

Polycyclic aromatic hydrocarbons (PAHs) in toys

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Numerous polycyclic aromatic hydrocarbons (PAHs) are carcinogenic substances and are classified as CMR substances. CMR substances are carcinogenic, mutagenic or toxic to reproduction. PAHs usually refer to a substance mixture of over one hundred individual components. PAHs can be part of direct contact consumer goods made of rubber or elastomers including children's toys. This is due to the use of PAH-containing plasticiser oils or carbon black in which PAHs occur naturally and which are added during the production of rubber or elastomers to provide the materials with different mechanical and process related properties as needed.

The increasing cases of cancer in children require urgent action to minimise exposure to CMR substances as much as possible. The Federal Institute for Risk Assessment (BfR) has applied the regulations on CMR substances of the new Toy Safety Directive of the EC to PAHs and assessed it with regard to their health risk. The Institute concludes that the currently valid levels neither protect children's health adequately, nor do they meet the requirement on exposure minimisation for CMR substances. BfR maintains the opinion that the ALARA principle (as low as reasonably achievable) should be applied to such substances. Studies of toys show that the technologically possible levels of PAHs substances are clearly below the maximum levels permitted by the Toy Safety Directive.

BfR recommends that regulations of CMR substances in toys should in general refer not to the content, but rather use the migration concept as it is applied for plastic materials and articles intended to come into contact with foodstuffs (Directive 2002/72/EC). For these materials, it is required that the migration of CMR substances is undetectable. According to BfR's knowledge, these requirements are technologically possible and are already best practice. The regulation for food contact materials should thus be assumed for all types of toy materials and without age limit in order to minimise children's exposure to CMR substances.

1 Subject of the Assessment

For children, special safety requirements concerning their exposure to chemicals must be made as they can react considerably more sensitively than adults. This is also true for CMR substances (substances that are classified as carcinogenic, mutagenic or toxic to reproduction). Data of the German Childhood Cancer Registry verify that since the beginning of documentation in 1980 until 2006 in Germany the number of new cases (incident number) of malign cancer in children under 15 years of age has increased continually and considerably. Over the past 20 years the Childhood Cancer Registry determined a rise in incidence of about 17% (German Childhood Cancer Registry 2008). This period of time first allowed a reliable trend prognosis since the registry data for this period were inclusive enough. Malignant neoplasms are the second most common cause of death in children (RKI 2008). The reasons are generally unclear.

For the purpose of health protection, measures to minimise children's exposure to CMR substances through all sources are urgently needed. This should also include the exposure through toys. On average, children up to 6 years of age have played about 15,000 hours. This number illustrates the relevance of exposure to CMR substance through toys. According to the latest European Toy Safety Directive (Directive 2009/48/EC, TSD), CMR substances

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such as PAHs are allowable if their concentrations in toys do not exceed the maximum levels specified in chemical legislation (Directive 1999/45/EC, Regulation (EC) No 1272/2008).

The case of polycyclic aromatic hydrocarbons (PAHs) exemplifies the insufficient health protection against CMR substances in the new TSD. The following paper thus presents a health risk assessment for PAHs as a relevant carcinogenic class of substances under special consideration of children and their exposure through toys.

2 Results

In light of the continuing increase in cancer incidence and due to the special sensitivity of children to chemicals, measures to minimise children's exposure to CMR substances are urgently needed. In this regard, toys can be a relevant, child-specific source of exposure, as the PAH example documents. Toys must therefore be incorporated into measures to minimise exposure to CMR substances.

PAHs are human carcinogens for which no safe minimum effect threshold can be determined due to their genotoxic mechanism of action. Assuming the allowable content of up to **100 mg/kg** according to the new TSD, the potential dermal uptake of benzo[a]pyrene (BaP), the reference compound of PAHs, through toys can distinctly exceed the oral intake through food. This allowable uptake through toys would exceed a level without risk to health by a factor of 300. This level without risk to health was derived by the TTC concept (Threshold of Toxicological Concern) for highly carcinogenic and mutagenic substances such as BaP and includes the intake through all exposure sources. The TTC value is based on a "socially accepted" lifetime cancer risk in some countries of 1 to 1 million. When the TTC value is exceeded considerably, an increased cancer risk must be assumed. The example of maximum allowable BaP exposure through toys and its comparison with the TTC value illustrate that a risk to children's health cannot be excluded for certain.

