

Safety Assessments Revised Toy Safety Directive 2009/48/EC

Contents

1. Obligations of Economic Operators
2. Introduction
3. Overview
4. How to use this guide
5. Approach to Safety Assessment
6. Documenting the Safety Assessment
7. Generic Safety Assessment Process
8. Chemical Safety Assessment Process

Appendix 1 – Sources of Hazard Information

Appendix 2 - Risk Assessment

Appendix 3 - Risk Reduction

Record of Amendments			
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2	03.06.11	Removed mention of document format in appendix and non-working nomograph weblink.	Page 3 Section 4 Page 6 Step 5
3	10.5.13	Addition of authorised Representative obligation. Incorporation of chemical safety assessment guide. Various other editorial changes	

LEGAL NOTICE

This document contains guidance only.

It is intended to explain obligations and how to fulfil them. However readers are reminded that the text of the original regulation, directive or standard is the only authentic legal reference and that the information in this document does not constitute legal advice.

The British Toy and Hobby Association does not accept any liability with regard to the contents of this document.

1. Obligations of Economic Operators

Obligation	Manufacturer		Importer		Distributor	Authorised Representative
Carry out the Safety Assessment	A4(2) A18	Obligated	A6(2)	Ensure its done	No obligation	No obligation

See separate BTHA guidance on the Obligations of Economic Operators which should be read first.

2. Introduction

The revised Toy Safety Directive (2009/48/EC) was adopted by the European Parliament on 18 December 2008 and the final text was formally adopted and published in the Official Journal of the European Union (OJ) on 30 June 2009. From this date, the overall timetable for implementation of the subject covered by this guidance document is July 2011.

Article 18 of the revised Toy Safety Directive specifies the following obligation for 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.

3. Overview

There is no set format within the Directive for Safety Assessments, however the potential sources of hazards are specified - *chemical, physical, mechanical, electrical, flammability, hygiene & radioactivity*.

Safety Assessments are mandatory for each toy and must be carried out before they are placed on the market. Changes in the design or characteristics of the toy or changes in harmonised standards applied or the identification of new hazards would require a review of the Safety Assessments.

Safety Assessments must be documented and held within the Technical Documentation.

This document provides a suggested approach for conducting a **Generic Safety Assessment** and an approach to the conducting the **Chemical Safety Assessment**.

Provided within this guide are flow charts giving a step-by-step approach for Safety Assessments, a basic summary of assessing risk and a suggested format for documenting each stage of the process.

In order to carry out a Safety Assessment three key skills are required:

- a detailed knowledge of the requirements of safety standards
- the ability to identify hazards
- the ability to evaluate risk

This document includes a suggested approach for conducting a **Chemical Safety Assessment** using a materials based approach. In order to follow this guidance it is necessary that information or expertise is available the likelihood of materials containing prohibited or limited substances or

substances that have been identified as a potential safety concern. This would include information regarding

- Regulated substances and the materials that are at risk of containing those substances,
- Substances that may be of a safety concern when used in toys.
- Restricted substances likely to be present in materials

With regards to the Chemical Safety Assessment, this guide predominantly shows how the information from the Toyograph ^{™1} tool can be used in carrying out a chemical Safety Assessment but the principles can be used when using other similar materials based information packages.

Where companies have any doubt about their ability to conduct a Safety Assessment third party expert help may be needed.

4. How to Use This Guide

This document describes the approach to the Safety Assessment, acknowledging that most of the hazards associated with toys are addressed by standards. Hereafter the guide is divided into two sections:

Section 6 concerns the Generic Safety Assessment. It is envisaged that this approach can be used to cover potential hazards related to the physical, mechanical, electrical, flammability, hygiene & radioactivity aspects of toys.

Section 7 concerns the Chemical Safety Assessment, which differs slightly as it uses a materials based approach.

Each section contains a flow chart showing the stages and this is followed by explanatory guidance for each step.

In order to use this guide, full details of the toy's specification is required together with a detailed Bill of Materials for the toy that will allow identification of the materials used to make the toy.

5. The Approach to the Safety Assessment

The Safety Assessment is intended to identify, assess and manage the hazards presented by a toy. Safety Assessments can be carried out at any stage within the development of a product. It is advantageous to carry out the assessment as early as possible in the conceptual/development cycle and to revisit the assessment at key stages in the development cycle as the product changes. More options are available for reducing risk at early stages of development. For example if the assessment is done at concept stage, the hazards presented (and therefore risks) can be reduced by design changes, correct selection of materials, functional changes etc. However for a finished product risk reduction methods may be limited to instructional changes and warning statements or by possibly by rejection of the product.

Regardless of the stage(s) at which the Safety Assessment is carried out, it is essential that the documented Safety Assessment reflect the final product to be placed on the market.

¹ The Toyograph, is an on-line 'Chemical Toolkit' which has been developed in partnership with the British Toy & Hobby Association (BTHA) and Bureau Veritas Consumer Products Services. The toolkit, exclusively available to BTHA members and Bureau Veritas' clients, provides an easy to use on-screen industry programme for material checks and aims at helping companies meet the challenges of the chemical requirements of the new Toy Safety Directive.

Many of the hazards that may be presented by a toy have already been identified and this has usually led to the development of reputable safety Standards, Directives, Regulations and industry codes of practice to manage these hazards. Because most hazards are already addressed, it is not considered necessary to revisit all of them again other than to establish that they are effectively managed by the existing standards. For instance, it is unnecessary to evaluate the potential hazard of sharp edges as this is already addressed by compliance with EN71-1. Likewise it would be unnecessary to evaluate the exposure to elements covered EN71-3 if the toy complies with that standard.

After a first assessment using the safety standards there may be a shortlist of remaining hazards that are outside of the scope of the selected standards. These remaining hazards need to be assessed to determine the probability of them causing injury and the severity of the injury (i.e. the risk).

With regards to the chemical Safety Assessment, the process is similar; after the initial assessment using the safety standards there may be list of hazardous substances that are outside of the scope of the selected standards. For example some restricted substances do not have a related safety standard (e.g. fragrances) and in these cases the Safety Assessment should consider the likelihood of the substances being present in a material and any safety risk to a consumer. These remaining substances need to be assessed to determine exposure to that substance in the toy concern and the severity of the injury / exposure to a substance (i.e. the risk).

For chemicals from 20th July 2013 the same process will apply however there are some significant differences. For example in some cases the substance may be present, may be below any legislative levels or the consumer may not be exposed to it in normal use.

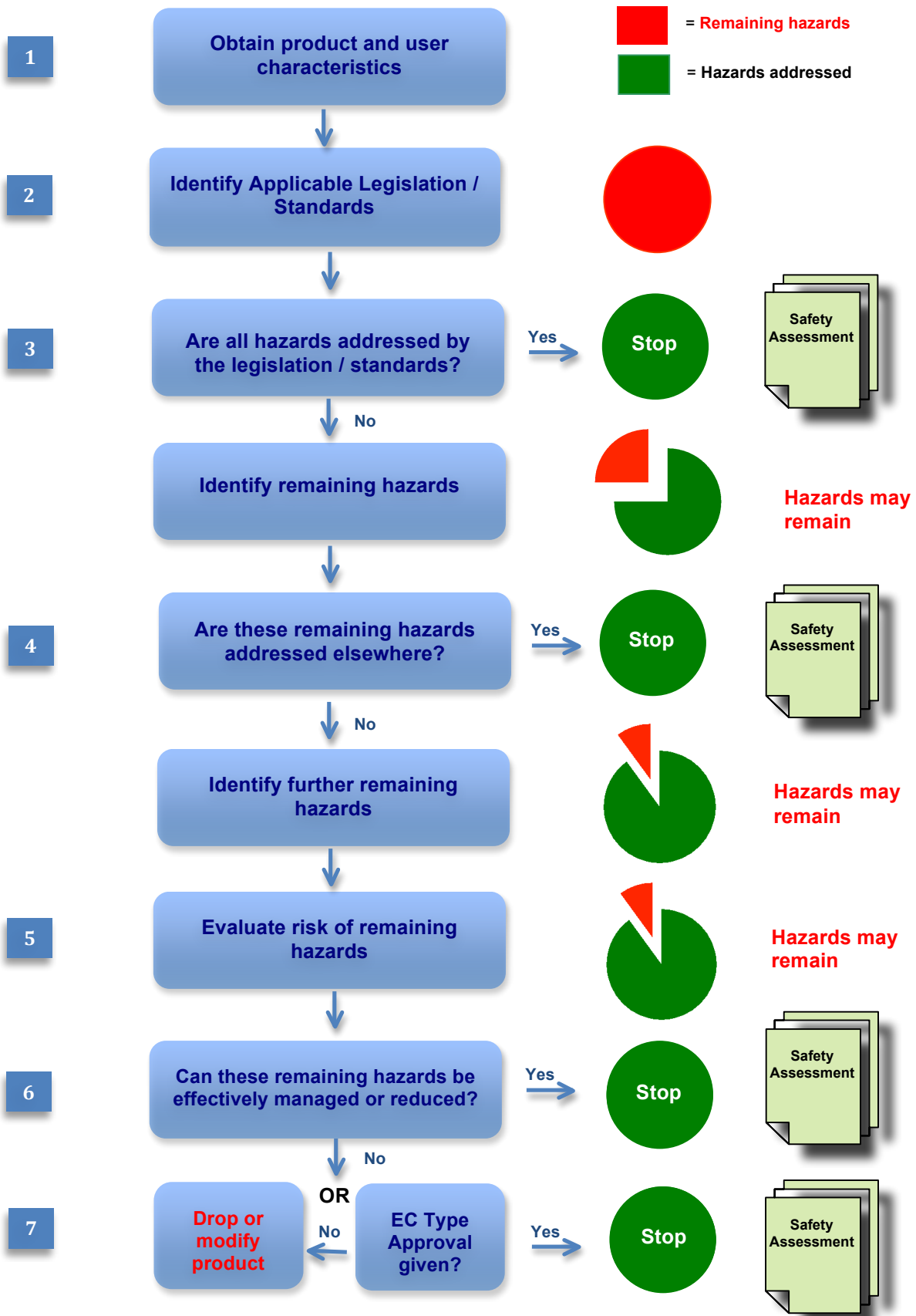
This approach means that instead of having a tick list exercise for known and controlled hazards the maximum attention is directed to these remaining hazards.

