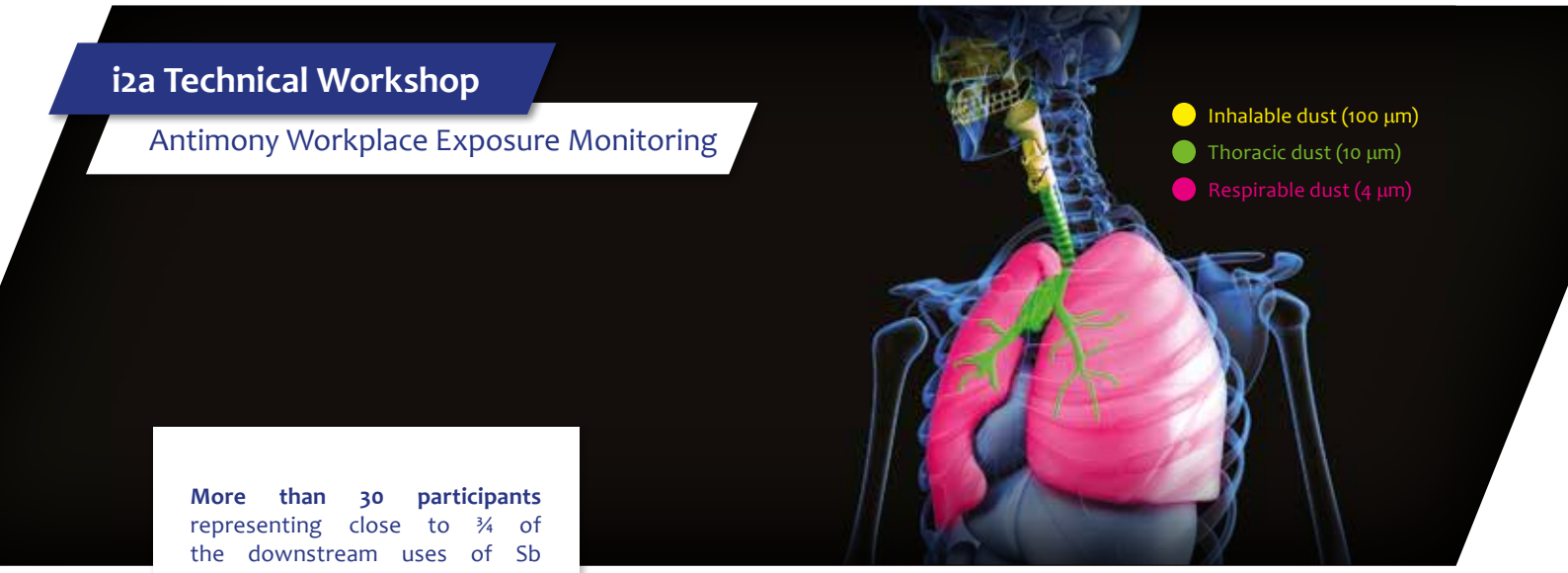
International Antimony Association

i2a Technical Workshop

Antimony Workplace Exposure Monitoring



More than 30 participants representing close to ¾ of the downstream uses of Sb substances, as well as EU evaluating authorities, joined i2a's technical workshop in Brussels on 6 June 2018. The workshop provided a forum for an open and instructive exchange about:

- concerns and knowledge gaps around possible antimony workplace exposures, and
- practical solutions to quantify the actual levels of antimony in workplace air in a meaningful manner.

The main takeaway message was the added-value of gathering as much (personal) exposure data as possible within a carefully defined contextual framework for the accurate description of job scenarios and following a harmonized reference analytical method and sampling strategy.

Only a harmonized and coordinated monitoring campaign would provide ACGIH, BAuA, and other regulatory bodies, with a comprehensive dataset that could guide definition of the need for, and implementation of, risk management measures that might be needed in the workplace.

This outcome further confirms and reinforces the main conclusion of the 2017 Antimony Day.

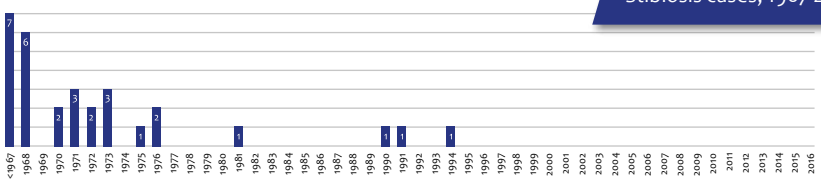
Why monitor occupational exposure to Antimony?

