



## Safety of toys: Chemical safety assessment

6 May 2011

*According to new Toy Safety Directive 2009/48/EC (TSD), manufacturers (including own-brand importers) must carry out a safety assessment of their toys before they are placed on the market. The safety assessment shall form part of the technical documentation.*

A first article on the safety assessment (which should be read in conjunction with this article) was circulated by TIE on 1 April 2011 and dealt with the analysis of mechanical, physical, flammability and electrical properties of toys as well as hygiene and radioactivity properties. The European standards for mechanical, physical, flammability and electrical properties are now being modified so that they support all the requirements of the new Directive. This means that safety assessment for these types of hazards does not need to be very complicated. Also, for hygiene and radioactivity hazards the safety assessment is relatively simple although there are no standards available to support the requirements for hygiene and radioactivity in the new Directive.

In the case of chemical hazards, there are standards available but these do not cover all the chemical requirements of the current or the new Directive. It is also not intended that the revised versions of the chemical standards will cover all the chemical requirements. Therefore, the chemical safety assessment will be more complex than that for flammability and mechanical, physical and electrical hazards.

A chemical safety assessment should focus on assessing the likelihood that the toy contains substances that are banned or whose use is subject to restrictions in standards and directives, but it should also include an assessment of other potentially undesirable substances. Examples of substances that should be handled in the safety assessment are those that are classified as CMR (carcinogenic, mutagenic or toxic to reproduction), fragrances, substances regulated under directives and regulations other than the TSD (e.g. Annex XVII of REACH), and substances that are suspected of being undesirable but have not yet been banned or restricted in toys (e.g. substances on the so called SVHC-list).

It is important to note that although the chemical requirements of the new Directive do not enter into force until 20 July 2013, the manufacturer is obliged to carry out a chemical safety assessment as from 20 July 2011. It is necessary to understand that the general chemical safety requirement in the current Directive (88/378/EEC) already specifies that toys are not permitted to contain hazardous substances in amounts that may harm the health of children. Thus, it can already be considered unacceptable to use CMR substances in toys (at certain concentration levels), even if the specific ban on CMRs in the new Directive only takes effect from 20 July 2013.

A good chemical safety assessment requires **knowledge**: knowledge about the toy, how it is used, the materials used, the substances used as well as knowledge about the restrictions imposed on certain substances, their scope and the substances that are under discussion as undesirable in toys. In order to stay updated on the substances under discussion, membership of a trade association is recommended.

The more knowledge you have, the easier it will be to carry out the safety assessment. It is invaluable to have access to a so-called “bill of materials” and a “bill of substances” (preferably with the CAS or EINECS numbers of substances/mixtures) and to safety data sheets (applicable in cases where the manufacturers of the chemical substance/mixtures is obliged to supply a safety data sheet). If you do not have such information or only have limited information, you can of course still carry out the safety assessment, but this typically includes more dialogue with the producer, making worst case assumptions and more chemical testing than is specified in the chemical standards. It is very valuable to have reliable suppliers who are prepared to provide the detailed information you need.

A model for carrying out a chemical safety assessment is to divide it into three stages:

- Identification
- Characterisation
- Evaluation

The **identification step** involves studying the toy and its documentation to identify materials and substances used, and preferably also to identify the quantities or concentrations of these substances. Knowledge of where these substances are present in the toy is also useful (e.g. if the substances are inaccessible, are accessible in parts that can be placed in the mouth, are available in parts that can be in prolonged skin contact, etc.).

The **characterisation step** includes checking the identified substances against:

- known prohibitions/restrictions to determine whether they fall within these, and
- scientific knowledge and/or discussions about potentially hazardous substances

To determine whether a substance is subject to a prohibition/restriction, it is necessary to know if and how the substance is classified (e.g. if a substance is classified as carcinogenic). This classification is available in Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP). On the internet, you can search for the CLP-classification using the CAS or EINECS number of the substances/preparations.

The characterisation intends to attribute the material/substance to one of two groups:

- materials/substances that are restricted in the standards or legislation/regulations
- materials/substances that are not subject to restrictions

The **evaluation step** involves determining the probability that a given material contains undesirable substances in quantities or concentrations that are high enough to cause an unacceptable risk taking into account the hazard and the user’s exposure to this hazard (this is where knowledge is needed regarding where in the toy the substance is present).

In the case of *materials/substances subject to restrictions/bans*, you need to assess the likelihood that any of the applicable limit-values are exceeded. Limits are either given as total content of a particular substance or as a maximum allowed migration of the substance under specified test conditions. It is important not to confuse these two types of limits.

In the case of *materials/substances which are not subject to restrictions*, these can be divided into two categories:

1. materials/substances that are classified as hazardous (1272/2008) (but not covered by any specific restriction)
2. materials/substances that are not classified as hazardous (1272/2008) (and not covered by any specific restriction)

Category 1 must be evaluated in terms of how the user (the child) is exposed to the substance during foreseeable use.

Category 2 could be substances that are not classified since they are considered “safe”, but this category could also include substances that are subject to discussion, e.g. for future classification as hazardous.

The result of the safety assessment should be a conclusion, indicating whether the toy can be considered safe in terms of chemical properties.

*This article provides only a general overview of an example of various steps in a chemical safety assessment. The European Commission has published a comprehensive guide on technical documentation for new Toy Safety Directive. This guidance document focuses on the chemical safety assessment in particular and is available here:*

[http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm)

#### **About TIE**

*Toy Industries of Europe (TIE) is the trade association for the European toy industry, which comprises over 25% of the total world toy market. The toy industry is highly international and is one of the most dynamic business sectors in Europe. Around 80% of the sector is composed of small and medium sized enterprises (SMEs) which have less than 50 employees. Members of TIE include corporate companies as well as national associations from Bulgaria, France, Germany, Italy, the Netherlands, Spain, Sweden, the UK and the Nordic region. TIE membership is open to both corporate companies with a presence in Europe and national associations from European Union Member States (including candidate countries).*

*The information in this article is not exhaustive. Toy Industries of Europe (TIE) does not assume any responsibility or liability for the accuracy or completeness of this article. Although we do our best to provide accurate information, toy safety requirements are subject to changes, and we therefore recommend that you consult the latest available information.*