



i2a 2nd Technical Workshop 21 February 2019

Antimony Workplace Exposure Monitoring

Representatives from more than 25 companies representing the majority of producers and downstream users of Sb substances, as well as EU evaluating authorities, and workplace exposure and REACH exposure assessment experts, joined iza's second technical workshop in Brussels on 21 February 2019'.

Following recent toxicological results, various scientific and regulatory authorities are requesting workplace exposure data, in order to better evaluate what the current situation is with regards to potential occupational exposures to Sb.

The workshop presented the context behind this call for workplace exposure data, and invited participants to join i2a's Workplace Exposure Monitoring Campaign starting in Q2 2019.

Acronyms

ACGIH: American Conference of Governmental Industrial Hygienists APC: Antimony pentachloride APO: Antimony pentoxide ATC: Antimony trichloride ATEG: Antimony trisethylene (glycolate) ATO: Antimony trioxide ATS: Antimony trisulfide BAuA: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin DNEL: Derived No-Effect Level eSDS: extended Safety Data Sheet (SDS + Exposure Scenarios) ES: Exposure Scenario IOM: Institute for Occupational Medicine ISO: International Organization for Standardization NTP: US National Toxicology Program OEL: Occupational Exposure Limit PHHA: Potasium hexahydroxoantimonate PSD: Particle Size Distribution REACH: EU Regulation on the Registration, Evaluation and Authorisation of CHemicals SAA: Sodium antimonate Sb: Antimony SEG: Similar Exposure Groups SHHA: Sodium hexahydroxoantimonate TLV: Threshold Limit Value

1 The first workshop took place on 6 June 2018; takeaways are available on www.antimony.com.

Main takeaways and call for action

The main takeaway message was that each Sb producer and downstream user site has its own specificities and requires a site-specific monitoring strategy.

This specific strategy can be set between each site and its occupational hygienist.

IOM offered all interested companies to share their site reality, so more specific recommendations can be provided, and practical examples added to the i2a Guidance.

The i2a Monitoring Guidance and its data collection template provide a framework (with recommended equipment, sample duration, number of samples, and analysis) within which specific strategies can be defined and deployed, to achieve a standardized approach and a robust data collection and assessment.

Comments on these documents will be collected until 15 March; after which final versions will be implemented by those companies having decided to participate in the Monitoring Campaign.

Twelve sites have already confirmed their intention to participate in the Monitoring Campaign, while **ideally three sites per type of substance and production/use are desired to participate** to maximize the representativity and aggregation/anonymization of the data. All volunteering companies will be identified by end March 2019.



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Practical steps, deliverables:

timeline for 2019

Exposure data will be collected over one or two days, somewhere between April and July 2019, in all participating sites. Results will be collected by 31 August, and then presented at the 2019 Sb Day (Antwerp, 1 October 2019).

The data reported will not only be used locally by each site to demonstrate compliance with existing and new workplace levels, but also regionally/internationally by i2a in its dialogues with the scientific and regulatory authorities investigating Sb exposures.

Comments on i2a Guidance and template + Decision to participateDefinition of monitoring planMonitoring > Nonitoring strategyMonitoring Partly completed data collection templateSubmission of templateDiscussion of results and stock-takingRepo of 20 Monitoring results and and template	February		March	April	April May		JUNE	JULY	August	Sept-Oct	Nov-Dec
update		Commer Guidance ar + Deci: partic > Final Gui tem + Signatur	nts on i2a nd template sion to cipate dance and olate re of MoU	Definiti monitori (includin; > Monitorin;	on of ng plan g SEGs) g strategy		Monitoring > Partly completed data collection template	Analysis > Complete data collection template	Submission of template to IOM > Analysis and database update	Discussion of results and stock-taking > Presentation at 2019 Sb Day	Reports of 2019 Monitoring Campaign results

Figure 1: Overview of the practical steps and deliverables foresee, in the first year of the Monitoring Campaign

Some Sb substances are classified as Carcinogen category 2 via inhalation and as Specific Target Organ Toxicity (STOT) category 2 for lung toxicity. Workplace legislation foresees that companies producing or using such substances perform regular monitoring of these in the air. In some countries, an OEL has been established to act as reference level that should not be exceeded. Existing OELs are typically of 0.5 mg inhalable Sb/m³ 8h time weighted averages (TWA). This means that workers' average exposure in any 8h work shift of a 40h work should not exceed 0.5 mg/m³ of Sb that is in the inhalable aerosol fraction (i.e. measuring 100 µm or less).

Recently, Japan (2017) and Germany (2018) have defined OELs for Sb substances. While Japan has defined an OEL of 0.1 mg inhalable Sb/m³, Germany has introduced an OEL of 0.006 mg Sb/m³ for the respirable aerosol (i.e. measuring 4 μ m or less). This is the first time an OEL for the respirable fraction is established for Sb². The finest fractions of Sb are indeed those able to reach the deep lung, and to cause the toxicities recently observed by the NTP in laboratory rodents³. It is therefore important that exposure to the respirable fraction is measured and appropriately controlled in the workplace.

