Risiken erkennen – Gesundheit schützen

Carcinogenic polycyclic aromatic hydrocarbons (PAHs) in consumer products to be regulated by the EU - risk assessment by BfR in the context of a restriction proposal under REACH

BfR Opinion Nr. 032/2010, 26 July 2010

Carcinogenic polycyclic aromatic hydrocarbons (PAHs) still are frequently found in consumer products such as toys, tool handles, bicycle grips, shoes or sporting goods, despite the fact that the health hazards of these substances have been known for a long time. PAHs may be present in plastics, elastomer or rubber materials, lacquers, varnishes, paints or other coatings. For this reason, Germany is currently urging the EU to restrict these hazardous compounds in a great variety of products. According to the European chemicals regulation REACH, EU Member States are entitled to propose such restrictions, if they believe that a chemical poses health risks which require Community-wide action.

In the context of this restriction procedure, the Federal Institute for Risk Assessment (BfR) has performed a human health risk assessment for PAHs in consumer products. Its focus was placed on evaluating the potential carcinogenic risk following contact and uptake via the skin. For this purpose, BfR has evaluated chemical-analytical data on the PAH content of more than 5,300 consumer products - including grips/handles, toys and sports equipment. These data originated from a number of different laboratories, consumer protection institutions or BfR itself. In over 90 % of the analysed products, no PAHs were detected. This result shows that the use of PAHs in consumer products is technically avoidable. Nevertheless, differences between product groups were noted. Products for everyday use by consumers and children in particular sometimes displayed very high PAH contents.

The BfR risk assessment is part of a restriction dossier compiled by several German authorities. It was handed over to the European Commission in June 2010. The dossier contains a recommendation to restrict the content of carcinogenic PAHs in consumer products to a maximum of 0.2 mg/kg. This limit value is based on the Limit of Quantification (LOQ) of the analytical test method used for the German GS (certified safety) mark. In addition, it is proposed that future technical progress is monitored and the limit value is adjusted to future (lower) analytical quantification limits as appropriate.

1 Subject of the assessment

Polycyclic aromatic hydrocarbons (PAHs) form a group of organic chemical substances usually present as complex mixtures of several hundred congeners. They originate from (incomplete) combustion of organic materials. PAHs are present in fossil fuels - such as coal or mineral oil - and are released into the environment from vehicle or factory exhausts. However, PAHs are also found in a multitude of consumer articles. Although they are not produced intentionally for this purpose, they are present in these products due to the use of plasticisers (e.g. extender oils) or carbon black (soot) in the manufacture of rubber or other elastomers.

Smoking of tobacco products or consumption of barbecued food constitute further possible human exposure pathways.

Aside from other hazardous properties, PAHs can be carcinogenic. Currently eight PAH congeners are classified as known carcinogens in Annex VI of Regulation (EC) 1272/2008 (CLP regulation). According to Annex XVII of Regulation (EC) 1907/2006 (REACH regulation), substances or mixtures containing these eight PAHs above certain concentration

limits have to be classified/labelled as carcinogenic themselves and may not be sold to the general public.

In accordance with the new EU Toy Directive (Directive 2009/48/EC), the same concentration limits for known carcinogenic PAHs apply to toys. The resulting protection level has been criticised as insufficient (BfR, 2009). Frequently, high PAH levels were also found in other consumer products such as tool handles or bicycle grips (BfR, 2009b; UBA, 2010; Wennemer, 2009). With the exception of extender oils used in the manufacture of tyres, PAH levels in consumer products are currently not restricted by EU.

On request by the Federal Ministries for the Environment, Protection of Nature and Nuclear Safety (BMU) and for Food, Agriculture and Consumer Protection (BMELV), the Federal Institute for Risk Assessment (BfR) together with other federal authorities[1] took part in the preparation of a restriction dossier for PAHs in consumer articles in accordance with Annex XV of the REACH Regulation. The restriction dossier prepared by the German authorities has recently been finalised (German Federal Government, 2010) and handed over to the European Commission. In this context, BfR has carried out a quantitative risk characterisation under particular consideration of the lead compound benzo(a)pyrene. It contains the following subsections:

- A summary of the relevant toxicological properties
- An overview of the results of the chemical analysis of consumer articles for their PAH content,
- An estimation of possible exposure, i.e. the extent to which consumers might become exposed to PAHs when using these products and
- A quantitative characterisation of the health risks arising from these estimated exposure levels.

2 Results

The most important results of the evaluation were as follows:

- Chemical-analytical data for more than 5,300 consumer products were evaluated for their content of BaP of the 16 PAHs listed by the US Environmental Protection Agency as priority environmental pollutants (EPA-PAH) and of the sum of 6 of the 8 PAHs listed as carcinogenic in Annex VI of the CLP Regulation (PAH-6).
- In a clear majority of analysed products, PAHs were non-detectable or present only to a very low degree.
- On the other hand, a considerable portion of samples displayed unacceptably high levels of contamination with BaP or PAH-6.
- Exposure calculations for various product types and use scenarios revealed significant exposure of both adults and children.
- A range of Derived Minimal Effect Levels (DMELs), i.e. levels above which only a minimum adverse effect (here: only a low number of additional cases of cancer) can be

[1] Federal Institute for Occupational Safety and Health (BAuA) and Federal Environment Agency (UBA)

expected, was established for the lead compound benzo[a]pyrene (BaP) based on the available carcinogenicity studies in animals.