Antimony can be used in various chemical and physical forms. Sb substances further exist in several valence states (0, 3+ and 5+). The quantity and quality of evidence defining the toxicological properties of the diverse array of antimony compounds varies significantly. The most extensively studied compound is ATO, which has been shown to be a respiratory toxicant for the human lung in historical evaluations conducted under conditions of heavy occupational exposure.
Lung toxicity appears to be mediated by a MoA in which very small «respirable» particles deposit in the deep alveolar regions of the lung and accumulate over time to yield high lung burdens.

Due to a lack of data on the other Sb substances (generally used in much smaller volumes than ATO), it is unknown whether the potential lung toxicity associated with ATO exposures should also be expected when exposure occurs to other Sb substances. This is why existing TLVs or OELs develop to protect against the toxic effects of ATO will typically be applied to Sb and other Sb compounds.
Current limits are typically 0.5 mg Sb/m³ for the inhalable fraction (< 100 µm) of occupational aerosols.

Available exposure monitoring data demonstrates general compliance with this limit within the industry, and a decrease in human lung toxicity since the exposure limits have been implemented, although this is sometimes achieved by the use respiratory protective equipment:

Stibiosis cases, 1967-2016



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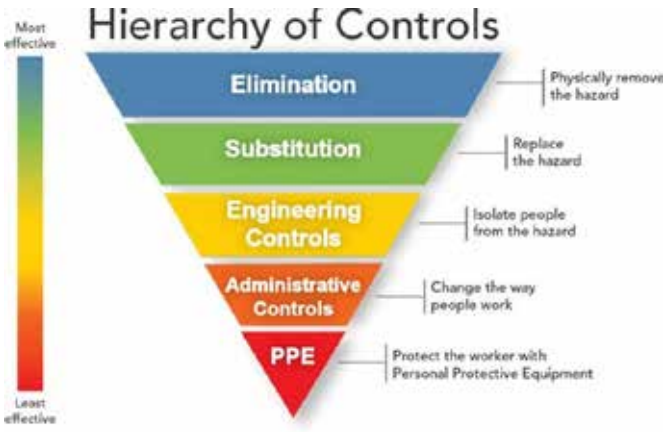
Why monitor occupational exposure to Antimony?

Despite the observed decrease and disapearance of lung toxicity in Antimony workplaces, animal toxicity studies released in 2017 have raised questions as to whether current exposure limits are adequately health protective and whether other measures should be put in place to safeguard the health of workers handling Sb substances. i2a has evaluated the recent toxicological evidence and calculated new long-term inhalation DNELs for each Sb substance. When meeting these new DNELs, safe use of antimony compounds can be achieved. Producers and users of Sb substances should comply with the measures recommended in the Exposure Scenario attached to the eSDS.

The new animal study evidence is also being used by authorities to review existing TLVs and OELs; on-going assessments suggest that these will be revised downwards, and that they will moreover be calculated to focus upon respirable particles (< 4 µm) in workplace aerosols as opposed to the inhalable particle size (< 100 µm) fraction that has been traditionally measured in the workplace. In light of this development, it is expected that current exposure controls will need to be improved following the applicable «hierarchy of controls», and that most existing exposure data defining inhalable exposure levels will not be sufficient to address questions expected to arise regarding levels of exposure to smaller respirable particles.

Representative exposure data will need to be generated for the inhalable and respirable fractions of occupational aerosols, for several workplaces and operational conditions, and each specific use of Sb substances. **The data will only be of value to regulatory agencies if a sufficient number of data points is collected (to reach the required statistical robustness), and each data point is collected with complete contextual information** that defines the work conditions, job activities and sampling time during personal monitoring.



Acronyms

ACGIH: American Conference of Governmental Industrial Hygienists
ATO: Diantimony trioxide
BAuA: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
DNEL: Derived No-Effect Level
EN: European Standard
eSDS: extended Safety Data Sheet
ISO: International Organization for Standardization
LoD: Limit of Detection
LoQ: Limit of Quantification
MoA : Mode of Action
OEL: Occupational Exposure Limit
OSH: Occupational Safety and Health
PET: Polyethylene terephthalate
R&D: Research & Development
REACH: Registration, Evaluation and Authorisation of CHemicals
Sb: Antimony
SEG: Similar Exposure Groups
TLV: Threshold Limit Value

Workplace Exposure Monitoring in practice

Two participating companies shared their specific experience with air exposure monitoring, and what it entailed in practice.

