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CONFLICT AND OPPORTUNITY:
Chemical Management, the Circular Economy & Precious Metals
5 DECEMBER 2018 - BRUSSELS

Substance in Substance: Outcome of the REACHLaw study

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Substance in Substance: Outcome of the REACHLaw study

- Introduction
- Study background and objective
- Key results of the legal study
- Illustrative example: Pb/PbO in the recycling of Precious Metals
- Conclusions and final remarks

Substance in Substance: Outcome of the REACHLaw study

Introduction

- Lead (Pb) is a Circular Economy enabler
  - Lead recovery > Primary sources (EC, 2018)
  - Carrier metal for Precious Metals recycling

- Chemicals Policy, through the inclusion of Lead (and other metals / inorganics fulfilling SVHC properties) in the REACH authorisation process, is a source of possible conflict:
  - Limited potential for substitution
  - Added regulatory burden and uncertainty
  - Legal scope of authorisation, especially: *What is a "substance"?*

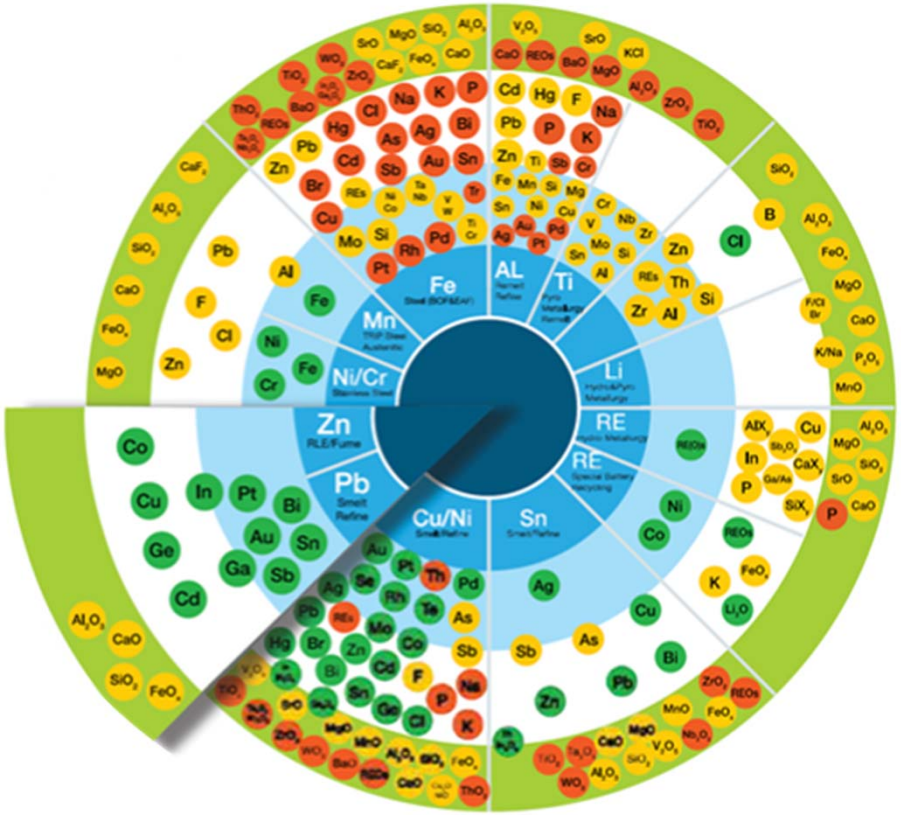

Figure source (based on UNEP 2013 "Metal Wheel"): Lead REACH Consortium, Lead: A key enabler of the circular economy, 2018

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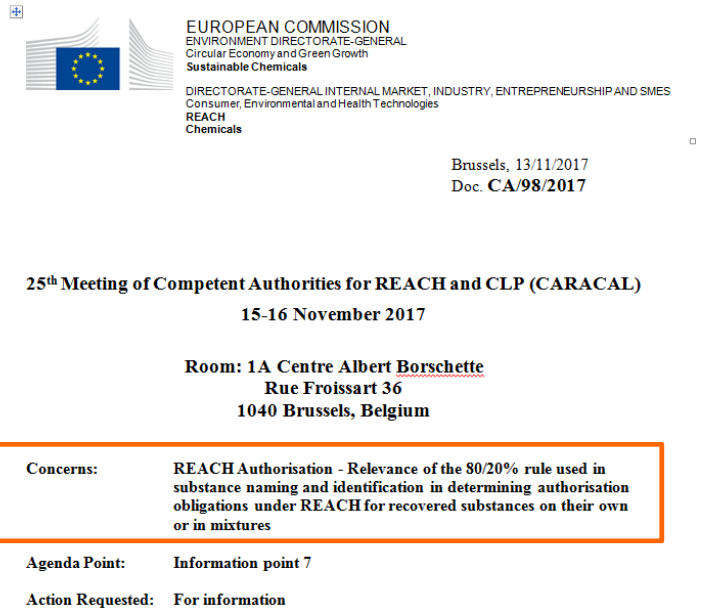
CARACAL paper CA/98/2017: More than the title suggests…



