

General Assembly meeting

16 May 2019; 9:00 am – 4 pm Hotel H10 Casanova Gran Via de les Corts Catalanes, 559 ES - 08011 Barcelona, Spain

Chairperson: Nathalie Branche (PCDLucette, AMG Antimony)

Draft Annotated Agenda
Conclusions added in blue
Action points marked with →

1. Welcome and introduction

1.1. Tour de table (All)

Participants included: M.-C. Bellés (ITACA), E. Blum (BASF), C. Braibant (i2a), N. Branche (AMG Antimony), T. De Loose (SPMP),
A. Doga (Productos ESEBE), S. Duarri-D'Haene (Umicore), R. Elías (Traxys), N. Francis (i2a), L. Hintz (Antraco), M. Huppert (i2a),
B. Korwett (Basylov), E. Linkett (S. Coldmann), M. Mellede (Braduette ESEBE), R. Necher (ITACA), B. Benrick (Compile), C.

P. Karwath (Recylex), F. Linkert (S. Goldmann), M. Mellado (Productos ESEBE), P. Nacher (ITACA), R. Repriels (Campine), C.

Swindon (RJH), H. Vercammen (Campine)

1.2. Approval of the FOR DECISION – Members will be invited to approve the proposed Agenda for the meeting. The Agenda was approved.

1.3. Anti-trustreminder (C.
Members will be reminded on their obligation to abide by Competition Law, as per i2a meeting rules (Annex 1).
Members were reminded on their obligations.

1.4. Actions agreed at the previous meeting (C. Members will be updated on the status of the actions agreed at the last conference call (28 February 2019) (cf. Annex 2 - Action table).

Most actions are on-going, with deadlines coming at the meeting or shortly after.

Braibant)

1.5. Approval of the conclusions of the last conference call (28 February 2019).

The conclusions were approved.

2. i2a Communication

Braibant)

the previous meeting (All)



2.1. i2a Website (N. Francis)

The new i2a website will be launched at the General Assembly meeting, and preliminary comments on the new layout/content collected by the Secretariat.

L. Hintz presented the new web interface of i2a, which reused the existing branding while giving the content a fresher look. The content of the website aims to serve the Sb Value Chain, balancing historic information with regulatory updates.

There is a dedicated webpage to inform about i2a's membership, and another one on its data and the possibility to refer to it or purchase it.

There will be a Members only area, in which all information will be made available to Members, surviving through changes of staff. Non-Members only have access to information that is already in the public domain or has been shared with authorities in a regulatory context.

→ The content of the website has been compiled in a Word document that will be circulated for comment/approval before the site is published.

2.2. Social media (N. Francis)

The most important social activity contents will be shared with the General Assembly, who will be invited to share the relevant posts via their personal LinkedIn and/or Twitter accounts.

L. Hintz presented the social profile of i2a on social media Twitter and LinkedIn. A weekly post is made on Fridays to raise awareness about (funny) anecdotes specific to Sb; these are called 'THAT'S Sb' and are expected to be shared by all followers of i2a. Social media are also used to announce public events of i2a or i2a's participation in specific meetings or topics.

→ Members were requested to 'follow' i2a on social media and to 'share' i2a's posts with their own social networks.

2.3. Sb Day (C. Braibant)

The Members will be updated on the Program and organization of the Sb Day, and invited to register ASAP and promote the event with their colleagues, suppliers and customers.

The 2019 edition of the Sb Day will be an improved version of the 2017 edition. Participants will be taken through the regulatory story of Sb, starting from a relative uncertain landscape, towards one of higher regulatory certainty. Members were invited to register for this event and share it with their value chain to ensure an increased participation.

3. i2a Membership matters

3.1. i2a By-laws (N. Francis)

Members will be updated on the status of the publication of the new by-laws of i2a.

→ Six signatures are still missing. However, the publication of the by-laws have been postponed until a couple of additional publications have been approved (cf. item 3.2 below).