6. Documenting the Safety Assessment

A Safety Assessment must be documented and retained with the Technical Documentation for the product. Safety Assessments must be stored and collated in line with the requirements for Technical Documentation **separate BTHA guidance is available regarding this.**

There is no set format for documenting Safety Assessments and companies are therefore able to design their own format or combine documentation and appraisals they already use to support this obligation.

7. Generic Safety Assessment Process (for Chemical Safety Assessment see section 8)



Generic Safety Assessment Steps

1 *Obtain Product and User Characteristics*

In order to carry out a Safety Assessment product details and user characteristics are required including:

- Intended design and function
- Samples / drawings
- Intended user characteristics (including age)
- Intended and likely play patterns (foreseeable use)
- Materials used e.g Bill of Materials (BoM)
- Formulation used e.g Bill of Substances (BoS) for liquids, gels, inks etc.
- Play environment
- Markets of sale
- Instructions
- Existing warning statements
- Packaging artwork

Availability of such details may vary depending on the stage in the development process at which the Safety Assessment is being carried out.

2 *Identify Applicable Legislation / Standards*

The majority of potential hazards that may be presented by a product are already addressed in existing standards, Directives and other legislation applicable to toys. You need to determine which of these apply to your toy.

A list of standards and legislation applicable to toys can be found on the BTHA website.

Full BTHA members also have full access to BS Online, which is a free service where safety standards applicable to toys can be viewed.

3 *Assess any hazards not addressed in Applicable Legislation / Safety Standards*

In order to carry out a Safety Assessment a detailed knowledge of the safety standards and the ability to identify hazards presented by a toy is required. Where companies have any doubt about their ability to conduct a Safety Assessment third party expert help may be needed.

The majority of hazards that are potentially presented by the toy are already addressed in these documents. For example, potentially hazardous edges are fully addressed by the requirements in EN71-1 and exposure to some toxic elements is addressed in EN71-3. Not all hazards will be applicable to all products. For example, if there is no electrical function then the hazards related to electricity will not exist.

Certain unique and unusual aspects related to the toy or the use of technologies that are not usually associated with toys may lead to hazards that are not already addressed by applicable legislation and safety standards.

The following are examples of such aspects that should be considered when assessing the toy.

