# Council Directive (EU) 2017/738 of 27 March 2017 amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead (Text with EEA relevance)

## COUNCIL DIRECTIVE (EU) 2017/738

## of 27 March 2017

## amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead

## (Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[1], and in particular Article 46(1)(b) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Directive 2009/48/EC lays down migration limits for toys or components of toys, for a range of elements, including lead, in dry, liquid and scraped-off toy material. The limits for lead are 13,5 mg/kg, 3,4 mg/kg and 160 mg/kg in each toy material, respectively.

(2) Those limits were based on the recommendations of the Dutch National Institute for Public Health and the Environment (RIVM) in a 2008 report entitled ‘Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements’. The RIVM recommendations were based on the conclusion that exposure of children to lead may not exceed a certain level, called ‘tolerable daily intake’. In that report, a tolerable daily intake of 3,6 microgram per kilogram body weight per day was determined as the toxicological reference value for lead.

(3) Since children are also exposed to lead from sources other than toys, only a certain percentage of the toxicological reference value should be allocated to toys. In its opinion on the ‘Assessment of the bioavailability of certain elements in toys’, adopted on 22 June 2004, the Scientific Committee on Toxicity, Ecotoxicity and Environment recommended that 10 % of the maximum tolerable intake of lead should be allowed as the maximum contribution from toys. In its opinion on the ‘Evaluation of the Migration Limits for Chemical Elements in Toys’, adopted on 1 July 2010, the Scientific Committee for Health and Environmental Risks (SCHER) concurred with the approach that the uptake of lead from toys should not exceed 10 % of a toxicology-based reference value. Furthermore, since lead is considered particularly toxic, its limits in Directive 2009/48/EC were set at half the level considered safe according to the criteria of

**Status:** *EU Directives are being published on this site to aid cross referencing from UK legislation. After exit day no further amendments will be applied to this version.*

the relevant Scientific Committee, in order to ensure that only traces of lead that are compatible with good manufacturing practice should be present. Accordingly, the limits for lead were set in that Directive at 5 % of the tolerable daily intake, determined as the migration of lead from toys.

(4) The European Food Safety Authority (EFSA) concluded that for lead, as a toxic metal, there is no threshold below which the exposure to lead has no critical health effects. Even low-level exposure to lead may cause neurotoxicity, namely damage to the nervous system and brain, in particular learning deficits. Therefore, according to that new scientific knowledge published by EFSA, the tolerable daily intake should no longer be used as the toxicological reference value.

(5) According to EFSA, the new toxicological reference to be used for establishing lead limits is the $BMDL_{01}$ (benchmark dose limit) relating to neurodevelopmental effects. The $BMDL_{01}$ is the lower confidence limit (95th percentile) of the benchmark dose of a 1 % extra risk of intellectual deficits in children measured by the Full Scale IQ score, that is a decrease in IQ by 1 point on that scale. The $BMDL_{01}$ is equivalent to a lead intake of 0,5 microgram per kilogram body weight per day.

(6) The Committee for Risk Assessment established under the European Chemicals Agency agreed with EFSA that the $BMDL_{01}$ is the highest tolerable exposure for lead. Since the current average blood lead levels in European children are up to four times higher than the highest tolerable exposure level, and since no threshold for the neurodevelopmental effects can be established, any additional exposure must be avoided as far as possible.

(7) Applying the latest scientific developments to the methodology in the 2008 RIVM report to calculate safe limits for elements in toys and applying the approach of Directive 2009/48/EC in managing the risks of particularly toxic elements such as lead, the limits for lead in toys laid down in Directive 2009/48/EC should be reviewed, and should be set at a 5 % allocation of the $BMDL_{01}$ for the protection of children's health.

(8) An erratum to the 2008 RIVM report, published in 2015, considered that the amounts of dry and liquid toy material which children are assumed to ingest, amounts upon which the 2008 RIVM report's recommendations for limit values were based, should be expressed as weekly amounts instead of daily amounts. SCHER subsequently contended that the ingestion amounts originally recommended are appropriate and should continue to be expressed as daily amounts rather than weekly amounts, thereby confirming that the methodology used in the 2008 RIVM report to calculate safe limits for elements in toys is correct. Accordingly, the methodology used in the 2008 RIVM report should continue to be applied for the purposes of laying down revised limits for lead in toys.

(9) Directive 2009/48/EC should therefore be amended accordingly.

(10) The committee established under Article 47 of Directive 2009/48/EC delivered no opinion on the measures provided for in this Directive; the Commission therefore submitted to the Council a proposal relating to those measures and forwarded it to the European Parliament,

HAS ADOPTED THIS DIRECTIVE: