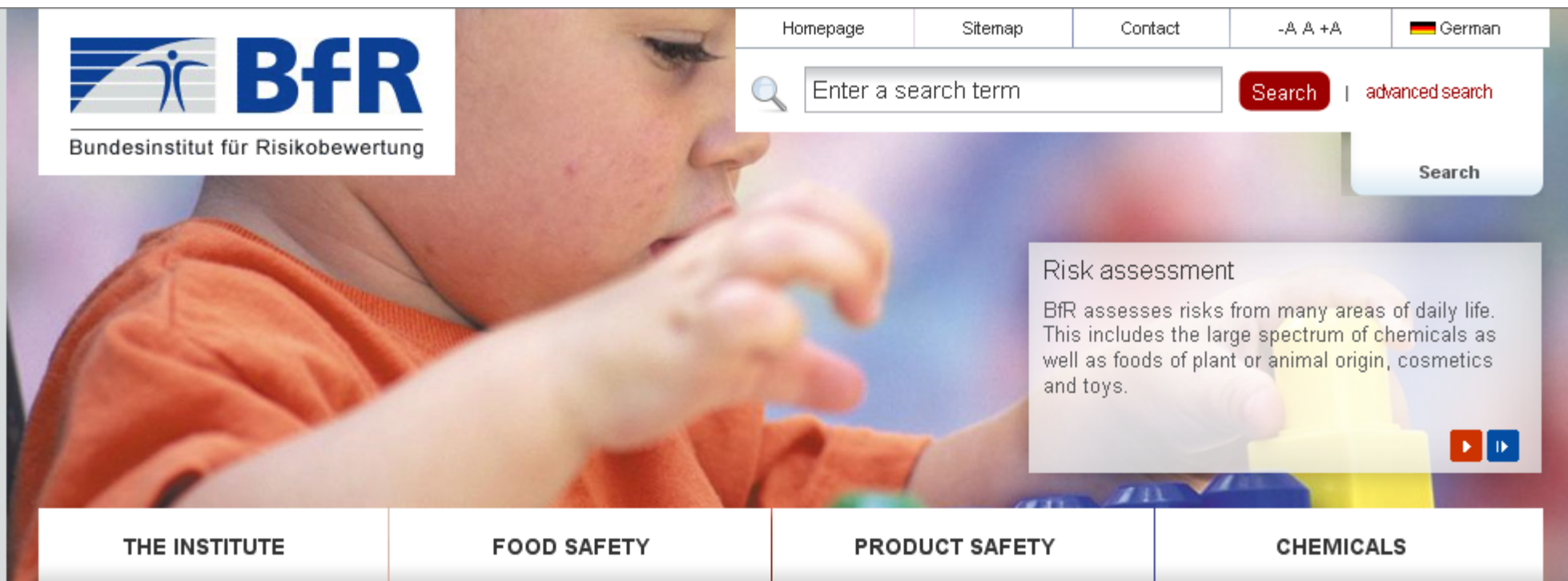


Toy Safety Directive 2009/48/EC

Bärbel Vieth

Federal Institute for Risk Assessment/Berlin

The Federal Institute for Risk Assessment (BfR, Berlin Germany)



The screenshot shows the BfR website homepage. At the top left is the BfR logo with the text "Bundesinstitut für Risikobewertung". To the right are navigation links for "Homepage", "Sitemap", and "Contact", along with a language selector set to "German". A search bar contains the text "Enter a search term" and a "Search" button. Below the search bar is a "Risk assessment" section with a video player showing a child playing with blocks. The text in this section reads: "Risk assessment. BfR assesses risks from many areas of daily life. This includes the large spectrum of chemicals as well as foods of plant or animal origin, cosmetics and toys." At the bottom of the page are four main navigation categories: "THE INSTITUTE", "FOOD SAFETY", "PRODUCT SAFETY", and "CHEMICALS".

Biological and Chemical Safety of Food & Consumer Products

► Publications

Toddler milk drinks are not better than cow

infections caused by vegetable
foods

www.bfr.bund.de

Children are not small adults

Different behavior depending on age

- Sucking and mouthing of small children → higher oral exposure
- Crawling of small children → oral and dermal exposure to contaminated surfaces, further exposure sources and pathways
- Different risk recognition
- Different risk behavior
- Different activity pattern

Exposure

- Higher intake of food related to body weight → higher intake of food contaminants like lead or cadmium
- Higher inhalation rate related to body weight → higher inhalative intake of air contaminants
- Relatively large skin surface area and low body weight → higher dermal exposure

