of decisions on testing are themselves a result of a form of chemical risk assessment and the data upon which they are based can be found from many sources. See Appendix III of these guidelines for further information.

1.5.3. Characterisation stage

The characterisation stage describes the work that is undertaken in order to determine whether a given material or substance is

- within the scope of a legal restriction
- covered by a restriction in a document such as a standard, or
- is suspected (or known) to present a hazard (i.e. have adverse health effects).

Many chemical substances and mixtures are already prohibited or restricted for use in toys. Other substances are in the process of becoming prohibited or restricted and yet others are under discussion as being undesirable for use in toys. There are of course many chemical substances that are not under suspicion and pose acceptably low risks when used in every day product like toys.

1.5.3.1.Characterisation – substance characterisation

Some substances may be identified in the BOM or in other documentation (e.g. supplier information exchange) by name and by one of the numbering conventions (e.g. CAS No.) but without any other information on the hazardous properties of the substance. However, some of the prohibitions/restrictions (see 1.5.3.2 and 1.5.3.3) are based on the hazard classification of the substance (i.e. also other classifications than CMR) and it is therefore necessary to find out whether a substance is classified as hazardous and whether any restrictions/prohibitions might apply. For this purpose, availability of CAS-numbers is very helpful. For example the new TSD places restrictions on any substance with a CMR hazard classification, so in order to assess the likelihood of non-conformity with this restriction, it is necessary to know any CMR-classifications of the substances named in the BOM.

Note: Also substances without harmonised classification, but where justified by the application of the precautionary principle, can sometimes be subject to restrictions. One example is the phthalates ester DINP which is not classified as hazardous and yet is restricted by REACH. Thus the characterisation process must take this into account.

The hazard classification scheme(s) to be applied to substances and mixtures is defined according to the methodology set out in Article 61 of the CLP Regulation 1272/2008. Substances shall be classified from 1 December 2010 until 1 June 2015 in accordance with both Directive 67/548/EEC on Dangerous Substances (DSD) and the CLP Regulation. Until 1 June 2015, mixtures shall be classified in accordance with Directive 1999/45/EC on dangerous preparations (DPD). However, mixtures may, before 1 June 2015, be classified, labelled and packaged in accordance with this Regulation 1272/2008. In that case, the provisions on labelling and packaging in Directive 1999/45/EC shall not apply. After 1 June 2015 the hazard classification of substances and mixtures is defined according to the methodology set out in Article 62 of the CLP Regulation 1272/2008. Only hazard classifications for health effects are relevant for the purposes of chemical safety assessment.

The steps to check the classification of a substance are:

1. **Search the EINECS or CAS number of the substance on following link: http://echa.europa.eu/web/guest/information-on-chemicals;jsessionid=9CFF5DB37E29F86DF2EAB5BD2EC596BE.live2**

2. **Search using the EINECS or CAS number if the substance appears in Annex I of Directive 67/548/EEC or Annex VI of the CLP Regulation (http://ec.europa.eu/growth/sectors/chemicals/legislation/index_en.htm** or **http://echa.europa.eu/information-on-chemicals/cl-inventory-database) and**

locate its classification under the heading "Classification and Labelling Information"

3. **Search using the EINECS or CAS number (until 31 May 2015) Directive 1999/45/EC for the generic or specific concentration limit based on its classification**
   http://ec.europa.eu/growth/sectors/chemicals/legislation/index_en.htm

4. **Search using the EINECS or CAS number from 1 June 2015 CLP Regulation 1272/2008 for the generic or specific concentration limit based on its classification**
   http://ec.europa.eu/growth/sectors/chemicals/legislation/index_en.htm

The above information sources may also be used to cross check on information provided in the BOM or BOS. When the hazard classification is known, it is possible to work through stages 1.5.3.2 and 1.5.3.3 and determine if the substance is within the scope of any kind of prohibitions/restrictions.

Where a substance does not have a hazard classification, it is necessary to check if there is an SDS which could be the case if the substance has been self-classified by the supplier. In such cases this self-classification should be used.

Substances that are not classified for health effects but are known, or under suspicion, to be undesirable for use in toys, should be subject to an assessment according to the work flow in section 1.5.4.2 b) of these guidelines. See Appendix IV of these guidelines for further information.

Be aware that if a harmonised hazard classification is available, this classification shall be used. However, the harmonised classification does not cover all endpoints, and therefore self-classifications provide additional information and should not be excluded for endpoints not covered by harmonised classifications as provided by Article 4(3) CLP.
Self-classifications available in the Classification and Labelling Inventory database can be used. However this database provides suggestions for different classifications for substances with the same CAS-number, which could be explained for instance as the result of impurities from different production processes etc. A self-classification for a specific substance from one supplier is therefore not necessarily valid for a substance with the same CAS-number but from another supplier (i.e. a substance with a different trade name), however CLP provides clear advice on the way supplier, distributor and downstream users should fulfil their responsibilities under CLP (Article 4 points 3 to 6). It should also be noted that the information in the database will not be verified by ECHA since it is the responsibility of industry to come to an agreed entry.

1.5.3.2.Characterisation - Prohibited/Restricted Substances (legal requirements)

Once the identification stage in 1.5.2 has been carried out, it is possible to determine which substances or material types are within the scope of the legal requirements set out in Appendix II of these guidelines and, in the case of substances, to determine if they are named and subject to restrictions.

For example if the BOM identified a plastic as “plasticised PVC” it will be concluded that it falls within the scope of the REACH restrictions in Annex XVII, Nos 51 and 52. If there is no mention of “plasticised” in the BOM the worst-case is presumed i.e. that a plasticiser is present.

In the case where a plasticiser is identified in the BOM then it is “characterised” as being within the scope of the REACH restriction and it is then possible to determine if it contravenes this restriction (which is part of the next stage, “Assessment”).

1.5.3.3. Characterisation - Prohibited/Restricted Substances (identified in safety standards)

In a similar manner to the above, materials and substances identified in the BOM should be reviewed against toy safety standards to determine if they are within the scope of these. The use of other standards that are not specific to toys is also relevant provided that they deal with direct health effects (some chemicals standards deal with environmental safety which is beyond the scope of the chemical safety assessment set out in this guide).

1.5.3.4. Characterisation – Substances not subject to any prohibition/restriction

Apart from reviewing substances for which the use is prohibited or restricted, also other undesirable substances should be characterized to determine if they are potentially hazardous and therefore need to be put through the assessment process as described in 1.5.4.2.

1.5.4. Assessment stage

There are two possible work flows depending upon whether the characterisation stage has identified some kind of relevant restriction or whether no relevant restriction has been identified.

1.5.4.1. Assessment of substances and materials subject to restrictions

From the previous stage it is known that a material or a substance is within the scope of a relevant restriction or prohibition. The work in the assessment stage is concerned with establishing the likelihood that the substance exceeds any limits set out in the restrictions. In the case of a substance and its percentage addition, it is straight forward to determine if a restriction is met or contravened by comparing against specified limits. These limits can be either for migration of the substance, or for the total content of the substance depending on the regulation and care needs to be taken to ensure that these limits are not confused with each other.

For example: The BOM identifies the plastic as PVC with 10 % of the plasticiser Di-n-octyl phthalate (DNOP) CAS No 117-84-0. The REACH restriction No. 52 states that DNOP “shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children”.

The plasticised PVC is in clear contravention with the total content limit, provided that the materials can be placed in the mouth. (Regarding “placed in the mouth”, see Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52

of Annex XVII to REACH Regulation 1907/2006 at http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm).

If a restricted substance is listed in the BOM without its percent addition, further information will be required either by further dialogue with the producer or by conducting analytical testing (see 1.5.2.2). However, this would not be necessary if for example the restriction only applied to accessible materials and the substance under assessment is in an inaccessible material. An example of this might be nickel plating on a metal screw where the screw is inside the toy and is inaccessible to any skin contact (see REACH restriction, Annex XVII, No.27).

If it can be established that the likelihood of the restricted substance exceeding a specified limit is low, this should be documented and the next material or substance in the BOM can be evaluated (1.5.3). This process is followed until all materials and substances have been evaluated.

For example:

An ABS plastic resin has a trace level of the CMR acrylonitrile (CAS No. 107-13-1) not greater than 0,05% according to the supplier's specification. Acrylonitrile is classified as a carcinogen category 1B without specific concentration limits, thus it is subject to a total concentration limit of 0.1% according to the new TSD and the rules on classification. It is not restricted in the toy safety standard EN 71-9. During the moulding process, the resin will be formed into part of a toy and it is reasonable to assume that any residues of acrylonitrile will be further reduced since it is a volatile substance. Furthermore acrylonitrile is not known to migrate from ABS in to aqueous simulants. It would be reasonable to conclude the plastic is "low risk" with respect to acrylonitrile and would be suitable for use in toys (provided any other substances are not found to present an unacceptable level).

In the case of CMR substances, the new TSD contains an exemption from the CMR restrictions for materials that are covered by and comply with the provisions on food contact materials (Regulation (EC) No 1935/2004) and the related specific measures for particular materials. This exemption does not have any effect on other legal restrictions that may impose prohibitions or restrictions on CMR substance in toys.

As mentioned already, the new TSD sets out various chemical requirements in Annex II, part III and it should be noted that these took legal effect as of 20th July 2013.

1.5.4.2. Assessment of materials and substances not covered by a prohibition/restriction

The materials and substances that fall under this heading are those characterized as:

a) Materials or substances with a hazard classification but not subject to specific restrictions

These substances may or may not have an acceptably low risk in a toy depending upon whether there are any pathways by which a child may be exposed.

b) Materials or substances with no hazard classification

Materials or substances in this category may be unclassified because they are regarded as safe but alternatively they may be under scientific investigation or under a formal review process. This is relevant information for the chemical safety assessment and should be taken into consideration (see 1.3.4).

There are various chemical and toxicological databases and information sources that can be consulted in order to find out more (see Appendix IV of these guidelines for further information).

In case a) above and in case b) when there are grounds to consider the substance or material may be classified as hazardous or undesirable for other reasons, it is necessary to assess the possible exposure of the child to the substance.

1.5.4.3.Factors influencing exposure

In order to properly assess the exposure a number of factors need to be considered:

- Intended age of the user
- Intended and foreseeable use, and
- Exposure routes

Intended age of the user

The age of the user for which the toy is intended needs to be considered when assessing the exposure. Some toys are obviously intended for certain age groups such as teething toys for very young children and conversely a craft toy requiring a high degree of manipulative skills would not be considered as intended for use by young children. The manufacturer's age indication is normally sufficient unless it is in conflict with the use that a parent or supervisor may reasonably be able to assume by virtue of the functions, dimensions and characteristics of the toy for children of the stated age group. For the purposes of the chemical safety assessment it is presumed that toys will be used in an age appropriate manner, i.e. toys with small parts are not played with by children under 3 years and that older children do not routinely ingest or mouth parts of the toy.

Intended and foreseeable use

The nature and intended and foreseeable use of the product is also fundamental to the exposure assessment. There has, however, to be an awareness regarding the reasonably foreseeable use of the toy since this could affect the outcome of the exposure assessment. An example of this would be a "snow storm"-type product sold as a toy where the water inside the globe is not intended to be accessed by the user. However, these toys have been known to leak over time and that children can, in some instances, access the liquid via the filling plug usually located on the base of the toy. The exposure assessment must include a decision on whether or not it is foreseeable that during the lifetime of the toy it will leak such that a child can be exposed to the liquid.