3.2. Chairmanships (N. Francis)

FOR DECISION – Members will be invited to elect the Chair of GA whose mandate is finishing in May 2019.

Members approved AMG's one-year chairmanship election until May 2020.

They also approved the formal appoint of C. Braibant as Secretary-General and N. Francis as Office Manager, with signature authority for both staff of i2a.

A number of administrative aspects are being revised under the supervision of the Chairpersons, following the change of accountant and social secretariat.



3.3. i2a Membership (N. Francis)

FOR DECISION – Members will be updated on the most recent status of i2a's membership, and invited to approve recent membership applications.

KANEKA's membership application was approved by all Members. KANEKA's request for more specific collaboration with i2a will be discussed by the Board.

Changes in membership can be summarized as follows:

- One Full Member became Associate Member
- Four Full Members left i2a
- Two Associate Members joined i2a
- 1 Full Member moved to a lower tonnage class
- 3 Full Members moved to a higher tonnage class

All departures were due to costs only. This is why the i2a Secretariat is working towards limiting any further increases of the i2a membership fee despite the increasing regulatory attention on Sb substances under various schemes and in several jurisdictions. Under REACH, departing Members become 'LoA' co-registrants and subject to *ad hoc* payments any time i2a's itemization work results in the need to re-invoice registrants. Membership enables regular payments of manageable amounts instead of *ad hoc* payments of cumulated amounts. REACH costs are resulting in an increase of Sb production/trade costs and possible changes in the Sb market.

3.4. i2a 2018 Accounts and Reserves (N. Francis)

FOR DECISION – Members will be invited to approve the final and audited accounts for 2018.

The closure of the 2018 accounts has been delayed due to the relatively bad performance of i2a's Accountant. Internal numbers show an expected transfer of around 1,000,000 € from 2018 to 2019. Final numbers were shared and agreed upon by the General Assembly (cf. Annex 5).

From 2019 accounts onwards, i2a is working with a new Accountant (cf. Annex 6 for corrected status of 2019 expenses by 1 May).

3.5. Socio-economic footprint of Sb (T. Höhne-Sparborth, Roskill)

Roskill will present the results of the socio-economic analysis they have performed on the Sb industry (at EEA level) and Members will be invited to comment and discuss the high-level findings shared during the presentation, and found in the final draft report (Annex 3).

Roskill has applied a conservative but realistic method to calculate the output and the value of the societal footprint of Sb in the EEA. It uses information provided by companies and statistics reported by EuroStat. It is based on a number of assumptions which are transparently identified and described in the report. The method has been used for Ni, Co and other metals. The aim of this sort of studies is to inform about the possible impact of a given regulatory decision.

While the production of Sb generated an average of € 290,000,000 in direct output over the period of 2010-2017, total economic activity (value addition) for that same period was closer to € 800,000,000. Direct benefits from the production and trade of Sb constitute only 1/3 of the total contribution of Sb to society, with 2/3 resulting from Sb's role indirect benefits in supporting other industries and employment. In the EEA, the Sb value chain contributes around 2,560 jobs directly and 9,600 jobs indirectly. The total contribution to labor income is estimated at around € 330,000,000 per year.

The method also shows that the earnings before interest, taxes, depreciation, and amortization (EBITDA) is much lower in the Sb sector than in the Ni one, for example; this shows that investment in regulatory compliance cannot take place with the same cadence in the Sb sector as it happens in the Ni one. Volumes placed on the market are also comparatively much lower for Sb than for Ni (volumes are often used as surrogates for exposure estimation, to justify regulatory attention).

On the positive side, the study indicates that the CO2 emissions of the Sb industry is comparatively much lower than those of other non-ferrous metal sectors, and that from 2010 to 2017, R&D expenditure attributable to Sb amounted to around € 17,600,000.

