baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Federal Institute for Occupational Safety and Health

Dortmund, 04/06/2010

German proposal for the restriction of PAHs in consumer products

1. Introduction

The government of the Federal Republic of Germany has asked the European Commission to propose a restriction for eight polycyclic aromatic hydrocarbon (PAH) compounds in accordance with **Article 68 paragraph 2** of the REACH Regulation.

In support of this initiative, the responsible German authorities have prepared a restriction dossier which proposes a limit of 0.2 mg/kg for PAHs in all articles which could be used by consumers (also referred to as 'consumer products'). The **dossier was submitted to the European Commission on 02/06/2010** and is based on the requirements of Annex XV (including analysis of risk management options and socio-economic impacts).

2. Hazard and need for action

Consumer products containing one or more polycyclic aromatic hydrocarbons (PAHs) are considered **severely hazardous** based on their carcinogenic and mutagenic properties, as well as their potential for being toxic to reproduction. All PAHs discussed in the dossier are classified **carcinogens** of category 2 (DSD, Dangerous Substances Directive 67/548/EEC) or 1B (CLP, Reg. (EC) 1272/2008 on classification, labelling and packaging), respectively. Benzo[a]pyrene (DSD Cat. 2) and chrysene (DSD Cat. 3) also are legally classified **mutagens**.

In toys, Directive 2009/48/EC – while stating that, in principle, no CMR substances of DSD categories 1 and 2 should be present – nevertheless allows BaP (Benzo(a)pyrene) contents up to the specific concentration limit as specified in the CLP regulation, i. e. 0.01 % or 100 mg BaP/kg article. This value is considered unacceptable from the perspective of risk assessment, in particular, as **children are seen as particularly vulnerable** to carcinogenic agents.

For consumer articles, currently no EU legislation limiting their PAH content is in place.

Based on the available data, it is concluded that the occurrence of highly PAH-contaminated consumer products is not limited to the German market or any other national market within the EU. Rather, it is noted that the single market of the EU is affected as a whole, in particular through imports of contaminated goods manufactured overseas. For these reasons, Germany deems swift and effective **EU-wide legal regulation necessary**.

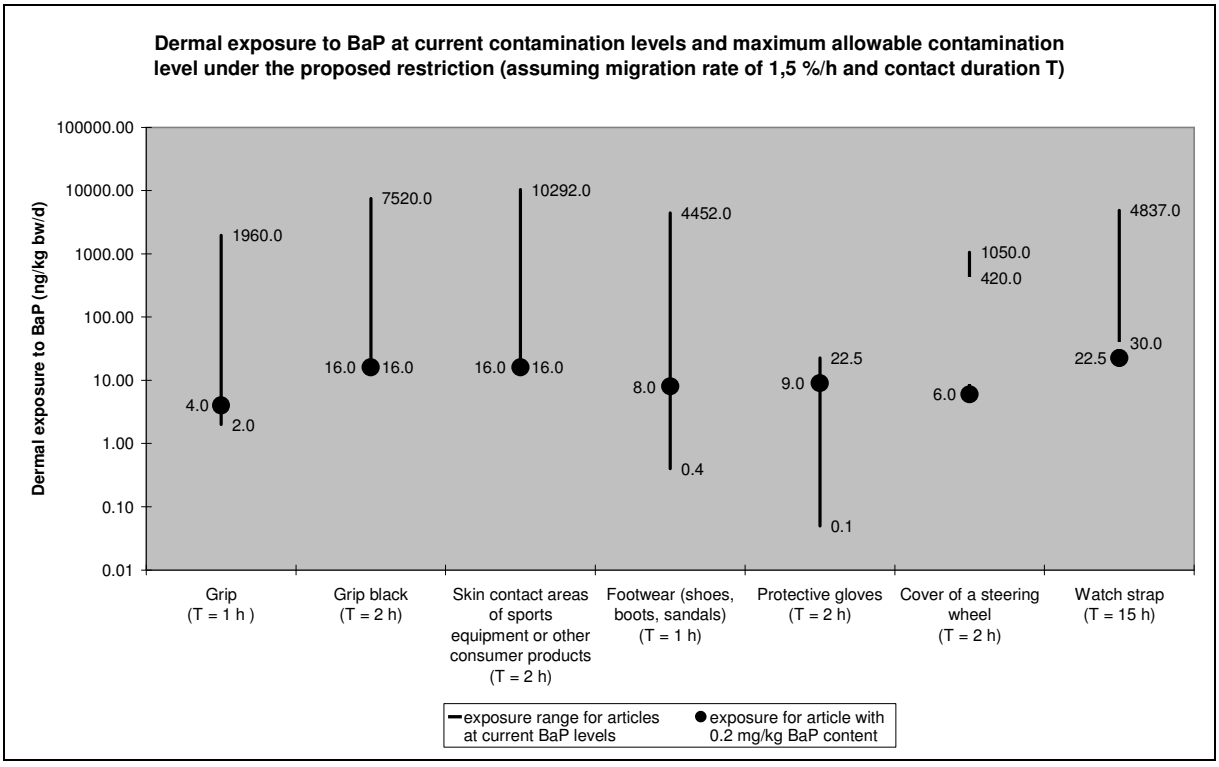
3. Proposed restriction

The proposed restriction applies to the following eight PAH compounds whose content in extender oils used for the production of tyres is already regulated under **No. 50 of Annex XVII** of the REACH Regulation (Reg. (EC) 1907/2006):

