Frequently asked questions about lead in children's toys

BfR FAQ of 13 March 2017

Toys shall not jeopardise the health of children. This is required by the EU directive 2009/48/EC on safety of toys. To take into account new toxicological findings regarding lead, the EU Commission has announced the tightening of the limit values for lead in the EU toys regulation in order to assure a high level of protection for children.

Germany had already established stricter limit values for lead in its national regulation on the safety of toys, and the proposed EU values now comply with or are even stricter than the German lead limits. With the future realignment of the EU limit values for lead, the German values will also be adjusted to comply with the new EU values. The Federal Institute for Risk Assessment (BfR) welcomes the planned tightening of the EU limit values as it increases the level of protection for children all over Europe.

Toy manufacturers are responsible for ensuring that their products do not jeopardise health and that they comply with legal provisions. The BfR has compiled selected frequently asked questions about lead in toys in order to inform parents first and foremost.

What is lead?

Lead is a heavy metal that occurs relatively frequently in the earth's crust, but it is also introduced into the environment through industrial processes. It is a toxic heavy metal which accumulate in the organism. Lead is to be found as a component of numerous products, such as car batteries, or as a stabiliser in PVC, as well as in some paints, glazes and ceramics. It used to be used for drinking water pipes and as an anti-knock agent (tetraethyl lead) in petrol. Humans ingest lead mainly through food and drinking water, but air, dust and soil particles are further sources.

Is lead harmful to human health?

Like most heavy metals, lead is poisonous. The symptoms of acute lead poisoning include vomiting, intestinal colic and constipation and even kidney failure in some cases, but it is relatively rare nowadays. The ingested lead accumulates in the body, the half-life is roughly 35 days in the blood and five to thirty years in the bones. Lead can be released from this deposit and contribute to chronic lead exposure. Chronic lead exposure can influence the central nervous system and thereby brain function, as well as the hormone system, and can be accompanied by anaemia, cardiovascular effects, loss of appetite, nervousness and kidney damage. Several lead salts are classified as toxic to reproduction and carcinogenic.

In its assessment of 2010, the European Food Safety Authority (EFSA) established that small children react particularly sensitively to lead. The effects on brain development are particularly critical here and impairments to the development of intelligence and attention, as well as behavioural disorders, have been described, even with small doses. A safe effect threshold cannot be derived for lead.

How does lead get into toys?

Natural contamination of dye pigments and fillers in toy materials such as coloured crayons, chalk, modelling clay or varnish, can result in lead or lead salts being contained in toy materials. Lead is also used as a stabiliser in PVC material, and it can also be contained in metal alloys such as brass or gunmetal.

How dangerous is lead in children's toys?
More recent scientific findings prove that lead is more toxic than was previously assumed. There is no safe toxicological threshold for the effects of lead on developmental neurotoxicity as even tiny quantities of lead can have a negative effect on the development of intelligence in children. EFSA has derived a daily intake dose ($BMDL_{01}$) of 0.5 µg of lead per kg body weight for the lead intake of children at which the health risk is negligible. This value was confirmed by the European Chemicals Agency (ECHA). If total lead intake from all sources is below this value, effects on the development of intelligence in children are hardly likely, but as the food-related lead intake of children already clearly exceeds the $BMDL_{01}$ value derived by EFSA, there is a clear requirement to minimise the lead intake of children from all sources.

Toys can also contribute to children's lead intake. Small children often put toys into their mouths (mouthing), nibble on them and swallow toy materials. For this reason, the limit values for lead in toys have to be adjusted to reflect the new scientific findings in order to guarantee a sufficient level of protection for children.

What quantities of lead may toys contain?
Toys have to be safe and may not jeopardize children's health. The European Commission anchored this safety requirement in the toy's safety directive2009/48/EC. Limit values for the release of lead from various toy materials were also established in this toy regulation. The limit values set in the EU-directive are based on the level of knowledge available at that time in 2008.

When implementing the EU directive into its national legislation, however, Germany retained its stricter limit values for the permissible quantities of lead that a child may ingest through toys on a daily basis. Accordingly, children's toys may only contain so much lead that a maximum of 0.7 micrograms per day are released when the materials contained in toys are swallowed and the lead they contain is dissolved by gastric acid. Toys sold in Germany must comply with these German limit values.

