



Additions and changes to the Toy Safety Directive

20 March 2014

Certain passages of the new Toy Safety Directive (TSD) can be modified by a decision of a committee consisting of the European Union Member States and the European Commission. To make changes to other parts of the Directive, it must be revised, which is considerably more complicated.

The committee can, for example, add chemical substances to an Appendix of the TSD (Appendix A) that specifies exemptions to the general total concentration limits for substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR). The committee may also impose specific limit values for chemicals that are used in toys intended for children under three years or intended to be placed in the mouth in another Appendix of the TSD (Appendix C).

The committee has recently decided to amend both Appendix A and Appendix C. These changes will come into force in the middle of 2015 for Appendix A and 6 months later for Appendix C.

- Appendix A: nickel in toy components which are intended to conduct an electrical current will be excluded from the total content requirements for substances classified as CMR;
- Appendix C: the flame-retardant plasticisers TCEP, TCPP and TDCP will be subject to a total content limit of 5 mg/kg;
- Appendix C: Bisphenol A will be subject to a migration limit of 0.1 mg/l when tested in accordance with EN 71-10 and EN 71-11.

Nickel as an electro-conductive material in Appendix A

Nickel as an element or a metal is used in toys for its good anti-corrosion properties or for its high electro-conductivity. Nickel is contained in stainless steel and is used as a conductive material, for example in battery and USB connectors as well as in model train rails.

Nickel is classified as a carcinogenic (category 2) because of the risks associated with its inhalation. This risk is not an issue for nickel in toys. However, because of its classification, a total concentration limit of 1 % is applied automatically.

When the Directive was adopted, it was understood that this limit would rule out the use of stainless steel in toys. As it was unanimously agreed that nickel in stainless steel does not pose any CMR-risk to children, an exemption to the 1 % limit was introduced in Appendix A for nickel when used in stainless steel. Experts later realised that the limit value for nickel would pose a problem for electro-conductive materials in toys and agreed that nickel as an electro-conductive material does not constitute a risk to the user.

As the Directive had already been adopted at that time, an administrative process was required to allow the use of nickel for this purpose. This included providing scientific evidence that there is no CMR-related risk by allowing nickel as an electro-conductive material in toys. This process is now completed and the committee decided during a meeting in February that nickel in toy components

which are intended to conduct an electrical current should be exempted from the CMR requirements and therefore added to Appendix A. The change was made by an amending Directive, which will come into force 12 months after its publication. However, this exemption has been applied in practice since the new chemical requirements came into force on 20 July 2013.

Note that the migration limit for nickel remains valid and that the parts coming into direct and prolonged contact with the skin should meet the “sensitizer requirement” for nickel in Annex XVII of REACH.

TCEP and BPA in Appendix C

Since the adoption of the TSD, discussion have been ongoing about whether stricter limits are needed for certain substances if they are present in toys intended for children under three years (who often put toys in their mouth) or in toys intended to be placed in the mouth. The idea behind this is that the exposure will be higher if a child puts toys in its mouth than if it just holds them.

In February, the committee decided to impose limits on certain substances, by including them in Appendix C:

Flame retardants

Tris(2-chloroethyl)phosphate (TCEP), Tris(2-chloro-1-methylethyl)phosphate (TCPP) and tris[2-chloro-1-(chloromethyl)ethyl]phosphate (TDCP) are flame retardants that can be used as additives in plastics. TCEP is classified as carcinogenic (category 2) and toxic for reproduction (category 1 b) and a total concentration limit of 0.3 % applies. TCEP is no longer produced in the EU but has occasionally been found in imported toys. Following the risk assessment, it was agreed to introduce a stricter limit for TCEP and the two alternatives TCPP and TDCP in Appendix C. The limit agreed upon is 5 mg/kg total content. This is in fact a total ban because the limit set corresponds to the amount that standard analytical methods are capable of detecting. This change was introduced by an amending Directive, which will only come into force 18 months after its publication.

Bisphenol A (BPA)

In the new TSD, BPA is automatically covered through a total concentration limit since it is classified as toxic for reproduction (category 2). When it comes to toys intended for children under three years or intended to be placed in the mouth, it was agreed to further increase safety by introducing in Appendix C the migration limit laid down in EN 71-9:2005 (Safety of toys - Organic chemical compounds). The limit is 0.1 mg/l when testing according to the methods laid down in EN 71-10 and EN 71-11.

In order to clarify that it is not necessary to test all materials for the presence of BPA, the European Commission’s guidance documents on the Directive will include a text explaining that BPA is a residual monomer that is normally found in trace levels only in polycarbonate and epoxy resin. This change was also introduced by an amending Directive, which will only come into force 18 months after its publication.

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Toy Industries of Europe

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