The PAH example demonstrates that the transfer of chemical legislation to the regulations of CMR substances in toys neither satisfies the requirement to minimise exposure, nor does it adequately protect children's health. From a toxicological point of view, it is imperative that technologically feasible measures to minimise exposure to CMR substances are established. Data on PAH content in toys show that technologically feasible levels are distinctly lower than the maximum levels allowed according to the new TSD which are based on chemical legislation. The high exposure of children to PAHs through toys is technologically avoidable and thus unacceptable. The highest level of child protection is achieved if the regulations for CMR substances in food contact materials are applied to toys.

BfR recommends that, in general, regulations for CMR substances in toys should not apply to the content but instead to the migration since only this is relevant to exposure. The regulation of CMR substances in food contact materials requires that the release of CMR substances is not detectable (<0.01 mg/kg). This is technologically feasible and already best practice. It should be adopted for all toy materials without age limit in order to minimise the exposure of children to CMR substances.

3 Reasons

3.1 Risk assessment

3.1.1 Possible risk sources

PAHs consist of a substance mixture of over 100 individual components, which may be detectable in toys made of rubber and plastics. They can end up in toys as components of plasticiser oils which are added to rubber products in order to provide suitable functional properties. Oils that are low in PAHs are also available, yet comparably more expensive. PAHs are natural components of crude oil. Carbon black is an additional source, which is often added to elastomers in order to provide certain product properties (i.e. elasticity, cushioning and solubility in the polymer matrix). Plasticiser oils and carbon black can also be added to varnish and coating materials. PAHs have been detected in consumer products as well as in toys (BfR 2009).

3.1.2 Hazard potential

A current BfR Opinion on this class of substances in consumer products is available on the BfR website (BfR 2009). The following information on hazard potential thus pertains to selected aspects.

Since it has been known for quite a while that numerous PAHs can cause tumours, the substances have been classified as carcinogenic. Benzo[a]pyrene (BaP) serves as reference compound for PAHs. The International Agency for Research on Cancer (IARC) classified BaP as carcinogenic for humans (Straif et al. 2005) some years ago. Because of the genotoxic mechanism no safe lowest effect threshold can be deduced for a number of these PAHs. Furthermore, some PAH representatives, such as the reference compound BaP, have a mutagenic effect on humans and impair reproduction (DFG 2004). Mutations through DNA adduct development of highly reactive PAH metabolites can induce the development of cancer (DFG 2008). PAHs are highly likely to be absorbed through the skin.

In addition to mutagenic and carcinogenic effects, gene activation through PAHs has also been documented. The induction of enzymes of xenobiotic metabolism, which can entail an increase of PAH metabolisation as well as the degradation of endogenous substances, is well studied (DFG 2008). Since mutagenicity and carcinogenicity can only be triggered by toxicologically relevant metabolites, enzyme induction can boost these effects through repeated exposure.

As a consequence of the large number of PAHs, various lists of important PAH compounds have been compiled. As one of the most important compounds, the reference compound BaP is included in the EPA list, which contains 16 PAHs of environmental relevance, as well as in the EFSA list, which contains 16 PAHs of food relevance, and the MAK list, which contains 19 PAHs of occupational health relevance (cp. table 1).

Table 1: Comparison of different PAH lists and Toxic Equivalency Factors (TEF)

Compound	CAS No	US-EPA, 1984	EFSA, 2008	DFG, 2008	DFG-TEF
Acenaphthene	83-32-9	x			
Acenaphthylene	208-96-8	x			
Anthanthrene	191-26-4			x	0.1
Anthracene	120-12-7	x			
Benzo[<i>a</i>]anthracene	56-55-3	x	x	x	0.1
Benzo[<i>b</i>]fluoranthene	205-99-2	x	x	x	0.1
Benzo[<i>j</i>]fluoranthene	205-82-3		x	x	0.1
Benzo[<i>k</i>]fluoranthene	207-08-9	x	x	x	0.1
Benzo[<i>c</i>]fluorene	205-12-9		x		
Benzo[<i>b</i>]naphtho[2,1- <i>d</i>]thiophene	239-35-0			x	0.01
Benzo[<i>ghi</i>]perylene	191-24-2	x	x		
Benzo[<i>a</i>]pyrene	50-32-8	x	x	x	1
Chrysene	218-01-9	x	x	x	0.01
Cyclopenta[<i>cd</i>]pyrene	27208-37-3		x	x	0.1
Dibenz[<i>a,h</i>]anthracene	53-70-3	x	x	x	1
Dibenz[<i>a,l</i>]pyrene	191-30-0		x	x	10
Dibenz[<i>a,e</i>]pyrene	192-65-4		x	x	1
Dibenz[<i>a,h</i>]pyrene	189-64-0		x	x	10
Dibenz[<i>a,l</i>]pyrene	189-55-9		x	x	10
Fluoranthene	206-44-0	x			
Fluorene	86-73-7	x			
Indeno[1,2,3- <i>cd</i>]pyrene	193-39-5	x	x	x	0.1
Naphthalene	91-20-3	x		x	0.001
Phenanthrene	85-01-8	x		x	0.001
Pyrene	129-00-0	x		x	0.001
1-Methylpyrene	2381-21-7			x	0.1
5-Methylchrysene	3697-24-3		x		

