Precious Metals & Rhenium Consortium
Brussels, 10 October 2014, 10:00-14:30

PM Refiners Work Group Meeting

1. Welcome & Introduction

Edwin BROEKAERT

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Approval of the Agenda
- Approval of minutes of the last meeting (1 April 2014) – including status of action points

Agenda

1. Welcome and introduction
2. Environmental exposure assessment of PM Refinables
3. Substance identity (SID) of PM Refinables
4. Classification of PM Refinables
5. Future work programme
6. Next steps, AOB, next meetings/calls and closing remarks

Actions (1)

Action	Who?	Status
Substance identification (SID)		
Follow-up registration fee issue for splitted dossiers with ECHA	PMC Sec / EM	Ongoing
Develop decision tree to be used to define Refinable dossier scope / SID including source, process, composition & classification (with the two latter ones serving validation purposes)	PMC Sec; review by PM Ref WG	Ongoing – presentation/discussion today
Check all Refinables using the decision tree and the possibility/need for further splitting	PM Ref WG	
Check if concentration ranges in ID cards cover LE specific composition and inform PMC Sec if concentration ranges have to be enlarged	PM Ref WG	Done
Update analytical methods in ID cards	PMC Sec	
Enter LE specific composition (elemental + speciation if available) in IUCLID section 1.2 so that it matches the analytical information entered in section 1.4	All PM Ref registrants	
Collect updated LE specific compositions to further refine SID (composition + speciation)	PMC Sec	Q4 2014
Perform further speciation analysis where needed	PMC Sec	Q1 2015
Update ID cards and IUCLID files/CSRs following refinement SID	PMC Sec/EBRC/WCA	Q1-Q2 2015
PM Slags CSR: reword section on reason for registering the 2 sub-groups together for this April 2014 version of the registration (i.e. remove reference to fees)	PMC Sec	Done
PM Slags dossier: split once we have clarity from ECHA regarding procedure/fees	PMC Sec	After AP1
Classification		
Review Doré composition/classification to reflect presence of metallic Pb/Cu	ARCHE	Done
Perform 28d TDP test on Doré to refine the classification	PMC Sec	Q1 2015
Change the formulas in the classification-related compositions into elemental compositions (max of typical) where possible and update IUCLID files	ARCHE	Q4 2014
CSR – generic sections		
Provide input to CSR sections 2.1 (Manufacture) and 2.3 (this will be a manually added section entitled 'Manufacture and use of PM Refinables')	LRs	Done
Merge the PROCs for manufacture/use under SCC and manufacture/use not under SCC	WCA	
Make sure only appropriate PROCs are reported in company-specific IUCLID file	All registrants	
Draft strategy/checklist for next update	PMC Sec with EBRC & WCA	Done – presentation today

Actions (2)

Action	Who?	Status
CSR – human health and occupational sections		
Update DNEL table in generic occupational ES according to status data-sharing agreements	EBRC	Done
Inform EBRC if inconsistencies are found in the company-specific RC tables	All registrants with comp.-spec. ES	
Inform EBRC/the PMC secretariat if new monitoring data are available	All registrants	As appropriate
Attach site-specific occupational ES to the dossier	All registrants with comp.-spec. ES	Done
Provide comments to site-specific occupational ES	Heraeus	
Changes/additions for the next update: • Include additional activity class (AC4) for some companies • Close current data gaps and issue questionnaires if needed • Include additional PROCs (4 and 27b) for some ACs • Correct RC tables where needed • Include additional info on assessment of typical dermal exposure levels in methodology paper • Check OCs and RMMs for Pb • Improve/extend uncertainty analysis and consideration of combined toxicity • Include MvE assessment	EBRC	Q1-Q2 2015
Send statement on MvE assessment to WCA for inclusion in site-specific env. RA	EBRC	Done
Inform EBRC/PMC Sec if additional compounds need to be taken into account for occupational assessment	All registrants	As appropriate
CSR – environmental sections		
Changes/additions for the next update: • Collect waste-water monitoring data for Se, Te, Co, Sn and PGMs to include in env. RA • Collect monitoring data of stack emissions • Improve/extend consideration of combined toxicity	WCA	Q4 2014 – Q1 2015
Add secondary poisoning consideration to SSRAs	WCA	Done
Phys-chem testing		
Follow-up ongoing phys-chem testing	WCA	Done
Check for which substances TDP testing may be needed	PMC Sec	After SID refinement
Have TDP tests conducted at ECTX for Flue dust and other Refinables identified above	WCA	

