

Migration of toxicologically relevant substances from toys

BfR Expert Opinion, 31 January 2003

Summary: Toys must be safe. There are various statutory regulations. Any heavy metals contained in toys may only be released in amounts which are safe for children and, at the same time, only constitute part of general exposure to substances of this nature. This also applies when the toy is placed in the mouth, licked or swallowed. To guarantee this, maximum levels for the release of a series of elements from toys are laid down on the European level in Directive 88/378/EEC. With regard to the planned amendment to this Directive, BfR has examined these maximum levels for their health relevance. The Institute comes to the following conclusions:

1. The maximum levels were set in 1988. The total exposure of children to heavy metals and other elements which was the basis for the establishment of these levels at that time, has probably fallen considerably since then. BfR, therefore, believes it is necessary to adapt and, where appropriate, to lower the maximum levels laid down in the Toys Directive. If there are any acceptable daily intakes or comparable values (e.g. of WHO) for the individual substances, then they should be taken into account when setting the new maximum levels.
2. For chromium there is currently a maximum level that applies both to the "more harmless" chromium III as well as to the "more critical" chromium VI. BfR is of the opinion that chromium VI should have its "own" maximum level instead of this joint limit value.
3. Nickel can trigger allergies. BfR, therefore, recommends examining whether nickel is contained in toys and whether there could be lengthier contact between the skin or mucosa and nickel-containing toy parts. If this is the case, BfR believes it is necessary on precautionary grounds to take steps to rule out a risk.

Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys regulates the amounts of specific elements which may be bioavailable from toys. The soluble extract is deemed to be bioavailable. In the DIN EN 71-3 standard "Safety of Toys Part 3: Migration of specific elements" limit values were established for the various elements for extraction from toy material to implement the Directive. They were calculated on the basis of bioavailable amounts in accordance with Directive 88/378/EEC and an assumed daily intake of 8 mg toy material.

Against the backdrop of the forthcoming amendment to Directive 88/378/EEC, BfR has undertaken a scientific review and health assessment of the amounts of bioavailable heavy metals laid down in the Directive, the choice of elements for which a maximum level for bioavailability was set and the stipulation of an average total intake of 8 mg toy material as well as the limit values derived from this.

Results

The maximum levels laid down in accordance with Directive 88/378/EEC are based on literature data on the weekly dietary intake of metals by adults, available data on the metal content of paints, findings about toxicokinetic specificities in children and specific toxic effects. The intake of heavy metals from toys was limited to a part of the regular tolerable intake. In the opinion of BfR heavy metal exposure from toys should only constitute a small part of this in future, too.

WHO has established tolerable daily intakes (TDIs) and provisional tolerable weekly intakes (PTWIs) as guidance values for heavy metal intake. We carried out a risk assessment involving a comparison of the WHO guidance values with the maximum levels for bioavailability pursuant to Directive 88/378/EEC. Our estimate was undertaken for an infant weighing 10 kg assuming that this child swallows 8 mg toy material from which the maximum amounts of the individual elements are bioavailable. Under these conditions the proportionate WHO guidance values for lead are lower by factor 1.95 for lead, by factor 2 for barium and mercury, by factor 2.4 for cadmium and by factor 10 for arsenic than the maximum levels laid down in Directive 88/378/EEC. Assuming a daily intake of 8 mg toy material, the percentage proportions of the TDI or PTWI could be exceeded even when the maximum migration levels are complied with for infants. This applies in particular to arsenic.

Because of the reduction of anthropogenic inputs into the environment, a lower exposure to heavy metals can be assumed. The maximum levels of bioavailable elements from toys should, therefore, be adapted to the current situation. No comprehensive health assessment of individual heavy metals in toys could be undertaken by us in the short time available given the complex nature of this subject. It is recommended that a scientific committee on the European level examines the extent to which the maximum daily bioavailable amounts of certain elements laid down as target values in Directive 88/378/EEC still correspond to today's level of knowledge. From the health angle it should also be examined whether nickel is used in toys and, if so, whether there could be lengthier skin or mucosa contact with nickel-containing toy parts. Furthermore, it should be examined whether the limit value for chromium should be replaced by a specific limitation applicable to chromium VI.

The intake of 8 mg specified as a convention is an assumed mean value. New findings would be necessary to amend the stipulated average total intake.

