Scope of Authorisation

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1. Context: identify possible vulnerabilities regarding scope of authorisation

The EU Commission paper presented on 15-16 November 2017 at CARACAL opens the door for a wider scope of authorisation than has been the case up to now.

In particular, the paper suggests that authorisation may apply to any substance on the authorisation list present in a mixture above 0,1% (incl. as impurity and UVCB constituent) This is called the 'Substance in Mixture' approach (SiM)

Annex XIV may also cover a substance "as a constituent of other substances". This is called a "group entry" using the 'Substance in Substance' approach (SiS).

The CARACAL paper also hints at a possible broadening of the scope of authorisation for recovery.

A broadened scope of authorisation may have serious implications for the PM industry in terms of business impacts, costs and workload for authorisation etc. Regarding the intermediate status of refinables, a significant interpretation exercise has been performed during a workshop with ECHA in 2017.

However considering the SIM/SIS issue will not be settled by **Q3 2019** (possible date of the Public Consultation), it is advisable to revisit the exercise and address possible vulnerabilities, and thus

- Consider all possible regulatory interpretations (SiM, SiS)
- Assess exemptions (lab uses, intermediates)

2. Suggested approach to identify potential scoping issues

a. Data sheets

It is proposed to explore and describe the regulatory status under REACH authorisation of Pb or Pb-containing substances used in the PM processes through a series of data sheets per 'substance' where lead appears. Each data sheet will present:

- the potential interpretation issues,
- the presence of Pb in the substance,
- the role Pb plays (or not),
- the fate of the material and of Pb.

b. Tentative timeline

Q1 2019: Data sheets and overview

Q2 2019 onwards: Internal review and further refinement in function of possible developments (Commission e.g.).