



Use of RCR in PM Consortium Refinables Project

Draft for discussion with other metals consortia under umbrella of EM
16 December 2011

In follow-up of the 16 December 2011 Eurométaux SCC meeting, the Precious Metals and Rhenium Consortium (PMC) volunteered to document how it intends to use Risk Characterisation Ratio (RCR) in both updates and upgrades of UVCB intermediate registration files submitted in 2010.

This document summarises such use and invites other metal consortia and Eurométaux experts to brainstorm, correct or complete the proposed approach.

Generally

RCR is calculated for human health and the environment as follows:

- HH: modelled or site-specific monitored exposure data is compared with DNELs
- ENV: modelled or site-specific measured emission data is compared with PNECs

How the RCR would be derived

Whether it is used for updates or upgrades, the difficulty is in deriving an RCR for the UVCB intermediate as such. Indeed, available exposure and effects data is for the constituents of the intermediate and not for the intermediate as such. How to read-across or extrapolate from the constituent to the refinable in a reasonable and scientifically robust manner?

Decisive DNEL- and MECLAS- like principles could be used to derive an RCR for the constituent of the UVCB intermediate driving the risk (exposure and effects-based). Since this RCR would consider the worst constituent for a given endpoint, it would be protective for all other constituents and hence useable for the full UVCB intermediate.

How RCR would be used for UPDATES

- ✓ RCR is used as qualitative supporting evidence of compliance with Strictly Controlled Conditions (SCC).
- ✓ Although authorities do not propose a fixed RCR level under which residual exposure or emissions can be demonstrated to be negligible and considered as validating or confirming SCC compliance, exposure and emission data can be used to demonstrate the efficiency of the rigorous containment.
- ✓ The use of this exposure and emission data seems unclear however: should this exposure data be compared to OEL and ELV? To DNEL and PNEC? What ratio should there be between the data and the used references?
- ✓ PMC expects (local) authorities will only accept significantly low RCR levels, assumed to be in the order of < 0,1 in the context of SCC validation.
- ✓ The legal entity-specific RCR would be kept by each legal entity with the information demonstrating SCC in-house (as per Appendix 2 of Dec 2010 ECHA Guidance on intermediates) and used as supporting evidence of SCC compliance upon request by (local) authorities.

How RCR would be used for UPGRADES

- ✓ RCR is used in CSR to demonstrate safe use in registration dossier in IUCLID 5.