The individual PAHs have a generally comparable carcinogenic potential. However, they do exhibit different carcinogenic potencies. The aim of a recent analysis was to compare the carcinogenic potencies of PAHs in regard to the reference compound BaP. BaP was first assigned a TEF of 1. Many substances exhibit a much weaker effect than BaP and thus receive a lower TEF such as naphthalene, pyrene or phenanthrene, each of which was assigned a factor of 0.001. This TEF means that these substances are ascribed with only one thousandth of the potency of BaP in regard to carcinogenic effect. In contrast to this, other substances have a much greater carcinogenic effect than BaP. Dibenz[*a,l*]pyrene as well as other dibenzopyrenes thus receive a TEF of 10, as their carcinogenic effect is considerably higher than that of BaP (cp. Table 1) (DFG 2008).

Whether or not the carcinogenic potency of individual PAHs can be added up to a total potency or if synergetic effects can lead to an overadditive effect has not been clarified completely (DFG 2008).

3.1.3 Exposure

The German association for experimental and clinical pharmacology and toxicology (*Deutsche Gesellschaft für experimentelle und klinische Pharmakologie und Toxikologie – DGPT*) has estimated the oral and inhalative daily intake for adults through various sources. Food (fats, oils, barbecue and the like) provides about 200 – 500 ng BaP per day. The daily inhalative intake amounts to levels up to 450 ng BaP through indoor air and up to 100 ng through outdoor air to a comparable extent. Individuals who smoke tobacco are exposed additionally. Smoking 20 cigarettes a day entails the additional intake of up to 400 ng BaP (DGPT 2000). In regard to body weight, the alimentary as well as inhalative intake of harmful substances for children is greater than for adults, which leads to higher internal doses.

As PAHs easily penetrate the skin, dermal exposure should not be underestimated. Human skin absorption of PAHs is well documented. Occupational health studies have shown that workers exposed to creosote oil (tar oil) take in the PAH affiliated compound pyrene considerably more through the skin than through inhalation (Elovaara et al. 1995). A study involving voluntary test persons examined whether pyrene and BaP in coal tar ointment can penetrate the skin, and whether its metabolites are excreted along with urine. After treatment with the ointment, the excretion of hydroxy metabolites of pyrene and BaP increased considerably. Seven days after the end of treatment, urine discharge again displayed the levels which were recorded prior to treatment (Godschalk et al. 1998). The dermal contact with toys that contain PAHs could thus depict a relevant contribution to children's exposure to these genotoxic carcinogens.

In order to obtain an overview on PAH concentrations in toys, BfR has assessed a number of analysis results on PAH concentrations in different toys provided by a commercial enterprise. In about 70% of the 104 examined toy samples, PAHs were below detectable levels or contained less than 1 mg/kg PAHs. Between 1-10 mg/kg PAHs were detected in 19% and between 10-100 mg/kg PAHs in 7% of the samples. Furthermore, highest values between 100-1000 mg/kg PAHs were detected in 3% of the samples. Recent results of 40 toys report PAH content of < 0.2 mg/kg in 39 samples (BfR 2009a). These data show that the current state of technology most certainly facilitates the production of materials made of rubber or soft plastic which contain low or undetectable amounts of PAHs.

However it should be critically noted that the available data are limited to the analysis of the 16 PAHs in the EPA list (see table 1), which was compiled based on aspects of environmental analysis and relevance. Thus, no data are available on higher molecular PAHs such as the dibenzopyrene isomers. These were assigned a TEF of 10 due to their high carcinogenic potency and receive a more critical health assessment than the reference compound BaP.