According to BfR the migration limit values in the DIN EN 71-3 standard should be selected in such a way for safety reasons that intake of the postulated daily amount of toy material does not exceed the maximum level laid down in Directive 88/378/EEC.

Reasons

The basis for the maximum levels laid down in Directive 88/378/EEC for the elements antimony (Sb), arsenic (As), barium (Ba), cadmium (Cd), chromium (Cr), lead (Pb), mercury (Hg) and selenium (Se), which are probably bioavailable from toys, is the expert opinion drawn up by the Scientific Advisory Committee to Examine the Toxicity and Ecotoxicity of Chemical Compounds (CSTE). *An overall approach for the preparation of recommendations on the migration limits of metals to be applied to dry coating films of paint or other materials of toys which contain these metals* (CSTE/84/62/V/E/2). CSTE derived the migration limit values from literature data on the weekly dietary metal intake of adults and from available data on the metal contents of paints. Consideration was also given to findings on toxicokinetic specificities in children (higher resorption rates of lead) and to specific toxic effects like the neurotoxicity of lead, possible carcinogenic or mutagenic potential of arsenic and chromium VI, the bioaccumulation and neurotoxicity of mercury and the bioaccumulation and nephrotoxicity of cadmium. For barium high exposure through barium-containing foods was taken into account.

In addition, because of children's lower body weight the levels for weekly intake were restricted to 50 % of the levels set for adults. The intake of the maximum weekly levels from toys was also restricted to 10 % for antimony, mercury and selenium, 5 % for barium and cadmium, 1 % for chromium and lead and 0.1 % for arsenic. The selected percentage limita-

tion has not been precisely scientifically established but reflects the special situation of children, the diverse exposure to heavy metals and the substance-specific toxic properties of the individual elements. CSTE also recommended this procedure for other metals and substances which could migrate from toys. CSTE is of the opinion that toys should not contain any organic mercury compounds. The stiffening of requirements concerning metal permeability and the assessment criteria of CSTE were supported and extensively evaluated by us at the time (BGA: C IV-2732-373/85, 16 April 1986, CIV-2732-1449/88, 25 April 1988).

BfR undertook the following exposure and risk assessment of the exposure of children to heavy metals from toys.

Exposure

BfR does not have any experiment-based data about which heavy metals are contained in toy materials or which amounts of individual metals are, in fact, released in conjunction with the correct and foreseeable use of toys. The heavy metal intake from toys probably also depends very much on the type of toy and individual play behaviour. The exposure of children to heavy metals from toys can, therefore, only be estimated approximately. The limit values in the DIN EN 71-3 standard are based on the assumption that 8 mg toy per day are swallowed. Exposure from licking toy material is not taken into account here. If the maximum amounts of migratable heavy metals were actually released from toy material after swallowing, this would lead to the intakes for children listed in Table 1 when they swallow 8 mg toy material daily.

Risk characterisation

Table 1 shows that even when the migration limit values in accordance with DIN EN 71-3 are complied with, the maximum bioavailable levels stipulated in Directive 88/378/EEC for antimony, arsenic, chromium and lead can be exceeded if 8 mg toy material are swallowed. BfR does not, however, have any data about the extent to which the migration limit values are exhausted and whether all elements are actually used in toy material.

WHO laid down guidance values for the regular intake of heavy metals from drinking water. For the elements arsenic, cadmium, mercury and lead it took the PTWIs (Provisional Tolerable Weekly Intake) for dietary intake of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For antimony and barium TDIs (tolerable daily intake) were established. BfR used these guidance values as the basis for its risk assessment and reduced them by 50 % for children (for lead the PTWI established by JECFA specifically for children) provided that only the percentage proportion of individual elements laid down by CSTE may be taken up from toys. This then leads to the proportionate guidance values for an infant weighing 10 kg given in Table 1.

They are lower by factor 1.95 for lead, by factor 2 for barium and mercury, by factor 2.4 for cadmium and by factor 10 for arsenic than the maximum levels laid down in Directive 88/378/EEC (see Table 1, rows in bold). It cannot, therefore, be ruled out that the TDI or PTWI can be exceeded in the case of infants who swallow larger amounts of toy material.