The EU Commission is currently in the process of adjusting the limit values for lead contained in the EU directive to the level of scientific progress that has been achieved. In future, the maximum quantity of lead that children may ingest via toys must not exceed 5% of the total intake dose derived by EFSA as posing a negligible risk to health. The migration limit values will then be 23 mg of lead per kg of scraped off toy material (e.g. plastics, textiles, varnishes), 2 mg of lead per kg of dry, powdered and pliable toy material (e.g. chalk, modelling clay) and 0.5 mg of lead per kg of liquid toy material (e.g. ink, finger paints). The future limit values will ensure a high level of protection for children. They comply with or are stricter than the currently valid German values contained in the German regulation on the safety of toys. The new EU limit values have to be integrated into national law. .

The vast majority of toys actually do satisfy the stricter EU limit values for lead that will apply in future and have done so for many years. This has been shown in extensive, representative surveys conducted within the scope of the national monitoring programmes conducted by the Federal States in 2011 which analysed toys from the German market.

What happens if toys release more lead than allowed?
As a basic principle, manufacturers and importers may only introduce toys to the European market that are not jeopardising to consumer health. The monitoring and control of toys in the German market is the responsibility of the Federal States (Laender). If they establish that a limit value has been exceeded, the responsible authorities of the Federal States take what-

ever measures are necessary. In this way, the authorities can demand the recall of the toys in question from the market, for example, or trigger an alarm via the European rapid alert system for consumer products (RAPEX) if necessary. All reports of consumer products which pose a serious health risk can be accessed by the general public in the EU Commission's RAPEX database.

What does the BfR recommend?
In the view of the BfR, the exposure of children and adults to lead should be kept as low as possible. The BfR welcomes every measure that reduces lead exposure from food and consumer products such as toys, thereby increasing the level of protection for consumers.

Can you recognise whether toys contain lead?
It cannot be recognised with the naked eye whether a toy contains ingredients such as paint which contain lead. Chemical analysis is required to do so. The self-responsibility of the manufacturers and alertness of the control authorities are therefore of special significance. Toys bearing the GS mark for tested safety in addition to the CE mark, which manufacturers award by themselves, have been additionally tested by an independent laboratory before they were put on the market.

Are fashion jewellery or other consumer products containing lead harmful to children's health?
In recent years, strict limit values were imposed for various products with which children come in contact or can put in their mouths. The goal of all these measures is to achieve a clear reduction of children's lead intake from various sources.

With fashion jewellery containing lead, for example, there is the risk of children putting it into their mouths, sucking and nibbling on it and even swallowing small parts of it. In order to minimise this possible source of lead intake too, the use and marketing of jewellery and parts thereof were legally regulated in the EU by Regulation (EU) No. 836/2012 of 18 September 2012 amending Annex XVII to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead. Thus, for example, bracelets, necklaces, rings, piercing jewellery, wristwatches, arm jewellery, brooches and cufflinks containing lead shall not be placed on the market or used in any single part of a piece of jewellery if the concentration of lead in such apart is equal or greater than 0.05% by weight. Jewellery placed on the market for the first time before 9 October 2013 is exempted from this restriction.

A limit value of 0.05% lead also applies to other consumer products which children could place into their mouths under foreseeable conditions of use. This was stipulated in Regulation (EU) 2015/628 of 22 April 2015 amending Annex XVII to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead.

More information on the subject

Overview of BfR publications on lead
http://www.bfr.bund.de/en/a-z_index/lead-129758.html

Opinion on fashion jewellery containing lead (German only)
http://www.bfr.bund.de/cm/343/kinder-sollten-keinen-bleihaltigen-modeschmuck-tragen.pdf

Opinion on the health risks through heavy metals from toys
http://www.bfr.bund.de/cm/349/health-risks-through-heavy-metals-from-toys.pdf

EU rapid alert system for consumer products (RAPEX)
http://ec.europa.eu/consumers/consumers_safety/rapex/index_en.htm

About the BfR

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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