

Testing for Chemical Compliance

The **Toy Safety Directive 2009/48/EC** (TSD) has placed new responsibilities on manufacturers, importers, and retailers of toys for sale in Europe. The TSD was published in the *Official Journal of the European Union* and entered into force on 20 July 2009.

The 2009 TSD is written to be aligned with the current practices of toy manufacturers and strengthens the rules as laid down in earlier European Directives. As a result, the TSD has required adaptations in the manufacturing chain, as well as new procedures along the supply chain.

The general provisions of the TSD are applicable to toys placed on the market from 20 July 2011, while the chemical provisions will be applicable to toys placed on the market as of 20 July 2013 (additional 2-year transition period for chemical properties).

It is important to note that the TSD does not affect the requirement that all items must comply with the existing **General Product Safety Directive (2001/95/EC)**, which defines a safe product as one that 'presents minimal or no risk when used in a foreseeable way'.

The TSD and its supporting standards

The new **EN 71-1** standard on mechanical and physical properties of toys was published in June 2011 (EN71-1 is one of the main toy safety standards as it contains requirements for the design, strength, performance and labelling of toys). **EN71-2** standard on flammability of toys was published in September 2011.

- **EN71-3** on the migration of certain elements from toys is expected to be submitted for formal vote in February 2013.
- **EN71-8** was harmonised in October 2011.



- **EN71-X** on nitrosamines and nitrosatable substances is expected to be submitted for formal vote in February 2013.
- **EN 62115** standard on electric toys was published August 2011.

Discrepancy

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 carcinogenic, mutagenic or toxic to reproduction (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 about:

- The toy and how it is used
- Materials used
- Substances used
- Restrictions imposed on certain substances and their scope
- 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.

Carrying out a chemical safety assessment

The more knowledge you have, the easier it will be to carry out the safety assessment.

A chemical safety assessment should focus on assessing the likelihood that a 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
- Fragrances
- Substances regulated under directives and regulations other than the TSD e.g. Annex XVII of REACH (**R**egistration, **E**valuati-

on, **A**uthorisation and restriction of **C**hemicals)

- Substances that are suspected of being undesirable but have not yet been banned or restricted in toys e.g. substances on the so called **S**ubstances of **V**ery **H**igh **C**oncern (SVHC)-list.

It is invaluable to have access to the **B**ill of **M**aterials (BoM) and a **B**ill of **S**ubstances (BoS), preferably with the CAS or EINECS numbers of substances/mixtures and safety data sheets (SDS). Manufacturers of the chemical substance/mixtures are obliged to supply SDS's. 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. This emphasizes how valuable it is to have reliable suppliers who are prepared to provide the detailed information you need.



A **m**odel for carrying out a **c**hemical **s**afety **a**ssessment is to divide it into three stages:

1. **I**dentification
2. **C**haracterisation
3. **E**valuation

The **i**dentification step involves studying the toy and its documen-

tation 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.

- Substances are inaccessible?
- Are substances accessible in parts that can be placed in the mouth?
- Are they available in parts that can be in prolonged skin contact?

The **c**haracterisation step includes checking the identified substances against:

- Known prohibitions/restrictions
- 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 a CMR. This classification is available in Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

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 **e**valuation step involves determining the probability that a given material contains undesirable substances in quantities or concentrations that are high enough to cause an unaccepta-

ble 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 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 '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.

Challenges ahead with the new EN71-3

Eurofins' experts closely track the developments in the relevant standardisation committees as well as proactively participating in the development programs. This also applies to the **new requirements for the chemical safety** of toys which are planned to apply from **July 2013** onwards. By that time, the products must be free from CMR substances. These new regulations will affect around **1,500 substances**.



So what's different with the new standard?

Lead and other toxic metals have long been regulated in paint for children's products, but new regulations now require even lower levels and extend to more than just paint and toys. Now the substrate that the paint covers also needs to be tested to ensure it meets acceptable levels, and an expanded list of products

sold to children age 12 and under is included.

- Current Restrictions cover 8 heavy metals
- The new standard restricts the use of 19 metals/ compounds
- In the new standard the permitted limits on these metals/ compounds are now split into 3 categories or toy materials:
 - Dry brittle, powder like or pliable materials (e.g. chalk)
 - Liquid or sticky material (e.g. bubble solution, slimy balls)
 - Scraped off material (paint coating, plastics)
- Due to the chemical elements involved and the need to measure to very low quantifiable limits, changes to the analytic methods and calibration of the equipment is required to screen for
 - 17 of the elements
 - Hexavalent Chrome, Cr (VI)
 - Organic Tin

How can we help you minimise the impact of chemical compliance?

From manufacturers, importers and retailers to authorised agents in the EU, our toy experts at Eurofins support you, offering a broad service portfolio:

- Support during product development
- Consultancy on risk assessment
- Covering staff training in quality management or certification of production processes including CSR (corporate social responsibility) criteria
- Monitoring all potential risks across the product chain e.g.
 - Flammability
 - Heavy-metal content

- Small parts that may involve a choking hazard.

“By using our know-how in toy safety at an early stage, all stakeholders can minimise their risks and ultimately save costs”, says Derek Hepburn, Managing Director at Eurofins UK. Manufacturers, retailers and importers also benefit from Eurofins status among consumers and from the worldwide presence of the service corporation.

EN71-3 does not permit composite testing as chemicals in different materials can react and give false negative results. However, cross-referencing, given sufficient evidence is allowed so careful consideration on the materials you use when developing a toy can result in significant savings.

Finally, the **new chemical requirements apply to any toy item put onto the European market after the 20 July 2013**. It is important that there is sufficient traceability to be able to demonstrate **when** the specific toy item was placed on the market, not just identical models of the toy.



Our service

To help clients assess the risk of future non-compliance, we have developed an **EN 71-3 screen test** that takes into account the future limits for the 17 heavy metals. It is particularly useful for toys that have a long life-cycle or for raw materials and components that are intended to be used in the manufacture of toys by July 2013. The EN71-3 screen test gives our clients

enough time to re-think their product design or find alternative materials if chemical non-compliance is found. With 10,000 employees across 150 sites in 30 countries, Eurofins is a leading international group of laboratories providing an unparalleled range of testing and support services to the pharmaceutical, food, environmental and consumer products industries and to governments. Our customers access a portfolio of over 100,000 analytical methods addressing the authenticity, origin, safety, identity, composition and purity of products.

Eurofins has a network of 9 sites within the UK and Ireland.

The group has a major presence in China where it operates two major toy test labs located in Shanghai and Shenzhen, both ISO17025 accredited. From those sites it provides in addition to testing, consultancy, factory inspections and pre-shipment inspections.

The Laboratory in Manchester is accredited to ISO17025 and is a Notified Body under Regulation 8 of the Toys (Safety) Regulations to carry out examinations and tests and issue EC type-examination certificates in respect of models of toys.



Eurofins stands for

- Excellent service
- Accurate results and timely results
- Technical consultation by highly qualified employees
- State-of-the-art equipment
- International presence currently in 30 countries
- Auditing by our customers
- Continuous performance control by internal quality management and participation in inter-laboratory comparisons.



We offer you our services in several countries worldwide.

Your industry is our focus

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