EUROPEAN COMMISSION
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Circular Economy and Green Growth
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DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Consumer, Environmental and Health Technologies
REACH
Chemicals

Brussels, 13/11/2017
Doc. **CA/98/2017**

25th Meeting of Competent Authorities for REACH and CLP (CARACAL)

15-16 November 2017

Room: 1A Centre Albert Borschette
Rue Froissart 36
1040 Brussels, Belgium

Concerns:	**REACH Authorisation - Relevance of the 80/20% rule used in substance naming and identification in determining authorisation obligations under REACH for recovered substances on their own or in mixtures**
Agenda Point:	**Information point 7**
Action Requested:	**For information**

The paper suggests a wide scope of authorisation

- Applies to any substance (incl. impurity and UVCB constituent) in a mixture above Article 56(6) limits, if in Annex XIV → **Substance in Mixture "SiM"** approach
- Annex XIV may cover a substance *"as a constituent of other substances"* → so-called "group entry" using the **Substance in Substance "SiS"** approach
- Possible widening of authorisation scope for recovery

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CARACAL paper CA/98/2017: More than the title suggests…

The paper raises a number of issues

- Multiple authorisation for SVHCs present in primary and recovered metals / inorganics?
- Implications for Risk Management Option Analysis (RMOA) and ECHA priority setting
- Possible conflict with other EU policies like Circular Economy
- **Legal validity** of CARACAL interpretations, esp. ”SiS” and ”SiM”?

Overall study objective

- **To conduct a study to apply a critical *legal* review of the CARACAL position as part of a legal investigation to clarify the status of substances* in substances (“SiS”) or mixtures (“SiM”) from the perspective of authorisation in case the substance* is listed on Annex XIV (i.e. the applicability of the authorisation requirement)**
- **To clarify whether the two options of wider Annex XIV entries raised are valid**
- **Prepared with a view to the metals sector.**

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Article 56(1)(a) defines the legal boundaries of authorisation

"Article 56 - General provisions

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:

(a) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or"

[followed by par. 2-6 with a number of special provisions, e.g. exemptions]

Condition 1: *"Substance included in Annex XIV"*

"Substance" is **legally defined in Article 3(1)**, *"including any impurity"* / **constituent** as its integral legal part; it can be suitably called **"Parent Substance"***, as opposed to its constituents.

Condition 2: *"Use of that substance"*

is legally defined in **Article 3(24)** … almost any activity carried out with a substance as such or in a mixture which could lead to an exposure to that substance. Refers to **"that substance"**, i.e. the Parent Substance according to Article 3(1).

*Note: The ECHA Guidance for Intermediates (Version 2, December 2010, p. 48) uses the term "parent substance" differently, there referring to a precursor substance (other than an intermediate) of its transformation product.

