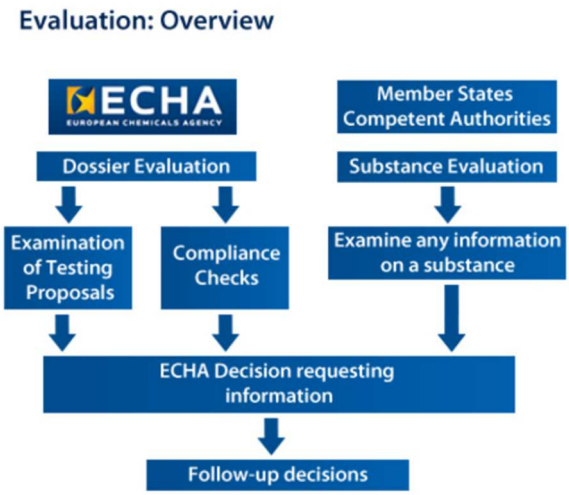
Press release
31 May 2019

i2a Members and other co-registrants successfully submit their responses to 9 REACH Evaluation Draft Decisions

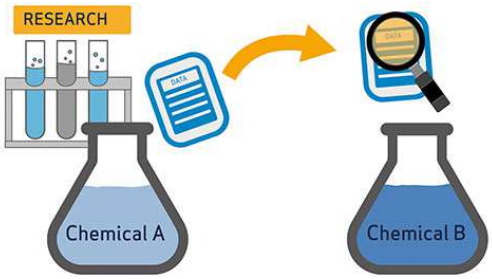
Nine REACH Evaluation Draft Decisions were sent by the European Chemicals Agency (ECHA) to the registrants of Sb metal, Sb trioxide, Sb trisulphide, Sb glycolate, and Sb trichloride on 18 April 2019, with comments due by 28 May 2019.



There are five Compliance Check (CCH) Draft Decisions (one per Sb substance) and four Substance Evaluation (SEv) Draft Decisions (for all Sb substances but the trichloride). The CCH is performed by ECHA whereas the SEv is performed by an evaluating Member State Competent Authority (eMSCA), in this case by the German BAuA. i2a lead the preparation of all the due comments, in due consultation and representation of the lead and co-registrants, and successfully submitted these to ECHA on 28 May 2019.

What information is being requested by ECHA?

The CCH looks at how information requirements specified in the REACH Annexes VI-XI have been complied with, whereas the SEv looks at clarifying the toxicological profile and risk management of the Sb substances. Both Evaluation processes point towards the need to reinforce the grouping/read-across and weight of evidence documentation. In the absence of a more robust justification, ECHA and the eMSCA request that testing on individual substances is performed for a number of toxicological endpoints (genotoxicity, reproductive toxicity, systemic toxicity, inhalation toxicity).



Applying a grouping/read-across approach aims to facilitate the effectiveness and efficiency of the Registration Dossier preparation, and reduce the need for experimental testing, especially those requiring (vertebrate) animals. It is with these objectives in mind, that co-registrants continue to elaborate the approach rather than considering direct testing on each and every substance for each and every endpoint.

Conducting all the substance-specific tests requested in the Evaluation Draft Decisions dated 18 April would neither be cost-effective, nor scientifically efficient (many REACH-relevant questions would remain unanswered), and far from acceptable from an animal welfare standpoint. i2a's revised research program (started during i2a's voluntary participation in COLLA (2017), and formal engagement in MISA (2018)) addresses both the CCH requests and the SEv concerns. It was submitted to ECHA and the eMSCA as an Annex to the comments on the Draft Decisions, hoping that the multiple parallel tests requested in the Draft Decisions are transformed into an integrated sequential testing program similar to i2a's program instead.

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What next?

ECHA's (amended) Draft Decisions may more or less, or not at all, consider any of the comments submitted by the registrants. As regards the next (amended) CCH Draft Decision, there is no deadline for ECHA foreseen in the REACH text. For the SEv process however, the (amended) SEv Draft Decision will be sent to the Member States - so they can submit proposals for amendments (PfA) - any time between Nov 2019 and May 2020. The SEv should not be finalized before Spring or Autumn 2020 at the earliest. None of the SEv tests can be started before a final decision has been adopted.

i2a will therefore continue with the first tiers of its revised research program launched with COLLA and MISA, which includes *in vitro* inhalation studies, and gastric tolerance studies followed by screening reproductive toxicity studies. These are aimed to: i) compare and rank the various Sb substances, ii) further refine/confirm the grouping/read-across and iii) identify optimal test candidates to undergo studies aimed to clarify the influence Sb may have on relevant health parameters. By the time these initial tier studies are finalized, the SEv Decisions should have progressed, and the subsequent tiers/study needs will be refined accordingly.

i2a will furthermore continue supporting its Workplace Exposure Monitoring Campaign and broader communication to the Sb Value Chain about the generally challenging regulatory horizon producers, distributors and users of Sb substances are facing. REACH Registrants in particular, will be informed/reminded about the next steps of the Evaluation process, and their rights and obligations within this process, to enable informed business decisions to be made by all.

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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