



SUMMARY

Classification

- ✓ PMC Members agreed to replace the existing pick-lists in some of the Registration Dossiers by the classification profiles derived by ARCHE by cluster analysis
- ✓ ARCHE will review all classification profiles of all Refinables to update them in light of the 2nd ATP to CLP (changes in sensitization categories and M-factors for Ag)
- ✓ ARCHE will prepare an overview of all updated classifications per Refinable for approval by PMC Members
- ✓ Once approved, WCA will update all IUCLID 5 files of all Refinables for re-submission to ECHA by LR and implementation by all concerned companies before Dec 2012

EM advocacy on SCC with ECHA

- ✓ Despite the recent feed-back from ECHA, PMC Members agreed to give the on-going advocacy programme by EM a chance to deliver before quitting on it
- ✓ Once ECHA feed-back is available (by end Mar/mid-Apr 2012), PMC Members will be informed and invited to run RiCoG formally in order to confirm the Refinables for which they can and cannot demonstrate RiCo based on RiCoG and expert judgment
- ✓ A first PMC survey shall be circulated at that time to collect Members' feed-back on Refinables/process steps where RiCo can be demonstrated and those where further (exposure assessment) work is needed

Exposure assessment for RiCo demonstration

- ✓ For those Refinables for which RiCo cannot be demonstrated with RiCoG and expert judgement, an exposure assessment will be run
- ✓ Following the assessment of exposure data, RCR will be calculated as a means to demonstrate as part of a larger weight of evidence approach, whether the (residual) exposure is significantly higher or lower than the relevant DNEL or OEL, or PNEC
- ✓ In order to run the exposure assessment and calculate the RCR, the DNEL or OEL, and PNEC of all constituents are necessary. Once they are available the driving constituents will be identified (using MeClas and/or Decisive DNEL) and the RCR calculated for these constituents in particular

Updates vs Upgrades

- ✓ A second PMC survey will be circulated to collect Members' feed-back on Refinables where SCC compliance can be demonstrated and those where upgrading of the files is necessary
- ✓ If SCC cannot be demonstrated for all streams covered in the same Registration Dossier by a given registrant for the entire life-cycle and supply chain of the Refinable (by RiCoG, exposure assessment and expert judgment), upgrades will be required
- ✓ Upgrades may also be requested by registrants by business decision; PMC will list all aspects which can be considered in making this decision
- ✓ For some Refinables both update and upgrade information may be necessary (some Members may claim SCC compliance for one Refinable where others would not)
- ✓ Appendix 2 and 3 will be prepared by the companies needing an update only (with minor supervision by PMC secretariat). An Appendix 3 representative of all companies being able to demonstrate SCC will be extracted from this by PMC secretariat, to be submitted by the LR.
- ✓ REACH information requirements for upgrades will be prepared by PMC following an approach agreed by EM and ECHA



Chaired by PMC secretariat

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- ✓ Whether an update or an upgrade is required, the intermediate (i.e. undergoing a chemical modification based on the EM/EUromines factsheet on chemical modification) and UVCB (large variability in composition) status of each Refinable will be documented (by detailing the description of each intermediate and the processes they undergo, and using the results of the cluster analysis performed by ARCHE) and attached to each relevant IUCLID 5 file

Budget and cost-sharing

- ✓ The 2012 budget for the PM Refinables project will be of 250 000 €
- ✓ The cost-sharing of the PM Refinables project will remain unchanged (one share per Member and Refinable)
- ✓ The budget and cost-sharing will be reviewed in the second half of 2012 according to the outcomes of the on-going work on RiCo demonstration and upgrade preparation