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#### ore than 80 participants from EU, US, Middle-East and Asia participated in the third edition of the i2a's Sb Day in Antwerp.

Participantswere updated on regulatory developments affecting Sb substances directly, such as the ongoing US NTP RoC, EU-REACH and EU-RoHS processes; as well as on policy trends affecting products in which Sb substances are used, such as the EU Plastics Strategy and the on-going pressure on the Pb sector, while Pb batteries are increasingly recognized as essential to meet tomorrow's energy storage and electromobility needs.

The key conclusion of the third edition of the Sb Day is that, for Sb and its compounds to survive all direct and indirect regulatory developments, there are three crucial actions to be undertaken:

- 1) value chain engagement and support towards i2a,
- 2) bolder/prouder communication on the societal value and importance of Sb and the products it is used in, and
- 3) a more holistic and coherent integration of environmental policy goals both at EU and international levels.



# Scientific assessment of Sb substances

Since the US NTP Carcinogenicity studies on Sb trioxide have been released in 2017, classification and workplace limit related discussions have been (re-)opened across various jurisdictions. These scientific and regulatory discussions are sometimes limited to

Sb trioxide, and in other cases they address Sb metal and the other Sb compounds as well. It is no secret that regulatory efficiency is expected to increase by assessing substances in groups rather than in isolation.



Classification and listings of Sb in the US: What's there and what's coming?

On the basis of its Carcinogenicity studies, the US NTP has recommended that Sb trioxide is added to the Report on Carcinogens (RoC). This would by default stigmatize the substance, which is critical to the US society and can be used safely when avoiding exposure to fine powder forms.

i2a will submit to the US NTP a **Request for Correction** (RfC) under the Information Quality Act, so as to stress the importance of working with other international authorities, of awaiting the additional evidence that may result from the REACH Evaluation process. The RfC will also call for a tailoring the RoC conclusion to the most up to date, complete, relevant and reliable evidence.

A similar note will be shared with US States who have historically included Sb compounds on a number of chemical lists, based on assumed concerns, and never on the basis of in-depth and robust assessments.

i2a seeks to obtain support from US-based companies to accomplish this challenging task, starting with the State of Washington. This State will typically set a precedent and any Washington State list will likely be copy-pasted by other States in the US. If a **de-listing** works in Washington, it may more easily be considered in other States too.

#### EU-REACH evaluation: Update from the evaluating Competent Authorities

The REACH Evaluation is aimed to **improve the quality** of the information and justifications submitted by Industry in its various REACH Registration Dossiers, while at the same time **clarifying any possible concerns** and risks

associated to the production or use of the evaluated Sb substances, and identifying risk management measures to enable their continued safe use. Such risk management measures could be a revision of the



existing classification, or of the workplace limits in place. ECHA and the German REACH Competent authorities (BAuA) are running a group REACH Evaluation encompassing Sb metal and four trivalent Sb compounds, including Sb trioxide. The Evaluation of these first five Sb substances, will inform on whether the remaining five pentavalent Sb compounds should be evaluated too. The updated decisions on the first five Sb substances are expected to be sent to Member States by end October 2019. Member States can then propose amendments (PfA) which i2a will have the opportunity to comment. The PfAs should become available by end 2019. **Final Decisions** will likely be issued around mid-2020 and include a request for additional toxicology studies to be conducted. Only after the results of these studies are submitted in REACH Dossier updates, will the authorities explore the applicable risk management measures.

#### Industry's work: Collective work conducted under i2a

Ever since its first Sb Day, i2a recognized the immense value of hard data, hard evidence. Following the scientific and regulatory developments in the US, EU and Japan, among others, i2a has designed a **research program** tailored to address the knowledge gaps regarding the adverse health effects that may be caused by excessive exposure to Sb substances. A tiered program is foreseen to minimize unnecessary animal testing, although some animal studies will be necessary to meet the regulatory requirements.

In parallel, i2a is also coordinating a **workplace exposure monitoring campaign** to take stock of the most recent workplace practice among producers and users of Sb substances worldwide. With a robust hazard and exposure dataset, the likelihood of over-conservative worst-case assumptions and decisions decreases.



Finally, i2a is also working at collecting quantitative data on the **socio-economic value** of Sb for modern societies. Contributions to employment, R&D and products needs to be considered in regulatory decision-making.

Industry's work: Example of companies' proactive work

In addition to the collective work performed by i2a, individual Members of i2a (e.g. Campine and ICL) are also working to demonstrate the safety of some of their Sb-based products, e.g. Br-Sb flame retardant polymers. A combined approach of SAFR® and measured blooming of Br and Sb under a number of ageing conditions, demonstrates that the release of Sb or Br from matrices used in electric and electronic

equipment (EEE), for example, is minimum/far below any concerning hazard level. This exercise is performed for specific products which are representative of other products found on the market, and can be completed to cover the most relevant variations of such products. Such consumer product information is essential to demonstrate the safety of Sb substances used in consumer products, i.e. beyond the workplace.

## International Antimony Association IT'S A RESTRICTION IT'S NOT A LIST ... EATH ENTENCE International Antimony Association

### **Product restrictions** related to Sb substances

b substances are not the first chemicals undergoing toxicological tests and risk assessments. It is important to anticipate the impacts of the results of these exercises on the continued use of Sb metal and its compounds. There are many precedents showing that regulatory assessments and decisions do not trigger death sentences, but rather a revised approach to using the chemical safely in the products where it delivers irreplaceable functions and value.