The following table depicts a worst-case exposure assessment of dermal intake in a few examples for the reference compound BaP. In order to warrant the comparability of the results, the evaluation is based on an assumed exposure scenario with a 10 kg child that has 1 hour of contact with a 200 g heavy PAH-containing object (e.g. two bicycle handles) (BfR 2009). However, reliable methods to determine the migration rate for PAHs under realistic conditions that adequately incorporate the role of sebum are still needed. Based on TÜV data on the migration of PAHs from a tool handle to a latex glove treated with sweat simulation, BfR assumes a migration of 1% in a temporary worst-case estimation (BfR 2009).

The assessment of internal exposure further requires data on skin penetration of PAHs. These vary significantly depending on species, individuals, method of investigation and matrix. No valid studies on PAH penetration of human skin, especially for hands, are available as of yet. Resorption factors between 3 and 43% (GESTIS-database on hazardous sub-

stances) are reported in scientific literature. After a discussion of the ad hoc workgroup PAHs of the interim Plastics Committee, BfR considers a resorption factor of 22% for justifiable. This factor serves as basis for the following exposure assessments (BfR 2006).

Table 2: Attainable BaP intake and dose for a 10 kg child by applying the concentration limit for consumer products of different regulations to toys

Regulation	BaP concentration limit [mg/kg]	BaP intake [ng/person]	BaP dose [ng/kg KG]	Factor
Toy Safety Directive 2009/48/EC	100	44,000¹	4,400	1
GS (safety tested) mark	1^{2,3}	440¹	44	1:100
REACH Regulation for tyres (EC) No 552/2009	0.1^{3,4}	44¹	4.4	1:1000
Food contact material RL 2007/19/EG	0.00625³	2.75¹	0.275	1:16,000
TTC-Concept		150⁵	15	1:300

¹ Assumptions: 1% migration, 22% skin penetration, 1 hour of skin contact, 200 g material in contact with skin.

² The basis for this assessment is the maximum allowable content of BaP that is necessary to receive the GS mark for consumer products with anticipated skin contact of more than 30 seconds; ZLS 2008.

³ For this assessment, it was assumed that each limit value applies to toys.

⁴ Plasticiser oils for the production of car tyres may contain a maximum of 1 mg BaP/kg. If it is assumed that the finished product contains 10% plasticiser oil, the maximum BaP content is 0.1 mg/kg.

⁵ The safety threshold value assigned for humans according to the TTC concept for highly potent mutagenic/carcinogenic substances, such as BaP, on the basis of a socially accepted lifetime cancer risk of 1 to 1 million (Munro 1990, Munro et al. 1996, 2008)

Because the regulation of the new TSD concerning CMR substances is based on the chemical legislation, toys can contain the reference compound BaP up to a concentration of 100 mg/kg (according to Annex VI of Regulation (EC) No 1272/2008 the specific concentration level for BaP is CAS 50-32-8, $\geq 0.01\%$). Based on this concentration limit for BaP in toys, children who have one hour of skin contact/play time could uptake a multiple amount of carcinogenic BaP dermally of what is contained in the smoke of 40 cigarettes a day. BaP content that is in line with this limit value would lead to a BaP dose that is 100 times as high as the BaP dose which would result from toys that have received a GS mark and consequently may contain up to 1 mg BaP/kg. In the production of car tyres, only plasticiser oils may be used that contain less than 1 mg/kg BaP. If we assume that 10% plasticiser oil is used during the production of car tyres, the finished product contains 0.1 mg/kg BaP. If this BaP content is applied to toys, the BaP dose absorbed through the skin during play time would be 1000 times lower than the amount allowed by the new TSD. Regulations for food contact materials are even more rigorous. These define a maximum allowable concentration of up to 6.25 μg BaP/kg plastic material for the use of carbon black as additive. The application of this limit value to toys would mean a BaP dose that is 16,000 times lower compared to the BaP content allowed according to the new TSD (100 mg/kg). The highest level of protection would therefore be provided if the regulation for food contact materials were applied to toys.

The table also contains an added comparison with the BaP dose according to the TTC concept. The TTC concept aims to define a substance safety threshold for humans without long-

term animal testing for the substance (Munro 1990, Munro et al. 1996, 2008). The safety threshold is defined on the basis of evaluations of the Cancer Potency Database and the in some countries socially accepted lifetime cancer risk of 1 to 1 million. In the concept, highly potent mutagenic/carcinogenic substances such as BaP are assigned an especially low TTC dose of 0.15 µg/day/person. According to this, the total allowable daily intake of BaP through all sources would be 300 times lower than the currently maximum allowable intake for toys only.

