



International
Antimony Association



REGULATORY COHERENCE FOR CRITICAL RAW MATERIALS: The Sb example

11th Edition of the CRM Day

Sustainable Policy for Critical Raw Materials

25 September 2019 Venue

L42 Business Centre, Rue de la Loi 42, Brussels

Content

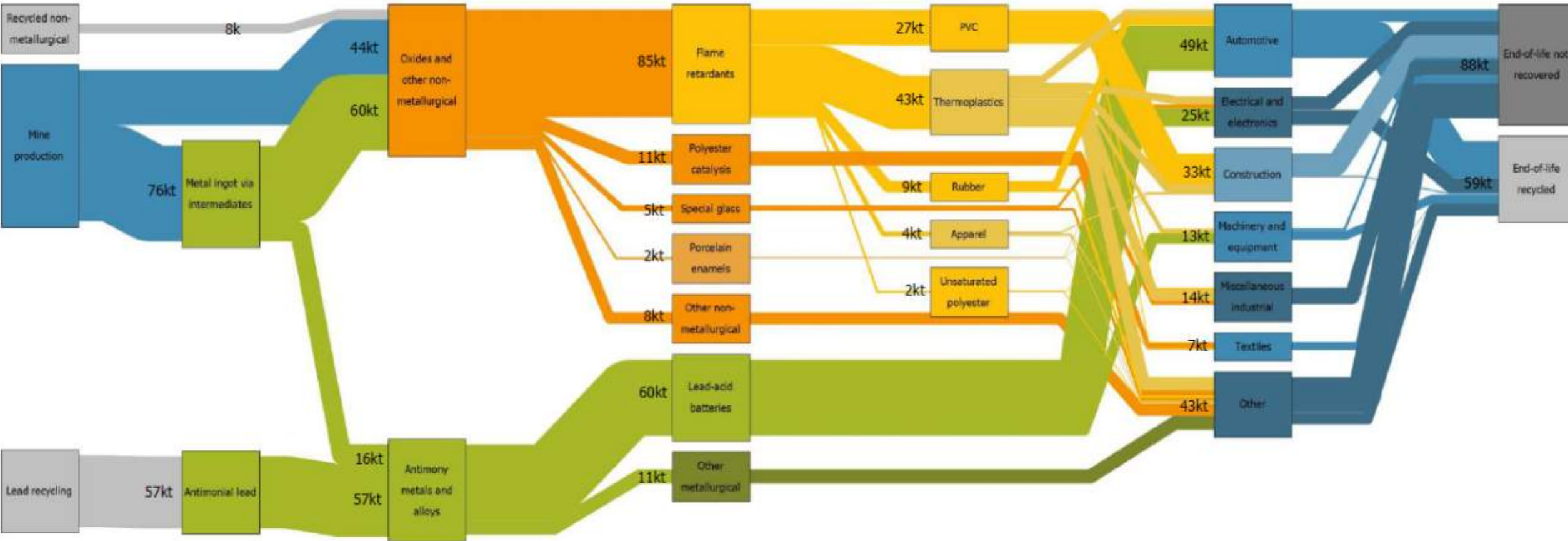
1. Antimony and i2a
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3. How could the situation improve?
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1. Antimony and i2a

