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Addendum to arsenic and inorganic arsenic compounds (with the exception of arsine)

Assessment Values in Biological Material – Translation of the German version from 2016

E. Ochsmann[1], T. Göen[2], B. Michalke[3], W. Weistenhöfer[2], K. Klotz[2], H. Drexler[4,*], A. Hartwig[5,*], MAK Commission[6,*]

1 *University Hospital Schleswig-Holstein, Institute of Occupational Medicine, Prevention and Occupational Health Management, Ratzeburger Allee 160, 23562 Lübeck, Germany*

2 *Friedrich-Alexander-Universität Erlangen-Nürnberg, Institute and Outpatient Clinic of Occupational, Social, and Environmental Medicine, Henkestraße 9–11, 91054 Erlangen, Germany*

3 *Helmholtz Zentrum München, German Research Center for Environmental Health (GmbH), Research Unit Analytical BioGeoChemistry, Ingolstädter Landstraße 1, 85764 Neuherberg, Germany*

4 *Head of the working group "Assessment Values in Biological Material" of the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Friedrich-Alexander-Universität Erlangen-Nürnberg, Institute and Outpatient Clinic of Occupational, Social, and Environmental Medicine, Henkestraße 9–11, 91054 Erlangen, Germany*

5 *Chair of the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Institute of Applied Biosciences, Department of Food Chemistry and Toxicology, Karlsruhe Institute of Technology (KIT), Adenauerring 20a, Building 50.41, 76131 Karlsruhe, Germany*

6 *Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Kennedyallee 40, 53175 Bonn, Germany*

***** *email: H. Drexler (hans.drexler@fau.de), A. Hartwig (andrea.hartwig@kit.edu), MAK Commission (arbeitsstoffkommission@dfg.de)*

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Addendum to Arsenic and Inorganic Arsenic Compounds (with the exception of arsine)

BAT Value Documentation

E. Ochsmann[1], T. Göen[2], B. Michalke[3], W. Weistenhöfer[2], K. Klotz[2], H. Drexler[4, *], A. Hartwig[5, *], MAK Commission[6, *]

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Abstract

The German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area has re-evaluated the "Biologischer Arbeitsstoff-Referenzwert" (BAR) as well as the exposure equivalents for carcinogenic substances (EKA) for arsenic and inorganic arsenic compounds (with the exception of arsenic hydride). Available publications are described in detail.

The quantification of the various arsenic species is essential to understand the hazardous potential of the arsenic compounds which differ highly in their toxicity. Therefore the BAR for the sum of different arsenic species is no longer valid. Considering published data from occupational not exposed persons, new BAR for the arsenic species of 0.5 µg/l urine for arsenic (+III), 0.5 µg/l urine for arsenic (+V), 2 µg/l urine for monomethylarsonic acid (MMA) and 10 µg/l urine for dimethylarsinic acid (DMA) were evaluated. The differentiation of arsenic species now allows for the estimation of the individual health risks taking into account special influences like seafood consumption. Sampling time is at the end of exposure or the end of the working shift and after long term exposure at the end of the working shift after several shifts.

Data of a correlation of arsenic in the air and the sum of the arsenic species in urine were considered for the evaluation of the exposure equivalents for carcinogenic substances. This correlation is in good accordance with the EKA correlation of arsenic trioxide, which is based on former studies in which also the urinary concentrations of the sum of As (+III), As (+V), MMA and DMA were measured. Sampling time is at the end of exposure or the end of the working shift and after long term exposure at the end of the working shift after several shifts.