Another example is a toy consisting of an ink-soaked pad and a small stamping device to produce an ink pattern on paper. Usually these toys are intended for children 5 years and above. It is foreseeable that a 5 year old child will use the stamper to produce a temporary

tattoo effect on the skin, although the instructions might indicate that this is not the intended use. This needs to be considered in the exposure assessment.

Routes of exposure

Taking into consideration the intended age of the user and the intended use of the toy, the most likely routes of chemical exposure are:

- Dermal exposure
- Oral exposure
    - ingestion
    - sucking and licking
- Eye contact
- Inhalation

When the exposure from these different routes is assessed, assumptions have to be made. For example assumptions on the time of exposure, the surface of the exposed toy and the age of the child have to be made. As a starting point the assumptions should be a conservative worst case estimate. If such an estimate results in a conclusion that the risk is not present or is very low, it can be concluded that the toy is safe to use. If a worst case estimate leads to a conclusion that there is a risk, then a more realistic scenario should also be considered.

For many toy materials, the presence of traces of hazardous substances does not pose a toxicological risk since in many cases the substances are chemically bound to the material and are not capable of being released in toxicologically significant amounts.

For example, ABS-plastic is not known to exhibit migration of the substances used in the manufacturing, during the normal and foreseeable use of the toy. For such a material it would be sufficient for the chemical safety assessment to include the rationale supporting this position and that no further chemical risk assessment is required.

However, there is no universal rule and there will be a number of exceptions one of which is dealt with below.

Plasticised PVC will exhibit the migration of certain plasticisers from the surface of toy materials. Plasticisers are generally effective solvents for other organic substances and it is envisaged that these other substance still present in the PVC, after the manufacturing process, will also co-migrate to a greater or lesser extent with the plasticiser. There is little data covering the migration of these other substances but a default position that they will migrate should be assumed. For ABS and the polyolefins experience shows that it is very unlikely that the monomers used in the manufacturing will be present at toxicologically significant levels (providing the polymerisation has proceeded effectively). This is critical for ABS as the monomers used include butadiene and acrylonitrile, both of which are CMRs. Incomplete polymerisation will be evident in the final product in any case as the material will not have the usual mechanical and physical properties. However, for some of the other polymers used in toys there is little data covering the migration of substances from toy materials into perspiration and mouth/stomach simulants.

Unless data is available either directly or by deduction, a worst case scenario should be adopted. If data are only available on the content of some substances, a worst case scenario could be to assume that the total content of the substance will migrate and with a 100 %

uptake. If such a worst case scenario show “no risk”, then it can be concluded that a realistic worst case scenario would not pose a risk as well, as it is unlikely that the total content of a substance will migrate and that the uptake will be 100 %.

Dermal exposure

For the majority of toys, dermal exposure due to skin contact will be foreseeable. For mixtures prolonged skin contact should be assumed unless age indication, adult supervision or the liquid being fully encapsulated imply that it is not foreseeable. For example, a small toy soldier for a 5 year old is unlikely to result in prolonged skin contact whereas a soft-filled toy is likely to result in prolonged skin contact.
The area of skin that could be in prolonged contact with the toy will also be of importance when addressing certain substances. A hand-held toy (e.g. the toy soldier) would only affect a small skin area whereas a liquid toy could cover a large area of skin.

The possibility of repeated use of the toy should also be considered. A stamper pad containing ink will generally dry out rapidly whereas a child’s formulated liquid toy could be packaged in a way that allows repeated use.

Oral exposure

Oral exposure includes exposure from ingestion, mouthing, sucking, licking and swallowing of toys. The highest risk of oral exposure is for children up to 18 months of age and it tails off towards 3 years. This does not preclude mouthing and ingestion by older children but the inclination to automatically mouth is behaviour of very young children. The mouthing of products for older children would be foreseeable for e.g. writing instruments, and toys intended to be put in the mouth.

For young children mixtures can readily be transferred to the mouth and should always be considered for this exposure route.

Inhalation

Exposure via inhalation will be highest in the case of toys intended to be entered (e.g. a tent) or intended to enclose the head (e.g. a mask). The actual amount of the substances inhaled is very small due to the dilution effect from the air around the child. There could though be cases where the exposure via inhalation should be investigated even for toys which are not entered or enclosing the head. This could for example be toys like puzzle mats for babies, where the babies are expected to be placed on the mats for longer periods every day with the nose and mouth close to the mat.

Hazardous substances may also be inhaled where a fine aerosol is produced such as in air brush functioning toys but the aerosol is generally away from the user but third parties should be considered.

More information on exposure can be found on following web page:

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/biocidal-products-directive