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EU RoHS: Update from the EU Commission & Exchange with Industry

Sb trioxide is currently under assessment for possible restriction under RoHS, and the consultants' conclusion as to whether it should be restricted or not, is expected by end October 2019. This consultation takes place in parallel with two other consultations: one on the RoHS Substance Inventory, and one on the RoHS 2021 Review. i2a is actively contributing to all such consultations, together with the most involved downstream users, and other commodities affected by RoHS restrictions. The EU-RoHS is actually copied across many more jurisdictions outside the EU, and makes it a legislation with international relevance and impact.

The Panel agreed that it would be extremely useful to share the results of the blooming research with the EU-RoHS authorities, who are concerned about possible exposures of consumers to hazardous chemicals used

in high-performance components in EEE. The recycling industry insisted on the importance of retaining some coherence between the chemicals policy objectives and the waste/circularity ones, and to avoid regrettable substitution scenarios that would limit the technical feasibility of any recycling. All Industry experts on the Panel further insisted on the fact that there are no 'ready-to-use -drop-in' alternatives to Sb trioxide, and that in order for EEE to retain its technical and economic performance without Sb trioxide, it would require 10-15 years of research and development and market validation. Recyclers further pointed at that any additional restriction under RoHS, has high impacts on how the sorting, screening, pre-processing and processing is organized at a recycler's site; adapting all these steps would also take years and likely prohibitive investments.

Sb in textiles: Complying with evolving requirements

Substitution has also been investigated in the textile sector, where Sb compounds are also used in flame retardant applications for upholstered furniture, back-coating of carpets or other textiles, among others.

There again, companies' experience shows that the development of alternatives is neither simple, quick or cheap. And even where solutions can be envisaged, they would never equal the technical performance



of the Sb/halogen combination. Whether required by regulators or by customers (e.g. Oeko-tex), flameretardant textile producers are used to comply with evolving specifications. Despite the hazard profile of the chemicals they have to use, their use is demonstrated to be safe, as a risk can only occur in the event users and consumers are exposed to very high amounts of these substances, which are not released from the textile.



Green policy trends related to Sb-containing products

n addition to the direct regulatory processes affecting Sb substances, a number of downstream user sectors of Sb substances are also undergoing regulatory pressure. These include: i) **PET plastic**, which is targeted by the Single-Use Plastics Directive, ii) **masterbatches**, which are unintentionally covered by the proposed restriction of microplastics, and iii) **Pb compounds used in batteries**, which seem to be undergoing significant regulatory pressure, and be forgotten and replaced by supposedly more innovative battery technologies in EU initiatives.

Sb in P.E.T. and masterbatches: How to ensure their continued use meets the aspiration of "zero-pollution"?

Sb trioxide and Sb glycolate are used as polycondensation catalysts in the production of PET. PET is one of the best recycled single-use plastics, but where improvements in terms of collection and sorting should be considered. The discussion concluded that there is a need to communicate more broadly about the proper attitude towards using and disposing of single-use plastics, so as to improve the quality and quantity of recycling outputs. Also, while the EU Plastics Strategy recognizes the added-value of some single-use packaging, this is buried under a very strong public perception that all plastics are bad and should be banned. **Positive communication about plastics** is also necessary, both at authority and industry levels.

Masterbatches are polymer-based 'pellets' containing a set of plastic additives, that facilitate safe use of additive

chemicals in the production of technical polymers. Masterbatches replace/avoid the supply of powdered chemicals which could lead to undesired exposures. Unfortunately, masterbatches fall under the definition of microplastics that are used in a way which yields environmental releases to and accumulation of plastics in the environment, and which are for that reason, subject to a restriction proposal. Authorities should ensure that their restriction proposal does not result in an **unintended restriction of masterbatches**, which actually are designed to avoid exposures and releases.

The continued use of PET and masterbatches is not incompatible with EU's aspiration of "zero-pollution", provided that the advantages of their use is preserved and communicated, and their proper use, disposal and recycling is promoted.



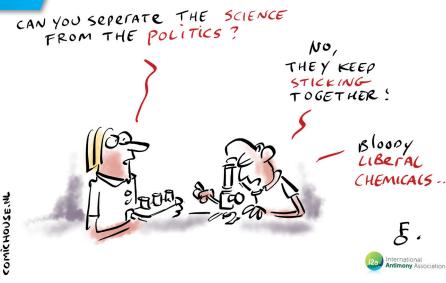
Sb in Pb and Pb batteries: Is there room for the most cost-efficient battery technology in the various EU policy objectives?

In addition to its geological affinity, Sb is highly efficient to harden Pb, and **enable a more sustainable use of this very cost-efficient metal** and its related technologies.

Pb is the perfect example of a chemical with known intrinsic hazardous properties, but which may, when used safely, actually deliver high value to society in terms of energy efficiency, for example.

The Pb Industry has realized the importance of improving the positive communication about Pb and Pb compounds only recently, and is actioning a number of very responsible initiatives to ensure that authorities adopt more integrated and coherent objectives across their various policy agendas, from chemicals management to circularity to energy and climate change.

The Horizon 2030 and the new EU Commission in place provides the ideal momentum to raise this need for integration once more.



There will be room for the continued use of Sb and Pbbased battery technologies provided that authorities better integrate their various policy objectives into a **coherent set of priorities and measures**.

Many thanks to our sponsors and all the participants for your energy and interest. See you in future events!