This applies in particular to arsenic which is classified as carcinogenic in category 1 of the MAC (maximum workplace concentration) and BAT (biological workplace tolerance level) lists. In order to afford special protection to infants and small children the limit value for arsenic in mineral water bearing the claim *suitable for the preparation of infant formula* was reduced to 5 µg/l (Ordinance on natural mineral water, spring water and table water).

Table 1: Risk assessment of the exposure of children to heavy metals from toys

		Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Maximum migration from toy material pursuant to EN 71-3	ng/mg	60	25	500	75	60	90	60	500
Assumed intake through swallowing ¹	µg/d	0.48	0.2	4	0.6	0.48	0.72	0.48	4
Maximum intake pursuant to Directive 88/378/EEC	µg/d	0.2	0.1	25.0	0.6	0.3	0.7	0.5	5.0
WHO guidance values for daily intake adults ²	µg/kg KG	0.86	2	51	1	-		0.5	-
Guidance values for daily intake children ³	µg/kg KG	0.43	1	25.5	0.5		3.6	0.25	
Daily intake by a child weighing 10 kg	µg	4.3	10	255	5		36	2.5	
Proportion from toy ⁴	%	10	0.1	5	5		1	10	
Proportionate guidance value	µg/d	0.43	0.01	12.75	0.25		0.36	0.25	

1 When swallowing 8 mg toy material

2 WHO: TDI for Sb, Ba, PTWI for As (15 µg/kg body weight), Cd (7 µg/kg body weight), Hg (3.3 µg/kg body weight), Pb (children: 25 µg/kg body weight). No limit values were established for chromium or selenium.

3 50 % of the values for adults; there is no limit value for lead for children

4 Proportionate guidance value for toys (according to percentage proportion in accordance with CSTE)

Assessment

Children are exposed to heavy metals via diverse routes like intake from food and drinking water, respiratory air or contact with metal-containing consumer products. The intake from toy material may certainly exceed 8 mg in individual cases; 8 mg are already reached for instance by swallowing two 2 x 2 x 1 mm pieces of children's plastic cutlery. However, there are no scientific findings at all concerning the amounts of toys which are regularly swallowed by children.

TDI and PTWI are limit values which are laid down on the basis of lifelong daily intake. Hence the exceeding of these limit values does not necessarily mean damage to health particularly when these limit values are only exceeded occasionally or for short periods of time. The exposure of older children to heavy metals from toys is probably far lower than that of infants. Firstly, as children grow older the swallowing of toy material certainly only plays a minor role, secondly the proportionate exhaustion of the TDI through toys is lower because of the higher body weight of older children. A special situation certainly exists in the case of toys where larger amounts are swallowed like finger paints. For them revised migration limit values have since been laid down in the European Standard EN 71-7 Safety of Toys – Part 7: Finger paints – Requirements and test methods which take into account the higher intake levels.

The regional public health department in Baden-Württemberg measured heavy metal concentrations in 10-year-old school pupils in conjunction with exposure and impact monitoring during the test period 2000/2001. Elevated levels of lead (in blood) and of arsenic and mercury (in urine) were detected in individual cases. However, the exposure situation varies considerably from individual to individual and is influenced by various factors. For instance a link between arsenic exposure and the frequency of fish consumption or between mercury exposure and the number of amalgam fillings has been proven.

BfR has no reports of concrete health damage caused by heavy metals in toys. Nevertheless, the exposure of children should be kept as low as possible in line with the dictates of minimisation. In this context the limit values for toys should, in our opinion, reflect the lower

environmental contamination and be established on the lowest level according to the technological state of the art.

In the opinion of BfR heavy metal exposure from toys should, in future, only account for a small share of total exposure. The percentage limitation of daily intakes undertaken by CSTE is, in our opinion too, a suitable procedure for this. A reduction in the weekly intakes identified for adults by 50 % could, however, prove to be insufficient for infants. Furthermore, because of the reduction in anthropogenic inputs into the environment¹ we can today assume lower exposure of the population than was assumed at the time by CSTE. The maximum levels of bioavailable elements from toys should, therefore, be reduced if possible in line with the current situation.