1.6. Outcome of the chemical safety assessment

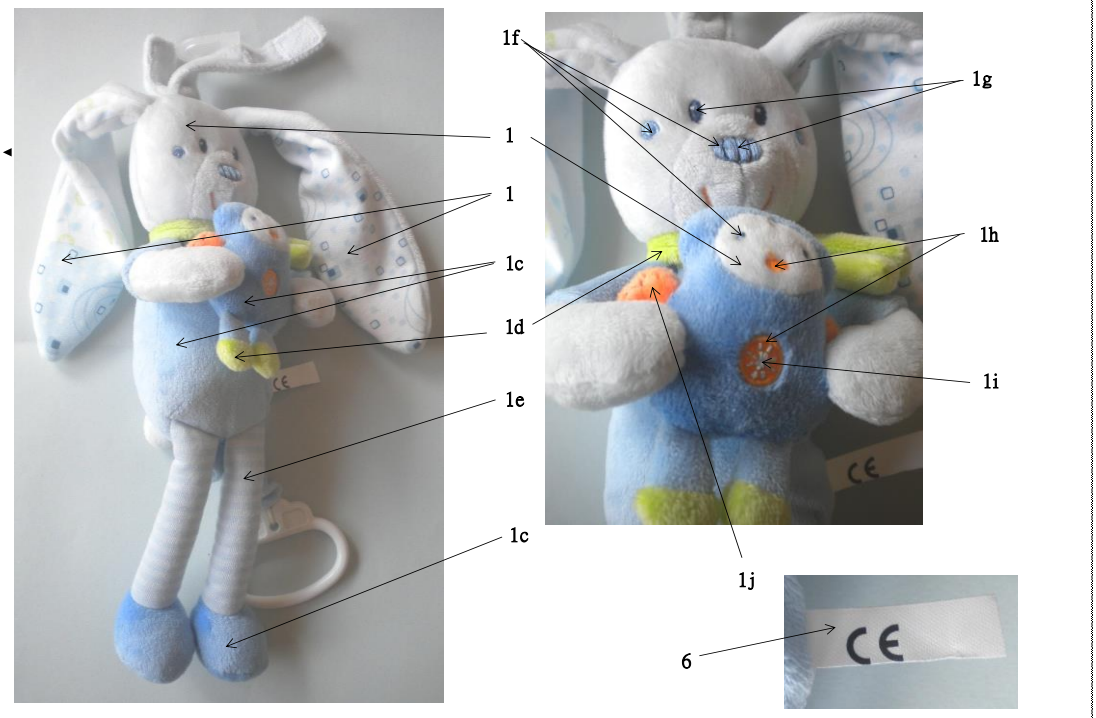
The conclusion of the safety assessment should be a statement regarding the safety of the toy in relation to the safety requirement of Article 18 of the Toy Safety Directive. This could, for the chemical part of the safety assessment, be based on a conclusion for each material or substance that has been listed as potentially hazardous, stating whether its exposure results in a risk that must be managed. Although a toy material might contain a hazardous substance, the substance might not be capable of becoming bioavailable (i.e. there is no exposure and the substance cannot be absorbed in to the body of the child). In toxicological terms, if there is no exposure there can be no risk. For certain materials a no-risk assumption can be made based on experience. For other materials the substances must be identified, their inherent hazards characterized and data on the potential for the substances to migrate has to be identified before the exposure assessment can result in a decision on whether risk management is necessary or not. It should also be emphasized that some substances have a greater potential to migrate than others, and even if the total concentration of one substance is considered to be relatively low, it cannot always be concluded that the migration will be even lower and therefore no risk, without making any analyses and assessment of the exposure and risk.

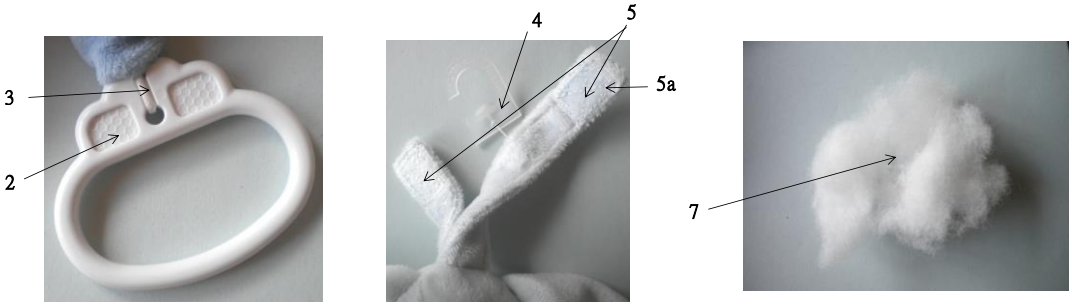
Appendix I: Bill of Materials (BOM) / Bill of Substances (BOS)

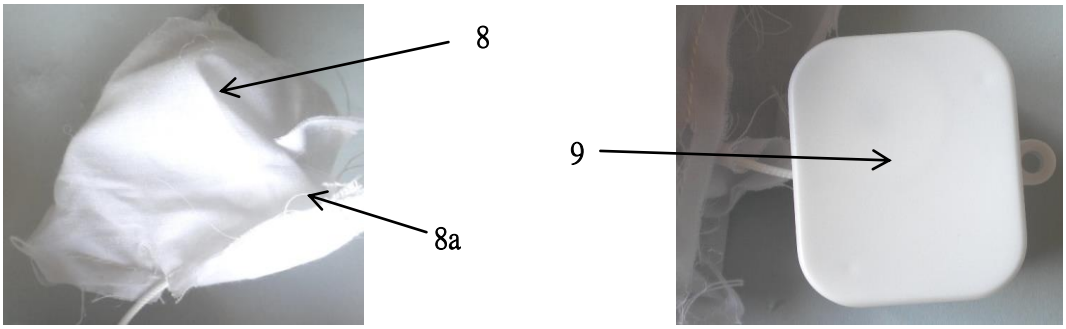
Example 1: Musical soft filled toy

Manufacturer's Name	ABCD
Item Number	147925
Product Name	MUSICAL SOFT FILLED TOY
Age Grade	0 month and over