Benzo(a)pyrene	CAS-No. 50-32-8	Benzo(b)fluoranthene	CAS-No. 205-99-2
Benzo(e)pyrene	CAS-No. 192-97-2	Benzo(j)fluoranthene	CAS-No. 205-82-3
Benzo(a)anthracene	CAS-No. 56-55-3	Benzo(k)fluoranthene	CAS-No. 207-08-9
Chrysene	CAS-No. 218-01-9	Dibenzo(a,h)anthracene	CAS-No. 53-70-3

In essence, an extension of the existing entry 50 of Annex XVII of the REACH Regulation is suggested, as the identical substances are addressed within the attached restriction dossier. It is recommended to **limit the content of the above mentioned substances to the currently technically achievable analytical limit of quantitation (LOQ) of 0.2 mg PAH/kg article.**

The following graph shows the dermal exposure of adults to BaP, calculated for various groups of consumer articles. The dermal exposure ranges are estimations based on measured BaP concentrations in real-life product samples. A limit of 0.2 mg/kg under the proposed restriction can be shown to bring exposure down to a level that could be considered as tolerable for the bulk of products/uses examined.



Since the listed PAHs are carcinogens, for which no threshold can be assumed, the restriction for articles used by consumers containing more than 0.2 mg PAH/kg article is **proportionate**. In the light of a specific vulnerability of children, it is considered reasonable and proportionate to follow the **ALARA principle** (as low as reasonably achievable).

4. Suggested restriction route (Art. 68(2))

To address the problem of PAHs in consumer products, the **following risk management options** (RMO) were analysed:

	Route and relevant legislation	**Expected effectiveness**
RMO 1	Authorisation under REACH (1907/2006/EC)	Low
RMO 2	Restriction under REACH via Art. 68(1); common approach for all target groups	High
RMO 3	Restriction under REACH via Art. 68(2); direct approach for CMR substances in consumer products	High
RMO 4	Restriction under Toy Safety Directive (2009/48/EC)	Average
RMO 5	Restriction under General Product Safety Directive (2001/95/EC)	Average
RMO 6	Voluntary action by industry	Low

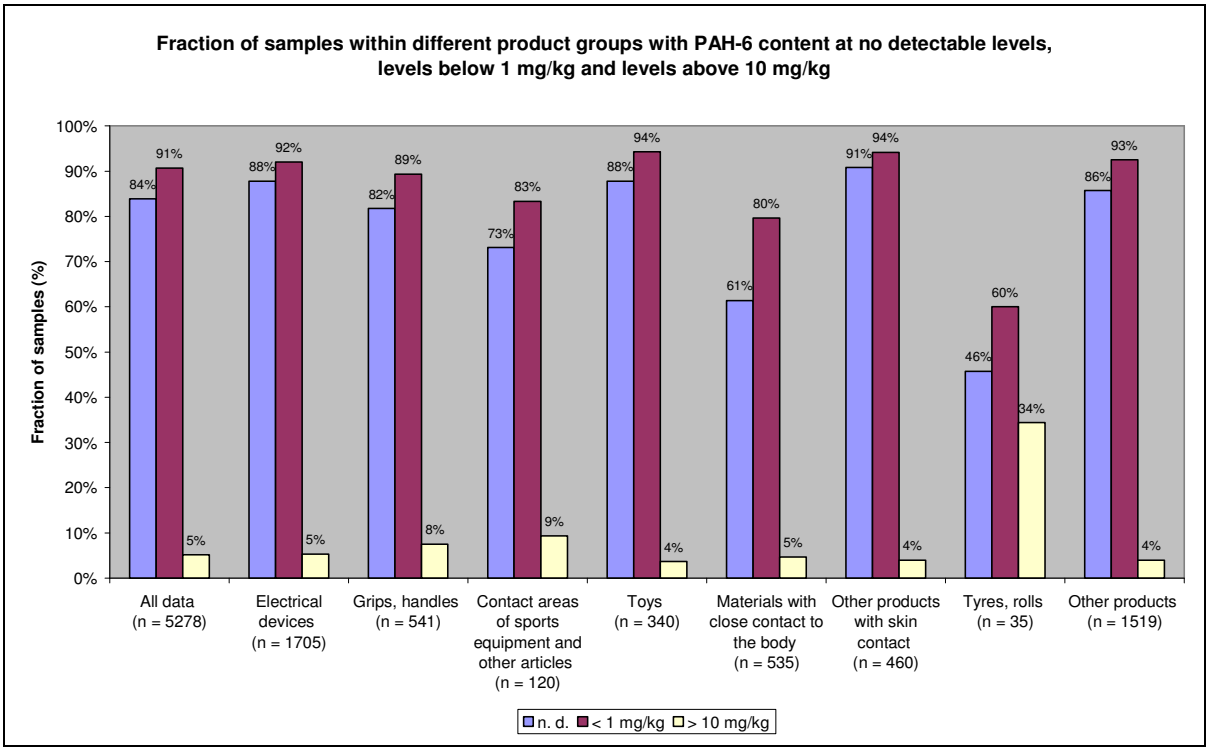
Effectiveness of RMO 6 is regarded as low because voluntary agreements and certification schemes specifying PAH limits already exist within the EU (such as the German GS mark and the EU Eco-Label) but have not solved the PAH problem satisfactorily. RMO 1 would fail to cover imports and would likely not be appropriate since PAHs are not produced as substances per se, occurring instead as by-products and impurities. RMO 4 is limited to a small percentage of toys (toys intended for use by children under 36 months or toys intended to be placed in the mouth) and would therefore not impact on a large portion of potentially PAH-contaminated consumer products on the market. RMO 5 is too restricted in scope, as the General Product Safety Directive is designed to apply only to consumer products not covered by sector-specific legislation (such as toys, for example).