- For contaminated products, risk characterisation identified significant exposure of adults and children and thus a strong need for action with regard to reduction/avoidance of PAH contamination in consumer articles.
- At the same time, the absence of detectable PAH levels in the majority of investigated products has demonstrated that avoidance is technically feasible.

As an overall result, the German authorities recommend that marketing and use of PAH-contaminated products should be limited. In particular, they recommend that the content of each of the eight PAHs legally classified as carcinogens is restricted in consumer products or any of their parts to a maximum of 0.2 mg/kg. This value is based on the currently technically attainable PAH levels (thus following the ALARA = 'As Low As Reasonably Achievable' principle) as well as the routinely achievable Limit of Quantification (LOQ) of current chemical-analytical methods.

At the beginning of June 2010, the restriction dossier prepared by the German authorities was submitted to the European Commission alongside a request to initiate a restriction of PAHs in consumer products following the simplified procedure of Art. 68 (2) of the REACH regulation.

3 Reasons (risk assessment)

3.1 Possible risk source

The assumption that PAHs in consumer products can be considered a possible source of risk is suggested by the fact that, for a number of these substances, carcinogenicity and mutagenicity as well as toxicity to reproduction (so-called CMR properties) have been demonstrated in animal experiments (see below, section 3.2 Hazard potential for details).

Investigations by independent laboratories have revealed that a considerable number of products on the market display unacceptably high PAH contamination levels - notwithstanding that the majority of samples was contaminated only to a low degree or found with no detectable PAH content at all (see below, section 3.3 Exposure for details; cf. also BfR, 2009).

3.2 Hazard potential

3.2.1 General information on hazard with regard to human health

A number of comprehensive toxicological evaluations of PAHs is available in the published literature e.g. ATSDR (1995), WHO (1998 and 2003) and EFSA (2008). Therefore many aspects of PAH toxicity other than carcinogenicity are not treated in-depth or even are omitted in this evaluation, if they were not considered relevant for its purpose.

All eight PAHs discussed here ('EU-PAH')[1] are legally classified carcinogens of Category 2 (acc. to Dir. 67/548/EEC, the 'Dangerous Substance Directive' or 'DSD') or Category 1B acc.

[1] Benzo[a]pyrene (BaP), benzo[e]pyrene (BeP), benzo[a]antracene (BaA), chrysene (CHR), benzo[b]fluoranthene (BbF), benzo[j]fluoranthene (BjF), benzo[k]fluoranthene (BkF), dibenzo[a,h]antracene (DBAhA)

to the CLP regulation. Benzo[a]pyrene (BaP) and chrysene (CHR) are also legally classified mutagens (BaP: DSD Cat. 2/CLP Cat. 1B; CHR: DSD Cat. 3/CLP Cat. 2). In addition, BaP is a classified reprotoxicant (DSD Cat. 2/CLP: Cat. 1B). Lack of 'CMR' classification[1] for the other congeners does not necessarily reflect absence of toxicity, but may rather be attributed to the comparatively limited database available for these compounds. There are indications that the carcinogenic potency of some further PAH congeners, e.g. some of the dibenzopyrenes, may even be considerably higher than that of the lead compound BaP (Greim, 2008).

The focus of this evaluation is placed on the carcinogenicity of BaP following dermal exposure. Mutagenic properties were considered in a qualitative way: there is ample evidence for a genotoxic mode of action behind PAH carcinogenicity.

According to today's state of knowledge the potential mechanisms behind chemical carcinogenesis are highly complex. However, the central paradigm of the risk assessment of genotoxic carcinogens - i.e. that a threshold for the tumourigenic activity of these substances cannot be set - is still generally accepted and applied in the characterisation of the potential risk caused by genotoxic carcinogens. As a consequence of the lack of thresholds for PAH carcinogenicity, 'Derived *Minimal* Effect Levels' (DMELs) instead of 'Derived *No* Effect Levels' (DNELs) were established (cf. subsequent section).

It is noted that with respect to carcinogenicity, children have to be considered as a particularly sensitive sub-population, both in terms of an inherent greater sensitivity and their longer remaining life-span (increasing the statistical risk for the development of cancer in later life following exposure towards PAHs).

Upon contact with skin, PAHs are generally very well absorbed. Evaluation of the database of animal tests regarding the dermal absorption of BaP, for example Ng et al. (1992) and Wester et al. (1990), resulted in the establishment of rough working estimates of 50 and 20 % from acetone or aqueous media (such as sweat), respectively.

3.2.2 Derivation of DMELs for the carcinogenic effects of BaP

For a general introduction to the concept and the methodology of DMEL derivation, cf. ECHA (2008). The procedure as laid out in this document has been closely followed in the present evaluation.

As a first step, suitable carcinogenicity studies have to be identified. Next, appropriate dose descriptors, e. g. the T25 (dose level causing 25 % net tumour incidence increase vs. control) or the BMD10 ('benchmark dose 10' = dose level associated with a 10 % net increase of tumour incidence vs. controls as obtained from a curve fit of the dose response relationship) has to be selected. It is then corrected for differences between the animal experiment and the human exposure situation.

Finally, depending on the approach chosen, extrapolation to lower dose levels is performed, either by applying a set of assessment factors (AF, usually amounting to an overall AF of 10,000 = 'Large Assessment Factor Approach') or by assuming a linear dose response relationship below the dose descriptor and identifying the dose corresponding to an additional tumour incidence of either 1:100,000 or 1:1,000,000 ('Linearised Approach' at the 10^{-5} or 10^{-6} risk level).