EXPLODED VIEW







BOM: Bill of Materials

	Product Name:	MUSICAL SOFT FILLED TOY							Item Number:	147925		
	Factory Name:	ABCD							Date:	DD/MM/YYYY		
	Age Grade:	0 month and over							Version Number:	1.00		
Level	Part Name	Part Number	Description	Materials	CAS Number	Concentration in %	Accessible in Final Products	SDS available (Y/N)	Supplier's sub declaration (Y/N)	Source	Wt of comp in grams	Note
1	Musical soft filled toy	147925										
2	Textile - Head	1a	White Textile	Polyester	113669-95-7		Y	N	N	P	168	
2	Textile - Ears	1b	White patterned textile	Cotton	0000-00-0		Y	N	N	P	20	
2	Textile - Body/Feet	1c	Blue textile	Polyester	113669-95-7		Y	N	Y	P	20	
2	Textile - Scarf	1d	Green textile	Polyester	113669-95-7		Y	N	Y	P	7	
2	Textile - Legs	1e	White textile with blue stripes	Polyester	113669-95-7		Y	N	N	P	10	
2	Textile - Stitching	1f	Light blue thread	Polyester	113669-95-7		Y	N	N	P	1	
2	Textile - Stitching	1g	Dark blue thread	Polyester	113669-95-7		Y	N	N	P	1	
2	Textile - Stitching	1h	Orange thread	Polyester	113669-95-7		Y	N	N	P	1	
2	Textile - Stitching	1i	Light grey thread	Polyester	113669-95-7		Y	N	N	P	1	
2	Textile - Arms	1j	Orange textile	Polyester	113669-95-7		Y	N	N	P	3	
2	Filling material	7	Filling fibre	Polyester	113669-95-7		N	N	N	P	15	
2	Musical box	2	Plastic handle	ABS	9003-56-9		Y	N	Y	P	20	
2	Musical box	9	Musical box	HIPS	9003-53-6		N	N	Y	P	50	
2	Musical box	3	Cord	Polyester	113669-95-7		Y	N	Y	P	5	
2	Textile envelope of the musical box	8	Textile envelope of the musical box	Cotton	0000-00-0		N	N	N	P	3	
2	Textile envelope of the musical box	8a	White Stitching thread	Polyester	113669-95-7		Y	N	N	P	1	
2	Label	6	Label	Polyester	113669-95-7		Y	N	N	P	2	
3				liquid Black ink			Y	N		O		
4				Carbon black	1333-86-4	0,3	Y	Y	N	R		
4				Toluene	108-88-3	0,7	Y	Y	N	R		
2	Velcro parts	5	Velcro	Polyester	113669-95-7		Y	N	N	P	2	
2	Velcro parts	5a	White Stitching thread	Polyester	113669-95-7		Y	N	N	P	2	
2	Packaging	4	Plastic hook	Polypropylene	9003-07-0		Y	N	N	P	4	

BOS: Bill of Substances

Product Name:	MUSICAL SOFT FILLED TOY								Item Number:	147925		
Factory Name:	ABCD								Date:	DD/MM/YYYY		
Age Grade:	0 month and over								Version Number:	1.00		

Part Name	Part Number	Description	Materials	CAS Number	Substance name	Function	Concentration in %	Accessible in Final Products	SDS available (Y/N)	Supplier's sub declaration (Y/N)	Source	Wt of comp in grams	Note
Musical soft filled toy	147925												
Textile - Head	1a	White Textile	Polyester					Y	N	N	P	168	
				113669-95-7	Polyester	substrate	1						
Textile - Ears	1b	White patterned textile	Cotton					Y	N	N	P	20	
				0000-00-0	cotton fibre	substrate	0,98						
				2503-73-3	Direct Blue 78	pattern colourant	0,02						
Textile - Body/Feet	1c	Blue textile	Polyester					Y	N	Y	P	20	
				113669-95-7	Polyester	substrate	0,98						
				undisclosed		Blue dye	0,02						
Textile - Scarf	1d	Green textile	Polyester					Y	N	Y	P	7	
				113669-95-7	Polyester	substrate	0,98						
				undisclosed		green dye	0,02						
Textile - Legs	1e	White textile with blue stripes	Polyester					Y	N	N	P	10	
				113669-95-7	Polyester	substrate	0,98						
				17354-14-2	Solvent Blue 35	Blue colourant of the stripes	0,02						
Textile - Stitching	1f	Light blue thread	Polyester					Y	N	N	P	1	
				113669-95-7	Polyester	substrate	0,98						
				17354-14-2	Solvent Blue 35	Light Blue dye	0,02						
Textile - Stitching	1g	Dark blue thread	Polyester					Y	N	N	P	1	
				113669-95-7	Polyester	substrate	0,98						
				14233-37-5	Solvent Blue 34	Dark Blue dye	0,02						
Textile - Stitching	1h	Orange thread	Polyester					Y	N	N	P	1	
				113669-95-7	Polyester	substrate	0,98						
				2481-94-9	Solvent Yellow 14	Orange dye	0,02						

Textile - Stitching	1i	Light grey thread	Polyester					Y	N	N	P	1	
				113669-95-7	Polyester	substrate	0,98						
				4395-53-3	Vat Black 25	Light grey dye	0,02						
Textile - Arms	1j	Orange textile	Polyester					Y	N	N	P	3	
				113669-95-7	Polyester	substrate	0,98						
				2481-94-9	Solvent Yellow 14	Orange dye	0,02						
Filling material	7	Filling fibre	Polyester					N	N	N	P	15	
				113669-95-7	Polyester	substrate	1						
Musical box	2	Plastic handle	ABS					Y	N	Y	P	20	
				9003-56-9	ABS	base resin	1						
Musical box	9	Musical box	HIPS					N	N	Y	P	50	
				9003-53-6	HIPS	base resin	1						
Musical box	3	Cord	Polyester					Y	N	Y	P	5	
				113669-95-7	Polyester	substrate	1						
Textile envelope of the musical box	8	Textile envelope of the musical box	Cotton					N	N	N	P	3	
				0000-00-0	cotton fibre	substrate	1						
Textile envelope of the musical box	8a	White Stitching thread	Polyester					Y	N	N	P	1	
				113669-95-7	Polyester	substrate	1						
Label	6	Label	Polyester					Y	N	N	P	2	
				113669-95-7	Polyester	substrate	0,95						
			Dried Black ink				0,05	Y	N		O		
				1333-86-4	Carbon black	black colourant	0,02	Y	Y	N	R		
				108-88-3	Toluene	Ink solvent	0,03	Y	Y	N	R		
Velcro parts	5	Velcro	Polyester					Y	N	N	P	2	
				113669-95-7	Polyester	substrate	1						
Velcro parts	5a	White Stitching thread	Polyester					Y	N	N	P	2	
				113669-95-7	Polyester	substrate	1						
Packaging	4	Plastic hook	Polypropylene					Y	N	N	P	4	
				9003-07-0	Polypropylene	base resin	1						