Overall this means, that under certain circumstances, the additional exposure to BaP through toys can thus be considerably higher than the amount that an adult takes in through food or as a smoker on a daily basis.

3.1.4 Risk characterisation

According to the DGPT, adults take in up to 500 ng BaP through food (DGPT). This ubiquitous exposure through food cannot be classified as irrelevant. Major epidemiological analyses of cancer causes for humans attribute 30% of tumour diseases on diet. The causes are diverse, but the intake of BaP or PAHs through food could also contribute to this result.

Children can be further exposed considerably through skin contact with PAH containing toys. If we assume the maximum allowable content of BaP in toys according to the TSD, this dermal uptake can be noticeably higher than the amount that an adult takes in daily through food or as smoker. This becomes even less tolerable against the background of increasing tumour incidences in children.

Due to a lack of valid data on the migration of PAHs under realistic conditions as well as a lack of data on human skin penetration, the exposure assessment remains uncertain. However, the exposure assessment clearly illustrates that regulations on CMR substances in toys defined in the new TSD are not suited to protect playing children in regard to health safety sufficiently. The direct comparison with values of the TTC concept underlines this as well. According to this concept, the safety threshold for the highly potent mutagenic and carcinogenic BaP is 15 ng/kg KG a day. This value covers the total intake through all sources and includes a socially accepted lifetime cancer risk of 1 to 1 million. The dermal BaP uptake allowed by the new TSD alone exceeds this assumed safety threshold by a factor of 300. Even if a child does not play with PAH containing toys on a daily basis, it can be assumed that these conditions would exceed the socially accepted lifetime cancer risk of some countries and instead may result in the probable increase of cancer rate. Children's exposure to PAHs must therefore be kept at a minimum.

The TSD demands that "toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures which they contain" (Directive 2009/48/EC). The example of maximum allowable BaP exposure through toys and its comparison to the TTC value illustrate that health damage cannot be ruled out. Child health protection is at its highest level if the regulations for CMR substances in food contact materials are applied.

Previous considerations are based on data on the 16 EPA PAHs and BaP. The considerably more potent carcinogenic PAHs, the dibenzopyrene isomers, are not included in the hitherto applied analysis method. It must be assumed that PAH containing toys include these congeners to some extent and can thus lead to children's exposure. This assessment could therefore also underestimate the carcinogenic risk of PAH exposure through toys.

3.2 Other aspects

The TSD demands that toys in the case of exposure to chemical substances which they contain may not cause risks of adverse effects to human health. Safety requirements on the content of CMR substances in toys were based on hazardous substances regulations of the European Union's chemical legislation. CMR substances are thus allowed in toys if their concentration does not exceed the concentration limits defined in chemical legislation. As they were originally intended for other purposes, the suitability of these regulations for health safety requirements for toys will now be discussed further.

The regulations on classification and labelling of substances (pure chemicals) are defined in Directive 67/548/EEC; that of preparations (substance mixtures) are defined in Directive 1999/45/EC. The criteria for the classification of hazards and the concentration limits were adopted with a few modifications in the so-called CLP Regulation (EC) No 1272/2008, which will replace both Directives. The criteria and levels thus apply to chemicals, biocides, pesticides and their mixtures as well as similar products such as detergent or all sorts of paints and varnishes.

Specific limit values for a number of CMR substances are currently specified in Directive 67/548/EEC for individual concentrations in preparations. For lack of limit values, Directive 1999/45/EC defines general concentration limits for preparations that contain CMR substances. If these concentration limits are exceeded, the preparation must be labelled accordingly. The new CLP Regulation (EC) No 1272/2008 provides similar regulations. The classification and labelling rules of the European CLP Regulation are applied to substances and their mixtures as well as to products with pyrotechnic ingredients (explosives, fireworks, etc.), but not to commodities such as toys or other consumer products.

While in many cases the definition of hazardous characteristics and their classification criteria were determined toxicologically, this is not the case for concentration limits of CMR substances in preparations/mixtures. These concentration limits were determined politically in the early 1980s and were based on the practical and technological feasibility of the time.