[1] Classification for Carcinogenicity, Mutagenicity, and/or toxicity to Reproduction

The different approaches for the derivation of DMELs offered within ECHA (2008) lead to substantially different results. For this reason, instead of choosing only one preferred method and selecting only one most relevant carcinogenicity study, all methods listed in the ECHA document were applied without prejudice to all relevant study results. As a result, DMEL ranges were obtained which better reflect the inherent uncertainties of the approach than a single DMEL alone.

3.2.3 Selection of suitable starting points for DMEL derivation

From a greater range of available carcinogenicity studies, those were included which had been considered as key studies in previous risk assessments[1]. In addition, a query of current literature was performed which, however, did not indicate any further relevant studies.

The following criteria were then applied to further limit the number of selectable studies and - within these studies, endpoints [2] - for DMEL calculation:

1. Only studies were considered, in which PAH mixtures (with defined BaP content) were administered.
2. Studies with deficits in experimental design and/or reporting were only considered if meaningful results could be obtained in spite of these flaws.
3. Within a study that had been selected in steps 1. and 2., only endpoints were considered for which a 'meaningful' dose-response relationship could be established, which was assumed to be the case:
    a. If at least 3 dose levels in addition to a concurrent control were administered. Studies with only two dose levels + control were ruled out for BMD calculation by definition and were only used for T25 calculations if the range of net tumour incidences observed included the net 25 increase, i.e. when at least one experimental value was obtained above the potential T25. Studies with only one dose level in addition to control were not used.
    b. If ideally, response increased monotonously with dose (although small deviations were tolerated)
    c. If ideally the highest observed substance-related net increase in incidence was above 50 %.
4. In a further selection step, BMD10/BMDL10 values were deselected for DMEL calculation when appropriate quality indicators pointed at a poor goodness-of-fit.

[1] (Culp et al., 1998 ; FhI, 1997; Habs et al., 1980; Heinrich et al., 1994; Kroese et al., 2001 ; Schmähl et al., 1977; Schneider et al., 2002 ; Schulte et al., 1994; Thyssen et al., 1981; Warshawsky & Barkley, 1987; Weyand et al., 1995)

[2] The term 'endpoint' in this subsection is used to designate different parameters used to highlight a dose-related increase in tumour incidence: a specific type of tumour in a certain tissue (e.g. 'skin carcinoma'), all types of observed tumours at a certain site (e.g. 'lung tumours') or even 'number of tumour-bearing animals' (i.e. regardless of tumour type or location).

3.2.4 Results of DMEL calculations for BaP

For each of the selected studies (where appropriate, cf. previous section) T25, BMD10, and BMDL10 estimates were used as dose descriptors. For all of these descriptors (from each of the studies), DMELs were calculated applying both the 'Large Assessment Factor' and the 'Linearised' approach (the latter at both the 10^{-5} and 10^{-6} risk levels and using the 'Probit' as well as the 'Multistage Cancer' algorithms provided by the software[1] for curve fitting).

Instead of taking a single (e.g. the most sensitive) DMEL from a single study for further quantitative risk characterisation, the whole range of DMELs obtained by using different approaches was taken into consideration. As a result, the following DMEL ranges were found:

- Large Assessment Factor approach: 0.1 - 30 ng/kg bw/d
- Linearised approach, 10^{-5} risk level: 0.03 - 10 ng/kg bw/d
- Linearised approach, 10^{-6} risk level: 0.004 - 1 ng/kg bw/d

The boundaries of these ranges roughly represent the results from the most (lower boundaries) and least (upper boundaries) sensitive studies, respectively.

3.3 Exposure

3.3.1 Origin of PAH in consumer products

PAHs in consumer products (including toys) may originate from the following various sources:

- Use of mineral oil- or coal-based extender oils in the production of rubber and plastics,
- Carbon black (soot), which is intentionally added to elastomers to achieve the required properties of the material (e.g. flexibility, damping),
- Recycled tyres.

Typically, PAHs are contained in certain elastomer/rubber materials, but potentially also in plastic materials, lacquers/varnishes, or coatings that may be encountered in or as part of consumer products, including toys. Numerous examples of such products[2] include e.g. tool handles, bicycle handlebars, slippers, flip-flops, beach sandals, diver equipment, toy car tyres or clay pigeons used in skeet shooting. PAHs may also be contained in synthetic turf or in materials used for construction work, e.g. flooring material.

Tyres that were placed on the market from 1 January 2010 must not contain extender oil exceeding the limits of more than 1 mg BaP/kg oil or more than 10 mg EU-PAHs/kg oil. With respect to recycled tyres, the situation is expected to only gradually improve over the next 5-10 years, as tyres typically are used for several years before being forwarded to recycling. In addition, in the production of tyres carbon black is also used, the PAH content of which is currently not restricted at the EU level.