Most workplaces however, do not normally monitor respirable fractions of the aerosols, as shown by EBRC, who has performed a number of exposure assessments for i2a since the 1990's. It is very possible that current OELs evolve towards 1) stricter values and, 2) a focus on respirable fractions, rather than inhalable ones.

Why monitor occupational exposure to Antimony?

For example, the ACGIH 2017 TLV proposal was 0.03 mg respirable Sb/m³, while its 2019 draft TLV proposal is of 0.02 mg inhalable Sb/m³ (draft for comment by 31 May 2019)⁴...

The EU-REACH Regulation foresees that the production and use of chemicals is subject to a risk assessment, in which hazard is compared to exposure, to determine whether or not there is a risk. The current EU-REACH risk assessments are based on relatively old data (~ 2000's), not provided for all sectors, and inhalable values. Today, the EU REACH Competent authorities evaluating Sb substances (BAuA), request recent and robust workplace exposure data which can demonstrate safe use across production and use sites based on the most recent findings. Where no data is provided for certain uses, their safety may not be demonstrated, and instead, **such uses may become unacceptable and 'advised against' under REACH**. Exposure data also enables the refinement of exposure scenarios, which are currently generic in nature, due amongst others, to the need to group uses because of a lack of specific exposure data.

Whether it is to comply with workplace legislation, existing or new OELs, or demonstrate safe use (and enable continued use) under REACH, there is a need to generate new, robust workplace exposure data for both the inhalable and respirable aerosol fractions across production and downstream user sites.

² More information in i2a's Press Release dated 14 August 2018 and its complementary Annex dated 18 October 2018.

³ In the absence of occupational exposure data, OELs are set only on the basis of the doses which caused toxicity in laboratory animals, under conditions not at all representative of actual workplaces. 4 More information in i2a's Press Release dated 7 February 2019.



How to monitor Sb on the workplace?

Some sites are already monitoring chemicals in the air while others not yet. Some are already monitoring Sb specifically while for others this has never been requested. There are a number of aspects to be considered when designing the applicable sitespecific monitoring strategy.

The generic i2a Monitoring Guidance recommendations must be tailored to the specifics of every participating site.

- Identifying and defining the ES or SEG for the site, the workers involved in the activities or tasks of each ES or SEG, and the typical working practice and dynamics for each ES or SEG
- Placing two samplers on each worker to be monitored for the applicable ES and SEGs, one to measure the Sb present in the inhalable fraction (IOM conductive plastic sampler), and another to measure the Sb present in the respirable fraction (HD Cyclone sampler)
- · Monitoring the exposure during an agreed sample

duration (depending on the filter used and workplace level of reference, and its related LoD and LoQ)

- Collecting at least six paired samples for each ES or SEG
- Having the Sb, Pb and As content in the samples analyzed according to ISO 15202-3 (2012), in a laboratory applying good laboratory practice and the relevant quality control and assurance methods
- Recording all information and analytical methods and results in the dedicated template developed by i2a

Figure 2. Specific requirements for the monitoring of Sb in the workplace aerosol

The monitoring is conducted once per year over two years (2019 and 2020), before iza will report the aggregated result to the relevant scientific and regulatory authorities, in order to identify any applicable follow-up steps (in addition to interim stock-taking presentations at iza's Sb Days). It may be that the monitoring is continued after 2020, depending on the result of the two first years.

For those sites not having a direct access to an occupational hygienist, i2a recommends to work with IOM (who have been tasked with the coordination of the Monitoring Campaign and the collection of urine samples and PSD⁵ data at selected sites). This is to increase the similarity of approaches around sites, decrease the possible subjectivity and variability across sites, and **maximize the robustness and credibility of the data collected**.

How can exposure data be used for OEL/TLV compliance and REACH?

One of the main advantages of participating in i2a's Monitoring Campaign is to document the site-specific Sb workplace exposure situations.

This serves two purposes: (1) Checking compliance status vis-àvis existing OELs or TLVs, and (2) Informing the REACH exposure assessment for specific production and use conditions.

In practice however, OEL/TLV compliance and REACH safe production/ use compliance are not fully comparable (cf. Table 1).

	OEL/TLV compliance	REACH compliance				
Type of exposure sampling ⁶	Personal	Personal				
PPE	Not considered	Considered				
Reference value	OEL or TLV (calculated from the adverse health effect most relevant for the workplaces)	DNEL (calculated from the adverse health effect caused in a laboratory animal)				
To comply, exposure must be	A number of times below the OEL/TLV over an entire working shift	Controlled as per the operational conditions and risk management measures prescribed in the eSDS for a given activity or task				

Table 1. High-level comparison between OEL/TLV and REACH compliance

Although complying with OELs and demonstrating safe use under REACH follow different approaches, **there is a way to reconcile both objectives on a site-specific basis, provided the data is collected having both aims in mind from the start**. This can be done by carefully designing the site-specific monitoring strategy (cf. step 2 in Figure 1), following consultation with the relevant occupational hygienist.

