Transfer of the IARC monograph on bitumen in European ways of working

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Digital Object Identifier (DOI): dx.doi.org/10.14311/EE.2016.145

ABSTRACT

In Germany, the DFG Senate Commission (MAK Commission) and the Committee on Hazardous Substances (Ausschuss für Gefahrstoffe, AGS) scientifically evaluate and rank substances with regard to possible carcinogenic effects. In many European states the decisions and recommendations of the MAK Commission are a substantial basis for classifications. In Germany, the Federal Ministry of Labour and Social Affairs implements the classification of the AGS by publication in national law.

Following the publication of the IARC monograph "bitumen and emissions from bitumen" the MAK Commission and afterwards the AGS will review their existing classifications. In the technical chapter of the IARC monograph also methods and materials which are not used in Germany or Europe are covered. Therefore, the German Bitumen Forum has made a transfer of the technical chapter on European practise and standards, thus the MAK Commission may take into account the working methods and materials that are common in Europe. Methods and materials that are not used in Germany or Europe will not be subject of the transfer paper.

An essential part of the transfer is the presentation of exposure data on vapors and aerosols out of hot bitumen and the evaluation of these working place exposures. The German Bitumen Forum holts the largest pool of exposure data when handling hot bitumen, including data from many European countries.

Keywords: Exposure, Fumes, Health Safety and Environment, Warm Asphalt Mixture

Introduction

The German MAK Commission is going to revise its classification of bitumen in order to account for the standards set by IARC Monograph 103 "Bitumens and Bitumen Emissions, and Some N- and S-Heterocyclic Polycyclic Aromatic Hydrocarbons". To make sure that the future classification is based on working methods usually applied in Germany and Europe, the German Bitumen Forum transfers (i.e. not only translates but also 'tranports' to the European techniques) the technical part of the IARC Monograph to German and European standards. In addition, new exposure data for workers will be taken into account. This article informs about those activities and about the different categories for carcinogenic effects in the IARC and the MAK Commission.

Why is a transfer of the IARC Monograph 103 necessary?

In February 1984, the IARC Working Group, categorized bitumens into eight classes representing the major types used in the industry at that time, written down in Volume 35 (IARC, 1985). The IARC Working Group for the Monograph 103 reconsidered these categories and defined six classes according to their current uses (Table 1). Class 1 “straight-run bitumens” now encompasses the former class 1 “penetration bitumens” and class 4 “hard bitumens”, while classes 6 and 7 have been merged into a single class 5 “modified bitumens”.

This categorisation into six classes is unusual in Europe. Either the bitumen and bituminous products are divided according to the European requirement standards. Or the classification is based on the CAS numbers, under which bitumen in context of REACh (European Union Regulation 1907/2006 “Registration, Evaluation, Authorisation and Restriction of Chemicals”) has been registered.

Table 1: Comparison of the classes of bitumen as defined for Volume 35 and for Volume 103 (IARC, 2013)

Volume 35		Volume 103	
Class	**Definition**	**Class**	**Definition**
Class 1	Penetration bitumens	Class 1	Straight-run bitumens
Class 4	Hard bitumens		
Class 2[a]	Oxidized bitumens	Class 2	Oxidized bitumens
Class 3	Cutback bitumens	Class 3	Cutback bitumens
Class 5	Bitumen emulsions	Class 4	Bitumen emulsions
Class 6	Blended or fluxed bitumens	Class 5	Modified bitumens
Class 7	Modified bitumens		
Class 8	Thermal bitumens	Class 6	Thermally-cracked bitumens

[a] It is noteworthy that class 2 “oxidized bitumens” (CAS No. 64742-93-4) comprises two grades of oxidized bitumens, namely fully-oxidized (penetration index > 2) and air-rectified (semi-blown) (penetration index ≤ 2). These grades differ by their degree of oxidation during production, which leads to very different characteristics and uses. Air-rectified bitumens have applications similar to those of class 1 bitumens.

The European requirement standards have a technical basis which relate to technical qualities, not chemical compositions. However, toxicologists in general do not evaluate technical qualities of bitumen, which are often made by mixing various starting materials, but focus their evaluation on bitumen base materials: straight run, air rectified and oxidized bitumen.

