

COLLECTIVE EXPERT APPRAISAL: SUMMARY AND CONCLUSIONS

**regarding the expert appraisal for recommending occupational exposure limits
for chemical agents
concerning the assessment of measurement methods for two substances listed
in the appendix of the European Directive (EU) 2019/983**

This document summarises the work of the Expert Committee on “Health Reference Values” (HRV Committee) and the Working Group on Metrology.

Presentation of the issue

Prior to the transposition of European occupational exposure limits (OEL) into French law, ANSES is mandated by the Ministry of Labour to conduct an assessment of the measurement methods available for the substances listed in the European Directives.

Scientific and legal background

European objectives, intended to protect workers from risks associated with exposure to chemical agents, are set via European directives, in particular in the form of occupational exposure limits (OELs).

Since the European Commission relies on recommendations issued by European scientific expert committees (SCOEL¹ or RAC²) for the establishment of European OELs, ANSES does not reassess the health effects of the substances in question when European directives establishing OELs are published.

However, given that neither SCOEL nor RAC undertakes in-depth assessments of the available measurement methods with regard to the European OELs, ANSES is asked to undertake these assessments so that the French Ministry of Labour can have all of the information necessary to establish the binding or indicative nature of the limit values in national law.

Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019, amending Directive 2004/37/EC, establishes a list of binding occupational exposure limit values for five new carcinogens and mutagens.

Of these five substances, beryllium, cadmium and formaldehyde were covered by a previous expert appraisal undertaken by ANSES to establish OELs and recommend measurement methods associated with these OEL proposals (Anses, 2010, 2018a, 2018b). Thus, the measurement methods for these compounds were not reassessed as part of this expert appraisal, since these assessments are already available.

¹ SCOEL: Scientific Committee on Occupational Exposure Limits

² RAC: Committee for Risk Assessment

As part of the memorandum of understanding on occupational exposure limits and biological limit values (OELs and BLVs) established between the Ministry of Labour and ANSES, the Directorate General for Labour (DGT) mandated ANSES to undertake the metrological expert appraisal for the following substances only:

- 4,4'-Methylene-bis(2-chloroaniline) (or MOCA) (8h-OEL of 0.01 mg.m⁻³)
- arsenic acid and its salts, as well as inorganic arsenic compounds (8h-OEL of 0.01 mg.m⁻³, inhalable fraction)

Organisation of the expert appraisal

ANSES entrusted examination of this request to the Expert Committee on "Health Reference Values" (HRV Committee). The Agency also mandated the Working Group on Metrology.

The methodological and scientific aspects of the work of this group were regularly submitted to the Expert Committee.

This report has been prepared from metrology reports developed individually for each substance by the Working Group on Metrology. The Working Group reports take into account the additional observations and information provided by the members of the HRV Committee. In light of the question asked, the relevance of the values laid down by the Directive has not been investigated.

This expert appraisal was therefore conducted by a group of experts with complementary skills. It was carried out in accordance with the French Standard NF X 50-110 "Quality in Expertise Activities".

Description of the method

An assessment report of the measurement methods was prepared by the Working Group on Metrology for each substance and submitted to the HRV Committee, for comments and validation. Each assessment report presents the various protocols for measuring the respective substance in workplace atmospheres grouped together based on the methods they use. These methods were then assessed and classified based on the performance requirements set out particularly in the French Standard NF EN 482: "Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents" and the decision-making criteria listed in the methodology report (Anses, 2020a). A list of the main sources consulted is detailed in the methodology report (Anses, 2020a).

These methods were classified as follows:

- category 1A: validated methods (all of the performance criteria are met);
- category 1B: partially validated methods (the essential performance criteria are met);
- category 2: indicative methods (essential criteria for validation are not clear enough or else the method requires adjustments that need to be validated);
- category 3: the methods are not recommended (essential criteria for validation are lacking or inappropriate). This category encompasses unsuitable methods for which essential validation criteria have not been met, and non-assessable methods (falling in category 3⁽¹⁾) for which essential validation criteria have not been documented.

NB: For the measurement of aerosols and substances in mixed phases, an initial classification is established with regard to the performance criteria for sampling methods. A second classification is then established with regard to the performance criteria for analytical methods. The final classification of the method corresponds to the least favourable of these two classifications.