⁵ These measurements are more complex to perform and require specialized equipment and expertise on-site.

⁶ HSE (2011) highlights that static or background sampling will not reflect personal exposure. ECHA (2016) states that data collected using static samplers should only be used in the exposure estimation if there is sufficient information provided to demonstrate how they reflect personal exposures or that they provide a conservative estimate of personal exposures (i.e. that in this situation personal exposure levels would be lower than results from static samples).

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i2a Workplace Exposure Monitoring Campaign coverage so far

Talks around i2a's Workplace Exposure Monitoring program started in autumn 2017, when the Sb Day concluded that "Providing specific evidence about typical airborne exposure levels, releases from matrices, etc. related to the production and use of antimony substances, will decrease uncertainty and enable authorities to decide on more realistic risk management measures." Since these initial talks, a number of companies have come forward to confirm their intention to participate in the first campaign (Figure 3).

	Sb	ATO	ATS	ATEG	ATC	APC	APO	SAA	SHHA	PHHA
Production	1	1		0		0			1	0
Recycling	1	1							1	
Pb metal/alloy applications: general	1									
Pb metal/alloy applications: batteries, ammunitions										
Lubricants and primers for ammunition										
Catalysis applications: PET resin		1		1						
Catalysis applications: Polyester										
Catalysis applications: Tetrafluoroethylene										
Flame retardant applications: soft PVC										
Flame retardant applications: non-PVC plastics		1								
Flame retardant applications: textiles										
Flame retardant applications: in wood, rubber, sealing materials										
Lubricant applications: brake pads, etc.										
Glass applications: photovoltaic cells, solar cells, etc									1	
Glass applications: technology crystal										
Semiconductors										
Ceramic applications: glazing										
Pigments applications										
Explosives, e.g. in civil works, mining, quarries and other civil applications										1
Pyrotechnics										1
Semiconductors: Carbon products, seal and pump industry, graphite ceramics, recordable media										
				5						

 Under immediate regulatory scrutiny
 Not applicable
 1
 At least one participating company confirmed
 0
 No access to the producing company (outside EU)

 Figure 3. Sb substances and uses covered by the companies having confirmed their participation in the Monitoring Campaign 2019-2020
 Solution
 Solution

i2a's goal to have at least 10 volunteering companies has been achieved, so the Monitoring Campaign can commence. However, from a coverage point of view, additional sites (especially for the substances and uses which are still in blank in Figure 1 above) are still necessary. It is important to fill all such blanks to ensure that the exposure assessment for these uses registered under REACH can be done on the basis of actual exposure data rather than extrapolated assumptions.

In the near-term, focus will be given on obtaining participating sites for the substances and uses in green, as these are those which are currently under direct regulatory scrutiny. Participation for the other substances and uses is very beneficial as it may allow an early detection of possible concerns and remediating these before a formal scientific or regulatory evaluation process commences for these. All producers and users of the Sb substances in scope are invited to participate.

Monitoring workplace exposure brings to companies an insight on:

- Control measures in place and their performance
- What measurements were taken, and how
- How and where samples were analyzed
- Exposure limits or benchmarks, and comments on these
- Industry standards of good control practice
- Monitoring results, calculations and 8-hour time-weighted average exposures
- Exposure sources and adequacy of the control measures
- Assessment of risk
- Any matters of concern, and how to address them
- Recommendations for improvement or further surveys

Figure 4. List of main benefits brought by occupational monitoring in general

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Next steps

The next steps now are:

- By 15 March: Finalize the monitoring campaign materials with the comments received while securing additional participating companies in the monitoring campaign
- **By 30 March:** Have Memorandums of Understanding (MoUs) signed, and identify all those companies having decided to work with IOM for the monitoring
- 3 April: Have each participating company develop its site-specific monitoring strategy and planning their 2019 monitoring campaign
- By 31 Aug: Have all 2019 monitoring results sent to IOM for verification, analysis, aggregation, anonymization and reporting

5 On 1 Oct: Present available data collected in first monitoring round at 2019 Sb Day

NOTE: i2a collects all workplace exposure data collected during the production and use of Sb substances, also when collected following an approach which differs from the one described in the i2a Guidance. A specific template can be made available to collect such non-standardized data.

The mission of the International Antimony Association is to inspire product stewardship along the antimony value chain. This mission is accomplished by generating and sharing information concerning the environmental and health safety and societal benefits of antimony and antimony compounds. Through a common evidence base, i2a promotes a harmonized risk management and continued safe use of antimony and antimony substances across the value chain and geographical borders.

For further information: www.antimony.com