Children are not small adults

Children can react more sensitive to chemicals than adults

- **Liver:** metabolic enzym system underdeveloped, adult levels reached within 1-3 years, special risk for small children
- **Brain:** under development
more sensitive to neurotoxic effects
blood brain barrier is underdeveloped
- **Immune system:**
high level of tissue proliferation and differentiation
animal studies indicate, that changes in immune function induced by toxins may be more persistent

Consequences

- A chemical may induce adverse effects in children at doses lower than those in adults
- Other adverse effects in children than in adults possible
- Children may be especially vulnerable to chemicals

Children are not small adults

Conclusions

- Children should be considered as a separate **sensitive sub-group** of the population regard to chemical risks
- Limit values related to products for children should follow the **precautionary principle**

General question

- Does the toys safety directive follow these specific requirements concerning the health safety of children

General safety requirements (article 10):

- Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way bearing in mind the **behavior of children**
- The **ability of** the users shall be taken into account, in particular in the case of toys for use by **children under 36 months** or by other age groups.
- Specific behavior of children and especially young children is addressed in the TSD

Particular Safety Requirements

Chemical with long lasting effects regulated

Particular safety requirement to chemical properties

- **No risk of adverse effects** on human health due to exposure to the chemical substances or mixtures of which toys are composed or which they contain

Focus on chemicals with long lasting effects important

- Substances that are carcinogenic, mutagenic or toxic for reproduction (CMR substances)
- Heavy metals, elements and organotin compounds
- Allergenic fragrances

CMR-Substances –Regulation

CMR-Substances may cause very serious (even life-threatening effects)

Children may be more vulnerable than adults especially to genotoxic carcinogens (without a safe threshold value)

Regulation:



➤ CMR Substances shall not be used in toys

➤ But may be used, when concentrations are equal or smaller than in the CLP-regulation (e.g. 200 mg/kg)

➤ Substances which are known or presumed to have carcinogenic potential for humans are allowed in concentrations up to 0.1% (1g/kg) in toy

De facto the ban of CMR-substances is overridden by this exception

Do the limit values of the CLP-Regulation protect the health of children sufficiently?

CLP-Regulation for classification, labelling and packaging of substances and mixtures and explosive articles

- Limit values are mostly based on an agreement for worker's protection
- Limit values are not derived by scientific risk assessment
- Not derived for consumer products like toys
- Not all known CMR substances are classified in the CLP-Regulation

Conclusions:

The limit values of the CLP-regulation are not suitable to protect the health of the children sufficiently.

Further problems:

- Only used CMR-Substances are addressed in the TSD
- What is with CMR-Substances, formed during the chemical reaction (like formamide)?

CMR-Substances –Regulation –Example Benzo[a]pyrene (BaP)

Reference compound of polycyclic aromatic hydrocarbons (PAHs)
genotoxic carcinogen, high rate of skin penetration

Limit value for BaP in toys allowed: 100 mg/kg

Toxicological reference value

(no safe threshold value *)

DMEL = 0,004-1 ng/kg b.w./d

*) cancer risk 10^{-6}

Dermal exposure toys

0,1-1008 ng/kg KG/d

(Max. value 66 mg/kg)

Dermal exposure by toys >> DMEL

Risk of higher cancer rate to children !!

(Risk of adverse effects to children exists)

Scientific Committee on Health and Environmental Risks (SCHER) Opinion on CMR-Substances in Toys

Clear opinion of SCHER:

- Suitability of the classification approach applied to toy is quite limited
- **Risk based approach** instead of the hazard based classification limits should be applied
- Safe **migration limit values** are recommended

Regulation of CMR-Substances in food contact materials

- Based on comprehensive toxicological evaluations
- Migration of genotoxic carcinogens used in food contact materials under use condition should be not detectable
- High safety standard

Requirements for CMR-Substances in toys

- Children can be more susceptible to carcinogens than adults
- Regulations should protect the health of small children
→ precautionary principle
- Limit values should be based on migration data
- Regulations for food contact materials should be adopted to toys: no release of CMR substances under the contact conditions of playing (skin, ingestion, mouthing) from toys
- CMR substances formed during reaction should be included (e.g. formamide in puzzle mats)
- Aggregate exposure to the same CMR substance by other products should be considered (e.g. PAHs, phthalates)

Heavy metals, elements

Increased migration limits for scraped-off toy material
Impairment of the protection level

Element	TSD 2009/48/EC (mg/kg)	EN 71-3 (mg/kg)	Factor
Antimony (Sb)	560	60	9.3
Arsenic (As)	47	25	1.9
Barium (Ba)	56000	1000	56
Lead (Pb)	160	90	1.8
Mercury	94	60	1.6
Cadmium	23	75	0.3

The industry has been complied with the lower „old“ values without problems (good manufacturing practice)

Lead is neurotoxic

- Effects on the central nervous systems
- Children (developing brain) are distinctly more vulnerable
- Learning deficits, reduced Intelligence Quotient (IQ)
- New scientific finding: no safe threshold value

EFSA opinion

- In infants and children there is potential concern at current levels of exposure to lead for effects on neurodevelopment

Conclusion

ALARA-principle (as low as reasonably achievable) must be applied to the release of lead from toys.