[1] Software 'BMDS v.2.1.1' by the US Environmental Protection Agency (US EPA)
[2] cf. also BfR (2009 and 2009b)

3.3.2 PAH levels in consumer goods

The present assessment is based on the evaluation of more than 5,300 samples from consumer articles analysed for their PAH content. The samples were analysed for the 16 PAHs from the EPA list ('EPA-PAH'). These data were collected from (and supplied to the BfR by) a number of German quality control or consumer protection organisations such as TÜV Rheinland, Stiftung Warentest, 'ÖkoTEST', and monitoring authorities of the German Federal States. The samples analysed cover a multitude of different consumer products, which - based on similar exposure patterns - were subdivided into the following eight broader categories:

1. Electrical devices
2. Grips/handles
3. Skin contact areas of sports equipment or other consumer products,
4. Toys,
5. Materials with close contact to the body,
6. Other products with skin contact,
7. Tyres and rolls, and
8. Other products.

An overview of the analytical findings with respect to the PAH burden of the examined samples is given in Table 1.

Table 1: Overview of the analytical data, maximum levels, and fractions of samples with no detectable level, with a level below 1 mg/kg, and with a level above 10 mg/kg

Category	Analytes	Max. content (mg/kg)	Fraction of samples (%) with levels…		
			< LOQ [1]	< 1 mg/kg	> 10 mg/kg
All data (n = 5278)	BaP	1200	91.9	95.3	2.8
	EPA-PAHs [2]	25400	22	50	14.9
	PAH-6 [3]	6930	83.9	90.7	5.2
Electrical devices (n = 1705)	BaP	195	91.9	94.8	3
	EPA-PAHs [2]	4516	16.2	46	17.2
	PAH-6 [3]	1915	87.8	92	5.3
Grips, handles (n = 541)	BaP	98	90.4	92.8	5.6
	EPA-PAHs [2]	3699	20.7	46.6	18.5
	PAH-6 [3]	2483	81.7	89.3	7.5
Contact areas of sports equipment and other articles (n = 120)	BaP	129	87.5	90	5.8
	EPA-PAHs [2]	1801	5.8	24	22.3
	PAH-6 [3]	995	73.1	83.3	9.3

Category	Analytes	Max. content (mg/kg)	Fraction of samples (%) with levels…		
			< LOQ [1]	< 1 mg/kg	> 10 mg/kg
Toys (n = 340)	BaP	65.9	94.7	97.1	0.9
	EPA-PAHs [2]	1992	18.5	50.6	9.7
	PAH-6 [3]	447	87.8	94.3	3.7
Materials in close contact to the body (n = 535)	BaP	111	88.2	97.6	1.3
	EPA-PAHs [2]	1503	18.1	37.8	19.7
	PAH-6 [3]	412	61.4	79.6	4.7
Other products with skin contact (n = 460)	BaP	530	94.8	96.5	2.6
	EPA-PAHs [2]	9300	23.3	60.4	8.1
	PAH-6 [3]	3380	90.8	94.1	4
Tyres, rolls (n = 35)	BaP	1200	60	65.7	22.9
	EPA-PAHs [2]	25400	2.9	20	42.9
	PAH-6 [3]	6930	45.7	60	34.4
Other products (n = 1519)	BaP	380	93.2	96.1	1.9
	EPA-PAHs [2]	9574	32.5	59.1	11.4
	PAH-6 [3]	1994	85.7	92.5	4

[1] the exact Limit of Quantification ('LOQ') might have varied between the different laboratories the results of which were included in the present evaluation. However, based on the well-established analysis method ZEK 01.2-08 (ZEK, 2008) it was assumed that the LOQ was always 0.2 mg PAH/kg sample or lower.

[2] EPA-PAHs = list of 16 PAHs often used as lead compounds in environmental PAH analysis and covered by the method ZEK 01.2-08 (ZEK, 2008).

[3] PAH-6 = list of 6 PAHs common to both the EU-PAH and EPA-PAH lists, i.e. BaP (benzo(a)pyrene), BaA(benzo(a)anthracene, CHR (chrysene), BbF (benzo(b)fluoranthene), BkF (benzo(k)fluoranthene), and DBAhA (dibenzo(a,h)anthracene).

Combining all product groups, in 91.9 % of all samples BaP was not detectable; in 95 % of all samples the concentration was below 1 mg/kg. For the sum of the 6 EU-PAHs contained in the EPA-PAH list ('PAH-6'), the corresponding values were 83.9 % not detectable, and 90.7 % below 1 mg/kg, respectively. However, detected levels vary considerably between different product groups. Highest PAH levels were found in the product category 'tyres and rolls', i.e. 1,200 mg/kg for BaP, 25,400 mg/kg for the sum of all EPA-PAHs and 6,930 mg/kg for the sum of PAH-6.

Taking all data together, the results clearly show that consumer products may contain high amounts of polycyclic hydrocarbons. On the other hand, these data also demonstrate that levels of BaP or PAH-6 above the LOQ (of method ZEK 01.2-8 (ZEK, 2008), i.e. above 0.2 mg PAH congener/kg sample, apparently are not state-of-the-art and therefore can be considered avoidable acc. to the ALARA principle.

3.3.3 Migration rates

Different experimental approaches have been investigated and different materials included for the determination of PAH migration rates. Results varied over several orders of magnitude. The migration rate depends on several factors which are discussed below.

As a principle, real contact conditions are only inadequately reflected by static experimental settings because dynamic processes such as movement, friction or strong contact pressure are not accounted for. However, under realistic conditions of use, migration rates are strongly influenced by these factors. Moreover, when aqueous sweat simulants are used, the role of lipophilic (i.e. dissolvable in oil or fat) sweat constituents or skin fat, which is of relevance for the migration of lipophilic substances, is not adequately considered. As PAH display high lipophilicity, migration rates which have been obtained using aqueous simulants (< 0.001-0.01 %; WDK, 2007; BfR, 2009b; Hamm et al., 2009) can be expected to considerably underestimate migration under real skin contact conditions. The use of more lipophilic simulants such as isooctane or 95 % ethanol results in clearly higher migration rates (BfR, 2009b; UBA, 2010). However, these solvents have the potential to react with/dissolve the product surface or lead to swelling which in these cases might influence migration rates.