Keywords

arsenic; arsenic trioxide; monomethylarsonic acid; dimethylarsinic acid; occupational exposure; biological tolerance value; BAT value; biological reference value; EKA; BAR; toxicity

Author Information

[1] University Hospital Schleswig-Holstein, Institute of Occupational Medicine, Prevention and Occupational Health Management, Ratzeburger Allee 160, 23562 Lübeck, Germany

[2] Institute and Outpatient Clinic of Occupational, Social and Environmental Medicine, Friedrich-Alexander University Erlangen-Nürnberg (FAU), Henkestr. 9-11, 91054 Erlangen, Germany

[3] Helmholtz Zentrum München, German Research Center for Environmental Health (GmbH), Research Unit Analytical BioGeoChemistry, Ingolstädter Landstraße 1, 85764 Neuherberg, Germany

[4] Chair of the Working Group "Setting of Threshold Limit Values in Biological Materials", Deutsche Forschungsgemeinschaft, Institute and Outpatient Clinic of Occupational, Social and Environmental Medicine, Friedrich-Alexander University Erlangen-Nürnberg (FAU), Henkestr. 9-11, 91054 Erlangen, Germany

[5] Chair of the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Department of Food Chemistry and Toxicology, Institute of Applied Biosciences, Karlsruhe Institute of Technology (KIT), Adenauerring 20a, Building 50.41, 76131 Karlsruhe, Germany

[6] Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Kennedyallee 40, 53175 Bonn, Germany

* Email: H. Drexler (hans.drexler@fau.de), A. Hartwig (andrea.hartwig@kit.edu), MAK Commission (arbeitsstoffkommission@dfg.de)

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BAR (2015)

0.5 µg arsenic (+III)/l urine
0.5 µg arsenic (+V)/l urine
2 µg monomethylarsonic acid/l urine
10 µg dimethylarsinic acid/l urine

Sampling time: end of exposure or end of shift; for long-term exposures: after several shifts

EKA (2015)

The following correlations between external and internal exposure were obtained:

Air **Arsenic and inorganic arsenic compounds (with the exception of arsine)** **[µg/m3]**	**Urine** **Σ As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid** **[µg/l]**
1	15
5	30
10	50
50	90
100	130

Sampling time: end of exposure or end of shift; for long-term exposures: at the end of the shift after several shifts

MAK value **not established**

Absorption through the skin (2014) H*

Carcinogenicity (1971) Carcinogen Category 1

* with the exception of metallic arsenic and gallium arsenide

19 Re-evaluation

In 1993, a relationship between the arsenic trioxide concentration in the air and the elimination of arsenic in biological materials (EKA, exposure equivalents for carcinogenic substances) was examined and published by the Working Group "Setting of Threshold Limit Values in Biological Materials" (see BAT Documentation 1994, translated). In 2002, a BLW (biological guidance value) of 50 µg inorganic arsenic and methylated metabolites (volatile arsenic compounds determined by direct hydration)/l urine was derived for arsenic and inorganic arsenic compounds (see BAT Documentation 2003, translated) and a BAR (biological reference value) of 15 µg inorganic arsenic and methylated metabolites (volatile arsenic compounds determined by direct hydration)/l urine was established in 2010 (see BAT Documentation 2011).

Different arsenic compounds have, however, different toxic properties, so that a differentiation of the arsenic species is indispensable for an assessment. The present Addendum aims at examining whether a BAR as well as an EKA for the individual arsenic species can be derived.

19.1 Selection of the indicators

For the determination of the internal arsenic exposure of humans, precise, validated methods are now available allowing conclusions about the total arsenic content in urine on the one hand and on the contents of individual arsenic species such as As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid on the other hand. The selection of indicators in the present derivation therefore always relates to those parameters, for which a valid and reliable database is available to allow for the derivation of a threshold value.

Following exposure at the workplace to inorganic arsenic, the determination of those arsenic species in urine is recommended, which enables a differentiation from those arsenic compounds which have been taken up by food.

