Risiken erkennen – Gesundheit schützen

PAHs in consumer products must be reduced as much as possible

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Polycyclic aromatic hydrocarbons (PAHs) are complex mixtures of organic compounds that are often found as environmental pollutants . They are formed during incomplete combustion processes from coal, fuel, tobacco and during grilling. Numerous PAHs are also natural components of crude oil. Human exposure to PAHs occurs mainly via breathing air and food. More than 100 individual PAHs are known. Already in the 1980s the US Environmental Protection Agency (EPA) established a list of 16 PAHs that have been most frequently detected in environmental samples. The reference compound in this substance group is benzo[*a*]pyrene (BaP). Contaminations of consumer products like tool handles or beach sandles can occur through the use of PAH-containing extender oils in the production of rubber and plastics. PAHs can be absorbed through the skin. Some PAHs are very probably mutagenic in man, reprotoxic or carcinogenic.

In 2005, the German *Stiftung Warentest* (a product testing NGO) had detected high levels of PAHs in some tool handles and cable sheaths [1]. To reduce the health risks, guidance values for technically unavoidable PAH levels were proposed for manufacturers to comply on a voluntary basis. The Federal Institute for Risk Assessment (BfR) was asked to assess these guidance values and the occurrence of PAHs in consumer products. Based on the assessment of analytical data provided by various German testing institutes, BfR came to the conclusion that compliance with the proposed guidance values for tool handles and other consumer products that come into contact with the skin is technically feasible. However, these values should not necessarily be applied to other products and product groups as manufacturing processes may differ considerably and hence both lower and, in special cases, only higher unavoidable concentrations may be achieved. In addition, when setting guidance values, consideration should be given not only to technical avoidability but also to possible exposure levels of consumers. However, the total PAH-content in consumer products is less relevant for assessment of health risks than migration of these substances onto skin and dermal absorption.

In the spring of 2009 TÜV Rheinland examined the PAH concentrations in various products like tool handles, beach sandals and ball horns from do-it-yourself stores and low budget stores. The result: in some cases the guidance values are still considerably exceeded in the consumer products examined for PAHs. According to the knowledge currently available, the BfR must assume that defective products are still being marketed. Such products do not comply with good manufacturing practice and constitute a risk for human health.

In general, manufacturers should reduce PAH concentrations in their products as much as possible since no threshold values can be given for some PAHs below which health risks can be excluded. In order to protect consumers from health risks, BfR proposes the setting of statutory limit values for PAHs and BaP. Compliance should be a precondition for the marketability of consumer products that come into contact with the skin.

1 Objective

In 2005, the TÜV Rheinland published concentration levels of polycyclic aromatic hydrocarbons (PAHs) measured in consumer products like tool handles, beach sandals and ball horns [2]. Laboratory tests had shown that some of these products contain high PAH concentrations. Similar findings by Stiftung Warentest had already prompted a commercial enterprise in 2005 to derive guidance values for PAHs in order to minimise any potential risk from

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these products. In conjunction with these guidance values a breakdown is undertaken in the following product groups: for products or relevant parts like tool handles intended to come into contact with the skin, the total amount of PAHs should not exceed 10 mg per kg product or part and the level of benzo[*a*]pyrene (BaP) should not exceed 1 mg per kg product or part. For products with only short skin contact (e.g. cable sheaths), guidance values were set at 200 mg PAHs and 20 mg BaP per kg product or part, respectively. The sum of all PAHs includes the 16 compounds listed by the US Environmental Protection Agency (EPA) (see below).

The Federal Institute for Risk Assessment (BfR) had commented then and again in 2007 on these values from the view point of precautionary consumer protection and issued an expert opinion on the problems of PAHs in consumer products. The new results and the assessment by TÜV Rheinland prompted BfR to update its expert opinion.

2 Results

The term PAH describes a group of substances with more than 100 individual compounds that are present in the environment as complex mixtures. Some PAHs have proved to be carcinogenic in animal experiments and it is assumed that corresponding effects are very likely in humans, too. For these compounds no safe concentration threshold values can be derived to exclude risks to human health. In the opinion of theBfR PAH concentrations must be reduced in consumer products as much as possible and appropriate measures (limit values) are necessary in order to reduce exposure.

The analytical data submitted to the BfR confirm that the above-mentioned guidance values are considerably exceeded in some products. At the same time, analytical data also show that compliance is feasible with the suggested guidance values for tool handles and other consumer products.

The BfR points out that the technically unavoidable PAH concentrations in various consumer products may vary. Besides technical necessities, guidance values should also take account of possible consumer exposure. Pronounced exceedings of these values, as observed by Stiftung Warentest and TÜV Rheinland are alarming because of potential health effects and not reconcilable with good manufacturing practice.

For the purposes of scientifically valid exposure assessment, data are needed on the release of PAHs from the corresponding products. Accordingly, for products or parts of products that come into contact with skin (e.g. tool handles), the migration of PAHs from the product to a skin sweat simulant should be determined in order to conduct a more robust exposure assessment. However, no standardised migration test method is currently available. Furthermore, data are needed on the passage of PAHs from the skin surface into the body.