In contrast scientific discussions concerning the health safety relevance of these concentration limits were generally left out of the development of these limit values. Originally, concentration limit values were defined at which mixtures that contain CMR substances must be labelled as carcinogenic, mutagenic or toxic to reproduction. These limits were intended for package labelling regulations. Originally, the main purpose herein was to ensure occupational safety. In 1990 within the framework of the rationale for Directive 90/394/EEC (Directive on the protection of workers) it was stated that "[...] current scientific knowledge is not such that a level can be established below which risks to health cease to exist, a reduction in exposure to carcinogens will nonetheless reduce those risks" (Directive 90/394/EEC).

From a toxicological point of view, the application of concentration limits defined in hazardous substances legislation to products or even toys with which children come into direct contact is in no way justified. Their application to toys to regulate health related safety requirements is thus unacceptable.

Children's exposure to chemicals in general and CMR substances in particular demands special safety requirements. We are thus in need of a regulation that takes children's special sensitivity to the effects of chemicals into account, whereby the use of CMR substances in products for children is forbidden and only residues, in accordance with the state of the art, should be tolerated.

3.3 Discussion

Due to genotoxic mode of action, it is not possible to determine a definite lowest effect threshold for a number of PAHs. Instead, from a toxicological point of view it is absolutely necessary that minimisation of CMR substances is required in accordance with technological feasibility. The PAHs concentration data available to BfR substantiate that it is technically possible for many manufacturers to produce toys with an undetectable amount of PAH. In 70% of toys examined, the PAH content was below 1 mg/kg. Plasticiser oils and carbon black with suitably low amounts of PAHs or none at all are commercially available. Children's high exposure to PAHs through toys is therefore technologically avoidable and thus unacceptable.

The example of PAHs illustrates that the application of regulations in chemical legislation to the content of CMR substances in toys neither meets the requirement on exposure minimisation, nor does it assure sufficient health protection for children.

In general, regulations concerning the migration instead of regulations on content are necessary if exposure is to be minimised. Regulations for food contact materials according to which the release of used CMR substances must be below detectable, have proven reliable and are technologically feasible (Directive 2002/72/EC). They are more suitable for the minimisation of oral as well as dermal exposure of children to CMR substances. The new TSD only provides these regulations for food contact materials in regard to toys for children under three years of age and for toys that are intended for oral purposes. This age limit takes into consideration neither that a small child commonly puts the toys of elder sibling's into its mouth nor does it provide for the dermal contact of older children with CMR containing toys.

3.4 Scope for action/ measures

Measures are necessary to reduce the exposure of children to CMR substances.

As the PAH example illustrates, toys must be considered as a special source of exposure for children as a target group. This means that measures must not only take into account the reduction of PAH content in food, but must also aim to minimise exposure through toys since the intake of CMR substances during play time can lead to much greater exposure than alimentary exposure.

Additional research is necessary for the analysis and migration of PAHs from products in order to obtain valid and realistic data for exposure and health risk assessment. Toxicologically relevant congeners such as dibenzopyrenes must hereby be taken into account.

In regard to children's exposure to PAHs in toys, BfR maintains the opinion that the ALARA principle (as low as reasonably achievable) should be applied to these genotoxic carcinogens due to a missing safe lowest effect threshold. From a toxicological point of view, a minimisation requirement in accordance with technological feasibility is absolutely imperative. BaP content below 1 mg/kg and content of the 16 EPA-PAHs below 10mg/kg are in accordance with the state of the art and should thus shortly be taken as a first step towards exposure minimisation. Allowable content of up to 100 mg/kg BaP, on the other hand, could lead to a considerable increase in current exposure through toys.

In general, regulations for CMR substances in toys should pertain to migration, as only migration is relevant for exposure. The regulations for CMR substances in food contact materi-

als according to which the release of CMR substances must be below detectable levels are technologically feasible and are already best practice. They should be applied to all types of toy materials.

