15 Avril 2019

EHS topics update
(to be read in conjunction with tracking sheet (Annex 2))

1	**REACH**	
	Substance Evaluation	**For information** - **As expected, Draft REACH Substance Evaluation Decisions (DD) have been received by registrants of Sb metal, Diantimony trioxide, Antimony tris(ethylene glycolate), and Diantimony trisulfide on 18 April**. All DD were made available to the i2a Secretariat by 24 April, and have been immediately shared with the relevant scientific and legal experts. Separately, BAuA has informed i2a that antimony trichloride will not be part of the Substance Evaluation. The official responses to each DD will be prepared as follows, by 28 May: 1) Week 1, to 25 April: Draft response to be prepared with Lindsay Aveyard (reprotox points), Craig Boreiko and Matthew Boyles (lung toxicity points), and Karen Galea and Daniel Vetter (workplace exposure) + Legal review/advice by Mayer Brown 2) Week 2, to 3 May: Draft response to be checked/commented by Tox TF and EHS Group 3) Week 3, to 10 May: Update of response and circulation to Board for approval 4) Week 4, to 17 May: Finalization of response, legal review by Mayer Brown, and submission to ECHA by each LR The DD received include requests for: • Annex VII and VIII genotoxicity and reproductive toxicity studies on the individual Sb substances (vs the proposed read-across and weight of evidence followed so far); and • in vivo inhalation and oral subchronic studies to clarify the lung toxicity and carcinogenicity, genotoxicity, and cardiotoxicity effects, as well as to understand the systemic availability aspects; all of which is aimed to inform the (dis)similarity between Sb substances and the related read-across/grouping approach • No reference to any (re-)classification proposal for any of the Sb substances • No reference to or request for the workplace exposure data needed to perform a risk assessment EHS Group conference calls invitations have been sent to discuss, comment and finalize the responses that the registrants will need to address via the LR to ECHA by 28 May, latest.
2	**EHS strategy**	
	1. Scientific publications	**For information** - The **"Genotoxic properties assessed by ToxTracker"** were supposed to be reported by Rita Cortvrindt (GermFact) in a scientific publication. Unfortunately, following the release of the first draft of the publication and the review by i2a and Craig in

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		February, we have decided to interrupt and end the contract between i2a and GermFact. Indeed, the amount of comments was abnormally important, requesting unexpected time to review (statements not supported by evidence, lack of figures and graphs, level of English not at the scientific international level). We have concluded that the draft did not meet the quality criteria of i2a. In order to not stop this project, which is part of the EHS strategy, Craig has accepted to take the lead and to be the main author of this publication, assisted by Dr Toby Rossman (expert in genotoxicology), and Giel Hendriks, the author of the Tox Trackers results. This change of situation will not impact the original budget allocated for this task. i2a is currently identifying the date of delivery of the "new" first draft, ideally in June. The aim remains to have a final publication for submission to selected journals by the end of 2019. - The draft publication **"Analysis and synthesis of genotoxicity data on antimony substances"** was prepared by Craig Boreiko and Toby Rossman. Some ToxTracker data was incorporated to reinforce the reactive oxygen species (ROS) argument and the non-direct genotoxicity. The draft will be shared with the Toxicologist TF for comment by mid of May.
	2. In vitro Inhalation Study	**For Information/Preparation** The in vitro inhalation study proposal from IOM has been finalized (Annex 1). All comments and questions from i2a toxicologist TF were addressed by IOM. Following calls and new updates, the final proposal has been released and accepted. The study plan will be circulated to the EHS group, before it is submitted to the Board for approval. This study is not included in the SEv or CCH Draft Decisions received from ECHA on 18 April. However, it is aimed to reinforce the read-across and grouping justification, which has been challenged in the CCH Decisions. The proposal has thus been shared with BAuA, following the usual communication line in place since COLLA, to collect their scientific opinion on the proposed approach. As all antimony substances will be tested, LRs will receive an email request to send samples to IOM in May or June, after BAuA has shared its views on the proposed study.
	3. Reprotoxicity study	**For information** As communicated at the last call, the reprotox study was on pause until the release of the SEv DD in order to check that it will address all concerns from authorities around reprotoxicity. Based on the DD received, there are several reproductive toxicity tests requested, so there is a need to re-design the reproductive toxicity study to ideally combined ECHA requested studies with the study planned to clarify the maternal toxicity and delayed ossification questions.