3 Reasons

3.1 Levels

PAHs in consumer products can originate from various sources:

- extender oils that are added to rubber materials to achieve the desired material properties (PAH-depleted variants of these oils are available but comparatively expensive. PAHs are natural components of crude oil)

- soot, which is added to elastomers to achieve the required properties of the material (e.g. flexibility, damping, solubility in the polymer matrix).

Extender oils and soot may also be used and applied in plastics, lacquers and coatings.

The BfR has evaluated a series of data on PAH concentrations in various consumer products which were made available by a commercial enterprise. The evaluation revealed that no PAHs could be detected in approximately 23% of the over 1,400 samples examined whereas 27% had a low (0 up to 1 mg/kg) and 13% a higher concentration (>10 mg/kg).

PAHs are ubiquitously present. The US-EPA identified the following 16 individual PAHs which have relevant shares in the total content of PAHs found in environmental samples: naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benz[*a*]anthracene, chrysene, benzo[*b*]fluoranthene, benzo[*k*]fluoranthene, BaP, dibenz[*a,h*]anthracene, benzo[*g,h,i*]perylene, and indeno[1,2,3-*cd*]pyrene. This list mainly takes into account environmental aspects and emissions; it is a selection of volatile to hardly volatile components. The reference component used for the assessment of total PAH exposure is BaP.

3.2 Exposure

In its study TÜV Rheinland distinguished between the duration of skin contact of the objects examined. The category of materials with foreseeable skin contact (more than 30 seconds) is of particular importance for consumers. 15 objects (various tools, clogs, beach sandals, bicycle handlebars, watch straps amongst others) in this category were examined. In some of the products the PAH content was clearly below the guidance values of 10 mg per kg product or product part and 1 mg BaP per kg product or product part. On the other hand, maximum values of more than 9,900 mg PAHs and more than 500 mg BaP per kg product or part were determined. This study confirmed the results of an earlier study by Stiftung Warentest in which tool handles were found to have maximum levels of 2,000 mg PAHs and 87 mg BaP per kg product [1].

In order to estimate consumer exposure and undertake a health assessment, it is not the PAH concentrations in the material that are relevant but the amounts of PAHs released. The BfR carried out the following exposure assessment:

Assuming a tool handle has a concentration of 500 mg BaP/kg and a handle weight of 200g and assuming that 1% of the BaP contained in the handle migrates within an hour[1] , this leads to external exposure of 1 mg BaP per one-hour use.

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[1] The assumptions for migration to skin take into account the following experimental results: *Stiftung Warentest* conducted studies on the migration of PAHs in isooctane as a fat simulant. In the case of a window handle with a PAH level of 10,707 mg/kg, values were determined in the sum of all PAH values between 89,924 µg/dm^2 and 131,014 µg/dm^2, for the individual compound BaP values between 4,673 µg/dm^2 and 7,417 µg/dm^2 depending on temperature (20°C, 37°C) and extraction duration (20 and 120 minutes). If one assumes for the handle a compound of 100 g and a surface of 1 dm^2, this means that maximum 12% of the PAHs migrated under the test conditions. When using water as the extraction agent, the sum of the maximum migrating PAHs is reduced to 33.97 µg/dm^2 which equals about 0.003%. However, because of the extraction media these results only permit a limited transfer to the migration conditions of the skin. In the case of studies by TÜV on the migration of

The data on skin penetration of BaP and PAHs differ considerably depending on species, individual, type of study (*in vivo*, *in vitro*, site of application) and matrix. The data in the literature on dermal absorption of PAHs vary between 3-43% [3]. However, some studies that revealed low levels only determined complete penetration through the skin. The share of PAHs that remained in the skin was not taken into account. BfR, therefore, believes that the inclusion of an absorption factor of 22%, which was presented at the first meeting of the ad hoc PAH working group of the provisional BfR Plastics Committee, is justified [4]. If one takes this factor of 22% as basis, an internal exposure of 220 µg BaP is postulated for an adult weighing 60 kg and one-hour use (This equals 3.67 µg BaP/kg body weight.). However, there is still an extensive need for research on the question of dermal exposure to PAHs from consumer products.

Consumers are exposed to PAHs (and in particular to BaP) not only by skin contact with consumer products but also through food and, if applicable, tobacco smoke. The Toxicology Section of the German Society for Experimental and Clinical Pharmacology and Toxicology (DGPT) provides estimates of the daily intake of BaP (as the reference compound for PAH mixtures) amongst others as follows: dietary intake 0.2 up to 0.5 µg and inhalation from tobacco smoke 0.4 µg [5]. The World Health Organisation (WHO) indicates an average daily intake for the general population of 0.001-0.005 µg/kg bodyweight [6]. The Scientific Committee on Food (SCF) indicates a maximum daily intake of 0.42 µg/person which approximately corresponds to 0.006 µg per kg bodyweight [7].