RMO 2 and RMO 3 remain as the only options which would address health risks arising from PAHs to consumers effectively. Compared to RMO 2, RMO 3 would benefit from a more streamlined and expeditious process designed specifically to deal with hazards of CMR substances to consumers. Therefore, a **restriction via REACH Art. 68 (2) clearly emerges as the preferred risk management option.**

5. Data on PAHs in consumer products

Many EU Member States as well as independent consumer protection organisations, e.g. the German 'Stiftung Warentest' or 'TÜV Rheinland', have repeatedly reported on consumer products found to be highly contaminated with PAHs in analytical chemical examinations.

The dossier prepared by Germany is based on the evaluation of more than **5300 samples from consumer articles** analysed for their PAH content. Calculated over all product groups, BaP was not detectable in 91.9 % of the cases. In 3.1 % of all samples, BaP was detected above LOQ and below 1 mg/kg. The corresponding values were 83.9 % not detectable and 6.8 % detected below 1 mg/kg for the sum of the 6 EU-PAHs contained in the EPA-PAH list ('PAH-6', consisting of Benzo(a)pyrene, Benzo(b)fluoranthene, Benzo(a)anthracene, Benzo(k)fluoranthene, Chrysene and Dibenzo(a,h)anthracene). However, detected levels vary considerably between different product groups.



The **highest PAH levels** found were **1200 mg/kg** for BaP, **25400 mg/kg** for the sum of all EPA-PAHs and **6930 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 demonstrate that levels of BaP and of PAH-6 above LOQ (0.2 mg/kg) in consumer products are technically avoidable**.**

6. Results of stakeholder consultations

A **consultation addressed to EU member states and German NGOs/companies/industry associations** was conducted in order to gather additional information about specific products and exposures regarding PAH in consumer products and to contribute to the transparency and representativeness of the restriction proposal. Almost all respondents agreed on a need for action in respect to PAH in consumer products and on the fact that child protection in terms of PAHs is currently insufficient.

The statements of important industrial organisations also implicate that PAHs in consumer products are not necessary. For example, Plastics Europe replied to the questionnaire: “The member companies of Plastics Europe do not use PAHs intentionally in their products. Only in plastics which use carbon black as filling material technical contaminations with PAHs cannot be excluded” (statement translated from German to English). This statement is backed by the answers of different single companies in the questionnaire.

It therefore seems that the problem of PAHs in consumer products might be mainly a **problem of imported goods**. In fact, in the majority of products tested, the problem lies in the low-price sector products. This indicates that the use of PAH–containing additives is mostly due to economical reasons and not for reasons concerning the technical properties of the PAH. Nonetheless, it should be noted that high PAH concentrations were also found in premium products.

7. Alternatives

The most important argument for the availability of alternatives comes from the product tests. The analytical data of various tested product groups has shown that most products do not contain PAHs while only some products of the same group contained PAHs. Apparently, it is technically very well possible to produce consumer products with PAH levels below limit of quantitation by means of known alternatives like extender oils with reduced PAH content, carbon black with reduced PAH content, thermoplastic elastomers (TPE) or surrender of use.

In extender oils used for tyres placed on the European market the PAH-content is restricted since 01/01/2010 according to the REACH regulation, Annex XVII, No 50. Industry therefore already experienced the replacement of PAH-containing extender oils for a high volume product which has to comply with high technical requirements. This example shows that **alternatives exist and can be used**.