A detailed comparative study of the methods in Categories 1A, 1B and 2 was conducted with respect to their various validation data and technical feasibility, in order to recommend the most suitable method(s) for measuring concentrations for comparison with OELs.

This overall report was prepared from metrology reports developed individually for each substance. The details concerning the adoption of each measurement method assessment report are given in the following table.

Table 1: Adoption dates of the individual reports by the Working Group on Metrology and by the HRV Committee

Substance		Adoption date	
Name	CAS number	By the WG	By the HRV Committee
4,4'-Methylene-bis(2-chloroaniline) (or MOCA)	101-14-4	16/04/2020	14/05/2020
Arsenic acid and its salts, as well as inorganic arsenic compounds	-	07/05/2020	26/06/2020

The overall report, as well as the summary and conclusions of the collective expert appraisal, were adopted by the HRV Committee for public consultation on 26/06/2020.

This collective expert appraisal work and the summary report were submitted to public consultation from 09/10/2020 to 25/11/2020. The people or organizations that contributed to the public consultation are listed in appendix of the report (only available in French). The comments received were reviewed by the Working Group on Metrology who finally adopted this version on 25/01/2021.

Results of the collective expert appraisal

Assessment of the measurement methods for MOCA

Three methods for measuring MOCA in workplace air were identified and assessed:

- method 1: active sampling on glass fibre filters impregnated with sulphuric acid (H₂SO₄) - Solvent extraction - Analysis by GC/ECD (OSHA 71);
- method 2: active sampling through an impinger containing H₂SO₄ - Analysis by GC/FID or GC/N-FID (Blome-1984);
- method 3: active sampling on glass fibre filter impregnated with sulphuric acid - Solvent extraction - Analysis by HPLC/UV (HSE MDHS 75/2).

Method 1 provides complete validation data. The conditions described by the OSHA 71 protocol enable the range of 0.1 to 2*8h-OEL to be covered, but with sampling for 100 minutes at the rate of 1 L·min⁻¹. However, the sampling device proposed in the OSHA 71 protocol (CFC alone) is not recommended for sampling the inhalable fraction. Method 1 was therefore classified in category 3.

Method 2 was classified in category 3 due to a sampling device unable to sample the inhalable fraction of aerosols and because most of the essential validation criteria are missing.

Despite a sampling device capable of sampling the inhalable fraction, method 3 was classified in category 3^(*) due to incomplete validation data.

Assessment of the measurement methods for arsenic acid and its salts, as well as inorganic arsenic compounds:

The assessment of methods for measuring "arsenic acid and its salts and inorganic arsenic compounds" in workplace air was divided into three separate assessments with respect to the form of the arsenic compounds of concern, namely:

- arsenic (total) and its non-volatile salts (i.e., particulate arsenic),
- arsenic (As) and arsenic trioxide (As₂O₃) jointly,
- arsane (AsH₃, better known as arsine, the name used later in this document) (gaseous compound), alone or jointly with arsenic and arsenic trioxide.

Total arsenic and its non-volatile salts

Six methods for measuring total arsenic in workplace air were assessed:

- method 1: active sampling on filter, acid mineralisation and analysis by ICP-AES (NF ISO 15202-1, -2, -3, NIOSH 7300, NIOSH 7301, NIOSH 7302, NIOSH 7303, NIOSH 7304, INRS MétroPol M122, INRS MétroPol M124, NF X 43-275, NIOSH 7306, INRS MétroPol M125);
- method 2a: active sampling on filter, acid mineralisation and analysis by ICP-MS (NF ISO 30011, OSHA 1006, IRSST 394);
- method 3: active sampling on filter, analysis by X-ray fluorescence spectrometry (HSE MDHS 91/2);
- method 4a: active sampling on filter, acid mineralisation and analysis by electrothermal / graphite furnace atomic absorption spectrometry (ETA-AAS) (DGUV Information 213-503 Method 04³, IFA 6195 (2014 and update to be published) , INRS MétroPol M 120, NF X 43-275);
- method 5a: active sampling on filters, acid mineralisation and analysis by atomic absorption spectrometry with flame arsine generation (NIOSH 7900);
- method 7: active sampling on filter, acid mineralisation and analysis by flame atomic absorption spectrometry (FAAS) (INRS MétroPol M-121, NF X 43-275).

Method 3 was classified in category 3 because the sampling device is not compliant for the inhalable fraction and the analytical method is unable to cover the range of 0.1 to 2*8h-OEL.