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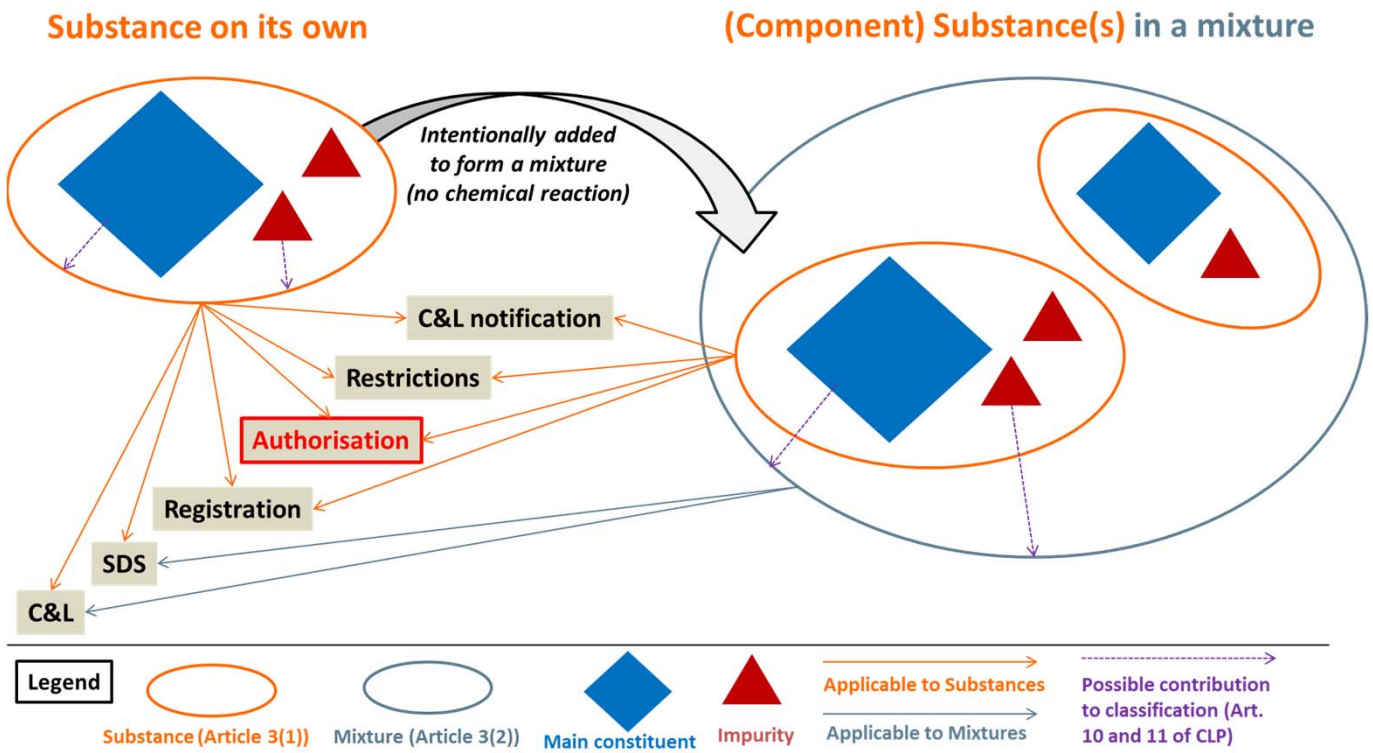
Parent Substance Concept ("PaS")

The regulatory logic pursuant to the **Parent Substance ("PaS") concept** is, that hazardous **constituents** of a substance are to be **regulated via their Parent Substance**. The PaS concept is generally **embodied in the REACH and CLP provisions**, including but not limited to authorisation.

See Figure illustrating the PaS concept for a mono-constituent substance



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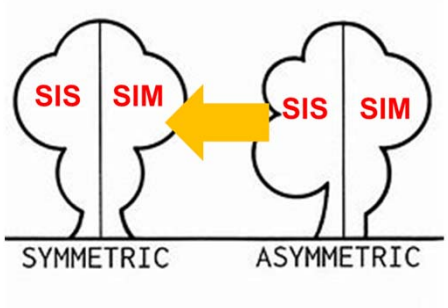
The two proposed options by CARACAL

- Two options to address the *asymmetry*:



1. To include in Annex XIV both the substance and its constituent (e.g. « substance X containing substance Y ») along with a separate entry for substance Y on its own

2. To include in Annex XIV an entry referring to « substance Y on its own or as a constituents of other substances » - group entry - substance in substance approach

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Reasons against the "SiS" approach – CARACAL option 2

- Pursuant to the "PaS" concept (Article 3(1)) it is for the *"other substances"* containing the constituent to fulfil listing requirements, not only the constituent → Non-compliance with the substance identification requirement in Article 58(1)(a) with Section 2 of Annex VI
- Analogy with Restrictions not valid: Restrictions may only address constituents in the "conditions of restriction" - safety net function!
- Far-reaching consequences, e.g. for ECHA priority setting (registration based) and unlimited blockage of future restrictions (Article 58(5))
- Conflict with general principles of EU law: Legal certainty incl. foreseeability; sound administration incl. duty to act diligently; proportionality

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Annex XIV inclusion of the Parent Substance based on its constituent – CARACAL option 1

- **Generally valid from a legal perspective, subject to certain limitations:**
  - ✓ The Parent Substance has to fulfil the SVHC criteria (Article 57) → may be based on the classification of its constituents above the relevant threshold (cf. CLP Article 10)
  - ✓ From a REACH legal standpoint the Candidate List inclusion of the constituent as a substance on its own does not appear to be a legal prerequisite for the identification of the Parent Substance. Also, it should not be included 'as a constituent' (*not the case in option 1*).
  - ✓ The listing of the Parent Substance based on its constituent may not always be the preferred Risk Management Option → highlights the importance of RMOA