- Unusual play patterns - products being used in a different way to that intended
- Unusual play environments - toy intended for indoor use being played with outside
- Innovative materials - a recent example being strong magnets
- Atypical age grading – consider the mental capability and dexterity skills of the intended user.
- Hygiene - leading to bacterial and microbiological hazards
- Cultural differences - may have a bearing. e.g. differing national festivals
- Technological innovations – new uses of technology not usually associated with toys
- Other hazards – examples of sources that may help identify potential hazards can be found in

Appendix 1

Carrying out this analysis may show that all potential hazards are adequately addressed as long as the product complies with the safety standards. If this is the case it must be documented as the Safety Assessment within the Technical Documentation. In some cases hazards that are not adequately addressed by safety standards may be identified, these remaining hazards must be documented. The Safety Assessment continues to Step 4.

4 *Assess if the Remaining hazards are addressed elsewhere*

Having evaluated the toy, and identified any remaining hazards consider whether any other Standards (not only EU Standards), EU Guidance or industry codes of practice are available to manage these hazards.

For instance the potential choking hazard that is presented by pen caps and end closures is not addressed by EN71 but is addressed in BS7272. Similarly, if a toy gun could be confused with a real firearm, the BTHA / TRA / Equitoy Toy Gun Code of Practice could be used to address this remaining hazard.

If additional guidance, standards or other legislation is considered to adequately cover the remaining hazards this must be documented within Safety Assessment within the Technical Documentation.

In some cases there may still be some remaining hazards not adequately addressed by these additional sources. These remaining hazards must be documented and the Safety Assessment continues to Step 5.

5 *Evaluate the risk of any Remaining hazards*

In order to carry out a risk assessment a detailed knowledge of risk assessment tools is required. Where companies have any doubt about their ability to conduct a Safety Assessment third party expert help may be needed.

When no standard or code of practice exists that addresses these remaining hazards, the hazards should be risk assessed. For example a Toxicological Risk Assessment by a suitably qualified person may be appropriate for a formulation (e.g. inks) to fully manage the chemical risks not covered in EN71-3. Most risk assessments are performed by considering the relationship between the likelihood of the hazard causing injury and the potential severity of the injury.

There are a number of different risk assessment tools that can be used. No one tool is necessarily better than another and companies can decide to adopt an existing method or can decide to use their own in-house method. For further details concerning approaches to Risk Assessment see **Appendix 2**.

6 *Reduce and Manage these Hazards*

Decisions need to be made regarding how to manage these remaining hazards. In some cases hazards cannot be eliminated sensibly and they will always remain. They are inherent to the product. There is no such thing as a “no risk” product. For example falls from climbing frames can never be eliminated. However, if a risk can sensibly be addressed or minimised, it should be.