Example 2: Bottle with bubble solution

Product Name : Bottle with bubble solution

Date: July 18, 2011

Identification Code: B20A5

Description	Part number	Number used	Material, Substance, Component	CAS, EINECS or CI	SDS required Y/N	Supplier's sub-declaration/test report present Y/N
Bottle Sub Assembly	1	1	PVC with colourant/plasticiser	NA		Y
CAP	2	100mg	PVC resin	9002-86-2	N	
CAP		100mg	Plasticiser	EC 229-176-9 CAS 6422-86-2	N	
CAP		1mg	Colourant		N	Y
Sticker	3	1	Printed Material on paper	NA		Y
Wand	4	1	PE resin	9002-88-4	N	
Bubble Solution	5	0,1 ml	Dodecanamide, N,N-bis(2-hydroxyethyl)	120-40-1	N	
Bubble Solution		0,5 ml	Glycerol	56-81-5	N	
Bubble Solution		0,5 ml	Sodium 2-[2-[2-(tridecyloxy)ethoxy]ethoxy]ethyl sulphate	25446-78-0	N	
Bubble Solution		0,5 ml	2-chloroacetamide	79-07-2	Y	
Bubble Solution		15 ml	Distilled Water	7732-18-5	N	

Appendix Ia Model letter recommending BOM/BOS template to suppliers

Dear Supplier:

On 30 June 2009, the new Toy Safety Directive (2009/48/EC) was published. The purpose of this letter is to communicate the obligation to supply certain information, which is needed to satisfy the mandatory requirements of this Directive.

The new Toy Safety Directive text requires that the technical file contains:

'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 supplier'

The Directive requires that the manufacturer (factory) is responsible for providing the technical file. Hence, the factory would be expected to supply a Bill of Materials (BOM)/Bill of Substances (BOS) as a part of the technical file that is generated for the toy. This is **a mandatory requirement**, which cannot be avoided for any reason, including commercial confidentiality.

There has already been much guidance from the European Union (EU) and other bodies as well as discussion about what a 'list of components and materials' actually refers to. In industry, a BOM/BOS is normally used to define the parts and materials used in a product so that it will satisfy the requirements.

From experience, we know that most factories have the BOM/BOS available because this is essential to the manufacturing process. However, there may be some confusion about what to include and what format to use for compliance purposes. Although this not defined, the BOM/BOS must include a minimum level of detail that allows the toy to be evaluated to ensure that it complies with the Toy Safety Directive, in particular the chemical requirements of the Directive. However, various formats have been designed by the EU, Toy Industries of Europe (TIE), the British Toy & Hobby Association and others, and these can be used as a template.

The BOM/BOS should show the parts and materials used to manufacture the toy and this information should be structured into levels where the finished toy is at the top (level 1). The levels identified may vary according to the complexity of the toy itself and how much of it is manufactured in house or purchased by the factory. When showing the parts that were purchased (for a part, sub-assembly, formulation or substance), the BOM/BOS should show how compliance to the legislation should be achieved (e.g. whether by declaration or testing).

The BOM/BOS example that is provided with this letter aims to provide a model format that contains both the detailed technical information required by the Toy Safety Directive and sufficient information in order to carry out a chemical safety assessment. Other BOM/BOS formats may be necessary where manufacturers use commercially available chemical safety assessments services or where manufacturers have already established their own system of collating the required information from their suppliers. In the absence of other BOM/BOS formats, it is highly recommended to adopt the accompanying model format.

We appreciate your support in working with us to ensure that we comply with the legal requirements in the Toy Safety Directive.

Yours faithfully,

Appendix Ib Model supplier's subdeclaration

SUPPLIER'S SUB-DECLARATION - TOY SAFETY DIRECTIVE 2009/48/EC

Specific Chemical Requirements

The Toy Safety Directive 2009/48/EC (TSD) (see link) applies to all toys placed on the European market from 20 July 2011 and requests manufacturers to draw up a technical file containing in particular the following (Annex IV of the TSD):

(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.

With regards to the chemical requirements, toys shall, when applicable, comply with the EN 71 harmonised standards series.

The Toy Safety Directive also requires compliance with the following chemical requirements, which are relevant for the purpose of this supplier's declaration:

Article 10 Essential safety requirements

1. Member States shall take all measures necessary to ensure that toys may not be placed on the market unless they comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2, and, as far as the particular safety requirements are concerned, in Annex II.
2. Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

Annex II - Particular Safety Requirements - Chapter III - Chemical Properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first subparagraph of Article 10(2).
Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.
2. Toys that are themselves substances or mixtures must comply also with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures.

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

The European Commission issued several guidance documents about the application of the TSD and in particular one related to the technical documentation (see link).

This guidance document explains in more details how to carry out a safety assessment. For the chemical aspects of the safety assessment, the following TSD restrictions should be taken into account:

- Substances classified as CMR (Carcinogenic, Mutagenic or Toxic for reproduction), considering the additional requirements in Appendixes A and C of the TSD

- Fragrances

Some substances, although not restricted because they do not have a CMR classification, are still potentially unacceptable in toy materials because they have other health effect classifications or are commonly known as undesirable in toys. Acute toxicity, corrosive properties, and the ability to trigger allergic reactions are examples of intrinsic properties that can be hazardous to health.