An experimental design which is closer to reality by accounting for dynamic aspects is attained by simulating real-life use conditions: the product containing PAH is held in one hand wearing a latex glove previously moistened with sweat simulant. In contrast to lipophilic solvents, latex gloves also possess lipophilic character, but do not interact with the product surface. Moreover, variable contact pressure between product surface and skin as well as mechanical friction can be simulated in a flexible way.

Using such dynamic test conditions, different grips/handles (hammer, torch), a rubber horn, a steering wheel cover and a tape measure were examined (Sander, 2006; Wennemer, 2009: TÜV Rheinland, 2010; Hutzler, 2009). For different materials, BaP migration rates of 0.02 - 10 % were deduced from these experiments. Comparative experiments with and without friction showed that - aside from the material itself - also mechanical effects can have a pronounced effect on the migration rate (Hutzler, 2009). This might be explained by adhesion of particles to the glove as a consequence of increased material abrasion due to friction. Thus, as a result, the migration rate might be overestimated. Another factor of uncertainty with respect to a possible overestimation of migration rates could lie in the extrapolation step from shorter to longer exposure duration. However, exact quantification of the extent of a possible overestimation due to these two factors is not possible.

For the exposure estimation of consumers in the present evaluation, migration rates quantified under dynamic conditions were used. In order to cover the different materials on the market and the influence of dynamic conditions on exposure, three different migration rates for BaP were used for the calculation:

- 10 %/h as the ‘worst case’ of dynamic migration with friction,
- 1.5 %/h as the geometric mean of the dynamic migration with friction,
- 0.2 %/h as the mean of dynamic migration without friction.

Based on currently available data, it is not possible to appraise the extent to which PAH-containing materials with possibly differing migration rates are used in consumer products on the market.

3.3.4 Exposure of children to rubber granules in sports field surfaces

The assessment of dermal exposure of children to rubber granules from synthetic turf was exemplarily performed using a) the ECETOC TRA approach and b) a similar approach, but considering migration. The results clearly show that rubber-based synthetic turf products may contain high amounts of PAHs. Knowledge on the release of these compounds is limited and

needs to be improved, but there is concern that under certain circumstances considerable amounts can be released.

3.3.5 External dermal exposure to BaP from consumer articles

The exposure assessment was largely carried out acc. to ECHA (2008b) on the articles listed above in Table 1 for which the presence of BaP had been analytically confirmed.

A body weight of 60 (adults) and 10 kg (children) was used for the calculations. No experimental data were available for the parameters contact time and frequency. Assumptions made for these parameters were based on practical experience and thus do not constitute 'worst case' assumptions.

In accordance with the basic calculation principles for long-term or repeated contact with products used on a regular scale (ECHA, 2008b, section 15.2.1.2), external dermal exposure by consumer products in terms of the external daily dose (based on the assumed mean daily contact time) was estimated in two different ways:

1. The results of the dynamic migration tests described in the previous section were used for estimating the external exposure of consumers to BaP when using the products included in these tests.

   The following formula was applied in these calculations:

$$D_{der} = \frac{M_{g/h} \times T_{contact} \times n}{BW} \times 1000$$

   with:

BW	=	body weight (kg)
D_{der}	=	external dermal dose (ng/kg bw/d)
$M_{g/h}$	=	migrated absolute amount of BaP (µg BaP/h)
n	=	average number of contacts per day (1/d)
$T_{contact}$	=	duration of contact between product and skin (h)

   By using this approach, external dermal exposure levels of between ca. 2 ng BaP/kg bw/d and 6.7 µg BaP/kg bw/d were estimated for a total of seven products (grips, a torch handle, a rubber horn, a steering wheel cover and a hammer grip).

2. External dermal exposure was estimated based on the three selected migration rates (cf. above) and on the available data on BaP concentrations in consumer products on the market (cf. Table 1).

   This approach was applied to > 100 products, for which use by adults was assumed. In addition, estimates for ca. 100 products assumed to be used by children were obtained. In all cases, calculations were performed using all three of the above migration rates and the following equation (ECHA, 2008b, p. 24):

$$D_{der} = \frac{Q_{prod} \times Fc_{prod} \times Fc_{migr} \times F_{contact} \times T_{contact} \times n}{BW} \times 1000$$

with:

BW	=	body weight (kg)
D_{der}	=	external dermal dose (ng/kg bw/d)
Fc_{migr}	=	migration rate (µg migrated/µg total in sample/h)
$F_{contact}$	=	fraction of the contact area in relationship to total skin surface (not all of the skin surface is in contact with the product)
n	=	average number of contacts per day (1/d)
Q_{prod}	=	mass of the product (g)
$T_{contact}$	=	duration of contact between product and skin (h)

Using the highest (most conservative) assumption of 10 % migration/h, exposure estimates of 0.3-68613 ng/kg bw/d for adults and 3-66780 ng/kg bw/d for children were obtained. Estimates using 1.5 or 0.2 % migration/h ranged lower by a factor of 6.67 or 50, respectively.

