



New chemical requirements for toys enter force this July

28 March 2013

The new Toy Safety Directive entered into force on 20 July 2011 with the exception of the new chemical requirements, which come into force on 20 July 2013. These new chemical requirements mean extensive changes so it is high time to check that any toys placed on the market after 20 July this year will meet the new requirements. The new requirements apply for all toys whether or not similar toys were manufactured or imported before the July deadline.

General safety

The Toy Safety Directive specifies a general requirement: *'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.'* This means that if a toy is considered to involve a chemical risk, market surveillance authorities may request action with reference to this general requirement even if the particular requirements (see below) are met.

Particular safety requirements

The Directive also stipulates that *'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.'* This can also be considered to be an all-embracing requirement.

Migration limits

The Directive sets maximum migration limits for 19 chemical elements. The limits are different depending on which of the three categories of material are used:

1. dry, brittle, powder-like or pliable
2. liquid or sticky
3. scraped-off

This means that the number of chemical elements regulated by migration limits has been extended from the current 8 to 19 in total, and that different limits apply depending on the toy material category. The limit values presently in place for the eight substances already regulated will generally become stricter. The reason for the different limits for different categories of material is that a child can, for example, ingest larger amounts of a liquid material such as a soap bubble solution, than of, for example, a thin layer of paint that has to be scraped off the surface of a toy. The elements covered by the migration requirements are aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin and zinc.

Prohibition of CMR substances

Substances that are carcinogenic, mutagenic or toxic for reproduction (CMRs) are banned in accessible parts of a toy in concentrations above those laid down in the Regulation on classification, labelling and packaging of substances (CLP Regulation 1272/2008). The limits depend on the substance classification (categories 1A, 1B or 2) and range from 0.1% to 3%. This requirement applies in addition to the migration limits and to each part of the toy. The requirement does not apply to CMRs that are inaccessible to children using the toy.

Prohibition of certain fragrances

55 allergenic fragrances are banned in the Directive and must not be used in toys (at levels greater than 100 mg/kg per fragrance). 11 additional fragrances must be labelled on the packaging if they are present in a concentration above 100 mg/kg. The requirements for fragrances in toys are stricter than those for cosmetic products.

Migration limits for nitrosamines

The Directive stipulates that nitrosamines, which can be found in rubber for example, and nitrosatable substances must not migrate from toy materials at levels greater than 0.05 ppm and 1 ppm respectively. These requirements apply to toys intended for children under 36 months and to other toys intended to be placed in the mouth.

The requirements may change

Some requirements of the Directive may be amended by a special Committee. The list of substances covered by migration limits, the migration limits themselves, as well as the list of banned fragrances can be altered. Even before the new requirements come into force, the migration limits for cadmium have changed and discussions about further changes for other substances are ongoing.

Other legislation

Toys must also comply with other relevant EU legislation relating to certain product categories and restrictions for certain substances and mixtures. This means that while these other chemical regulations were not always specifically written for toys, they apply also to certain toys and must be considered in terms of a toy's chemical safety. Examples of such legislation are:

- REACH Regulation 1907/2006 (Registration, Evaluation and Authorisation of Chemicals): regulates the presence of substances such as phthalates, benzene, AZO dyes and cadmium in particular toys
- RoHS Directive 2011/65 (Restriction on the use of certain Hazardous Substances in electric and electronic products): applies to electrical and electronic toys and regulates lead, mercury, hexavalent chromium, cadmium and flame retardants PBDE and PBB
- Cosmetics Regulation 1223/2009: cosmetic toys must comply with these rules (new rules applicable from 11 July 2013)
- Directive 94/62/EC on packaging and packaging waste: covers the presence of heavy metals in packaging including toy packaging
- Regulation 1935/2004 on materials and articles intended to come into contact with food: applies to toys that are intended to come into contact with food

Safety assessment

The requirements for toy safety, which are in force since 20 July 2011, oblige manufacturers to assess the safety of chemical hazards and exposure to them before the toy is placed on the market.

About TIE

Toy Industries of Europe (TIE) is the trade association for the European toy industry. The toy industry is highly international and is one of the most dynamic business sectors in Europe. Over 99% 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).

Readers are reminded that the text of the original directive or standard is the only authentic legal reference and that the information in this document does not constitute legal advice. Toy Industries of Europe (TIE) does not accept any liability with regard to the contents of this document.