19.2 Methods

For the determination of the arsenic species in urine, two procedures are available which have been evaluated by the Working Group "Analyses in Biological Material". The first procedure is based on coupling of liquid chromatography, a post-column derivatization to arsine and atomic absorption spectrometry (Begerow et al. 2000). The detection limits to be obtained by this procedure are: 0.9 µg arsenic/l for arsenite (As (+III)), 2.0 µg arsenic/l for arsenicate (As (+V)), 2.3 µg arsenic/l for dimethylarsinic acid and 1.4 µg arsenic/l for monomethylarsonic acid. The second procedure is based on the coupling of liquid chromatography with ICP-MS (Schramel et al. 2018, in print). With this procedure, determination of the analytes is achieved with the following detection limits: 0.03 µg arsenic/l for arsenite (As (+III)), 0.05 µg arsenic/l for arsenicate (As (+V)), 0.02 µg arsenic/l for dimethylarsinic acid, 0.04 µg arsenic/l

for monomethylarsonic acid, and 0.03 µg arsenic/l for arsenobetaine. The latter procedure is thus comparable with the analytical procedures used and described by Leese et al. (2014) and Heitland and Köster (2008).

19.3 Background exposure

The arsenic exposure of 82 persons occupationally not exposed to arsenic (32 men and 50 women) from Germany aged between 18 and 65 years was investigated by determining the arsenic species concentrations in urine (Heitland and Köster 2008). In the UK, Leese et al. (2014) determined arsenic species in the urine of 95 not occupationally exposed persons (53 men, 42 women; all older than 18 years; mean value 41.1 years). The results of the arsenic species concentrations determined in urine from these studies are given in Table 1.

Table 1 Arsenic species in the urine of persons not occupationally exposed to arsenic — results from the studies by Leese et al. (2014) and Heitland and Köster (2008)

Arsenic species	Leese et al. 2014		Heitland and Köster 2008	
	Median	95th percentile	Geometric mean value	95th percentile
As (+III)	0.11 µg/l	0.54 µg/l	0.15 µg/l	0.49 µg/l
As (+V)	< 0.04 µg/l	0.23 µg/l	0.11 µg/l	0.53 µg/l
Monomethylarsonic acid	0.56 µg/l	2.37 µg/l	0.33 µg/l	1.6 µg/l
Dimethylarsinic acid	2.44 µg/l	12.68 µg/l	2.6 µg/l	9.1 µg/l
Arsenobetaine	3.87 µg/l	126.7 µg/l	1.4 µg/l	22.7 µg/l

Abbreviations: As (+V) = pentavalent arsenic; As (+III) = trivalent arsenic

In the USA, the arsenic exposure of the general population was investigated by determining arsenic species in urine (CDC 2009).

In Northern Germany, arsenic species in the urine of 101 men, who were not occupationally exposed to arsenic, were determined using anion exchange chromatography and online hydride atomic absorption spectroscopy (Heinrich-Ramm et al. 2001; see BAT Documentation 2011).

19.4 Evaluation of new BAR

In 2010, a BAR of 15 µg inorganic arsenic and methylated metabolites (volatile arsenic compounds determined by direct hydration)/l urine was evaluated for arsenic and inorganic arsenic compounds.

In the assessment of arsenic exposure, however, a differentiation between the different arsenic compounds on account of their different toxic properties is indispensable.

On the basis of recent studies, therefore, BARs are derived for different arsenic species and

the BAR of 15 µg inorganic arsenic and methylated metabolites (volatile arsenic compounds determined by direct hydration)/l urine is withdrawn.

For the derivation of the BARs, the studies by Leese et al. (2014) as well as Heitland and Köster (2008) were used, who analyzed the arsenic species concentrations in the urine of a non-exposed population sample with a very sensitive analytical procedure based on coupling of liquid chromatography with ICP-MS techniques. Because of the regional differences in environmental exposure to arsenic, the study by the CDC (2009) from the USA is no longer included, and the study by Heinrich-Ramm et al. (2001) is also not taken into consideration due to the analytical methods applied by these authors which have, in the meantime, become outdated.

The BAR is based on the 95th percentile of the values measured in occupationally not exposed persons of working age in the general population.