BfR has no data about which heavy metals are contained in which toys. It assumes that the relevant elements for toy materials are regulated in Directive 88/378/EEC. There might be a need for further regulation of nickel if this element is used in toys and lengthier skin or mucosa contact with nickel-containing toy parts is possible. Nickel can trigger contact allergies. On the national level nickel-containing consumer products, which come into direct contact with the skin over longer periods, are regulated in the Consumer Products Ordinance and may only release a maximum of 0.5 µg nickel per cm². There could also be a special regulatory need in conjunction with chromium VI.

After lengthy deliberations the daily intake of toy material was fixed at 8 mg. It can indeed be assumed that this value can be exceeded in individual cases. But there are also toys which given their size or properties cannot be swallowed. The intake of 8 mg laid down as a convention is, therefore, an assumed mean value. BfR has no data about the amounts of toy material that children actually swallow. Nor does it have any information about a model on the basis of which this amount could be calculated. New findings would be necessary to amend the stipulated average total intake.

Additional factors were used to derive, for the individual elements, the migration limit values in DIN EN 71-3 from the maximum levels for bioavailability in accordance with Directive 88/378/EEC. We are not familiar with the criteria for selecting these factors. BfR believes, for safety reasons, that the migration limit values should be selected in such a way that intake of the postulated daily amount of toy material would not exceed the maximum levels laid down in Directive 88/378/EEC. This is not currently the case.

Measures

Children are a particularly sensitive risk group. This fact is increasingly taken into account in numerous programmes that address the health situation of children and, more particularly, environmental exposure. They include the joint action programme "Environment and Health" of the Ministry for Health and the Ministry for the Environment, Nature Conservation and Nuclear Safety. Within the framework of the action plan "Environment and Health for Europe" it takes a very close look at the exposure situation of children and endeavours to afford children greater protection from environmental contamination. The protection of children also takes on increasing importance when it comes to establishing limit and guidance values. The World Health Organisation (WHO) highlights the special situation of infants and small children in conjunction with the safety of food additives and contaminants (Environmental Health Criteria 70, Principles for the safety assessment of food additives and contaminants in food).

¹The emissions of various heavy metals were reduced between 1985 and 1995 by between 52 and 88 % (Source: Federal Environmental Agency, press release: Reduction in substance inputs).

In conjunction with the International Programme on Chemical Safety principles were laid down for the assessment of the health risks from chemicals specifically for children. (Environmental Health Criteria 59: Principles for evaluating health risks from chemicals during infancy and early childhood: the need for a special approach). Against this backdrop limit values for heavy metals in toys should also be required to meet stiff safety requirements.

It is recommended that a scientific body on the European level (e.g. CSTE or SCCNFP) review the extent to which the target parameter laid down in Directive 88/378/EEC – the maximum daily bioavailable amounts of specific elements – still corresponds to today's level of knowledge.

From the health angle it should also be examined whether nickel is used in toys and, if so, whether there could be lengthier skin or mucosa contact with nickel-containing toy parts. Furthermore, it should be examined whether the limit value for chromium should be replaced by a specific limitation for chromium VI.

The DIN EN 71-3 standard would have to be adapted to the new maximum levels. Should new findings become available about intake from toy material, they should be taken into account.

References

DIN EN 71-3 Safety of Toys Part 3: Migration of certain elements
Documentation on the action programme Environment and Health, 1999

Landesgesundheitsamt Baden-Württemberg, Belastungs- und Wirkungsmonitoring. Untersuchung 2000/2001 – Ergebnisse und Bewertung –

MAK- und BAT-Werte-Liste 2002

EN 71-7 Safety of Toys – Part 7: Finger paints – Requirements and test methods

Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys

Scientific Advisory Committee to Examine the Toxicity and Ecotoxicity of Chemical Compounds, An overall approach for the preparation of recommendations on the migration limits of metals to be applied to dry coating films of paint or other materials of toys which contain these metals (CSTE/84/62/V/E/2).

Umweltbundesamt, Presse-Information: Reduzierung der Stoffeinträge

Verordnung über natürliches Mineralwasser, Quellwasser und Tafelwasser

WHO Environmental Health Criteria 59: Principles for evaluating health risks from chemicals during infancy and early childhood: the need for a special approach

WHO Environmental Health Criteria 70, Principles for the safety assessment of food additives and contaminants in food

WHO Guidelines for drinking water quality 2nd edition Vol. 2 Health criteria and other supporting information, 1996