The transfer will therefore be argued with the importance to consider the production of bitumen. Thus, for example, we are not talking about paver bitumen, since paver bitumen can contain not only straight run bitumen but also air-rectified bitumen.

Another reason for the necessary transfer of the IARC Monograph is the origin of technical experts who have advised the IARC. The IARC collects its information for the IARC Monograph in a very open manner. In particular for chapter 1 ’Exposure Data’, in which the substances to be evaluated, their production, uses and exposures are described, so-called 'Observers' are invited. At the Bitumen Monograph, six of those Observers were representatives from the industry (IARC, 2013 p. 5/6), five of them from the United States. In addition, the Observers were accompanied by a further group of industry representatives, which were also mainly from the United States.

This is probably the reason, why applications that are common in Germany and Europe, are missing or only briefly mentioned in the IARC monograph 103. Exposure data from Europe are hardly mentioned.

Therefore the German Bitumen Forum has decided to tansfer Chapter 1 'Exposure Data' of the IARC monograph – i.e. to translate into German language and to transmit to European conditions.

In context of the transfer current issues, related to bitumen, are discussed. For example, the DNEL (derived no effect level) for vapors and aerosols of bitumen or the requirement to equip asphalt paver with exhaust systems.

Categories for carcinogenic effects in the IARC and the MAK Commission

The IARC (International Agency for Research of Cancer) is part of the World Health Organization (WHO), headquartered in Lyon. The IARC regularly reviews the publications on carcinogenic effects of substances. The results of these audits will be published in monographs, where all the available information for a substance on possible carcinogenic effects are evaluated. Meanwhile, the IARC has more than 100 monographs published (www.iarc.fr). The IARC knows four categories with regard to possible carcinogenic effects of substances (Fig. 1).

Group 1: The agent is carcinogenic to humans.

Group 2A: The agent is probably carcinogenic to humans.

Group 2B: The agent is possibly carcinogenic to humans.

Group 3: The agent is not classifiable as to its carcinogenicity to humans.

Group 4: The agent is probably not carcinogenic to humans.

Figure 1: IARC Categories for carcinogenic effects

In Germany, substances are scientifically evaluated and ranked, with regard to their carcinogenic effects, by the DFG Senate Commission (MAK-Commission) and by the Committee on Hazardous Substances (Ausschuss für Gefahrstoffe, AGS). The ranking criteria of the AGS and the EU are the same, but differ from the ranking criteria of the MAK-Commission. The Federal Ministry of Labour and Social Affairs implements the classification of the AGS into national law. The classification of a substance with respect to its carcinogenicity may well differ for the MAK-Commission and the AGS, because both institutions have different rating systems.

The MAK-Commission has five categories of a possible carcinogenic effect (Fig. 2). The MAK-Commission regularly publishes the 'MAK and BAT values list' in August, with all of the substances classified. In summer 2016 the 52nd edition will be published.

Category 1: Substances that cause cancer in human

Category 2: Substances that are considered to be carcinogenic for human

Category 3: Substances that cause concern that they could be carcinogenic for human but cannot be assessed conclusively because of lack of data.

Category 4: Substances with carcinogenic potential for which genotoxicity plays no or at most a minor role. No significant contribution to human cancer risk is expected provided the MAK value is observed.

Category 5: Substances with carcinogenic and genotoxic potential, the potency of which is considered to be so low that, provided the MAK value is observed, no significant contribution to human cancer risk is to be expected.

Figure 2: MAK Categories for carcinogenic effects

The Committee on Hazardous Substances (AGS) knows three categories for possible carcinogenic effects (Fig. 3). In the TRGS 905 (Technical Rule for Hazardous Substances 905) all substances that have been classified on the basis of reliable scientific data as carcinogenic, mutagenic or toxic for reproduction category 1, 2 or 3 are listed in accordance with the criteria of Annex VI to Directive 67/548 / EEC.