From the studies by Leese et al. (2014) and Heitland and Köster (2008), the following BARs for arsenic species in urine are derived:

0.5 µg As (+III)/l urine

0.5 µg As (+V)/l urine

2 µg monomethylarsonic acid/l urine

10 µg dimethylarsinic acid/l urine

Sampling is carried out at the end of exposure or the end of shift; for long-term exposures: at the end of the shift after several shifts.

The derivation of a BAR for arsenobetaine is not considered necessary, as this species is greatly influenced by eating habits, such as for example the consumption of sea-food.

19.5 Exposure and effects

19.5.1 Relationship between external and internal exposure

For the most recent evaluation of the EKA correlation for arsenic trioxide, the studies by Smith et al. (1977), Enterline et al. (1987), Yamauchi et al. (1989) and Offergelt et al. (1992) were included (see BAT Documentation 1994, translated; Table 2). Since then, more recent studies by Yager et al. (1997), Apostoli et al. (1999), Jakubowski et al. (1998) and Hakala and Pyy (1995) have been published. They report on the relationship between external arsenic concentration and internal exposure to total arsenic or arsenic species and their correlations.

Hakala and Pyy (1995) investigated 24 workers at a copper smelter where arsenic trioxide was produced as a by-product, and determined the concentration

of arsenic in the air as well as the arsenic species As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid in the urine. They established regression lines for the correlation of arsenic concentrations at different times after the end of a shift. For the sampling 0–8 hours after the end of a shift a relationship of $y = 0.322x + 31 (r = 0.167; P = 0.267)$ was derived from $n = 46$ samples, which corresponds to a concentration of 34 µg/l for the arsenic species at a concentration of 10 µg/m³ in the air. Significant relationships were only observed when dimethylarsinic acid was excluded, as this metabolite is obviously strongly affected by the diet. In this study, the air concentrations were determined partly by stationary and partly by personal measurements. Breathing masks were worn in the arsenic trioxide production area.

In the study by Jakubowski et al. (1998), the relationship between the arsenic exposure in the air determined by personal measurements and the excretion of arsenic species in the urine of 98 copper smelters was analyzed. The air measurements were made on the second day of each working week, and the urine samples were taken directly at the end of the shift on the same day. From the data of 58 persons, a relation of $y = 6.29x^{0.616}$ was obtained, which means that an air concentration of 10 µg/m³ corresponds to a concentration of 26 µg/l urine.

Spinazzè et al. (2015) investigated workers producing Cd/As-based photovoltaic systems and unexposed controls. At maximum air exposures of 0.13 µg/m³, maximum arsenic concentrations of 15 µg/l urine were determined for the sum of the species. As a result of the low exposure level, no significant difference between workers and controls was found.

Yager et al. (1997) investigated 40 workers at a coal-fired power plant in Slovakia including boiler cleaners, boiler repairers as well as technicians, all of whom had been exposed to arsenic at different levels. Inhalation exposure was determined by personal sampling (3 samples) and using stationary air measurements (4 samples). Pre-shift spot urine samples were collected at home on 5 consecutive days. The arsenic species were determined using hydride generation and AAS. The mean values of air exposure on all 5 days were compared with the mean values of urinary concentrations. The relationships between exposure and arsenic species in urine are shown in Table 2.

Apostoli et al. (1999) investigated a total of 51 male employees in the glass industry, who were exposed to inorganic arsenic compounds, mainly arsenic trioxide, and in whom personal air measurements of arsenic and biomonitoring of the arsenic species in urine were performed. In addition, 39 male controls without occupational exposure, without any other high oral arsenic intake (via the drinking water) and without any relevant consumption of fish and sea-food were examined. The median inhaled arsenic concentrations measured in the occupational area were 42 µg/m³ (mean value: 82.9 µg/m³) arsenic. There were great differences between the groups of workers investigated in the study. The concentrations of the arsenic species in urine were determined using HPLC-ICP-MS.