Methods 4a, 5a and 7 were classified in category 3(*) for regulatory technical control of the 8h-OEL due to:

- a sampling device not assessed with regard to the inhalable fraction and a partially validated analytical method, in particular a retention capacity validated over 2 hours. (method 4a);
- the absence of essential validation criteria, in particular uncertainties and the recovery rate (methods 5a and 7).

Method 1 provides complete validation data that were obtained by spiking materials and therefore do not take the mineralisation rate into account. It was classified in category 2, despite an analytical method complying with the main requirements of the NF EN 482 standard, due to indicative sampling devices for the inhalable fraction.

Method 2a provides complete validation data obtained by spiking numerous collection media but also by mineralisation of certified solid samples (urban dust). This method was classified in category 2, despite a fully validated analytical method complying with the requirements of the NF EN 482 standard, due to indicative sampling devices for the inhalable fraction.

Arsenic (As) and diarsenic trioxide (As₂O₃)

Three methods for the joint measurement of arsenic and arsenic trioxide (as total As) in workplace air were assessed:

- method 2b: active sampling on filter + impregnated backup pad, acid mineralisation and extraction, then analysis by ICP-MS (OSHA 1006);
- method 4b: active sampling on impregnated filter, acid mineralisation and analysis by electrothermal / graphite furnace atomic absorption spectrometry (ETA-AAS) (NIOSH 7901, DGUV Information 213-503 Method 04);
- method 5b: active sampling on impregnated filters, acid mineralisation and analysis by atomic absorption spectrometry with hydride production (ISO 11041:1996, INSHT MTA/MA-035/A96, INRS MétroPol M-283).

Methods 2b and 4b were classified in category 3 for regulatory technical control of the 8h-OEL, because the sampling devices are not compliant for the inhalable fraction and the analytical method is indicative due to partial validation data. It should be possible to implement these methods with a sampling device such as IOM, GSP 3.5, 7-hole or Button that is recommended for sampling the inhalable fraction and can be used with impregnated filters, subject to validation. Method 5b (atomic absorption spectrometry with hydride production), described in two protocols (INSHT MTA/MA-035/A96 and MétroPol M-283) and one standard (ISO 11041:1996), was

³ This protocol is currently being updated by DGUV.

classified in category 2 for regulatory technical control of the 8h-OEL. Although the analytical method provides complete validation data through the standard and the INSHT protocol (obtained by spiking with solution considering an air volume of 960 L) and complies with most of the requirements of the NF EN 482 standard, the sampling device for the inhalable fraction is not specified. The indicative sampling devices for the inhalable fraction that can be used with impregnated filters and are compatible with the 960 L air volume, i.e. IOM, GSP, 7-hole and Button, could be implemented subject to validation.

Arsine

Two methods for the measurement of arsine (as total As) in workplace air were assessed, one for the sampling of arsine (method 4c) and the other for the joint sampling of arsine, arsenic and arsenic trioxide (method 6):

- method 4c : active sampling on an adsorbent tube, acid desorption and analysis by electrothermal / graphite furnace atomic absorption spectrometry (ETA-AAS) (NIOSH 6001);
- method 6 : active joint sampling of arsenic, diarsenic trioxide and arsine on impregnated filters, acid mineralisation and analysis by ICP – AES (INRS MétroPol M-134).

Method 4c provides partial validation data. It is able to cover the range of 0.1 to 2*8h-OEL with an air volume of 10 L. However, the recovery and desorption rates were determined for a higher range of concentrations, and sampling interferences as well as recovery rates after storage are not specified. Measurement method 4c was therefore classified in category 2 for regulatory technical control of the 8h-OEL when only arsine is sampled.

Method 6 was classified in category 3 for regulatory technical control of the 8h-OEL, because the sampling device is not compliant for the inhalable fraction and certain essential validation data such as uncertainty data are missing.

Conclusions and recommendations of the collective expert appraisal

MOCA

The assessment of the applicable reference methods for the measurement of occupational exposure levels for MOCA found that none of the three identified measurement methods is recommended for the regulatory technical control of the 8h-OEL.

However, the use of a device recommended for sampling the inhalable fraction of aerosols (see ANSES, 2020b) and enabling the use of a filter impregnated with sulphuric acid and compatible with the analytical method described in the OSHA 71 protocol⁴ should enable MOCA concentrations to be measured for comparison with the 8h-OEL, subject to validation.