4 References

BfR 2006: *1. Sitzung der Ad-hoc-Arbeitsgruppe PAK der Vorläufigen Kunststoffkommission des BfR* [1st meeting of the ad hoc work group PAH of the interim plastics commission], report only available in German, 13 December 2006

http://www.bfr.bund.de/cm/216/1_sitzung_der_ad_hoc_arbeitsgruppe_pak_der_vorlaeufigen_kunststoff_kommission.pdf

BfR 2009: PAHs in consumer products must be reduced as much as possible. Updated BfR Expert Opinion No. 025/2009, 8 June 2009.

http://www.bfr.bund.de/cm/230/pahs_in_consumer_products_must_be_reduced_as_much_as_possible.pdf

BfR 2009a: Stellungnahme zu den Untersuchungsergebnissen von PAK in Spielwaren und anderen Bedarfsgegenständen, Report to BMELV, 10.7.2009, AZ: 7-5262056

DFG 2004: The Senate Commission of the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) on the Investigation of Health Hazards of Chemical Compounds in the Work Area, 2004 MAK and BAT Value Lists

DFG 2008: Greim, Helmut (ed.) *Gesundheitsschädliche Arbeitsstoffe. Toxikologisch-arbeitsmedizinische Begründungen von MAK-Werten und Einstufungen 43. Lieferung MAK-Werte Begründungen* (DFG) Volume 43: 1-210.

DGPT 2000: *Stellungnahme der Sektion Toxikologie der Deutschen Gesellschaft für experimentelle und klinische Pharmakologie und Toxikologie (DGPT) zur möglichen Gesundheitsgefährdung durch erhöhte Konzentrationen an polyzyklischen aromatischen Kohlenwasserstoffen (PAKs) im Trinkwasser*. [DGPT Opinion on health risk through increased PAH concentrations in drinking water, only available in German]

EFSA 2008: Polycyclic Aromatic Hydrocarbons in Food. Scientific Opinion of the Panel on Contaminants in the Food Chain (Question No. EFSA-Q-2007-136) Adopted on 9 June 2008. The EFSA Journal 724: 1-114

Elovaara E, Heikkilä P, Pyy L, Mutanen P, Riihimäki V (1995): Significance of dermal and respiratory uptake in creosote workers: exposure to polycyclic aromatic hydrocarbons and urinary excretion of 1-hydroxypyrene. *Occup Environ Med*, 1995 March; 52(3):196-203.

GESTIS-database on hazardous substances: Information system on hazardous substances of the Berufsgenossenschaften; <http://www.dguv.de/bgia/en/gestis/stoffdb/index.jsp>

Godschalk RW, Ostertag JU, Moonen EJ, Neumann HA, Kleinjans JC, van Schooten FJ (1998): Aromatic DNA adducts in human white blood cells and skin after dermal application of coal tar. *Cancer Epidemiol Biomarkers Prev*, 1998 September; 7(9):767-73.

Munro IC (1990): Safety assessment procedures for indirect food additives: an overview. Report of a workshop. *Regul Toxicol Pharmacol*, 1990 August; 12(1):2-12.

Munro IC, Ford RA, Kennepohl E, Sprenger JG (1996): Correlation of structural class with no-observed-effect levels: a proposal for establishing a threshold of concern. *Food Chem Toxicol*, 1996 September; 34(9):829-67.

Munro IC, Renwick AG, Danielewska-Nikiel B (2008): The Threshold of Toxicological Concern (TTC) in risk assessment. *Toxicol Lett*, 2008 August 15; 180(2):151-6.

Directive 67/548/EEC: COUNCIL DIRECTIVE of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Directive 90/394/EEC: COUNCIL DIRECTIVE of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work.

Directive 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Directive 2002/72/EC: COMMISSION DIRECTIVE of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs

Directive 2007/19/EC: COMMISSION DIRECTIVE of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

Directive 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys

RKI 2008: Cancer in Germany 2003 – 2004. Incidence and Trends. Published jointly by the Robert Koch Institute and the Association of Population-based Cancer Registries in Germany, 6th edition, Berlin, 2008.

Straif K, Baan R, Grosse Y, Secretan B, El Ghissassi F, Cogliano V; WHO International Agency for Research on Cancer Monograph Working Group (2005): Carcinogenicity of polycyclic aromatic hydrocarbons. *Lancet Oncol*, 2005 December; 6(12):931-2.

Regulation (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Regulation (EC) No 552/2009 of 22 June 2009 amending 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 Annex XVII

ZLS 2008: *Prüfung und Bewertung von Polyzyklischen Aromatischen Kohlewasserstoffen (PAK) bei der GS-Zeichen-Zuerkennung*; ZEK 01.2-08
http://www.zls-muenchen.de/de/left/aktuell/pdf/zek_01_2-08_pak_verbindlich_mindermengen.pdf [Control and assessment by the central German Länder authority of polycyclic aromatic hydrocarbons (PAH) in awarding seals of approval, only available in German]