General Assembly meeting
30 September 2019; 14:00 – 17:00 pm
Lindner WTC Hotel & City Lounge Hotel
Lange Kievitstraat 125, 2018 Antwerp, Belgium

Chairperson: *Raymond Devaux (AMG Antimony)*

Draft Annotated Agenda
Conclusions added in blue
Agreed actions marked with a →

1.	**Welcome and introduction** *(R. Devaux)*	
1.1.	**Tour de table** *(All)*	The list of participants is attached as Annex 3.
1.2.	**Approval of the Agenda** *(All)*	**FOR DECISION** – Members will be invited to approve the proposed Agenda for the meeting. The Agenda was approved.
1.3.	**Anti-trust reminder** *(C. Braibant)*	Members will be reminded on their obligation to abide by Competition Law, as per i2a meeting rules (Annex 1). Members were reminded about the meeting rules.
1.4.	**Actions agreed at the previous meeting** *(C. Braibant)*	Members will be updated on the status of the actions agreed at the last meeting (16 May 2019) (cf. Annex 2 - Action table). Members were invited to look at the table of actions and revert with any specific questions they may have on any of them. The only action on which reactions were collected is the current lack of / insufficient sharing of i2a's LinkedIn and Twitter posts.
1.5.	**Approval of the conclusions of the previous meeting** *(All)*	**FOR DECISION** – Members will be invited to approve the conclusions of the last meeting (16 May 2019). The conclusions were approved.
2.	**Regulatory challenges** *(C. Braibant)*	i2a Members will be given a brief update of all regulatory challenges affecting Sb substances. Compared to the May 2019 situations, the following changes have been made to the overview of regulatory processes overseen by i2a:

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium//Phone : +32 (0) 32 2 762 30 93 / Fax : +32 (2) 762 82 29
www.antimony.com

- IARC, US ATSDR, ACGIH and Oeko-tex do not require any further action except monitoring
- US NTP RoC, EU-REACH and EU-RoHS remain high on i2a's agenda
- The Washington CHCC de-listing activities and the OEL reviews in Australia have been added to the regulatory overview

The latest updates on every regulatory challenge are:

Classifications items:

- **IARC** has confirmed that the review of the classification of Sb trioxide is of medium priority and that no work is anticipated on Sb trioxide until end of the 2020-2024 work program period
- **US NTP** has not responded favorably to any of the requests to limit the scope of the listing of ATO on the RoC, submitted by mail and formal legal letter. Bergeson & Campbell are now producing an Information Quality Act Petition (IQA Petition) which will force US NTP to review the evidence on the basis of which they are recommending the addition of all forms of ATO on the RoC. This should 1) delay the addition of ATO onto the RoC, and 2) ensure that only powder forms of ATO < 4 µm are ultimately added to the RoC. → The petition will be submitted in early October, following approval of the Board. Expenses related to this process were not budgeted and are currently taken from the i2a reserves (~ 40,000 € excluding the petition finalization and submission). → In parallel to submitting the petition, i2a is seeking support from US-based companies to sponsor the US-relevant work.
- Beveridge & Diamond have met with the Washington State Department of Ecology in early Sep in order to find out about the feasibility of a de-listing of Sb & Sb compounds from the **Washington Chemicals of High Concern for Children (CHCC) list**. Precedents exist for the de-listing of chemicals from that list, if the science can demonstrate that there is no need for the listing. B&D and Intertox are now preparing, with the support of KANEKA (financial) and i2a (technical), a → de-listing petition that should be available around mid-November 2019. All expenses of this process are covered by KANEKA.
- **US ATSDR** has not responded to i2a's submission dated 20 May 2019. i2a will continue monitoring ATSDR's work.

Risk assessment items:

- i2a has remained in contact with BAuA since the submission of the responses to the draft **Evaluation** decisions in May 2019, and the submission of updated dossiers in June 2019. Testing has continued as per the research program submitted as an Annex to the responses. BAuA is consulted on every draft protocol or proposal even if for now, the tests planned are not those requested in the Substance Evaluation draft decisions. BAuA will participate in the Sb Day and should update participants on latest developments around the process. → Without further notice from BAuA, the final Evaluation decisions are expected between Autumn 2020 and Spring 2021.
- **Health Canada** has confirmed that despite the recent decision that a number of Sb compounds pose no concern, they will continue monitoring international developments relevant for Sb substances, to eventually update their conclusion.

Workplace restriction items:

- **ACGIH** has not responded to i2a's comment dated 31 March 2019 regarding their most recent TLV proposal of 0.02 mg/m³ inhalable Sb. i2a will continue monitoring ACGIH's work.

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium//Phone : +32 (0) 32 2 762 30 93 / Fax : +32 (2) 762 82 29
www.antimony.com

- **Australia** has recently opened a consultation on changes to the TLVs of all their chemicals, working in alphabetical order. For ATO and Sb compounds, Australia is proposing to merge them into one single category, applying the TLV for ATO to all Sb compounds. i2a has sent them an e-mail informing about the on-going processes, the difference there is between the toxicity of trivalent and pentavalent species, and requesting clarity on the scientific background justifying a general TLV for all Sb compounds.