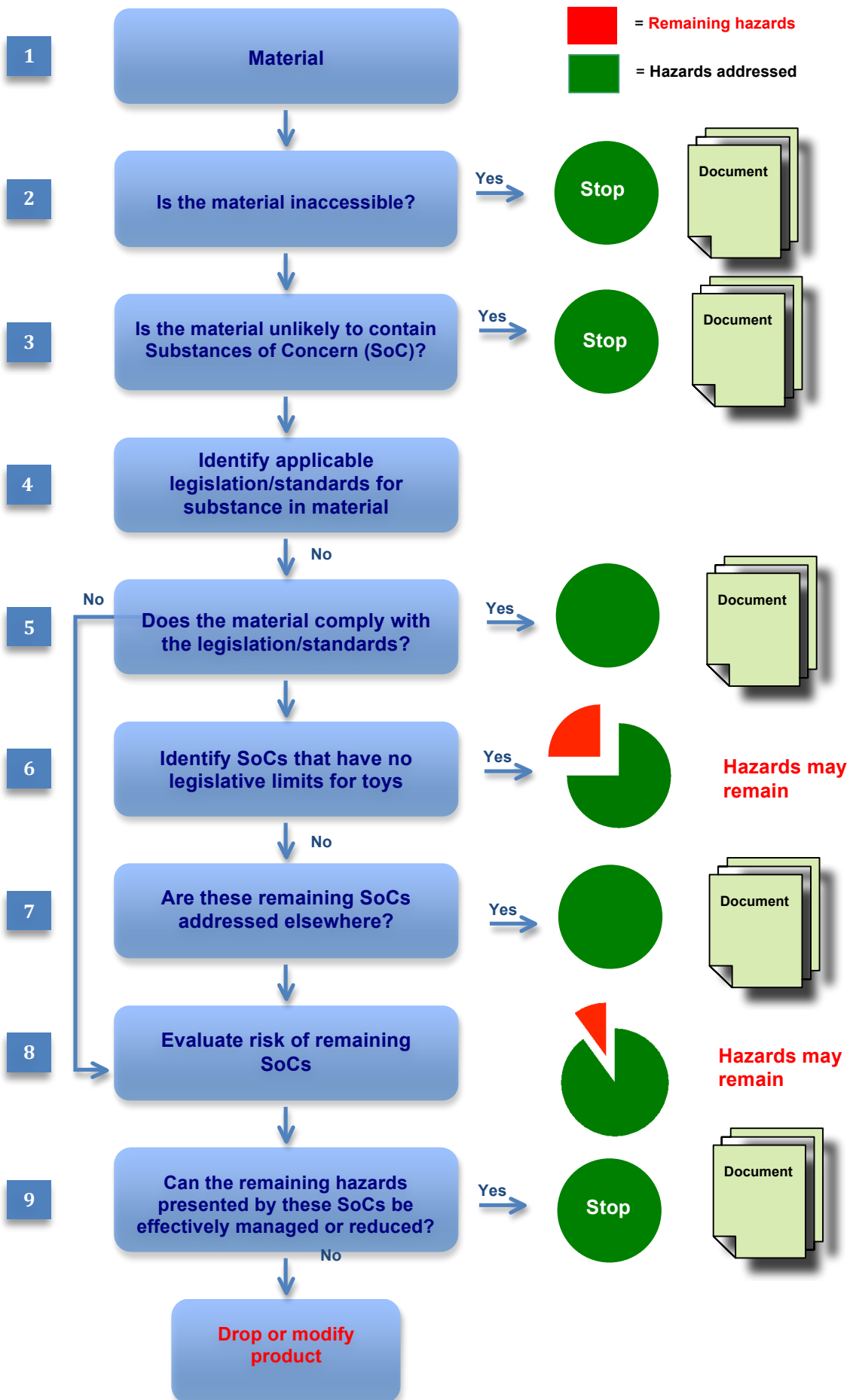
The actions taken must be proportionate to the level of risk identified. Example of measures aimed at reducing the risk can be found in **Appendix 3**.

Where there are risks that cannot be effectively managed or there is still doubt about the risk presented by the toy, EC Type Approval may be necessary to comply with the Toy Safety Directive. EC Type approval may only be conducted by approved Notified Bodies. These are specially qualified laboratories who may be asked to assess a toy against the provisions of the Directive itself, rather than merely applying the usual safety standards.

In addition EC Type Approval is required in the following cases, as referred to in Article 20, together with the conformity to type procedure set out in Module C of Annex II to Decision No 768/2008/EC:

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

8. Chemical Safety Assessment Process



Chemical Safety Assessment Steps

1 *Material*

Identify each material from the Bill of Materials for that toy.

The following steps need to be carried out for each material and each Substance of Concern (if applicable). The outcome of each material assessment needs to be recorded in the Technical Documentation for that toy. All material assessments should finally be collated together to form the Chemical Safety Assessment for the toy.

2 *Is the Material Inaccessible?*

If the material is not accessible in foreseeable use it is unlikely that there will be any exposure to any hazardous substances that may be found in that material.

3 *Is the material unlikely to contain Substances of Concern (SoC)*

There could be a risk that Substances of Concern may be present in the material. A Substance of Concern is a restricted substance or a substance that has been identified as a potential safety concern. If it is unlikely that Substances of Concern will be found, this should be documented in the Chemical Safety Assessment.

It is necessary that information or expertise is available the likelihood of materials containing Substances of Concern. This would include information regarding

- Regulated substances and the materials that are at risk of containing those substances,
- Substances that may be of a safety concern when used in toys.
- Restricted substances likely to be present in materials

Such information is found in the Toyograph™. Substances of Concern are termed “Priority Substances in the Toyograph™”.

Where companies have any doubt about their ability to conduct a Safety Assessment third party expert help may be needed.

If Substances of Concern have been identified the following steps need to be followed for each substance.

The material needs to be assessed to determine if it is a “generic” material or if it is likely to contain any specialist additives. If the material is unusual in any way, Manufacturers must obtain further information about the additives that may have been used and these must be assessed in the following steps.

4 *Identify Applicable Legislation / Standards for the substance*

The majority of Substances of Concern that may be at risk of being found in a material will be cited by legislation.

It may be the case that there are limits for substances in the material, however the scope of the legislation should be considered as these limits may only apply to accessible materials or materials likely to be mouthed.

Furthermore it may be the case that some Substances of Concern are regulated by more than one piece of legislation, e.g. cadmium has limits for migration in EN71 Part 3 and total content in REACH and in RoHS.

5 *Does the material comply with the legislation/standards?*

In most cases if you can demonstrate compliance with the legislation for each of the listed Substances of Concern, the material in question can be considered as low risk for that substance. There is no need to carry out additional Safety Assessments with regards to the material and substance as the legislation will have taken into account any potential hazards and limits set accordingly.

Demonstration of compliance should be documented in the chemical Safety Assessment.

6 *Identify Substances of Concern that have no legislative limits that apply to toys*

In rare cases there could be a risk that Substances of Concern may be present in the material that do not have limits or standards applicable to toys.

7 *Are these remaining Substances of Concern addressed elsewhere?*

If there is no applicable legislation regarding the substance, Manufacturers can consider whether any other Standards (not only EU Standards), EU Guidance or industry codes of practice are available that may manage the risk presented by the Substance of Concern. Demonstration of compliance can be documented in the chemical Safety Assessment and it could be considered that this means that the material is safe, providing the other guidance/standard have been applied appropriately.

8 *Evaluate the risk of any remaining Substances of Concern*

In order to evaluate the risk of these substances further information about the substance needs to be obtained. For example, if a substance is listed as toxic by ingestion Manufacturers should consider restricting the levels in toy materials that could be mouthed or ingested.

When no standard or code of practice exists that addresses these remaining substances, these should be risk assessed. For example a Toxicological Risk Assessment by a suitably qualified person may be appropriate for a formulation-(e.g. inks).

If the material you are using contains specialist substances, e.g. colour change additives, specialist preservatives, unusual colorants etc., these must be identified and the hazards presented by these evaluated separately.

Chemical safety assessments follow the principle of identifying the hazard and then estimating the likelihood of the substance causing harm. If you are unsure, then expert help should be sought.

9 *Can you reduce or effectively manage remaining hazards presented by the SoC's*

It may be the case that some Substances of Concern remain in the materials in the toy. Manufacturers must use the risk assessment in step 7 to determine if the risk needs to be reduced. Manufactures may decide to modify the product by using a material that does not have Substances of Concern. Example of measures aimed at reducing the risk can be found in **Appendix 2**.

Appendix 1 – Sources of hazard information

- Consumer Product Safety Commission” (CPSC) information and newsletters (USA).
- RAPEX”. Rapid recall alert system for non-food consumer products. Published weekly.
- Other International standards such as those published by ASTM, ISO and IEC.
- Customer complaints>Returns/Insurance claims from your own organisation.
- Trade Associations and test laboratories information and newsletters.
- Distributor’s feedback.
- Recalls from other countries which may have a bearing on the design of your product.
- “Childata” handbook of child measurements and capabilities.
- Anthropometry of infants and children (USA).
- Age determination guidelines relating children’s ages to toy characteristics and play behaviour” (USA).
- US CPSC Recall data base
- US CPSC NEISS injury database
- Consumer studies Accident and other Data

In some cases this risk assessment may indicate that the use of warnings or specific instructions for use may be enough to manage a low risk. In other cases where the risk is higher, redesigns or rejection of product may be necessary. In most cases this is a subjective decision based on the experience of the person conducting the assessment.

Appendix 2 – Risk Assessment

Examples of Risk assessment tool / protocols:

Risk Nomograph
RAPEX guidelines
CoPRA Consumer Product Risk assessment
Dutch Consumer Safety Institute risk assessment

Simple Risk Assessment Approach

A simple four-step process can be used to carry out the risk evaluation:

(a) Estimate the likelihood of the hazard causing an injury

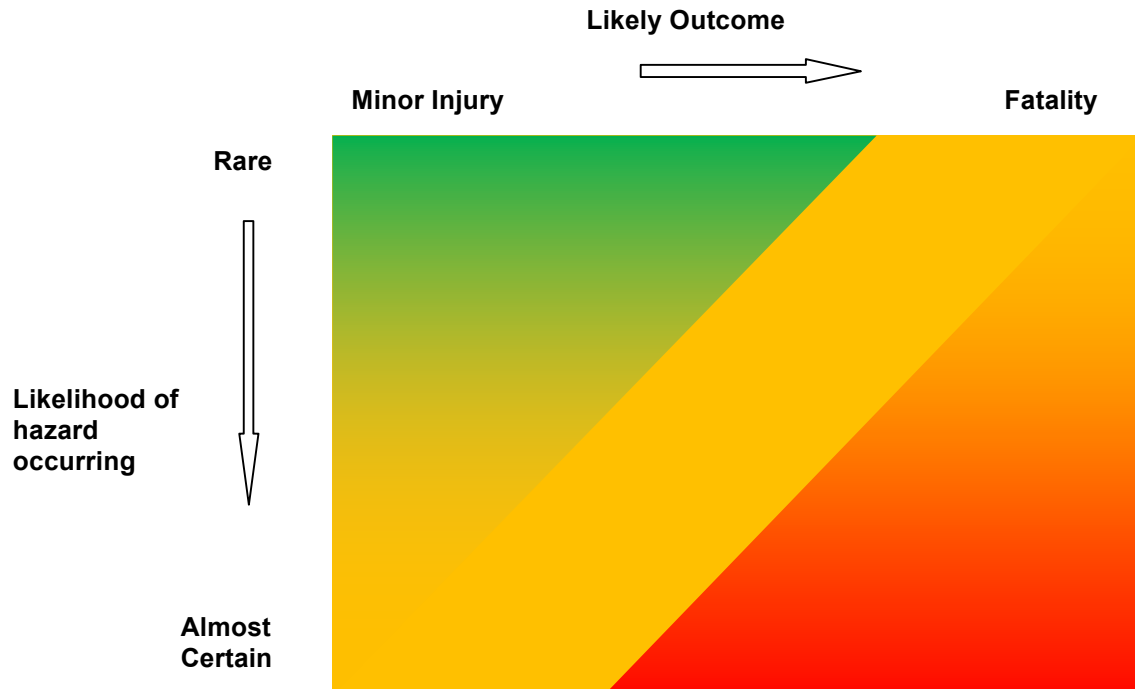
Depending on the hazard and the circumstances in which it may occur, the likelihood of an injury occurring can vary between “rare” and “inevitable”.

(b) Assess the likely outcome should injury occur

In deciding what the outcome could be from a particular hazard, a realistic view should be taken of the potential injury that could occur. This could range from a minor injury requiring first aid treatment to a potential fatality.

(c) Evaluate the risk

Now that the likelihood the hazard causing injury has been determined and a realistic outcome has been identified the risk can be simply estimated using the diagram below.



Green: Low risk

Amber: Medium risk

Red: High risk

Appendix 3 - Risk Reduction

Advice to consumers

The Safety Assessment may lead a manufacturer to conclude that a toy should carry advice to consumers regarding hazards and precautions in addition to any mandatory warning requirements.

Advice to consumers can be communicated in instructions, on packaging and other point of purchase information. Additionally warnings can also be applied directly to toys.

Examples of such advice are supervision guidance, correct use, protective equipment precautions, age grading and other warnings etc. The necessity for such advice and its placement (on the product or on the packaging for example) should be proportionate to the degree of risk presented. It is important not to use warnings to reduce risks that can be reduced by other means. For example, it is not acceptable to use a warning against the use of a toy by children under 36 months when the toy is obviously intended and suitable for children under 36 months.

Design changes

The level of risk identified (high, medium or low) may lead a Manufacturer to conclude that the product may require modification. Changes in materials, changes in design, changes in functional use can all be used to reduce the level of risk identified.

Examples of such modifications include changes in materials to increase strength or to reduce the risk of the presence of restricted chemicals; changes in construction to eliminate entrapment hazards.

Production controls

Certain risks can be controlled during production. For example, additional QC for checking strength of identified components, additional goods inward controls to reduce the risk of non compliant materials being used.

Separate BTHA Guidance is available on Conformity of Series production. Guidance is also available in the Product Monitoring Guide.

Rejection of product

In some cases a Manufacturer may decide that the risk is too great or that the necessary changes are uneconomic for the toy to be placed on the market. This decision can be taken at any stage during the Safety Assessment.