Cadmium, Arsen, Barium

Cadmium, Arsen

- Current assessments from EFSA
- Cadmium toxic to kidney
- Arsenic can cause lung cancer
- Lower toxicological threshold values by EFSA derived
- The intake via food exceeds these threshold values
- Exposure by food and by other products should be reduced
- **ALARA-principle**

Barium

- The scientific basis of the toxicological threshold value for deriving the migration limit values is not clear
- The migration limit allows an intake which exceeds the the threshold value (TDI) of WHO by a factor of 3
- In general the WHO-TDI should be used for deriving migration limits

Conclusion:

- The increased limit values of arsenic, barium, lead and cadmium in toys may result in **adverse effects to the health of children**.
- The limit values should be based on **Good Manufacturing Practice** and in the some cases the **ALARA**-principle.
- Exposure by **other sources** should be considered for limit values for toys (SCHER)

Contact allergy/ allergenic fragrances

Contact allergy (dermal contact):

- An acquired contact allergy exists lifelong
- Only the symptoms, but not the causes can be treated
- Important contact allergens: **nickel, fragrances, preserving agents**

Fragrances :

- In toys no technological function
- About 2% of children react sensitively to fragrances.
- Synergistic effects for allergenic fragrances scientifically proven

Use of 55 allergenic fragrances forbidden in toys

- Permitted traces up to 100 mg/kg are not in accordance with Good Manufacturing Practice

11 allergenic fragrances shall be listed on toys

- Declaration limit 100 mg/kg should be decreased to 10 mg/kg (like the declaration limit for leave-on products in Cosmetics Directive)



Fragrances in toys for children below 36 months

- Because of the mouthing behaviour these toys should not contain fragrances (mostly only dermal assessment of fragrances)

The most important contact allergen is Nickel

- About 10% of children are sensitive to nickel
- Dermal release of nickel is not regulated in the TSD

Many preserving agents are contact allergens

- No regulation in the TSD
- Preserving agents in toys should be regulated like in Cosmetics Directive

Requirements on safe toys and regulations in the TSD

General requirements

High level of consumer protection is necessary for toys reflecting the specific requirements for children

Use of the precautionary principle

Aggregate exposure to the substances by other sources/products should be considered

→ Regulation of different products should be harmonized

Regulations for food contact materials and the Cosmetics Directive should be adopted to toys

Requirements on safe toys and regulations in the TSD

CMR-substances:

- CLP-regulation is not adequate to protect childrens health
- Risk based instead hazard based limit values (SCHER)
- Adoption of regulations on food contact materials
- No release of CMR substances under the contact conditions of play (skin, ingestion, mouthing) for all toys

Heavy metals, elements

- Protection level should be improved
- Distinctly lower migration limits are needed at least for lead, cadmium, arsenic and barium

Contact allergens/allergenic fragrances:

- Allergenic fragrances in toys are avoidable, no function
- Regulation for allergenic fragrances should be adopted to the leave-products in cosmetics directive and in toys for children below 36 months forbidden
- Allergenic preserving agents and nickel should be regulated in toys (Cosmetic Directive and REACH)

Possibilities for amending the TSD by comitology procedure

The Commission may adopted (Article 46/1)

- The regulations for **allergenic fragrances**
- The migration limits for **heavy metals/ elements**

The Commission may adopt (Article 46/2)

- Specific limit values for toys for **children under 36 months** and for toys intended to be placed in the mouth
- The **regulations for food contact materials** should be taken into account to these toys
- At least for these toys the limit values of food contact materials for **CMR-substances** should be adopted !
- The release of genotoxic carcinogens should be not detectable

Open points for amending the TSD

CMR-Substances

- Small children prefer playing (and mouthing) with toys of older brothers and sisters
- Dermal uptake of carcinogenic substances from toys by all age groups can be of relevance (BaP)
- Migration limit values for all age groups are needed
- The opinion of SCHER should be followed.
- Very important point for preventing adverse health effects as required by the TSD

Further contact allergens

- Possibilities for regulations are missing
- Fragrances in toys for children under 36 months

Thank you for your attention

Bärbel Vieth

Federal Institute for Risk Assessment

Thielallee 88-92 • D-14195 Berlin

Tel. +49 30 - 184 12 - 0 • Fax +49 30 - 184 12 - 47 41

baerbel.vieth@bfr.bund.de • www.bfr.bund.de