Category 1: Substances known to be carcinogenic to human. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2: Substances which should be regarded as if they are carcinogenic to human. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:
- appropriate long-term animal studies,
- other relevant information.

Category 3: Substances which cause concern for human owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

Figure 3: AGS Categories for carcinogenic effects

Exposure data sampled by the German Bitumen Forum

In opposite to the IARC monograph, additional exposure data are listed in the transfer, including exposure data measured during the production of car body sound deadening systems and the production of asphalt.

All exposure data were obtained from the German Bitumen Forum through numerous workplace measurements during handling with hot bitumen - not only in Germany, but also in many other European countries. Vapours and aerosols were measured during handling with hot bitumen. The measuring method detects all organic compounds with aliphatic C-H bonds (BIA-Working folder, 1997). Therefore possibly also other substances such as emissions from combustion engines (for example non-combusted fuel components) were detected.

40 measurements were carried out in the neighborhood of construction sites where no work with hot bitumen was conducted (Table 2). In this way, for example, the impact of road traffic on the results of exposure measurements in rolled asphalt work can be estimated.

Table 2: "Exposures" in the unloaded environment of construction sites (mg/m³)

Number	Min	50-Percentile	95-Percentile	Max
40	0.07	0.30	1.72	2.30

The measurement data of the German Bitumen Forum are usually task or activity related exposure data. This means that it will only be measured when the workers are exposed. Site changes, conversions or other exposure-free times are not taken into account. In practice, exposed activities can last over the entire shift (then the activity value is equal to the shift value). In summer, the respective activities can be significantly longer than eight hours (then the shift value = activity value x exposure duration / 8). But especially on construction sites workers are often exposed less than 8 hours. Then the shift exposure may be significantly lower than the activity exposure.

In the Human Bitumen Study (Raulf-Heimsoth et al., 2011) the exposure was measured during the shift to allow a comparison with the biological data. The measuring pump thus also ran in exposure-free periods. For mastic asphalt workers, this led to a shift exposure of 3.5 mg/m³ (50% value in Breuer et al., 2011; 95%-value 15,3 mg/m³). This is significantly lower than the former activity values. Until 2008, mastic asphalt was installed at temperatures up to 250°C, the measurements for the human study were carried out between 2001 and 2008. The activity levels were then up to 57.8 mg/m³ (charger, mechanical laying of mastic asphalt) or 34.0 mg/m³ (smoother, manual work with mastic asphalt).

The IARC-Monograph describes the exposure of laying conventionel mastic asphalt with laying temperatures up to 250°C. In the transfer, the exposure data for mastic asphalt workers refers to a laying temperature of max. 230°C (mastic asphalt with additives), required since 2008 (Ruehl, 2008).

In the transfer exposure values are given for all activities with hot bitumen. Among that are many current data and older data, that have not yet been published. For example, Figure 4 shows the exposures during laying conventional asphalt (laying temperature 160°C) and warm mix asphalt (asphalt with additives, laying temperature below 160°C). The latest exposure data can be found on the website of the German Bitumen Forum (www.bgbau.de/koop/gespraechskreis-bitumen).