Overall, the additional exposure to BaP in tool handles may be considerably higher than the corresponding amounts ingested daily from food or tobacco smoke. However,such exposure is unlikely to happen on a daily basis and the amounts that migrate to skin decrease over the period of use of the tool. Comparisons of estimated BaP exposure from tool handles or other consumer products via the skin with exposure to BaP in tobacco smoke, as undertaken by TÜV Rheinland, are problematic for the following reasons. Firstly, tobacco smoke contains not only BaP and PAHs but also thousands of other compounds that can cause various diseases and are, in some cases, carcinogenic like for instance acrolein, benzene, hydrogen cyanide, formaldehyde and the radioactive polonium 210. Secondly, BaP is very quickly absorbed following inhalational intake. This is demonstrated by data from animal experiments in rats [8]. Hence, the inhalation of tobacco smoke is likely to very quickly lead to comparatively high peak concentrations of BaP in blood and tissue.

3.3 Hazard and risk characterisation

Some compounds in the group of PAHs are carcinogenic. Tar and tar oils (pyrolysis products of organic material) were, therefore, classified as Category 1 carcinogens by the Senate Commission for the Testing of Harmful Working Materials (MAK Commission).(This category encompasses compounds which are known to induce cancer in humans. Category 1 compounds are assumed to be important contributors to the human cancer risk.). Some PAHs, including BaP, can induce skin tumours. In addition, BaP is classified as a human mutagen (EU Category M2) and a human reprotoxic substance (EU Category RE2). PAHs can be readily absorbed through human skin (MAK labelling H) [9].

PAHs from a tool handle to a latex glove treated with the sweat simulant, 1.3% of the total content and 0.7% of the BaP content were detected in the glove. For exposure assessment BfR assumes migration of 1% in a worst case scenario.

3.4 Regulatory situation

At the present time, there are largely no specific regulations for PAHs in consumer products. According to the Revision of the Act on the Safety of Technical Working Materials and Consumer Products, products must comply with the intended health and safety requirements in order to be released onto the market. They may not constitute a health hazard for users or third parties during conventional use or prospective incorrect use. § 30 of the German Food and Feed Act (LFGB) prohibits the manufacture or treating of consumer products in such a way that their correct or foreseeable use could harm human health due to their material composition, especially toxicological agents or impurities. It also prohibits marketing of such articles or agents as consumer products which are capable of harming health through their material composition when they are used in an intended or foreseeable manner.

There are no specific provisions for tar oils or PAHs in commodities and other consumer products. The Chemical Ban Ordinance bans the use of tar oils in wood preserving agents and products made from wood and wood materials if they are not exclusively used commercially or industrially. Extender oils may not be placed on the market and used for the production of tyres or parts of tyres if they contain more than 1 mg BaP per kg or more than 10 mg of the listed PAHs per kg (Directive 69/2005/EC; laws, regulations and administrative provisions necessary to comply with this Directive have to be applied by the Member States from 1 January 2010). The Flavourings Ordinance indicates a limit value for BaP of 0.03 µg per kg food. EC Regulation 208/200 sets maximum levels for PAHs in various foods of between 1 and 10 µg per kg wet weight.

According to Directive 67/548/EEC, Annex I (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) preparations containing BaP >0.01% (100 mg/kg = 100 ppm) are classified as carcinogenic. In addition, the Technical Rules for Dangerous Substances (TRGS) serve as national provisions for the protection of employees. According to TRGS 551 (tar and other pyrolysis products from organic material), the use of various PAH-containing products with a specific amount of BaP is prohibited. This affects products like binding agents for road construction, coatings for corrosion prevention or adhesives. According to TRGS 905 (list of carcinogenic, mutagenic and reprotoxic substances), preparations containing BaP ≥0.005% (50 mg/kg = 50 ppm) are regarded to be carcinogenic. Furthermore, according to the 1998 UN/ECE Protocol [10], PAHs are considered to be persistent organic compounds (POPs). Hence, POPs are subject to the general obligation of reducing the amount of annual releases into the environment.

4 Management options

The data obtained by TÜV Rheinland on PAH concentrations in various consumer products indicate extremely high levels in some cases although the manufacture of products with lower levels is known to be technically feasible. The BfR is therefore of the opinion that binding requirements for PAH concentrations should be established that cover all relevant consumer products. Attention should focus not only on objects made of elastomer materials (like the discussed tool handles) but also on affected plastic products and products with corresponding varnishes, in particular toys. The corresponding provisions should be oriented towards the ALARA principle (as low as reasonably achievable).

The guidance values established in 2005 are thus the first step towards regulation. They are not, however, binding and should, furthermore, be regularly aligned with technological devel-

opments. Verification of compliance with guidance values is now a precondition for the award of the GS mark. However, this is only issued if the manufacturer or importer applies for it but is not compulsory. Hence, it does not afford consumers comprehensive protection.

5 References

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