Summarising the results, there is clear evidence from the results of exposure estimation that under normal use conditions considerable amounts of BaP can be released even when a comparatively low migration rate is assumed.

3.3.6 Simulation of the proposed restriction conditions

In order to simulate the effect of the proposed restriction, another comprehensive set of calculations was carried out, this time assuming that the same products used with approach 2 before would have contained only 0.2 mg BaP/kg product. All other assumptions regarding exposure scenarios and migration rates were kept. In addition, in order to find out whether a less severe restriction proposal might be sufficient, a second scenario with a hypothetical content of 1 mg BaP/kg product was tested.

The 1 mg BaP/kg article simulation resulted in a dermal exposure range of 133.3 - 750 ng/kg bw/d for adults assuming 10 % migration/h (children: 8.5 - 1600 ng/kg bw/d). Estimates using 1.5 or 0.2 % migration/h were lower by a factor of 6.67 or 50, respectively.

For the 0.2 mg BaP/kg article simulation, the results from the previous paragraph had to be divided by a further factor of 5, in correspondence with the 5-fold lesser concentration. Consequently, a range of 26.67 - 150 ng/kg bw/d for adults assuming 10 % migration/h was calculated (children: 1.7 - 320 ng/kg bw/d). Estimates using 1.5 or 0.2 % migration/h again ranged lower by a factor of 6.67 or 50, respectively.

In Table 2 below, the results are summarised and contrasted with exposure estimates based on real-life BaP contents.

Table 2: Comparison of dermal exposure of adults and children to BaP at current contamination levels with the hypothetical exposure following restriction to 0.2 or 1 mg BaP/kg product

Category/ Sample	n [1]	Type [2]	Concentration in product (mg BaP/kg)	$D_{der\ BaP}$ (ng/kg bw/d) [3] at…		
				10 % migr./h	1.5 % migr./h	0.2 % migr./h
ADULTS						
Grip/Tool	27	M	0.1-98	13-13067	2-1960	0.3-261
		H	0.2	26.67	4	0.53
			1	133.33	20	2.67
Grip black/Treated as bicycle grip	17	M	0.2-94	106-50133	16-7520	2-1002
		H	0.2	106.67	16	2.13
			1	533.33	80	10.67
Skin contact areas of sports equipment or other consumer products/treated as grip	15	M	0.2-128	106-68613	16-10292	2-1372
		H	0.2	106.67	16	2.13
			1	533.33	80	10.67
Footwear (shoes, boots, sandals)/treated as sandals used as slippers	36	M	0.01-111	3-29680	0.4-4452	0.05-593
		H	0.2	53.33	8	1.07
			1	266.67	40	5.33
Protective gloves	12	M	0.001-0.5	0.3-150	0.05-22.5	0.01-3
		H	0.2	60	9	1.2
			1	300	45	6
Protective cover for steering wheels	3	M	14-35	2800-7000	420-1050	56-140
		H	0.2	40	6	0.8
			1	200	30	4
Watch strap	2	M	0.3-43	202-32250	30-4837	4-645
		H	0.2	150	22.5	3
			1	750	112.5	15

Category/ Sample	n [1]	Type [2]	Concentration in product (mg BaP/kg)	$D_{der\ BaP}$ (ng/kg bw/d) [3] at…		
				10 % migr./h	1.5 % migr./h	0.2 % migr./h
CHILDREN						
Grip black/treated as bicycle grip	27	M	0.2-94	60-28200	9-4230	1.2-564
		H	0.2	60	9	1.2
			1	300	45	6
Skin contact areas of sports equipment or other consumer products/treated as bicycle grip	15	M	0.2-128	60-38595	9-5789	1.2-772
		H	0.2	60	9	1,2
			1	300	45	6
Footwear/treated as sandals used as slippers	36	M	0.01-111	6-66780	0.9-10017	0.1-1336
		H	0.2	120	18	2.4
			1	600	90	12
Rubber boots/for children	11	M	0.04-1.4	62-2272	9-341	1.2-45
		H	0.2	320	48	6.4
			1	1600	240	32
Watch strap	2	M	0.3-43	270-43000	40-6450	5-860
		H	0.2	200	30	4
			1	1000	150	20
Toy car/tyre	3	M	0.2-66	3-1008	0.5-151	0.1-20.2
		H	0.2	3.1	0.5	0.1
			1	15.3	2.3	0.3
Training bike/tyre	8	M	1-34	6.3-283	1-42.5	0.1-5.7
		H	0.2	1.7	0.3	0.03
			1	8.5	1.3	0.2
Outdoor toys/grip of a shovel or watering can	2	M	0.07-0.4	5.3-30.2	0.8-4.5	0.1-0.6
		H	0.2	15	2.3	0.3
			1	75	11.3	1.5

[1] Number of measured values included
[2] M = measured, i.e. based on real-life analytical data; H = hypothetical, i.e. simulating restriction down to 0.2 or 1 mg BaP/kg (cf. text)
[3] Calculated (external) dermal dose

3.3.7 Exposure at the workplace, indirect exposure via the environment

Exposure at the workplace or indirect exposure via the environment via food or smoking has not been considered in the context of this assessment.

3.3.8 Combined/aggregate exposure assessment

Owing to lack of suitable data, a combined/aggregate human exposure assessment has not been performed in this evaluation. From the analytical data presented in this evaluation as well as from everyday experience, it is clear that consumers are exposed to a multitude of potentially PAH-containing articles via several routes and will most likely come in contact with more than just one of these products on a daily basis.

