Press release
29th June 2018

i2a volunteered to participate in collaborative project with ECHA and REACH Authorities

The REACH Regulation[1] foresees that Industry submits Registration Dossiers for each substance they manufacture or import into the EU at one or more tons/year. After the Dossiers are submitted, their compliance with REACH requirements is checked by ECHA, and the hazard, exposure and risk assessment evidence submitted in the dossier can be evaluated by a REACH Competent Authority. Until 2017, these evaluations would take place one substance at a time, with several parties complaining that the process is too slow and inefficient, when similar substances can actually be evaluated in groups, rather than sequentially.

As three of the ten[2] REACH registered Sb substances were already listed for Substance Evaluation in 2018 (CoRAP[3]), i2a decided to volunteer to participate in a collaborative (COLLA) pilot project between ECHA, Member States (MS) and registrants, aimed to explore how an early interaction could bring more efficiency to the Evaluation process. i2a's immediate interest in participating in this initiative were:

- the opportunity for enhanced dialogue with the German REACH Competent Authorities (BAuA and BfR) who would be evaluating the Sb substances as from 2018, and
- the chance to implement a targeted and more efficient preparation of REACH Dossier updates for the evaluation of these substances.

One year, three fruitful exchanges

Three exchanges took place between i2a and BAuA and BfR between Spring 2017 and Spring 2018. After each exchange, a number of tasks and deliverables (and the associated deadlines for submission) were agreed. Each deliverable and the feed-back exchanged on these helped registrants and authorities to understand each other's opinions and expectations much better. Thanks to this early collaboration, i2a understood what the main concerns around the Sb substances were and which specific questions required to be addressed for each one of these. Regulators in turn, decided to evaluate first all trivalent Sb substances on CoRAP, so as to proceed with a parallel evaluation of potentially similar substances, and be able to decide for each member of the group of substances:

- what additional data is needed,
- whether hazards and exposures are similar or different, and
- whether they require similar or different risk management measures (e.g. harmonized classification under CLP).

Benefits of participating in COLLA

If i2a had not participated in the COLLA, it would have missed:

- ❖ The opportunity of establishing a very constructive relationship with BAuA and BfR
- ❖ The necessary leverage to prompt participation in its first value chain event (2017 Sb Day) and preparation for a dedicated Workplace Exposure Monitoring Campaign as from 2019

[1] [1] Cf. https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:02006R1907-20180301&from=EN for more information about the REACH Regulation.

[2] [2] Sb metal, four trivalent (3+) Sb compounds, and five pentavalent (5+) Sb compounds, cf. http://www.antimony.com/en/antimony-compounds.aspx for more information on the Sb substances REACH registered by i2a Members.

[3] [3] Cf. https://echa.europa.eu/fr/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances for more information on the Community Rolling Action Plan (CoRAP) of substances listed for REACH Substance Evaluation.

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- ❖ The possibility to define a tiered testing plan to address the main concerns clarified by the regulators
- ❖ The chance of further developing and documenting the correct grouping and read-across approach
- ❖ The identification of the key elements to be addressed in the dossier updates

The fact that all trivalent forms of the ten REACH registered Sb substances are now on CoRAP, provides a **unique opportunity to define the correct classification per compound once and for all.** Sharing a similar valency is not sufficient reason to assume a similar toxicity!

ECHA's final report on the COLLA project can be found on:

https://echa.europa.eu/documents/10162/13628/colla_pilot_project_report_en.pdf

The Antimony pilot project is described in Appendix 2 of the report.

About i2a

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.

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