- → The study report has been circulated for comment by 15 Jun 2019, so Roskill can finalize it ASAP. → i2a will subsequently announce the report via a Press Release and share it with the European authorities (in particular those involved in the RoHS assessment of Sb, which foresees the consideration of SEA evidence) and in social media (the Full Report will only be available to Members). → It will also be used to update the volumes/use information reported in the REACH Dossiers.

 Among the comments received, the following were noted:
- Clarify that Sb does not rely mainly on recycling, but actually more on imports (which is why it is a critical raw material)
- Try to cover other Sb substances beyond Sb metal and Sb trioxide, especially pentavalent Sb species
- The SEA exercise can also be extended to calculate the value (on the basis of the amounts of Sb used vs the value of the resulting product) of Sb in specific uses (e.g. flame retardants, PET, pigments or glass), beyond the concentration of Sb present in these products (this is not reflective of Sb's importance); this can then be used to reach out to the Sb Value Chain to stimulate engagement in the i2a
- The SEA for Sb can also be used to compare Sb with the SEA and value brought by possible alternatives
- The SEA exercise can also be extended to assess more specific impacts of regulations

4. Regulatory challenges

4.1. REACH
Compliance
Check and
Substance
Evaluation & i2a
Research
Program (C.
Braibant & M.
Huppert)

FOR DECISION – The Members will be requested to discuss and approve the final draft responses of i2a to the nine REACH Compliance Check and Substance Evaluation draft decisions received on 18 April.

The discussion was preceded by an introductory video recording of J. Mossink (Head of Unit Chemistry, ECHA) about ECHA's Metals and Inorganics Sectorial Approach (MISA) (cf. Annex 7).

Following COLLA (2017), i2a engaged together with several other metals associations/consortia under MISA (2018) to work with the sector and authorities to improve the content of the dossiers of 292 metals and their compounds, over a three-year work program. With this Program, ECHA and Industry work towards identifying REACH parts which do not really 'fit' with inorganic chemistry, develop approaches to make it 'fit' and provide Industry with the opportunity to improve their dossiers.

The scoping exercise of the study showed that for human health endpoints, most of Sb Dossiers are based on adaptations and waivers (i.e. data requirements have been fulfilled via other means than direct testing), while the justifications are insufficiently documented. This has been picked-up under COLLA already, further discussed at a dedicated workshop on 10 October 2018 in which i2a participated, and i2a's research program aims to address this in a tiered manner. Bio-elution is one of the information points used in read-across justifications, and the use of these results will be specifically discussed with ECHA under MISA in 2019. While MISA is mainly aimed at promoting spontaneous updates of the Dossiers (rather than updates triggered by formal Evaluation processes), for Sb substances which were already in a formal Evaluation process, MISA could not prevent or stop such process.



However, i2a's participation in COLLA and MISA will probably increase the credibility of i2a's response (proposing a tiered approach) to the Evaluation Draft Decisions.

This will include a presentation and a discussion on the revised i2a Strategy and research program, which were currently mainly based on the COLLA and MISA engagements, and now need to reflect the more formal Evaluation process, in full consideration of all other regulatory challenges of relevance to Sb substances.

Nine Draft Decisions (DD) were received on 18 April with responses due 28 May: four Substance Evaluation (SEv) DD (expected) and five Compliance Check (CCH) DD (not expected).

While the CCH (looking at compliance with Annexes VII-XI REACH information requirements) is supposed to precede the SEv (looking at concerns and risks), the two processes ran in parallel for Sb substances.