Product restriction items:

- The final **EU-RoHS** consultation on the restriction assessment of Sb trioxide has faced considerable delay, and should become available towards the end of Oct 2019. Restriction reports for four of the seven shortlisted substances have been published and conclude that no restriction is necessary for these. The remaining three restriction reports are for Sb trioxide, TBBPA and MCCP. Sb trioxide and TBBPA are undergoing REACH Substance Evaluation with Germany and Denmark, respectively, and MCCP is actually being pushed for restriction by Sweden. The involvement of the various Member States may be influencing the finalization of the report. DG Environment will participate in the Sb Day and update participants on the latest status. → i2a also aims to participate in two additional consultations, with the support of Eurometaux and Cefic: consultation on a RoHS Substance Inventory, and consultation on the RoHS Review.
- The **Oeko-tex** website has been updated and the negative sentence regarding the use of Sb trioxide and Sb pentoxide as flame retardants has been removed. Oeko-tex were invited to justify the original sentence and indicated that they need to consider all stakeholders calls, including those of NGOs. They did not specify who has expressed concerns about Sb trioxide and Sb pentoxide. They were invited to participate in the 2019 Sb Day but declined the invitation.

3. i2a Research strategy *(M. Huppert)*

i2a Members will be given a brief update of the research strategy aimed to address the most immediate regulatory questions and concerns.

There are two axes of research under i2a's umbrella:

i. Lung toxicity and carcinogenicity/genotoxicity (inhalation toxicity)
ii. Systemic and reproductive toxicity (oral toxicity)

Both axes are developed on the basis of available data, data gaps, and assumptions or hypothesis. They both work in tiers, and aim to: i) produce comparable data for all 10 Sb substances registered under REACH, ii) clarify the nature and mode of action (MoA) behind the adverse effects published in literature, and iii) determine the applicable classification and threshold for each Sb substance.

The tiers of first axis include:

1. **ToxTracker** at Toxys in NL: Comparing and refining the MoA hypothesis behind the reported genotoxicity of the 10 Sb substances. This tier is finalized and a publication is on its way.
2. This tier includes two parallel tracks (starting in Q4 2019):
    a. **In vitro lung research** at IOM in UK: Comparing and refining the genotoxicity MoA and dose-response curve of the 10 Sb substances in lung cells of humans, rats and mice, due to deliver around mid-2020.

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium//Phone : +32 (0) 32 2 762 30 93 / Fax : +32 (2) 762 82 29
www.antimony.com

   b. **In vitro micronucleus assay** at ILS in US: (In)Validating the existing micronucleus assay results which (may) have been conducted with (in)correct staining agents, due to deliver around end Q4 2019.
3. **In vivo genotoxicity and (sub-)chronic inhalation toxicity research** (laboratory tbc, maybe Covance in UK): Tier 2 will inform on the optimum test item and test methods for further testing in vivo. The in vivo studies to be performed will also be influenced by the content of the Final Substance Evaluation decisions.

The tiers of the second axis include:

1. **Bioelution in artificial gastric media** at ECTX in Belgium: Predicting and comparing relative systemic absorption/availability potential of the 10 Sb substances. This tier is finalized and data is being used to inform next steps + to support Eurometaux with the validation of the bioelution gastric approach at EU level.
2. **Dose Range Finding Studies** at Covance in UK (starting Q1 2020 with set-up launched in Q4 2019): Determining ideal administration route (diet or gavage), vehicle, and dose, as well as comparing gastric tolerance and actual systemic absorption/availability potential of the 10 Sb substances. This information will allow to corroborate the predictions made on the basis of the bioelution results and reinforce the read-across. If the read-across is validated, it will reduce the number of higher tier in vivo systemic/reproductive toxicity tests necessary to address all REACH requirements.
3. **Screening Reproductive Toxicity study(ies) and/or Pre-Natal Developmental Toxicity (PNDT) study(ies)?** at Covance in UK: Tier 2 will inform on the optimum test item and administration route/vehicle for further testing in vivo. The in vivo studies to be performed will also be influenced by the content of the Final Dossier and Substance Evaluation decisions. (Sub-)Chronic in vivo studies via the oral route will be designed in such a way that questions on the maternal toxicity, influence on the Ca metabolism, cardiotoxicity and carcinogenicity via other routes than inhalation are investigated. If after the basic in vivo studies no Reproductive toxicity classification applies to Sb substances, an Extended One Generation Reproductive Toxicity Study (EOGRTS) will need to be conducted. Tier 3 in vivo studies should help to limit the scope and cost of the EOGRTS.

4. Workplace exposure monitoring
(S. Verpaele)

Steven Verpaele, from the Nickel Institute, will be giving a presentation about a project which is aimed to study the variations there are between exposure datasets collected on various sites with different samplers, and how this 'fragilizes' the scientific robustness of exposure data used in regulatory frameworks.