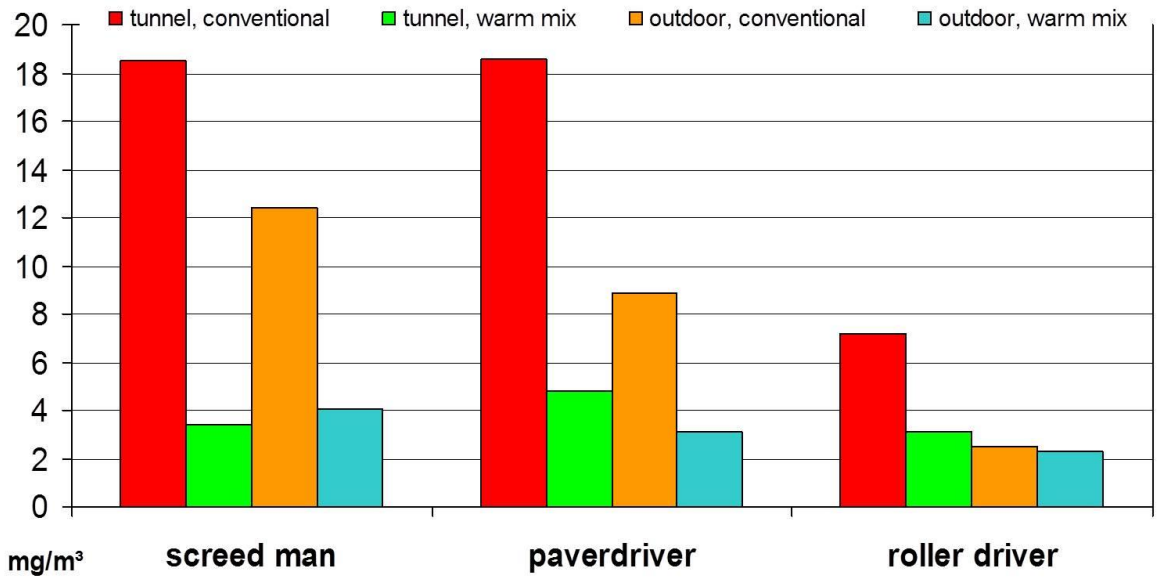

Figure 4: Vapour and aerosols during laying of conventional rolled asphalt and warm mix asphalt

Determination of shift exposures from task values

With the activity-based exposures one can determine every shift exposure to vapors and aerosols from hot bitumen. According to the formula Σ (exposure (mg/m³) / Duration (h)), the duration and the heights of exposures for the specific tasks are added.

Figure 5 explains the procedure for an employee, who in the morning first bonded a copper foil with hot bitumen (2 hours, oxidized bitumen), then about one hour torched bitumen sheets (straight run bitumen) and in the afternoon worked with mastic asphalt (as smoother, 3 hours; straight run and air rectified bitumen). The shift value here was 6.4 mg/m³ (9.8 mg/m³ x 2/8 + 2.8 mg/m³ x 1/8 + 9.5 mg/m³ x 3/8 + 0 mg/m³ x 2/8).