Details from the study are presented in Table 2.

Table 2 External and internalexposure (MV ± SD (range)) of workers occupationally exposed to arsenic

Activity	Arsenic in the air [µg/m³]	Arsenic species in urine [µg/g creatinine]			
		As (+III)	As (+V)	Monomethyl-arsonic acid	Dimethyl-arsinic acid
Yager et al. 1997*					
Boiler cleaners (n = 9)	59.5 ± 1.3	4.2 ± 1.1		4.3 ± 1.1	12.7 ± 1.1
Boiler repairers (n = 13)	17.2 ± 1.3	2.8 ± 1.2		2.3 ± 1.1	7.1 ± 1.2
Technicians (n = 18)	2.1 ± 1.2	3.0 ± 1.1		1.9 ± 1.1	5.5 ± 1.1
Apostoli et al. 1999					
Batch mixers (n = 10)	59 ± 56.4 (10–154)	15 ± 14** (1–57)**	6 ± 5** (1–17)**	30 ± 29** (1–95)**	58 ± 50** (10–232)**
Oven chargers (n = 28)	127.0 ± 89.4 (10–312)				
Moulders or finishers (n = 13)	4.1 ± 3.7 (1.5–15)				
Controls (n = 39)	no exposure	0.5 ± 0.6** (< DL–1.2)**	< DL**	1.2 ± 1.1** (0.5–2.2)**	6.8 ± 4.0** (2.1–14.4)**

* geometric mean; ** [µg/l];
Abbrevation: DL = detection limit

Mathematical linear equations were then derived from the relationships between external and internal exposure. Table 3 below shows the regression equations for the different arsenic species obtained from the study by Apostoli et al. (1999).

Analysis using the bootstrapping method revealed that the urinary parameters for the sum of As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid as well as the sum of As (+III) and As (+V) represent those parameters that best reflect the occupational inhalation exposure to arsenic trioxide.

Results from urinary arsenic species analysis are also given in the study by Apostoli et al. (1999) for an occupationally not exposed control collective (n = 39) without relevant arsenic ingestion (see Table 2).

Table 3 Regression equations between the inorganic arsenic concentration in the inhaled air (x) and the concentration of arsenic species in the urine (y) (Apostoli et al. 1999)

Species	Regression equation (log)	R	R^2	p value
As (+V)	y = 0.276 + 0.506x	0.74	0.55	0.0001
As (+III)	y = 0.048 + 0.599x	0.83	0.69	0.0001
Σ As (+III) and As (+V)	y = 0.090 + 0.635x	0.86	0.74	0.0001
Monomethylarsonic acid	y = 0.221 + 0.655x	0.86	0.75	0.0001
Dimethylarsinic acid	y = 1.067 + 0.364x	0.73	0.53	0.0001
Arsenobetaine (AsBet)	y = 1.541 + 0.100x	0.014	0.00	0.92
Σ As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid	y = 1.186 + 0.455x	0.87	0.75	0.0001

Abbreviations: As (+V) = pentavalent arsenic; As (+III) = trivalent arsenic

19.6 Evaluation of an EKA

New studies are available from which relationships between the arsenic concentration in the workplace air and the concentration of the sum of the arsenic species As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid can be established.

The study by Yager et al. (1997) is not suitable for the derivation of an EKA: The equivalence value for the sum of arsenite, arsenate, monomethylarsonic acid and dimethylarsinic acid in urine of 13 µg/g creatinine derived for an analytically determined inhalation exposure value to arsenic at the level of 10 µg arsenic/m^3 is clearly outside the range of values derived in other studies, from which urinary concentrations between 30 µg arsenic/l and 68 µg arsenic/g creatinine were calculated for 10 µg/m^3 (Enterline et al. 1987; Offergelt et al. 1992; Vahter et al. 1986; Yamauchi et al. 1989) (see BAT Documentation 1994, translated). This discrepancy can be explained by the fact that, in the study, personal sampling was partly not possible due to restricted space conditions and, instead, data from stationary measurements were used (Yager et al. 1997). As in the study by Hakala and Pyy (1995), both stationary and personal measurements were carried out, breathing masks were used part of the time, and a clear assignment is not possible, this study is also not used for this evaluation. In the study by Spinazzè et al. (2015), the airborne arsenic exposure concentrations were within such a low range that they cannot be used to evaluate an EKA.