More information can be found in the slides.

Members showed genuine interest in the project and its aims, which is directly relevant for i2a's monitoring campaign and recent/anticipated TLV/OEL reviews. Members were also surprised to learn that the issue had never been raised by anyone in Industry or standard agencies or countries so far.

→ Regarding i2a's contribution to the project, it will be facilitated via:

- Direct participation in the Eurometaux Human Health Task Force, who will be discussing this project;
- Indirect participation via IOM, who will participate in the project and use the Sb experience when and as appropriate and relevant;

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium//Phone : +32 (0) 32 2 762 30 93 / Fax : +32 (2) 762 82 29
www.antimony.com

- Possible participation of i2a Members to field work foreseen in the project.

5. i2a Membership matters

5.1. Status of i2a 2019 Accounts *(N. Francis)*

i2a Members will be informed about the status of incomes and expenses for 2019 and the predicted expenses by year-end (and the resulting reserve, if any).

All expenses are within budget.

It is expected that, as regards the study costs, around 100,000 € will remain unspent by end 2019. This is due to the fact that the REACH Evaluation decision process in Apr-May 2019 caused both a pause and re-orientation of some the originally anticipated research.

As regards the anticipated incomes, it is expected that around 90,000 € of unbudgeted LoA incomes will be received in 2019 too.

The estimated reserve at the end of 2019, and excluding the liquidation reserve of 150,000 €, should be of around 740,000 €.

5.2. i2a 2020 Budget proposal *(C. Braibant)*

FOR DECISION – i2a Members will be requested to discuss and approve the 2020 budget proposal, including a number of incomes options that must be considered to ensure the sustainable continuation of i2a's work for REACH and other legislative developments affecting Sb substances worldwide.

The budgeted expenses for 2020 is based on the administrative expenses of 2019, and the research strategy that was attached to the responses to the Evaluation decisions in May 2019, also summarized in Agenda item 4. above. In addition, it includes around 30,000 € to start three consumer exposure projects, aimed to review and publish the safe use of Sb in PET (to counter REACH authorities' request for testing on ATEG), in ammunitions (to address REACH authorities' request for monitoring of Sb in indoor shooting ranges), and in flame retardant polymers (very RoHS relevant). These three projects are to be shared with CPME/PETCore, AFEMS and BSEF, respectively. → It is expected that these DU associations would sponsor 50% of these projects which would run over two years.

As regards the budgeted incomes for 2020 are assuming that the 2020 membership invoices will not exceed those of 2019, and that in addition, the following incomes will be obtained: 25% of the corrective invoices to be sent to the LoA purchasers for the 2006-2018 itemization exercise, and 50,000 € from ad hoc support for e.g. US NTP RoC or Washington de-listing initiatives.

The itemization exercise for 2006-2018 shows that around 1,332,257 € can be invoiced to 46 non-Members of i2a. According to other associations/consortia, it is unlikely that the full amount will be recovered. i2a estimates that minimum 25% of the amount can be retrieved in 2020, and ideally as much as 50%. Depending on the success of the re-invoicing exercise, additional incomes could be expected for this past period of dossier updates.

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium//Phone : +32 (0) 32 2 762 30 93 / Fax : +32 (2) 762 82 29
www.antimony.com

The itemization exercise for 2019-2025 shows that around 6,230,919 should be invoiced to non-Members of i2a. This number is currently very speculative in that it is based on i2a's response to the draft Evaluation decisions (Final version will mandate ultimate research and update costs), and assuming that all registrants will remain in the same tonnage band and/or on the Sb market.

→ For this reason, i2a will start re-invoicing the due 2006-2018 amounts before refining and issuing any invoice for 2019-2025 work to non-Members.

Members approved the proposed 2020 budget.

6. AOB, next meetings and closing remarks

5.1 AOB *(All)*

i2a Members will be invited to share their views and experience with i2a's new website and social media visibility.

→ Due to time constraints, this could not be done during the meeting, and will be picked up at the next opportunity.

→ **Newsletter:** will be circulated later than usual, combined with the Takeaways of the Sb Day

5.2 Next meetings / calls *(N. Francis)*

- Antwerp, 1 October 2019 – 2019 Sb Day
- A number of dates will be proposed for 2020

Members were informed that there would be no Sb Day in 2020, to enable the i2a Secretariat to focus its limited resources on the Evaluation and other regulatory challenges announced for 2020. The next Sb Day will likely be organized in Q1 2021, before travel restrictions and busy agendas prevent proper participation in the event, and after the final Evaluation decisions have been received and discussed.

5.3 Closing remarks *(R. Devaux)*

Annexes:

1. i2a Meeting rules
2. i2a GA Action table (updated with actions agreed at the meeting)
3. Participants in the i2a GA meeting
4. Slides presented at the i2a GA meeting

International Antimony Association (VZW)
Avenue de Broqueville 12, 1150 Brussels, Belgium//Phone : +32 (0) 32 2 762 30 93 / Fax : +32 (2) 762 82 29
www.antimony.com