Both types of DD address the read-across and the (dis)similarity of effects that can be expected between the four evaluated Sb substances. There is a tiered logic between the information requested under CCH and that requested under SEv, and i2a basically 1) merged its original research program with some of the requests formulated in the DD to produce an updated program, and 2) prepared responses highlighting the following key issues:

- Processes should not be running in parallel but one after the other
- Read-across justification documentation will be updated regularly and included in the next version of the Dossiers
- i2a commits to the minimization of vertebrate animal testing through tiered research

Following a tour de table, the General Assembly agreed with the way forward developed by the Secretariat and the EHS Group and called upon an extension of the testing program timeframe, to enable a better preparation of each test, and a better interpretation and decision-making before any follow-up test. The extension of the timeframe was also recommended by the General Assembly as a solution to keep costs to a manageable level for all registrants, those inside i2a and those outside. As demonstrated in Roskill's study (cf. item 3.5 above), the Sb sector does not have the shoulders to carry the requested work in parallel. This will be mentioned to ECHA although the proposed tiered approach follows the scientific needs of the research first.

Regarding the financial obligations resulting from this revised research program, \rightarrow cost estimations will be refined against timing (regulatory process timings vs testing timings), and communicated ASAP to enable all co-registrants to decide whether or not to remain in the joint submissions. There is indeed a possibility to stop a registration (via the 'cease to manufacture' function) before the Final Decisions are issued; registrants failing to cease to manufacture before the Final Decision are obliged to share all costs related to the Evaluation.

→ The Secretariat will be requested to define a communication plan to all co-registrants (i2a Members and non-Members). This will start with the circulation of the final responses to the DD, to be reviewed and commented by all co-registrants and the legal counsels before submission by i2a on behalf of all co-registrants on 28 May 2019.

4.2. Regulatory update (C. Braibant)

Members will be updated on the status of existing and recent regulatory developments including:

Inclusion of ATO to IARC Monographs Program for 2020-2024;
 ATO has been selected as a medium priority substance for IARC 2020-2024 Monographs program; which means that IARC intends to update the Monograph/Classification for ATO. While the exact timing is not clear, ATO will be assessed after the high priority substances. This should coincide with the outcome of i2a's Workplace Monitoring Program, which data will be relevant



for IARC. Once IARC (a UN WHO entity) updates its Monograph/Classification for ATO, it will be taken up by all jurisdictions. Although the procedure is not very transparent, → i2a will try to find out more about it, the timing, and the possibilities to inform IARC about on-going research which would merit further patience.

Listing of ATO on the US NTP RoC;

Following the (internal) evaluation of the available science (mainly the US NTP Carcinogenicity studies in rats and mice), the US NTP decided to list ATO on its Report on Carcinogens (RoC). Since this announcement, i2a has been trying to 1) get ATO totally delisted, 2) ATO listed only in its respirable form (< 4 µm). Step 1) has proven to be unsuccessful, so step 2) has been insisted on with the support of Bergeson & Campbell. Despite clear scientific argumentations and legal requests (including a number of precedent-setting examples), the NTP officers have rejected i2a's requests. The last request was sent on 24 April, and Bergeson & Campbell have contacted Dr Ken Olden, former US NTP Director, to source additional strategic intelligence from him. → Feed-back on Dr Olden's view should become available w/c 20 May. The date of release of the next RoC is not announced yet; can be in 2019 or 2020.

- Identification of Sb as chemical meriting further evaluation by Environment and Health Canada; While Canadian authorities concluded in Sep 2018 that 11 Sb substances including APO, ATS, ATC, SAA and SHHA do not meet any relevant toxicity criteria, and do not require any follow-up activity, in Feb 2019, it announced that Sb may need further evaluation (because monitored/evaluated in other regions). i2a contacted the Canadian authorities, informed them about the on-going REACH Evaluation and i2a testing program, → hoping that Canada's attention on Sb substances will be paused/postponed.
- Nomination (?) of Antimony to the list of substances proposed to be evaluated for Toxicological Profile development under US ATSDR:

Sb is on the ATSDR's Substance Priority List (SPL), from which the substances to be considered for Toxicological Profile development will be selected (following a public consultation with deadline 20 May). The profiles aim to summarize all evidence available on a substance to inform about possible consumer risks. There was a profile in 2018, on which i2a commented, and no update of the profile has been published since. ATSDR now launched a call for the public to nominate substances for Toxicity Profile development/update.

i2a will find out whether it is best to remain silent or whether we should actively seek to discourage the nomination of Sb (due to on-going processes which will feed an ulterior nomination instead).