The regression lines from the study by Apostoli et al. (1999) can be used to derive a relationship between arsenic concentrations in the air and concentrations of arsenic species in urine. From the relevant regression equations, the following relationships between inhalation exposure to arsenic and urinary concentrations of arsenic species can be obtained (see Table 4).

Table 4 Calculated relationships (using the regression lines in Apostoli et al. 1999) between the exposure to arsenic in the air at the workplace [µg/m³] and the analyzed values of arsenic species in urine [µg/l]

Arsenic in the air [µg/m³]	Arsenic species in urine [µg/l]				
	As (+III)	As (+V)	Monomethyl-arsonic acid	Dimethyl-arsinic acid	Σ As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid
100	18	19	34	62	125
50	12	14	22	48	91
10	4	6	8	27	44
5	3	4	5	21	32
1	1	2	2	12	15

These data from Apostoli et al. (1999) on the correlation between arsenic in the air and the sum of urinary arsenic species can be used for the evaluation of an EKA correlation. The correlation thus determined agrees well with the EKA for arsenic trioxide as derived from the studies by Smith et al. (1977), Enterline et al. (1987), Yamauchi et al. (1989) and Offergelt et al. (1992), and in which also the renal arsenic elimination is given as sum of the concentrations of As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid. The study by Jakubowski et al. (1998) also supports this correlation.

On the basis of these data, the following EKA correlation is derived for arsenic and inorganic arsenic compounds including arsenic trioxide:

Air	Urine
Arsenic and inorganic arsenic compounds (with the exception of arsine)	Σ As (+III), As (+V), monomethylarsonic acid and dimethylarsinic acid
[µg/m³]	[µg/l]
1	15
5	30
10	50
50	90
100	130

Sampling time is at the end of exposure or end of shift; for long-term exposures: at the end of the shift after several shifts.

19.7 Interpretation of data

When interpreting the data for internal arsenic exposure, the eating habits of those examined must be taken into account, particularly regarding previous fish or seafood consumption, as this produces a marked increase in the content of organic arsenic compounds, also including dimethylarsinic acid, and thus also the total arsenic content. In addition, regional differences must also be considered, as the presence of natural arsenic in the drinking water can vary greatly, and is accordingly able to affect the results of the study. Finally, age, sex, smoking habits and alcohol consumption have been identified as possible factors influencing the arsenic concentration in biological material (see Heinrich-Ramm et al. 2001; Leese et al. 2014 for example).

All threshold values in biological material, particularly also the BAR and the EKA correlations, relate to normally concentrated urine, in which the creatinine concentration should be in the range of 0.3–3.0 g/l. In addition to this, the Commission considers it useful, for further improving the validity of the analyses, to select a narrower target range of 0.5–2.5 g/l for urine samples. As a rule, where urine samples are outside the above limits, a repetition of the measurement in normally hydrated volunteers is recommended (see BAT Documentation 2010, translated).

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Authors: E. Ochsmann, T. Göen, B. Michalke, W. Weistenhöfer, K. Klotz, H. Drexler (Chair of the Working Group "Setting of Threshold Limit Values in Biological Materials", Deutsche Forschungsgemeinschaft), A. Hartwig (Chair of the Permanent Senate Commission for the Investigation of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft), MAK Commission (Permanent Senate Commission for the Investigation of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft)

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