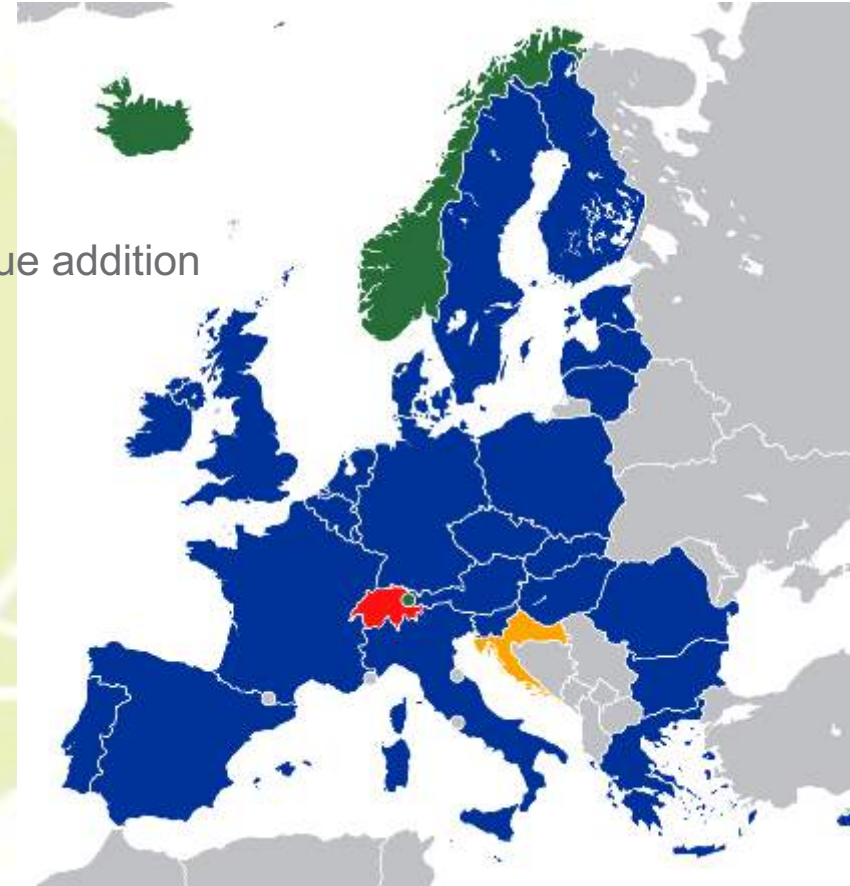


Antimony in the world



Antimony in the EEA

- **Total value in 2018: €1.26Bn (EEA = €300M)**
 - Direct value generated over 2010-2017: €904M
 - Indirect value generated over 2010-2017: €1,339M
- **Value addition:**
 - Direct value addition: €194M; Indirect value addition: €578M
 - Production: 32% of the total value addition; Applications: 68% of the total value addition
- **Total employment: 13,353 jobs**
 - Producers and downstream users: 21% of total employment
 - Supporting sectors: 79% of total employment
- **Labour contributions:**
 - Direct labour contributions over 2010-2017: €129M/year
 - Indirect labour contributions over 2010-2017: €233M/year
- **Contribution in taxes on products, production and corporation tax:**
 - Producers: €14.6M/year
 - Downstream users: €25.9M/year
- **SMEs:**
 - 93% of the businesses in the main sectors supporting the production of antimony would be SMEs.



Antimony substances under REACH

Group	Acronym	Name	CAS #
Metal	Sb	Antimony metal – powder & massive	7440-36-0
Sb 3+	ATO	Diantimony trioxide	1309-64-4
	ATS	Diantimony trisulfide	1345-04-6
	ATEG	Antimony tris(ethylene glycolate)	29736-75-2
	ATC	Antimony trichloride	10025-91-9
Sb 5+	SHHA	Sodium hexahydroxoantimonate	33908-66-6
	SAA	Sodium antimonate	15432-85-6
	APC	Antimony pentachloride	647-18-9
	APO	Antimony pentoxide	1314-60-9
	PHHA	Potassium hexahydroxoantimonate	12208-13-8

Falling prices of antimony → Low margins → Regulatory compliance costs disproportionately large burden



Vision, Mission, and Objectives of i2a

i2a Vision: a sustainable and responsible Sb industry, where **Sb substances continue to be the material of choice** for many technology-enabling applications.

i2a Mission/Mandate: to ensure the safe use of Sb substances, in other words, the **responsible management of Sb substances throughout their lifecycle**. A comprehensive concept to describe this is product stewardship. The mandate and role of i2a is to inspire product stewardship along the Sb value chain, from classification to sustainability profiling.


i2a Strategic objectives:

- **Address knowledge gaps** weakening the safe use and positive image of Sb substances
- Ensure that the most **up to date evidence** is used in any regulatory scrutiny of Sb substances
- Determine the most relevant, proportionate, and efficient **risk management measures** applicable for each use of Sb substances
- Support the Sb industry in implementing **responsible product stewardship practices**



Regulatory Coverage of i2a





2. Regulatory coherence for critical raw materials: the Sb example



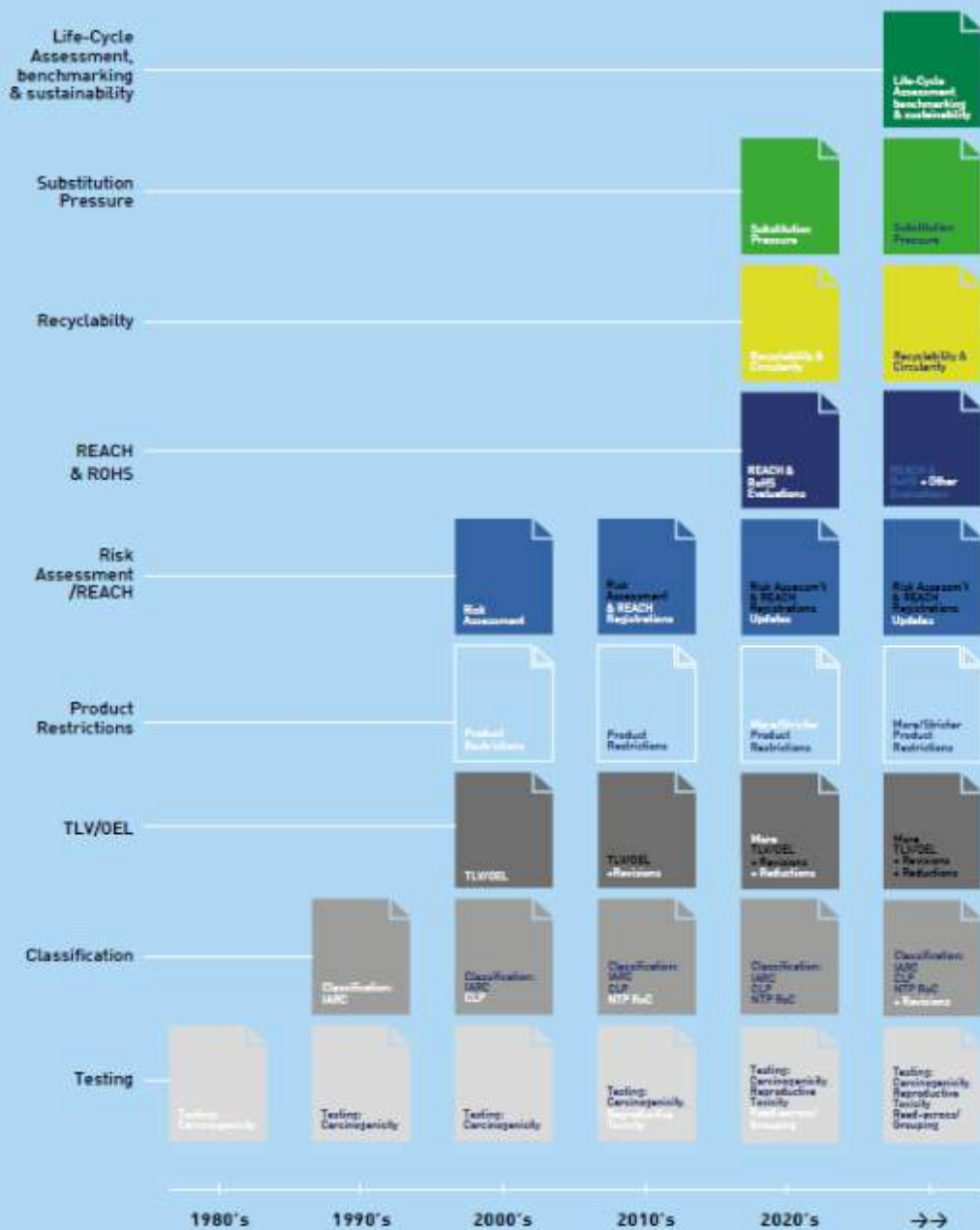
Some facts...