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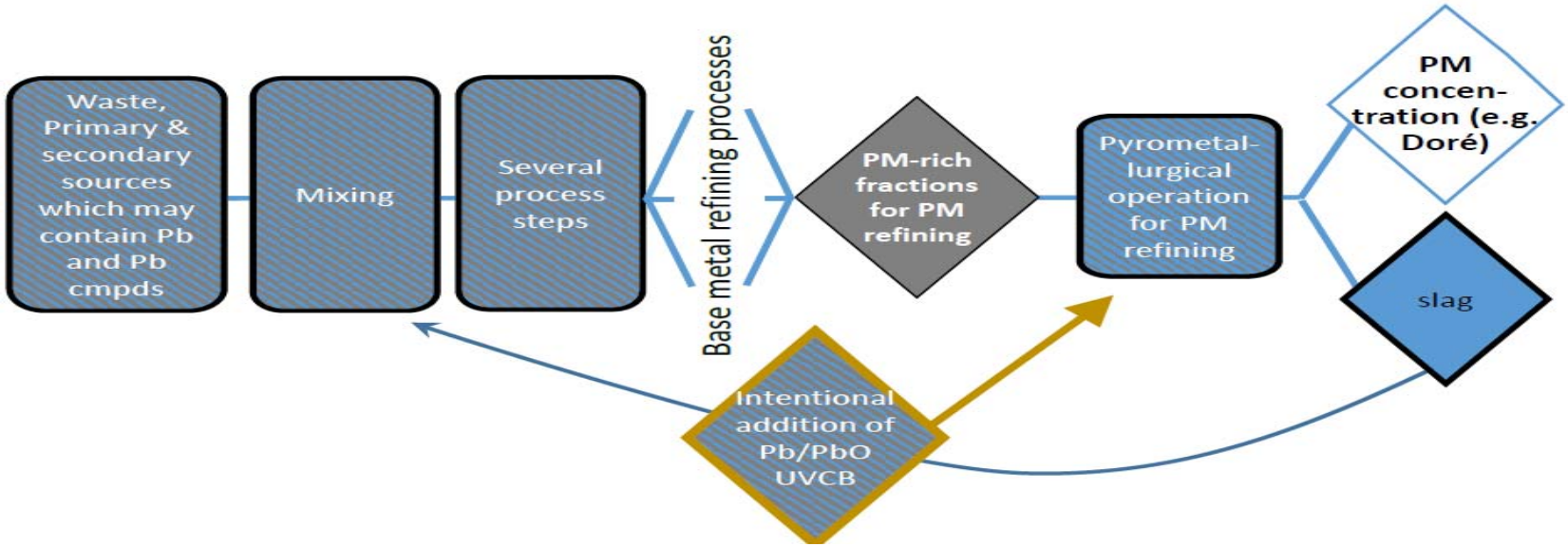
The case of Pb/PbO in Precious Metals recycling

Essential use as a carrier metal

Pb/PbO as UVCB constituent (*as substance only for laboratory use*)



Source: EPMF, 2017

Substance in Substance: Outcome of the REACHLaw study
The case of Pb/PbO in Precious Metals recycling

Parent Substance concept

- Annex XIV listing of Pb/PbO would not cover its presence as a constituent in UVCBs
- Have to identify and list (regulate) the UVCB or find a more suitable RMO, including to ensure coherence with other EU policy objectives

CARACAL position

- SiS: Presence as a constituent in UVCB substances potentially subject to authorisation,
  - ⇒ *if* Annex XIV would follow the SiS approach, i.e. *"Pb on its own or as a constituent of other substances"* (CARACAL option 2)
  - ⇒ *If* Intermediate use is not accepted
  - ⇒ *If* SVHC ≥ Generic / Specific Concentration Limit (CLP Article 10)