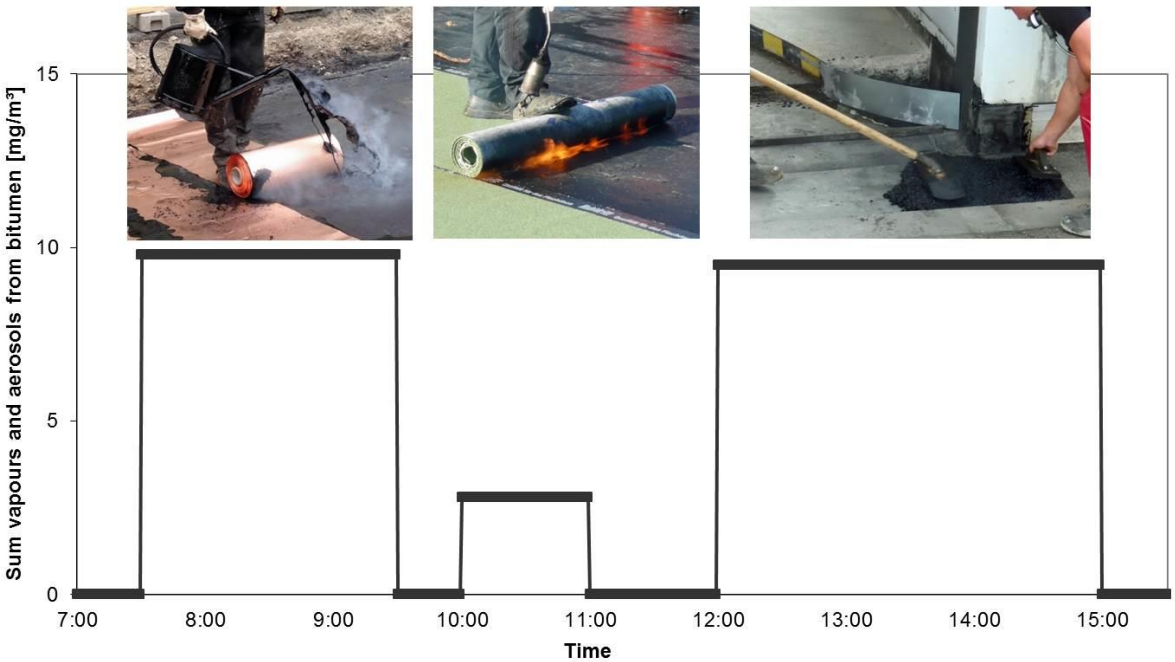

Figure 5: Determination of exposure over a shift with two hours of pouring of hot bitumen, one hour torching of bitumen sheeting and three hours manual work with mastic asphalt

Paver bitumen and roofer bitumen or straight run, air rectified und oxidized bitumen

Bitumen and tar are totally different materials with fundamentally different compositions. Tars are obtained by pyrolysis of coal and contain significantly higher concentrations of polycyclic aromatic hydrocarbons (PAHs) as bitumen. Bitumen, however, contains higher concentrations of paraffinic and naphthenic hydrocarbons and their derivatives. This differences are likely to be known among toxicologists.

Among the various bitumen the confusion is however still very large. The classification into six classes within the IARC monograph 103 (Table 1) is not common in Europe. Either the bitumen and bituminous binders are divided in accordance with the European standards requirement or reference is made to the CAS numbers, under which bitumen under REACh has been registered.

Usually, toxicologists classify pure substances. In this context, it is difficult to explain that bitumen is a mixture of many substances: a mixture which contains substances with a natural range regarding their concentrations. A mixture where the emissions have a different composition as the solid bitumen. Therefore, we have no bitumen fumes or bitumen aerosols, but vapors and aerosols from bitumen. All this does not facilitate the discussion.

The CAS numbers are only partially a help because they do not explain the difference between air rectified and oxidized bitumen.

Therefore, in the transfer paver bitumen or roofer bitumen are not considered. These terms refer to technical requirements which do not focus on the composition, but on properties such as softening point ring and ball or needle penetration. This way the requirements on 'paver bitumen' can be met by mixing straight run bitumen with air rectified bitumen.

In the transfer it is explained that in principle straight run bitumen is the substance from which inter alia, air rectified bitumen and oxidized bitumen are produced.

Classifications of bitumen at the MAK Commission - history and future

The MAK Commission has classified vapors and aerosols from bitumen until 1998 in category 3. In 2000, classification 3B occured. In 2001, the MAK Commission classified vapors and aerosols of bitumen in Category 2 and as a substance, which is absorbed through the skin (Fig. 6).

The classification as a skin resorptive is confusing, as the basis for this were the investigations of Walter and Knecht (2007), in which only the, already known, skin resorption of PAH was confirmed. Since 2007, bitumen is listed in the MAK list as a substance for which the carcinogenic potential is checked.

Stoff [CAS-Nummer]	Formel	MAK ml/m³ (ppm)	MAK mg/m³	Spitzenbegrenzung	H;S	Krebserzeugend Kategorie
Bitumen [8052-42-4] (Dampf und Aerosol)		–	–	–	H	2

Figure 6: Current classification of bitumen by the MAK Commission

It is assumed that the MAK Commission will present the result of their review of existing classification of vapors and aerosols from bitumen in the 52nd edition of the MAK list in the summer 2016.

The decision of the MAK Commission will affect the attitude of the relevant bodies in many countries. In Germany, the Committee on Hazardous Substances (AGS) will reconsider its classification for vapors and aerosols of bitumen. Although many members of the MAK Commission are also active in the AGS, this may take a while. In the AGS many

substances are waiting for review. A new and legally binding classification of vapors and aerosols from bitumen by the AGS is not expected before 2018.

Conclusion

The MAK Commission is currently evaluating its classification of vapors and aerosols from bitumen. With the transfer of the technical section of the IARC monograph on bitumen to European conditions, the German Bitumen Forum hopes to provide an ideal basis to this activity by the MAK Commission. In this context, numerous measurements in many European countries are carried out at the moment in order to update the exposure data base.

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