- **All chemicals have hazards**, it's just a question of time/resources to have them all studied and revealed
- **Hazards observed in animals are not systematically relevant** for humans:
 - Animals are under stress
 - Exposure routes/Doses/Frequency/Duration at which hazards are tested do not replicate plausible human scenarios
 - Genetic resemblance across species is not 100% - key differences in organs, systems and modes of action
 - Standard test guidelines are designed to identify at what level an effect takes place, not if an effect would take place under realistic conditions
- **An animal hazard evidence-based regulatory system** is predestined to deliver over-conservative and of limited value-addition decisions



REGULATORY SCRUTINY ON ANTIMONY

Increased and cumulative regulatory attention, reviews and requirements over time



Never-ending cycle

With shorter timeframes over time

Building upon (new) evidence

Looking at sustainability of Sb based on:

- Animal data
- Human exposure/epidemiology data
- Classification
- Risk assessments
- Workplace and product restrictions
- Recycling
- Circularity

y (in)coherence regarding Antimony
CRM Day 25 Sep 2019

Criticality should come first!

CRITICALITY

Antimony is recognized as a critical raw material/mineral in the EU, the US, Japan and Australia. The criticality criteria may vary across these lists, but is globally defined as:

- a high reliance on imports (risk of supply shortage)
- limited substitution options
- an essential function in the manufacture of products which are key to the regional economy and/or national security

The criticality implies not only a high value, but also a high dependence on Antimony, which may be further complicated by the imposition of over-conservative EHS requirements.

i2a works towards evidence-based decision-making to ensure that the use of Antimony faces the least number of irrelevant and/or inapplicable regulatory obstacles as possible.



Decisions today:

Example 1: Revising Sb substance's classification



(New) Hazard evidence on a Sb compound

Ad hoc prioritization of (re-)classifications

Classifications revised based on animal data

(New) Classification



More severe packaging and labeling obligations

More severe workplace restrictions

More severe product restrictions

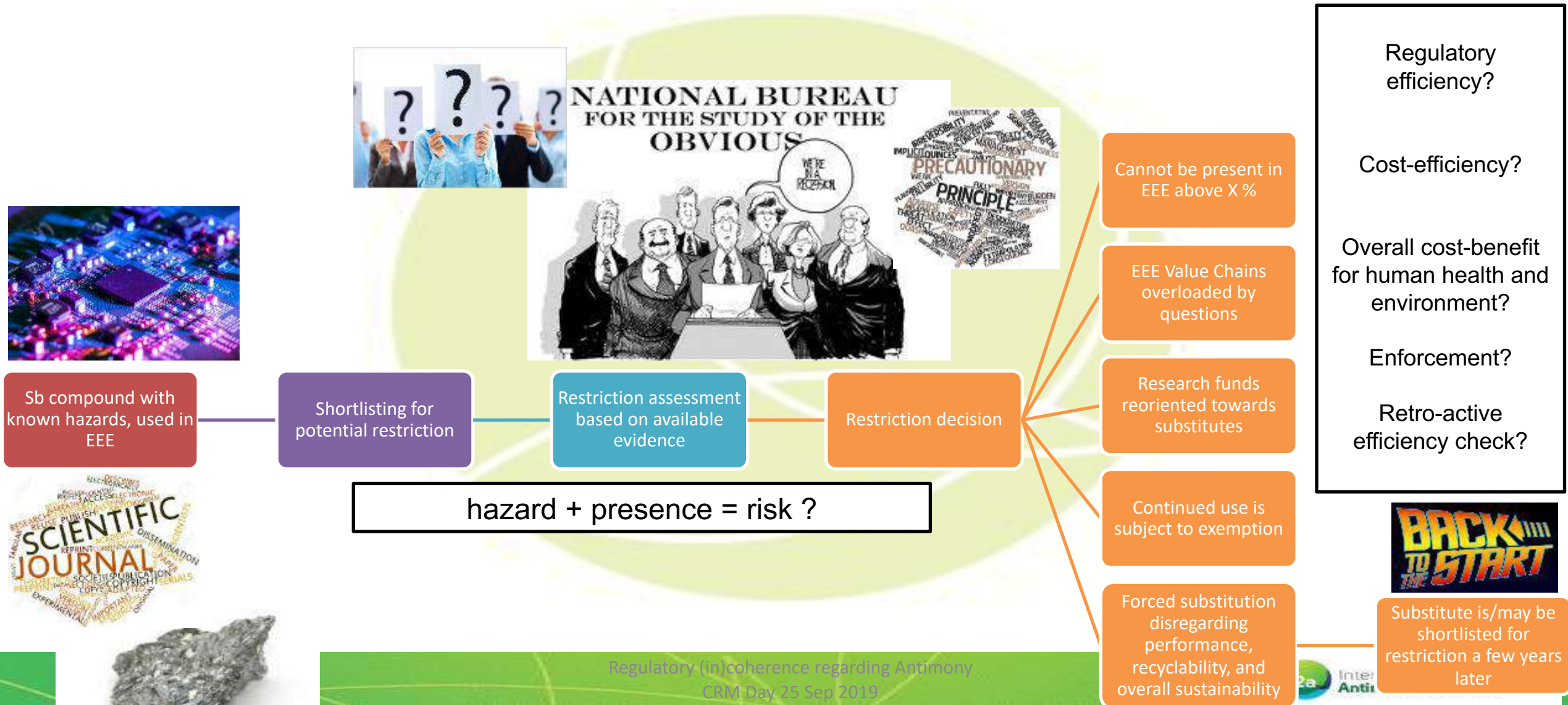
Bans

- Regulatory efficiency?
- Cost-efficiency?
- Overall cost-benefit for human health and environment?
- Enforcement?
- Retro-active efficiency check?



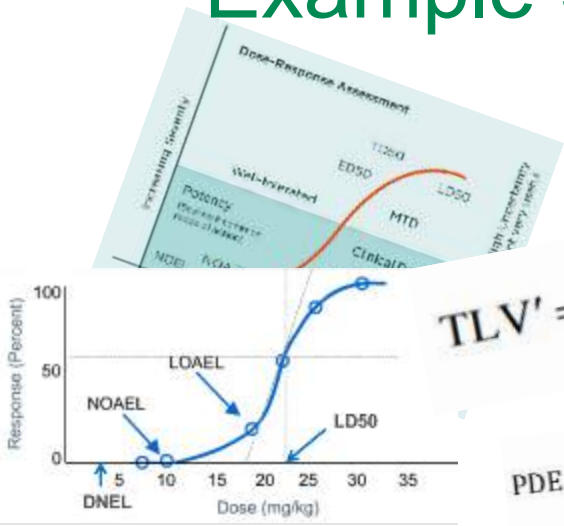
Decisions today:

Example 2: Restricting an Sb compound under RoHS



Decisions today:

Example 3: Establishing an OEL/TLV for Sb substances



$$TLV' = \frac{8 \text{ hrs}}{T \text{ hrs}} \times \frac{24 - T \text{ hrs}}{24 \text{ hrs}} \times TLV$$

$$Reference \ level = \frac{PoD \times BW}{UF_{1,2,3} \times SF \times MF \times A \times V}$$

$$PDE \ (mg/day) = \frac{NOAEL \ or \ LOAEL \times Body \ weight \ (kg)}{F1 \times F2 \times F3 \times F4 \times F5}$$