The use of the Safety Data Sheets (SDS) (see link) that may exist for a particular substance should be used when assessing whether that substance could be harmful to children when used in toys.

The Toy Safety Directive requires that toys comply with the REACH Regulation 1907/2006 (see link). This regulation contains some specific requirements and restrictions in its annex XVII (e.g. for Azo-colorants, Benzene, Cadmium, Nickel, Phthalates, etc.) and defines SVHC (Substances of Very High Concern) in its article 57.

The Toy Safety Directive requires that toys comply with other relevant Community legislation relating to certain categories of products (see link).

Some European countries also apply their own additional national chemical regulations to toys. A list of these additional regulations can be found in the technical documentation guidance document (see link).

By signing this document, you declare that the supplied toy materials / toy components, which are listed below, comply with all the above relevant requirements.

- **(list to be completed by the supplier)**

By signing this document, you take responsibility:

- **to immediately advise the recipient of this declaration of any change in the chemical composition of the supplied toy materials/toys components and to take the necessary measures to demonstrate compliance with the above relevant requirements, and,**
- **to monitor any change in the above relevant requirements and to take the necessary measures to demonstrate compliance of the affected supplied toy materials/toy components.**

Company name and address: **Name and Title of the Signatory:**

Date, signature and company stamp:

Note: all elements highlighted in red shall be completed.

Appendix II EU legislation applicable to toys

EU legislation applicable to toys

Many chemical substances and mixtures are already prohibited or restricted for use in toys. Other substances are in the process of becoming prohibited or restricted and yet others are under discussion as being undesirable for use in toys.

General lists of prohibited or restricted substances in e.g. toys can be found in:

- Directive 2009/48/EC on the safety of toys
- Directive 2011/65/EU 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)
- Regulation (EC) No 850/2004 on persistent organic pollutants
- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Cosmetic toys must also comply with Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

For toys or their parts and their packaging that can reasonably be expected to be brought into contact with food (e.g. toy tea cups) must comply with Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Toys that are themselves substances or mixtures e.g. poster paints, finger paints, slimes, modelling compounds, experimental sets need to comply the CLP Regulation (EC) No 1272/2008 related to classification, packaging and labelling.

The above mentioned Directives and Regulations and those in the following Table 1, are of course mandatory to comply with (if applicable).

Table 1: Compilation of European chemical legislation applicable to toys, including national regulations.

Important: for the latest updates on European legislation, please verify the European Commission's webpages.

Regulation	
Cosmetics Regulation (EC) No 1223/2009	http://ec.europa.eu/growth/sectors/cosmetics/index_en.htm
Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food	http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm
Directive 84/500/EEC relating to ceramic articles intended to come into contact with foodstuffs.	http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm
Directive 2011/65/EU RoHS	http://ec.europa.eu/environment/waste/rohs_eee/index_en.htm
Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators	 http://ec.europa.eu/environment/waste/batteries/index.htm

Regulation (EC) No 850/2004 on persistent organic pollutants	http://ec.europa.eu/environment/pops/index_en.htm
Regulation (EC) No 1907/2006 REACH restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	http://ec.europa.eu/growth/sectors/chemicals/legislation/index_en.htm http://ec.europa.eu/growth/sectors/chemicals/reach/restrictions/index_en.htm

DK	Phthalates	Toys	Statutory order no. 855 05/09/2009 on a ban on phthalates in toys and childcare articles. Denmark has a ban on all esters of o-phthalic acid, that are not regulated in REACH, in toys for children from 0-3 years and childcare articles for children from 0-3 years which are intended or normally can be expected to be placed in the mouth. The concentration limit is 0.05 % and the ban applies for the homogeneous parts of the product.
DK	Lead	Toys	Statutory order no. 856 05/09/2009 banning the import or sale of products containing lead. Denmark has a ban on the import and sale of chemical lead in all products with a limit of 100 ppm. Lead as metallic lead is only banned for some uses. The uses that could be relevant for toys are hobby products, products for decoration, including jewellery and bijouterie. The limit value for metallic lead is also 100 ppm and

			the ban applies for the homogeneous parts of the product.
DK	Cadmium	Coating Stabilizer	Statutory order no. 858 05/09/2009 banning the import, sale and manufacture of products containing cadmium. Denmark has a ban on the import, sale or manufacture of products in which cadmium has been used as a surface treatment (cadmium plating), colour pigment or plastic stabiliser. The limit value is 75 ppm and the ban applies for the homogeneous parts of the product.
DK	Mercury	Toys	Statutory order no. 627 01/07/2003 banning the import, sale and export of mercury and mercury-containing products. Denmark has a ban on the import, sale and export of products containing mercury including toys. The limit is 100 ppm and the ban applies for the homogeneous parts of the product.
SE	Mercury and methylene chloride, trichloroethylene, or tetrachloroethylene	Toys	Chemical Products (Handling, Import, and Export Prohibitions) Ordinance (1998:944) and in Chapter 5 of the Chemical Products and Biotechnical

			Organisms Regulations (KIFS 2008:2).
FI	Formaldehyde	Textiles	Government Decree on the maximum amounts of formaldehyde in certain textile products, (Finnish Statute Book 233/2012)
FI	Phenol	Toys	a recommendation from former National Board of Health
CZ	Formaldehyde	Toys for children < 3 – textile parts	30 mg/kg of free and hydrolysable formaldehyde Decree of Ministry of Health No.84/2001, as amended through 521/2005
CZ	Primary aromatic amines	Toys for children < 3 – textile parts	0,05 mg of Anilin Hydrochloride Decree of Ministry of Health No.84/2001, as amended 521/2005
CZ	Pathogenic and conditionally pathogenic microorganisms	Toys for children < 3	0 Decree of Ministry of Health No.84/2001, as amended 521/2005
CZ	Organostannic stabilizers	Plastic toys for children < 3	0