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	4.Bioelution test	**For information** VITO has finalized the analysis of all bioelution samples prepared by ECTX. (10 compounds, 2 loadings, 2 gastric media, i.e. around 40 samples and their replicates) Preliminary results of analysis have been released and reveal that the presence of proteins does not cause necessarily higher dissolution (had been questioned by BAuA during COLLA). Draft reports are currently being drafted by VITO and need to be reviewed by i2a before they are circulated to the EHS Group.
	5. Lung Genotoxicity research	**For information** A number of genotox testing avenues have been considered and developed with C. Boreiko. With the number of genotox studies requested in the ECHA DD, these avenues need to be reconsidered. An updated proposal will be tabled on the basis of the responses that will be prepared to the DDs.
	6. PSLT workshop	**For information** The PSLT (Poorly Soluble Low toxicity particles) workshop took place in Edinburgh on 1 and 2 April. Craig was present as an observer, together with observers from other metal sectors, including TiO2. The main aim of the workshop was to find a consensus on the following terms: - **Poorly Soluble**: it was agreed that a PSLT substance needs to be defined with separate criteria developed in a tiered strategy, largely based on dissolution and clearance rates on rats. - **Low Toxicity**: the tendency was to define such substance as not producing inflammation until overload is reached. Such definition would jeopardize our argumentation in our assessment as ATO induces inflammation and cytotoxicity at doses prior to the onset of overload and therefore would not meet the definition of PSLT. Definition of the “low toxicity” appears to be crucial in this context and has not been yet expressed in the preliminary outputs of the WS. - **Lung particle overload**: it occurs when the impaired clearance in which the deposited dose of inhaled PSLTs in the lung overwhelms clearance from the alveolar region. This leads to a reduction in the ability of the lung to remove particles resulting in an accumulation of particles greater than expected based on normal physiological clearance. - The **most suitable model** to assess the effects of lung overload: largely claimed to be the rat. However, lung overload in human has been discussed despite no case study has been reported. Different opinions were received pointing literature on cancers in coal miners. We are expecting more clarity on this discussion in the final report of the workshop.

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		The intention of the organizers is now to produce a publication on the outcome of the workshop with a separate report. i2a is assessing the need to continue the active collaboration with PSLT workshop organizers involving Craig in the coming calls and meetings. An alternative would be to follow up the discussion by receiving draft of report and publication and by providing comments and influencing the conclusion.
	7.Workplace air exposure monitoring	**For information** Following the successful workshop (Brussels, 21 February), the Secretariat and IOM have been working to collect all questions and comments from sites, reflecting these in updated Monitoring Guidance and data collection template, and producing General Terms & Conditions to formalize the participation of sites in the 2-year Campaign commencing in summer 2019. The invitation to join the Campaign has been shared at a number of public events, also in the US. The aim is to have 20 companies participating, covering a maximum of production and use scenarios, and a maximum of exposure data and contextual information already collected by end August 2019, so i2a can present a teaser/interim report at the 2019 Sb Day (Antwerp, 1 October). To date, around 15 sites have confirmed their intention to participate. The PVC and textile sectors remain to be organized/convinced.
3	**Next meetings/calls and AOB**	
	1. AOB	• **Advocacy RoHS update**: a Stakeholders Meeting took place on 24 April. The draft restriction methodology has been updated considering all stakeholder comments. It should be finalized in summer 2019. The shortlisted substances will then be analyzed according to the final methodology and the final substance dossiers (including for ATO) should be subject to a stakeholder consultation by the end of 2019 . • **Exposure data collection in indoor shooting range**: has been paused until main Monitoring Campaign kicks off. • **Advocacy classification**: will be reactivated after SEv process (no (re-)classification proposal is foreseen in the current SEv DD). • **Advocacy RMOA**: none actively engaged. But all work of i2a (including its participation in the CII or cross industry initiative for better regulation in chemicals management) will feed into an RMOA.
	2. Next meetings/calls	• i2a EHS Group conference call to discuss main contents of draft response to REACH SEv: 30 April 14:00 CET • i2a EHS Group conference call to discuss revised draft response to REACH SEv: 9 May 14:00 CET • i2a EHS meeting: Brussels, 19 June, 10:00 to 16:00 • i2a EHS regular call: 29 August 14:00 CET

Annex 1: IOM in vitro inhalation study proposal
Annex 2: i2a progress tracking excelsheet

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