Sb compound with known hazards produced/used on workplaces

Shortlisting for OEL derivation

OEL calculated based on available evidence

OEL decision

Cannot be present in workplace air above X $\mu\text{g}/\text{m}^3$

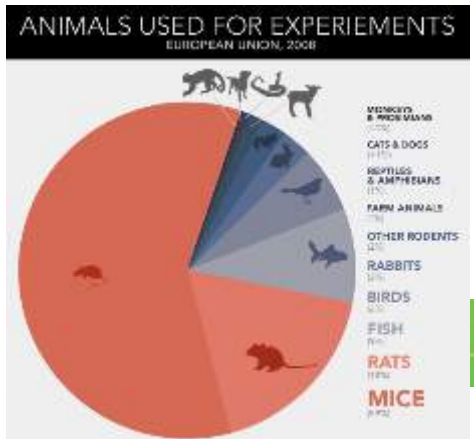
Technical and economic feasibility challenging

Sb Value Chains overloaded by questions

Research funds reoriented towards workplace monitoring and protection

Production and use moves to less regulated areas

- Regulatory efficiency?
- Cost-efficiency?
- Overall cost-benefit for human health and environment?
- Enforcement?
- Retro-active efficiency check?



...nce regarding Antimony 25 Sep 2019

And all this is taking place in parallel with an
EU-REACH Evaluation...

and a number of other international assessments...

With no consideration at all for the criticality of Sb!





3. How could the situation improve?





Let's m/take decisions with context

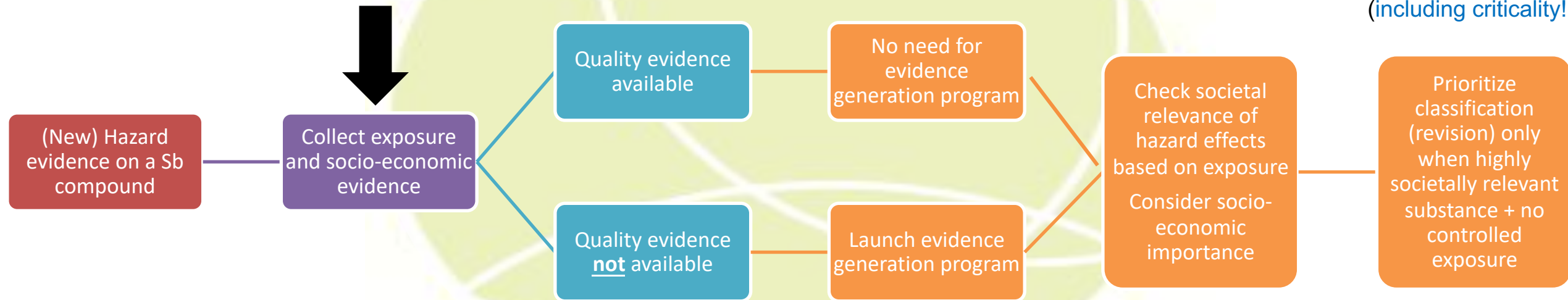


Decisions with context:

Example 1: Revising Sb substance's classification

- Classification is a risk management measure by triggering many costly obligations under other legislation
- Exposure evidence can indicate how relevant the substance is from a risk management decision viewpoint

Societal relevance =
Exposure
+
Socio-economics
(including criticality!)



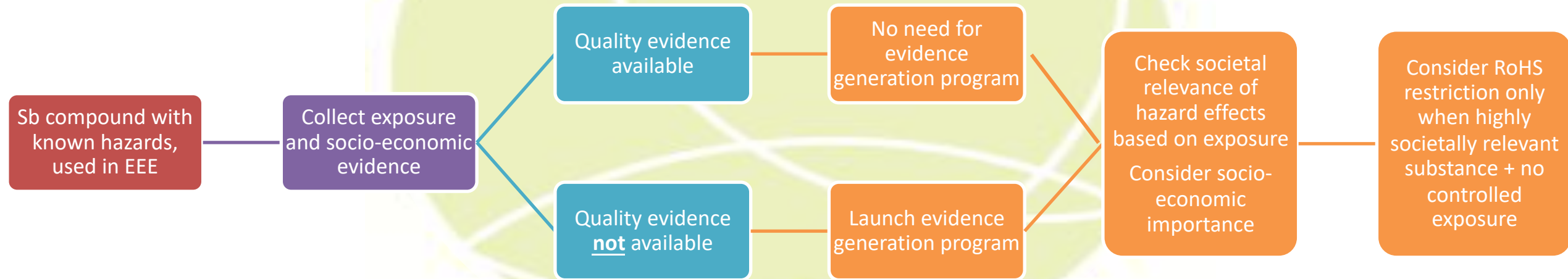
It is worth (re-)establishing the classification of a chemical if there is a demonstrated risk for producers and users, and classification can help managing that risk