			Decree of Ministry of Health No.84/2001, as amended 521/2005
CZ	Azodyes producing hazardous aromatic amines	Plastic toys	0 Decree of Ministry of Health No.84/2001, as amended 521/2005
CZ	Dyes	Toys for children < 3	no migration Decree of Ministry of Health No.84/2001, as amended 521/2005
CZ	Optical brighteners	Toys for children < 3	no migration Decree of Ministry of Health No.84/2001, as amended 521/2005
CZ	Selected phthalates	Plastic toys for children < 3	0,1 % Decree of Ministry of Health No.84/2001, as amended 521/2005
NO	Mercury and mercury compounds	Toys	Product regulations Article 2.3: Limit of 0.001 % by weight. Exception for products regulated elsewhere (REACH, RoHS, etc.).

NO	Formaldehyde	Textiles	Product regulations Article 2.10: Limit of 30 mg/kg textile for children < 2 years, otherwise 100 mg/kg.

National legislation non chemical related

DE	Toys intended for children under 36 months and toys intended to be placed in the mouth made of polymers, paper and board	Recommendation XLVII of January 2003
	Balloons	Modified Bedarfsgegenständeverordnung of December 1997
NL	Balloons	Besluit van 12 april 2010 Beleidsregel inzake normen veiligheid van ballonnen (Decree of 12 april 2010 – rules to be followed with regards to the safety of balloons)
FR	Stuffed bedding items	Decree 2000-164 Prevention of risks resulting from the use of bedding items (EN ISO 12952-1 et -2)

	Video games	Decree 96-360 relative to warnings for video games
	Toys attached to candies	Decree 2006-286 modified by Decree 2007-467 relative to products made of a candy and non edible elements, attached to it at the moment of consumption
UK	Electrical plugs and sockets	BS 1363 Plugs and Socket Regulations
	Upholstered furniture	The Furniture and Furnishings (Fire) (Safety) Regulations 1988 (as amended in 1989 and 1993)
	Writing instruments	BS 7272 Parts 1 and 2 : 2008 Writing and Marking instruments
	Toy firearms	Violent crime reduction act / BTHA Code of practice for toy firearms
DK	Water yo-yos	Bekendtgørelse om forbud mod udbud,

		forhandling og distribution af vandyoyoer nr. 365 af 23. maj 2003
BE	Yo-yo	22 MAI 2005. — Arrêté royal portant interdiction de la mise sur le marché de jouets de type yo-yo élastique comportant une boule remplie d'un liquide
	Magnetic toy	25 JUILLET 2008. — Arrêté royal obligeant l'apposition d'un avertissement sur les jouets magnétiques

Appendix III Materials that have been known to contain prohibited/restricted substances

Some examples of substances that can potentially be present in various materials or additives are given below (the list is not comprehensive):

- Plastics and rubber can contain lead contaminants, chromates, tin contaminants, chloroparaffins, phthalates and possibly polyaromatic hydrocarbons and nitrosamines.
- Textiles can contain formaldehyde, anti-mildew agents, flame retardants, dyes and impregnation agents, such as PFOS (Perfluoroctane sulphonate)
- Leather can contain tanning substances such as chrome
- Metals are basic elements such as lead, iron, copper, mercury, aluminium, nickel, silver, tin and zinc. Most metals found in commercial toys are in the form of alloys (special mixtures of different metals having distinct properties which are different to those of the individual constituents. For example stainless steel, for which the use of nickel is authorized in toys (Appendix A of the directive). Some metals like lead, cadmium,… have already been assessed and should not be intentionally used in those parts of toys that are accessible to children.
- Glass can contain lead, arsenic or antimony
- Wood can contain wood preservatives which in turn can contain chrome, arsenic, copper, creosote, etc.
- Paper can contain colouring agents that may contain heavy elements

It can often be helpful to consider if the material has been given certain functionality and in that case how this has been achieved. For example, have chemicals been added to give the material a colour, a fragrance, a preservation, fire protection, impregnation, mildew protection, softness, etc.

See also Appendix IV for information on sources of information that can be consulted regarding undesirable chemical substances.

Appendix IV Sources of information regarding undesirable chemical substances

- Industry associations
- The CLP (Classification Labelling and Packaging)-list which can be found e.g. on ECHA's website (www.echa.eu)
- The European Chemical Agency (ECHA) list of SVHC (Substances of Very High Concern) (www.echa.eu)
- International Agency for Research on Cancer (IARC) (http://www.iarc.fr)
- The REACH SIN-list (Substitute It Now) (http://www.sinlist.org)
- The California Government's Office of Environmental Health Hazard Assessment (OHEEA), Proposition 65 - Chemical Listed as Known to the State of California to Cause Cancer (http://oehha.ca.gov/prop65/prop65_list/Newlist.html)
- Databases such as the Swedish Chemical Agency's "PRIO-database" (www.kemi.se)
- Toxicological databases
    - ChemIDPlus Lite - http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
    - ChemIDPlus Advanced - http://chem.sis.nlm.nih.gov/chemidplus/
- The EU rapid alert system for all dangerous consumer products for the rapid exchange of information between Member States (RAPEX) (http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm)
- Restrictions for eco-label products. For examples of eco-labels, see: http://ec.europa.eu/environment/ecolabel/other-ecolabels.html
- EU Risk assessments and Impact assessments (e.g. http://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation)
- Homepages of Test houses and Research institutes
- Company specific "restricted substances lists" (some companies publish these on the internet)
- Internet search engines such as www.google.com