

New migration limits for lead in toys and other changes

At the end of March 2017, the EU decided to reduce the migration limits for lead in toys. The reduction will come into force 18 months after the publication of the amending directive. New limit values for phenol and bisphenol A in toys for children under three years have also been established recently.

Generalities about migration limit values

Migration limits under the Toy Safety Directive (TSD) are calculated on the basis of the limits set by the European Food Safety Authority (EFSA). EFSA's limit values are defined as the maximum amount of a particular substance that a person can get on a daily basis and per kilogram of its body weight, without any adverse health effects ("tolerable daily intake"). Such limit values can be "translated" into migration limit values for toy materials, inter alia by making assumptions about how much toy material a child might intake per day (by "eating" pieces of toys) and assumptions about how the substance may leak (migrate) from the toy material if it enters into the child's stomach.

Every time EFSA receives new scientific information on the potentially harmful health effects of a particular substance, it can revise the limit values. When limits are revised for a substance whose migration limits are also regulated under the TSD, the TSD limits will normally be lowered by the same factor as the EFSA's limit value was lowered.

New migration limits

Due to the fact that EFSA established a new lower limit for lead, discussions began few years ago to also reduce the migration limits for lead in toys. For several reasons, it took many years before a final decision was taken, but migration limit values about 7 times lower than the current ones were adopted at the end of March:

Material	mg/kg in dry, brittle, powdery or flexible toy material	mg/kg in liquid or sticky toy material	mg/kg avskavt leksaksmaterial
Current	13,5	3,4	160
Beslutade	2,0	0,5	23

The new limit values are laid down in an amending directive to the TSD. From the date the directive is published in the EU Commission's Official Journal, 18 months transition time is given before it applies to toys that are "placed on the market".

The Council Directive modifying the Toy Safety Directive limits for lead migration was published on 27 April. The new limits will apply as of 28 October 2018.

Tests and surveys have shown that a majority of toys already meet the new requirements. Manufacturers are therefore not expected to have to make changes to their products, but it is important to communicate the new requirements to suppliers and, if necessary, undertake tests to confirm compliance with the new limit values. It is known that some natural materials (e.g. kaolin clay) contain a natural content of lead. This could theoretically mean that toys made of such materials could have problems with the new migration limits (kaolin clay can be used e.g. in crayons and pencils).

New limit values for Phenol and Bisphenol A

Recently, new limit values for two other chemical substances, Phenol and Bisphenol A, have also been decided under the Toy Safety Directive. These limit values apply to toys intended for children under three years old, and other toys intended to be placed in the mouth.

The Commission Directive (modifying the TSD Appendix C for Phenol was published on 3 May and the new limit will apply as of 4 November 2018.

The Commission Directive (modifying the TSD Appendix C for Bisphenol A was published on 24 May and the new limit will apply as of 26 November 2018.

None of these new limit values are expected to bring big changes to the existing toys as the majority of them already meet these new requirements.

Bisphenol A	
Current migration limit values	0.1 mg / l (migration limit) according to the methods specified in EN 71-10: 2005 and EN 71-11: 2005
New migration limit values	0.04 mg / l (migration limit) according to the methods specified in EN 71-10: 2005 and EN 71-11: 2005

Traces of Bisphenol A in the form of residual monomers can only be detected in polycarbonate plastic and in certain epoxy resins. They can also be present as an additive (as polymerization aid) in some PVC materials.

Phenol	
Migration limits	5 mg / L in polymeric material

Total content limit	10 mg / kg as a preservative
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A potential source of phenol in toy materials can be a degradation product of antioxidants used in PVC, for example. Phenol can be used as monomer for phenolic resins in the manufacture of resin-bonded wood for toys. Phenol can also be used as a preservative in water-based toy materials (such as soap bubbles or ink in felt pens).