New Threshold Limit Value proposed for ATO by US ACGIH;

While ACGIH originally proposed a new TLV of 0.03 mg/m³ respirable in 2017, the most recent proposal (as opaque as the previous one) is for a TLV of 0.02 mg/m³ inhalable Sb! → i2a will submit comments on this most recent draft proposal by 31 May 2019, repeating the same comments formulated in 2017, and informing on the progress made with the workplace exposure monitoring program. i2a will also put forward the technical difficulty to detect and quantify Sb at such low levels, on the basis of the LoD/LoQ (detection limit & quantification limit) required to meet this TLV.



• Evaluation of ATO for possible restriction under EU-RoHS;

New restrictions on Sb-based FRs under Oeko-tex:

While Oeko-tex is not a regulation, it is a recognized certification system for textiles, including those containing flame retardants. The certification of textiles requires the identification of the identity and function of the various components, and Sb falls into two categories: 'heavy metals that can be extracted' and 'flame retardants'. Several textiles containing Sb have been certified under Oeko-tex already. Recently however, Oeko-tex added the following statement on its website: "Please note that the use of any flame retardant products / finishes which are based on antimony trioxide/-pentoxide etc. or contain these substances is not possible for a certification according to Appendix 6 of STANDARD 100, even if they are also listed here!". This is causing confusion for users of the Oeko-tex certification, for the consumers, and may result in liability issues. It was agreed that i2a would prepare a letter to be sent by one or more Members of i2a having certified products under Oeko-tex to: 1) request the removal of the new statement, 2) request justification for such a statement, and 3) inform them about the on-going REACH Evaluation which is the sole regulatory process able to clarify any health concerns related to ATO. i2a can then follow-up directly with Oeko-tex as necessary.

4.3. Deviations from CLP requirements (C. Braibant)

Members will be invited to share their experience regarding general compliance with CLP requirements. It has become apparent that some companies (co-registering within the joint submissions prepared by i2a), do not apply the correct self-classifications, despite these are mandatory as per Article 15 of CLP and Article 31 (9) of REACH. This results in unfair competition on the market. i2a Secretariat welcomes any examples which can be provided, in order to be shared with the ECHA Enforcement Forum in due course, and raise awareness on/find ways to remediate this discouraging practice.

The Members were informed about the situation, which is affecting some i2a Members already. As a principle, the classification reported in the MSDS should match the classification jointly submitted under REACH. However, some suppliers are not willing to classify their substances (especially Sb metal and Sb trisulphide) on the basis of read-across from ATO, and end-up with non-classified chemicals which do not require an MSDS. Some also supply natural forms of Sb trisulphide, which do not require registration under REACH (but do require classification under CLP). The Secretariat will circulate a specific e-mail request to collect other similar examples (even if not Sb ones), to build a case that can be brought forward to ECHA's Enforcement Forum.



5. AOB, next meetings and closing remarks

5.1 AOB (AII)

No other business was raised.

5.2 Next meetings / calls (N. Francis)

- Antwerp, 30 September 2019
- Antwerp, 1 October 2019 2019 Sb Day
- Conf call Dec 2019 (exact date and time tbc)

5.3 Closing remarks (N. Branche)

Annexes:

- 1. i2a Meeting rules
- 2. i2a GA Action table
- 3. Final draft Roskill Socio-economic analysis report (Apr 2019)
- 4. Slides presented at the meeting
- 5. Final 2018 accounts
- 6. Status of 2019 expenses by 1 May 2019
- 7. Video recording by J. Mossink (ECHA) on MISA (heavy file: not distributed with minutes but available on request)