Key success factors for an efficient and effective workplace air monitoring are:

- *Involve corporate management in developing workplace safety goals and means to achieve them*
- *Appoint and assign dedicated champions to coordinate and manage the exposure monitoring program*
- *Monitor exposure for purposes beyond TLV and OEL compliance; establish internal exposure level targets to stimulate continuous improvement and a smooth preparation for more severe regulations*
- *Monitor all workers: white and blue collar, direct and indirect, maintenance, administration, R&D, quality, engineering, logistics, etc.*
- *Use both area and personal sampling, as area sampling alone can be largely indicative of engineering control efficacy, but not sufficiently specific to the exposure of workers*
- *Perform several monitoring campaigns throughout the year, and collect too much rather than too few data points*
- *Share the exposure trends and the added-value of exposure data with the monitored workers to stimulate their personal involvement and commitment; involve Unions in communicating a common vision and plan*
- *Regard workplace monitoring as a long-term investment rather than as an ad hoc punctual exercise*

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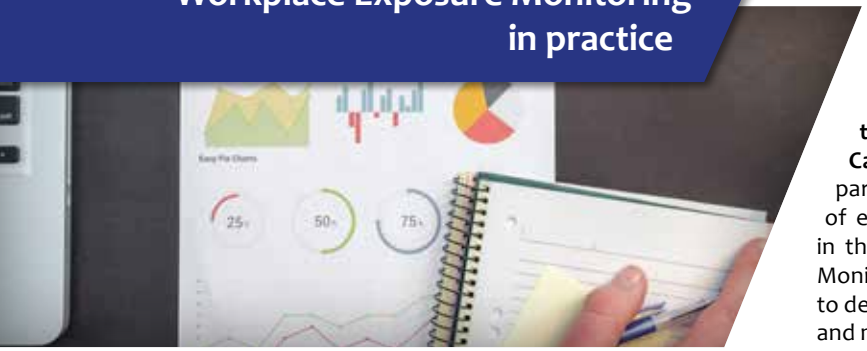
Workplace Exposure Monitoring in practice



On a sector scale, the success will furthermore depend on the structure and coordination of the data generation and collection exercise. **i2a is therefore developing a Monitoring Strategy and Practical Guide and preparing to launch a dedicated Workplace Exposure Monitoring Campaign across the Sb value chain.** This will allow interested parties to clearly understand and implement the requirements of effective exposure monitoring, and effectively participate in the Campaign. It is advised to centralize each step of the Monitoring Strategy across participating workplaces, in order to decrease the likelihood or severity of artifacts and variability, and maximize the robustness of the collected dataset.

The data collected with i2a's Monitoring Campaign will inform ACGIH, BAuA, and other regulatory bodies about current exposure levels during the handling of Sb in the workplace. In addition, these data will enable producers and users of Sb to locally demonstrate compliance with the decreasing occupational limits. The i2a sampling and analytical methods in the Strategy adhere to the applicable ISO and EN standards, follow both OSH and REACH requirements, and will be validated specifically for Sb.

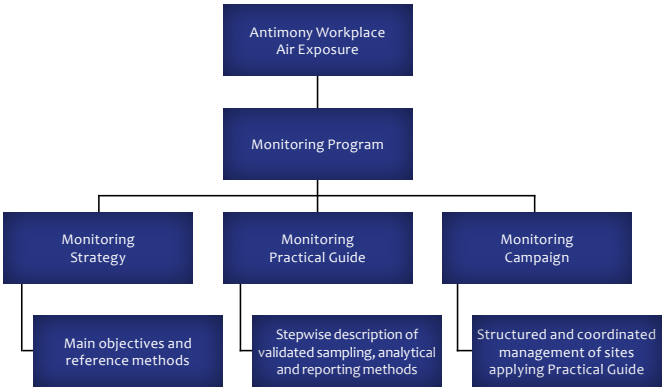
The Practical Guide prepared by i2a with the input of interested experts will clarify the type of monitoring, the duration, the equipment and recording requirements. Separate samplers are to be used simultaneously, capturing the inhalable and respirable fraction. The sample preparation and analytical methods will strive for the applicable LoD and LoQ required to meet the decreased exposure limits. The company-specific Monitoring approach will be defined with each participating company, based on a site-visit and the identification of SEG and possible co-exposures and existing monitoring practice specific to each workplace.

The Monitoring Program will in particular address the shortcomings identified in previous exposure assessments performed for risk assessment purposes (before and since REACH regulation), for example: the workplaces and uses where high variability was observed within the associated exposure data set. A dedicated Monitoring Task Force will be set-up under the umbrella of i2a to stimulate value chain participation in all steps of the Program.

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.

i2a Workplace Monitoring Program



The PET sector expressed a strong interest in the Campaign, in order to improve their existing exposure dataset. Indeed, although reported levels are already very low, the available data is relatively old, and specific to ATO (which is not the only Sb substance that can be used in the sector) and reflective of the inhalable fraction. The PET sector seized the value of fulfilling the exposure data requirements triggered by the more recent scientific and regulatory considerations. **This is a great example of product stewardship, that i2a hopes will inspire many more actors of the Sb value chain.**

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