A significantly higher PAH burden than calculated in this report might be expected when combined exposure is considered. However, in this assessment, concern has already been demonstrated for several exemplary exposure scenarios involving just one PAH source. For this reason, a combined exposure assessment did not appear necessary.

3.4 Risk characterisation

Under the restriction procedure as laid out in Art. 68 (2) of the REACH regulation, consumer exposure to Category 1 or 2 (DSD) CMR substances via consumer articles is by itself seen as a sufficient justification for restriction. Nevertheless, in this evaluation potential PAH exposure through consumer products was compared against derived DMELs for the lead compound BaP. Risk characterisation was only performed for the scenarios directly relevant for this dossier, i.e. use of PAH-contaminated consumer articles. Furthermore, only the dermal route was used for quantitative risk characterisation. A significant risk was demonstrated.

3.4.1 Risk characterisation for contaminated articles

DMELs (or rather, DMEL ranges) were contrasted with the exposure estimates given in Table 2 for adults and children for those consumer articles which had been tested positive for PAHs. For these products, the following conclusions with respect to the current risk situation (without restriction) were drawn:

- When using the most conservative estimate of a migration rate of 10 %/h, estimated external dermal exposure of adults may amount to as much as ca. 70 µg/kg bw/d (68613 ng BaP/kg bw/d). This would result in a more than 2,000-fold exceedance of the highest (i.e. least conservative) of the DMELs (‘Risk Characterisation Ratio’ (RCR) > 2000).

- Still, when using the least conservative migration assumption of only 0.2 %/h, adult exposure would reach up to almost 1.5 µg/kg bw/d with the most highly contaminated articles.

- For children, comparably high exposure estimates up to ca. 70 µg/kg bw/d (66780 ng BaP/kg bw/d assuming 10 % migration/h) and up to 1.3 µg/kg bw/d (0.2 %/h) were obtained (corresponding to RCRs of ca. 2,300 and 43, respectively).

3.4.2 Risk characterisation for the effect of simulated restrictions to 0.2 and 1 mg BaP/kg

Table 2 above gives exposure estimates for the hypothetical situation that BaP would be restricted to a limit of 1 mg/kg article or down to the LOQ of 0.2 mg/kg as achieved by the analytical method used for the German GS (certified safety) mark:

- A limit of 1 mg BaP/kg product would - depending on the exposure scenario - reduce exposure of adults to levels of up to 15 ng/kg bw/d (0.2 % migration/h), or 750 ng/kg bw/d (10 %/h). In light of the inherent uncertainties of the estimation, the latter value might seem acceptable. However, it is underlined that this would only be true if the least conservative assumptions were made.

- For children, on top of their postulated higher vulnerability, a clearly higher exposure of up to 1,600 ng/kg bw/d would be expected at a BaP level of 1 mg/kg product (10 % migration/h). Assuming a low migration rate of 0.2 %/h, exposure could be clearly reduced, the highest estimate still amounting to as much as 32 ng/kg bw/d, i.e. in the order of the least conservative DMEL derived, but clearly (by a factor of 30) above the upper limit of the most conservative DMEL range.

Finally, a hypothetical limit set at the LOQ of 0.2 mg/kg would bring exposure down to a level that could be considered as tolerable for the bulk of products/uses examined, although for some extremely contaminated articles still an exposure up to one order of magnitude above the least conservative DMELs is found when assuming the most conservative migration rate:

- According to the calculations performed, adults would at most be exposed to levels of 150 ng/kg bw/d when assuming 10 % migration/h, or 3 ng/kg bw/d, when using 0.2 %/h.

- For children, maximum exposure levels of 320 or 6.4 ng/kg bw/d are calculated, when migration rates are set to 10 or 0.2 %, respectively.

From a pragmatic point of view, there is at present no sense in postulating a restriction below the level of 0.2 mg BaP/kg sample, as lower levels cannot be determined with sufficient certainty by currently routinely available analytical methods. However, at least for articles with foreseeable use by children, future progress in analytical methodology should be frequently monitored and the technological feasibility of a further reduction considered.

Moreover, it should be kept in mind, that these substances are regulated as representatives/lead compounds for a group of hundreds of congeners, some of which are suspected to be even more carcinogenic than BaP. Therefore the results presented here suggest that the ALARA principle (in the form of setting the limit value to the analytical LOQ) should in the same way be applied to the other known carcinogenic PAHs.

Figure 1 below summarises the results of risk characterisation.