Arsenic acid and its salts, as well as inorganic arsenic compounds

For total arsenic and its non-volatile salts, two measurement methods classified in category 2 are recommended for the regulatory technical control of the 8h-OEL.

For the measurement of arsenic and As₂O₃, one measurement method classified in category 2, is recommended for the regulatory technical control of the 8h-OEL.

For arsine, one measurement method classified in Category 2 is recommended for the regulatory technical control of the 8h-OEL.

The table below summarises the measurement methods recommended for all these substances.

⁴ Analysis by gas chromatography detection ECD after solubilisation and derivatisation steps with heptafluorobutyric anhydride (HFAA)

Table 1 : Measurement methods recommended

Identification of the substance		Principle of the recommended method	Implementation protocols (References)	Classification for 8h- OEL regulatory technical control	Additional information				
Substance	CAS number								
MOCA	101-77-9	No recommended method			The use of a device recommended for sampling the inhalable fraction of aerosols (see ANSES, 2020b) and enabling the use of a filter impregnated with sulphuric acid and compatible with the analytical method described in the OSHA 71 protocol (solvent extraction, HFAA derivatisation, GC/ECD analysis) should enable MOCA concentrations to be measured for comparison with the 8h-OEL, subject to validation				
Arsenic	Particulate arsenic and its non-volatile salts (in total As)	Active sampling on filter, acid mineralisation and analysis by ICP – AES	Quartz fibres, MCE or PVC membrane, capsules	Inhalable fraction sampler (sampler type not specified)	NF ISO 15202-1, -2 and -3	2	<p><u>Sampling:</u> The sampling devices are indicative of the inhalable fraction and therefore classified in category 2 with regard to their compliance with this conventional fraction.</p> <p><u>Analysis:</u> The analytical method is classified in category 1B.</p>		
			MCE or PVC membrane	CFC with wall deposits accounted	NIOSH 7300				
			MCE membrane		NIOSH 7301				
			PVC membrane		NIOSH 7302				
			Quartz fibres		NIOSH 7303				
			MCE membrane		NIOSH 7304				
		MCE membrane	CFC + internal capsule	NIOSH 7306					
		Active sampling on filter, acid mineralisation and analysis by ICP–MS	MCE membrane	CFC with wall deposits accounted	OSHA 1006			2	<p><u>Sampling:</u> The sampling devices are indicative of the inhalable fraction and therefore classified in category 2 with regard to their compliance with this conventional fraction.</p> <p><u>Analysis:</u> The analytical method is classified in category 1A under the conditions of the OSHA 1006 protocol for the regulatory control of the 8h-OEL.</p>
				CFC + internal capsule	IRSST 394				

Identification of the substance		CAS number	Principle of the recommended method			Implementation protocols (References)	Classification for 8h- OEL regulatory technical control	Additional information
Substance								
As, As ₂ O ₃ (in total As)	-	-	Active sampling on impregnated filters	MCE membrane + Na ₂ CO ₃ impregnated backup pad	Inhalable fraction sampler (sampler type not specified)	ISO 11041:1996	2	<p><u>Sampling:</u> In the absence of further information, the sampling device recommended in these two protocols is not classified; it is advisable to choose an inhalable fraction sampler recommended in the expert appraisal on dust without specific effects (DWSE) (ANSES, 2020b) that can be used with impregnated filters and is compatible with an air volume of 960 L (such as IOM, 7-hole, GSP 3.5 or Button).</p> <p><u>Analysis:</u> The analytical method is classified in category 1B, provided that 960 L of air is sampled.</p>
			Acid mineralisation	Na ₂ CO ₃ impregnated MCE membrane		INSHT MTA/MA-035/A96		
AsH ₃ (in total As)	-	-	Active sampling on an adsorbent tube	Active charcoal tube (+MCE filter in front if particulate As is present)	NIOSH 6001	2	<p>The method is classified in category 2 because the average recovery and desorption rates were determined by spiking for a range of concentrations above 0.1-2*OEL-8h. Sampling interferences are not provided. Storage data are documented but recovery rates after storage are not specified.</p>	
Acid mineralisation	Analysis by electrothermal / graphite furnace	atomic absorption spectrometry (ETA-AAS)						

Bold: protocols with the most complete validation data

Validation date of the summary by the Working Group: 25 January 2021.

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