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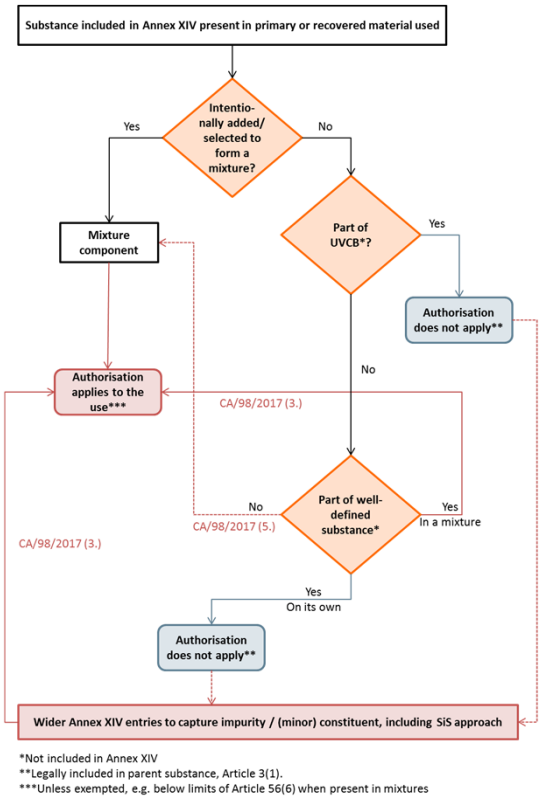
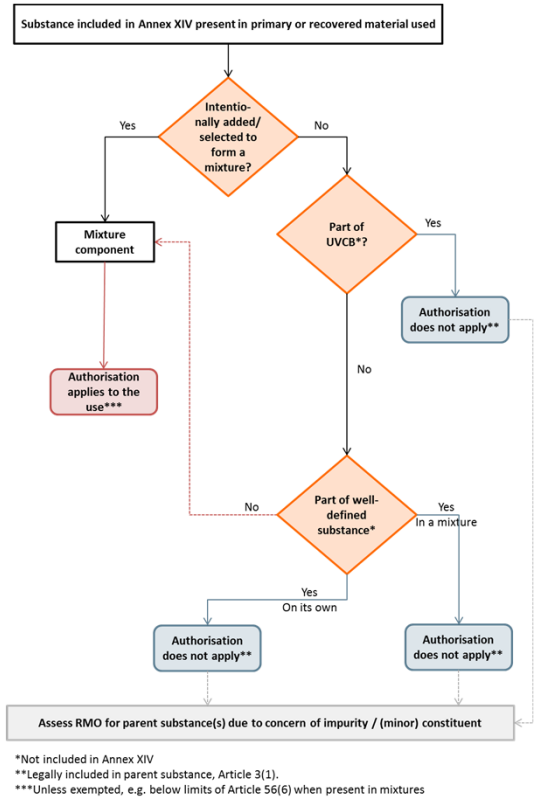
Key conclusions of the legal analysis of the CARACAL position



Summary of CARACAL position



Summary of REACHLaw position

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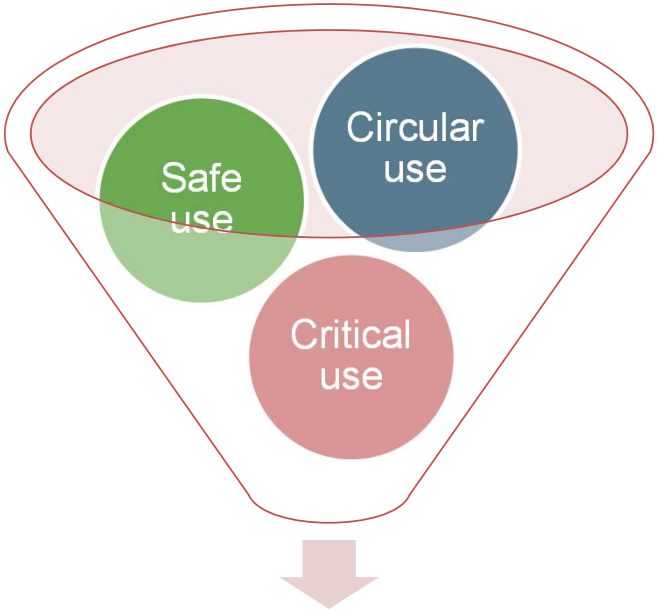
Final remarks

- Example of Pb as carrier material for the recycling of Precious Metals illustrates the possible far-reaching consequences of the CARACAL position, including on Circular Economy objectives

- Adequate RMO is needed

- Consider other options than REACH RMOs as they stand to address perceived safety concerns from SVHCs in recycling to reconcile Chemicals and Circular Economy policy objectives and improve legal certainty at the interface of chemicals, product and waste



Sustainable use

The full study report is available upon request. If interested, please send a mail to EHSAssistant@eurometaux.be

Thank you for your attention!

Questions ?

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List of abbreviations

Abbreviation	Explanation
CARACAL	Competent Authorities for REACH and CLP
CLP	Classification, Labelling and Packaging (Reg. (EC) 1272/2008)
CMR	Carcinogenic, Mutagenic, toxic to Reproduction
CRM	Critical Raw Materials
EC	European Commission
ECHA	European Chemicals Agency
PaS	Parent Substance (as defined in REACH Article 3(1))
RMO(A)	Risk Management Option (Analysis)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Reg. (EC) 1907/2006)
SiM	Substance in Mixture
SiS	Substance in Substance
SVHC	Substances of Very High Concern (as defined in REACH Article 57)

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