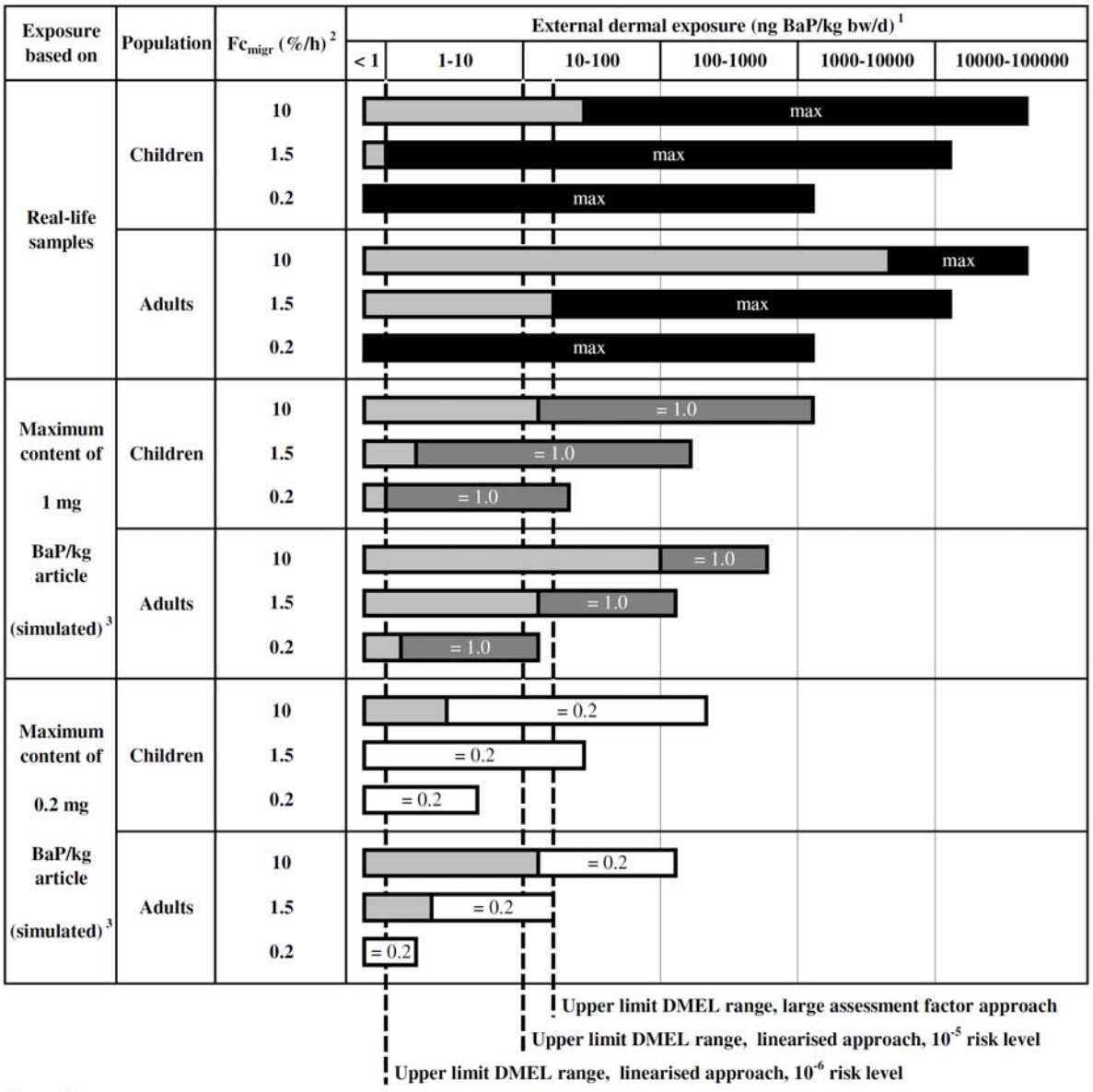

Figure 1: Overview of the results of risk characterisation

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Abbreviations

Abbreviation	Explanation
AF	Assessment factor
ALARA	As Low As Reasonably Achievable
Art.	Article
ATSDR	US Agency for Toxic Substances and Disease Registry
BaA	Benzo[a]anthracene
BaP	Benzo[a]pyrene
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health)
BbFA	Benzo[b]fluoranthene
BeP	Benzo[e]pyrene
BeP	Benzo[e]pyrene
BfR	Bundesinstitut für Risikobewertung (German Federal Institute for Risk Assessment)
BjFA	Benzo[j]fluoranthene
BkFA	Benzo[k]fluoranthene
BMD	Benchmark dose
BMD10	Benchmark dose for the effect in 10 % of a given population
BMDL10	Lower confidence limit of the benchmark dose for the effect in 10 % of a given population
bw	Body weight
CHR	Chrysene
CLP	Regulation (EC) 1272/2008 on the classification, Labelling, and Packaging of Chemicals
CMR	Carcinogenic, Mutagenic, and/or toxic to Reproduction
DBAhA	Dibenzo(a,h)anthracene
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
DSD	Dangerous Substances Directive (Dir. 67/548/EEC)
EC	European Communities
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EPA-PAHs	16 PAHs selected by the United States Environmental Agency to characterise environmental PAH pollution
EU	European Union
EU-PAHs	8 PAHs listed in entry 50 of annex XVII to Reg. (EC) 1907/2006

Abbreviation	Explanation
GS	Geprüfte Sicherheit (certified safety)
LOQ	Limit of quantification
PAH	Polycyclic Aromatic Hydrocarbon
PAH-6	6 PAHs common to both the EPA-PAH and EU-PAH lists
REACH	Regulation (EC) 1906/2007 on the Registration, Evaluation, Authorisation and restriction of Chemicals
RMO	Risk Management Option
T25	Dose level corresponding to a net increase in tumour incidence as compared to untreated controls
UBA	Umweltbundesamt (German Federal Environment Agency)
UVCB	(Substance of) Unknown or Variable Composition or Biological Origin
WHO	World Health Organization
ZEK	Zentrale Erfahrungsaustauschkreis der ZLS (circle for exchange of experience within the ZLS)
ZLS	Zentralstelle der Länder für Sicherheitstechnik (Central Agency for safety technology of the German Federal States)