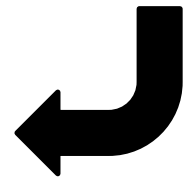
Decisions with context:

Example 2: Restricting an Sb compound under RoHS

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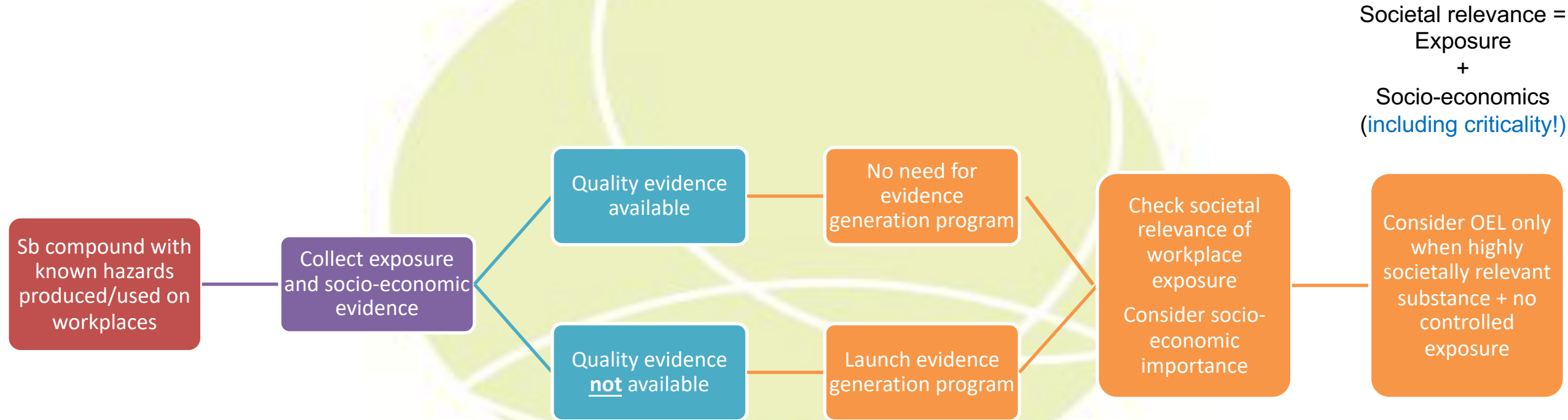


It is worth restricting the use of a chemical if there is a demonstrated risk for producers and users, and a RoHS restriction can help managing that risk

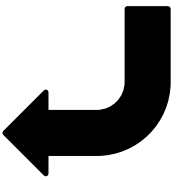


Decisions with context:

Example 3: Establishing an OEL for Sb substances



It is worth establishing an OEL if there is a demonstrated workplace risk for producers and users, and an OEL can help managing that risk





In short:

- ✓ Initiate assessments based on hazard, and **launch generation** of missing evidence
- ✓ **Consider societal importance** of the chemical in any assessment: exposure + socio-economic impacts and benefits (including criticality)
- ✓ Stop comparing chemicals based on hazard only, and **ensure equivalent evidence** is available before benchmarking
- ✓ For CRMs in particular, ensure assessments follow a **coherent order**
- ✓ **Expand the regulatory center** beyond national or regional borders: develop common methods and work together on chemicals of common interest





4. Find out more...



www.antimony.com



International Antimony Association



Antimony_i2a

Yearly Antimony Days



Avenue de Broqueville 12
B-1150 Brussels
BELGIUM

