International Antimony Association

REACH EVALUATION DECISIONS RECEIVED ON 18 APRIL 2019

i2a EHS Group conference call

30 April 2019, 2 pm CET

Summary

- Substance Evaluation Draft Decisions (SEv DD) received by announced date, accompanied by Compliance Check Draft decisions (CCH DD)
  - SEv decisions work to be shared by all registrants (Members + LoA) according to i2a's cost-sharing
  - CCH decisions work to be shared by registrants in specific tonnage bands

- ECHA and BAuA have considered all information, including when not in Dossier but provided by i2a

- BAuA has assessed NTP data very much in line with i2a's interpretation

- Information requested in DDs not fully what was expected; surprising content:
  - Read-across justification not supported: gentox and reprotox data missing according to ECHA
  - In vivo studies on Sb metal, ATS and ATEG to compare Sb substances re lung + systemic tox
  - No formal request for workplace exposure data
  - (Re-)classification postponed by at least 3 years, i.e. not before 2025-2028 at the earliest (until tests deliver and results are assessed)

- i2a research program, budget predictions and cost-sharing mechanisms will need to be adjusted (several scenarios possible)

Evaluation Draft Decisions received

	Compliance Check	Substance Evaluation	Other
Sb metal	X	X	
ATO	X	X	
ATS	X	X	
ATEG	X	X	
ATC			X

Logistics

	CCH	SEv	Other
Scope	REACH Annexes only	Any information to clarify risk	-
Leader	ECHA	BAuA	BAuA
Received on	18 Apr 2019	18 Apr 2019	20 Mar 2019
Deadline to respond	28 May	28 May	-
Cost-sharing	According to relevant tonnage bands	All registrants	-
Testing can commence	ASAP	Not before Final Decision (Spring 2020?)	-
Data to be provided by	12-18 mo after notification (Apr-Dec 2019)	21 mo after final decision (end 2022?)	-

Responses preparation/approval & communication steps

15-19 Apr	23-26 Apr	29 Apr-3 May	6-10 May	13-17 May	20-24 May	28 May
• Collection of DDs • First DDs and overview shared with experts	• General information mail • Collection of DDs (continued) • First DDs and overview shared with experts (continued) • Compilation of 1st i2a draft responses + draft costing/time needed for each test	• Updated costings/time needs for each test • **EHS Group cc** to collect comments on 1st i2a draft responses • Preparation of 2nd i2a draft responses	• General update mail • Final costings/time needs for each test • **EHS Group cc** to collect comments on 2nd i2a draft responses • Preparation of 3rd/final i2a draft responses	• **BoD and GA meetings** to agree on final response strategy, and collect final comments and approve final draft responses	• Final legal review • Final i2a responses circulated for approval by co-registrants	• **Submission of responses** by LRs to ECHA • Update of i2a website content

Experts involved all along:

- Gentox/Lung tox & carcinogenicity: Dr Craig Boreiko, Dr Matthew Boyles
- Reprotox: Dr Lindsay Aveyard
- Exposure: Daniel Vetter
- Legal: Mayer Brown

Information requests in each decision

	Compliance Check DD		Substance Evaluation DD
	Gentox	**Reprotox**	
Sb metal	AMES (OECD 471) In vitro MN (OECD 473 or 487) If negative: OECD 476 or 490	-	90d in vivo inhalation rat (OECD 413)
ATO	-	PNDT rabbit (OECD 414)	Combined COMET assay (OECD 489) + in vivo MN (OECD 474) inhalation, mice
ATS	AMES (OECD 471) In vitro MN (OECD 473 or 487) If negative: OECD 476 or 490	Screening (OECD 421/422) PNDT rat or rabbit (OECD 414)	90d in vivo inhalation rat (OECD 413)
ATEG	AMES (OECD 471) In vitro MN (OECD 473 or 487) If negative: OECD 476 or 490	Screening (OECD 421/422) PNDT rat or rabbit (OECD 414)	90d in vivo oral rat (OECD 408)
REASON	***Gentox read-across/WoE rejected by ECHA (Bioelution not sufficient, available evidence not 100% TG compliant)***	***Reprotox read-across/WoE rejected by ECHA (Bioelution not sufficient, available evidence not 100% TG compliant)***	***MoA behind carcinogenicity + (dis)similarity between Sb 3+ substances for risk management (classification, OEL, read-across)***

Reality vs expectations

ALSO:

- Quid workplace exposure data request?
- Quid (re-)classification?

	Compliance Check		Substance Evaluation
Sb metal	Not expected (i2a's MISA engagement foresees improvement of read-across justification)		Expected but not as in vivo test (although in vitro not valid/only supporting evidence)
ATO			Expected and welcomed: direct genotoxicity questioned, classification proposal not foreseen yet
ATS			Expected but not as in vivo test (although in vitro not valid/only supporting evidence)
ATEG			Expected but not as in vivo test (although in vitro not valid/only supporting evidence)
REASON	***Gentox read-across/WoE rejected by ECHA (Bioelution not sufficient, available evidence not 100% TG compliant)***	***Reprotox read-across/WoE rejected by ECHA (Bioelution not sufficient, available evidence not 100% TG compliant)***	***MoA behind carcinogenicity + (dis)similarity between Sb 3+ substances for risk management (classification, OEL, read-across)***