Actions (3)

Action	Who?	Status
Submission of upgrades		
Finalisation of CSRs and IUCLID files	WCA, EBRC & PMC Sec	Done
Develop guidance for dossier submission	PMC Sec	
Submission of dossier upgrades by LRs	LRs	
Submission of dossier upgrades by co-registrants	Co-registrants	
Once the dossiers have been finalized, review the LoA price to reflect the additional work done since the first submission in 2010	PMC Sec	
After the separate dossiers have been submitted, inform the SIEF, together with the LoA Agreement/price announcement	PMC Sec	Ongoing
Check schedule of dossier updates with other metal consortia for dossiers where the use phase of the ES is in another dossier (e.g. Cu electrolytic slimes & sludges used in the production of Doré) to align update frequency and strive towards parallel updates	PMC Sec with EM	
Update dossiers for Ag and Au electrolytes (SCC intermediates) as needed (for a transported SCC intermediate >1000 tonnes, the data requirements on the substance's intrinsic properties as specified in Annex VII must be included)	PMC Sec with WCA and EBRC	

Content

- Rationale for selection of driving constituents
  - » April 2014 registration and going forward
- Collection of monitoring data for additional constituents
  - » Se, Te, Co, Sn & PGMs
  - » Update of data for other constituents
- Emissions monitoring and exposure assessment going forward

Environmental Exposure Assessment of Refinables

- Environmental exposure assessed on the basis of individual constituents posing greatest risk

➢ 'Driving constituents'

- Assessed each constituent separately with holding statement on future intention to consider mixture toxicity
  - » We will follow approach for assessment of combined toxicity of inorganic UVCB mixtures being developed by Eurometaux

Selection of Driving Constituents – April 2014

- Criteria for selection of driving constituents for environmental exposure assessment
  - » Classified as hazardous to the environment
  - » Availability of PNEC for risk characterisation
  - » Availability of monitoring data to enable exposure assessment
- Ag, As, Cd, Cu, Ni, Pb & Zn considered in 2014 registration upgrades

Selection of Driving Constituents – Future Updates

- Additional constituents met selection criteria - potential risk addressed based on assessment for other constituents with higher tonnage & lower PNEC (e.g. Ag)
- Se, Te, Co, Sn to be added asap based on criteria for driving constituents
- + PGMs
  - » PGMs are not yet registered under REACH
  - » PGM compounds are or will be classified for environmental hazard following generation of test data (many will have low PNECs)

Environmental Exposure Questionnaire (again!)

- Recent environmental exposure questionnaire
  - Tonnages (⟶ update with recent values)
  - Emissions data (waste water and air) for the full list of driving constituents

➢ Ag, As, Cd, Co, Cu, Ni, Pb, Pd, Pt, Rh, Ru, Se, Sn, Te & Zn

- Please provide <u>all</u> available emissions data on the driving constituents present in refinables at your site

Environmental Exposure Questionnaire

- Need waste-water monitoring data for Se, Te, Co & Sn and PGMs (not requested previously)
  - » Also update emission data for other constituents (previously collected in 2011)
- Stack emissions to air for full list of constituents (very little provided previously)

➢ Additional exposure monitoring required where data not currently available

- » Waste water emissions for exposure assessment of aquatic environment
- » Measurement of stack emissions to inform risk assessment of man via the environment (MvE)

Refinables Process Emissions Monitoring Data

- Existing data provided for PGMs emissions can be transferred to refinables to avoid duplication of effort
  - » Emissions data for PGMs (Pd, Pt, Rh & Ru)
  - » Characteristics of receiving water environment (flow rate, dilution etc.)
- Exposure data welcomed from all companies, even if they haven't provided any previously

➢ Generation of exposure scenarios to represent whole sector

Environmental Exposure Assessment – Next Steps

- Compilation of emission data from questionnaires for full set of driving constituents
- Access to exposure modelling parameter values for additional driving constituents
- Generation of revised GES
- Updated site specific risk assessments (SSRAs)

3. Substance identity (SID) of PM Refinables

Katrien ARIJS

3.1. Further information from ECHA

- No feedback on dossier upgrades so far
- ECHA/EM call of 4 April to discuss SID:
  - ECHA specifically requested to discuss 4 PM examples: matte, slimes & sludges, residues from cementation and reduction, and flue dust
  - ECHA was satisfied with the explanations provided on variability for matte, residues, and flue dust
  - For **slimes and sludges** ECHA spontaneously asked why we had grouped slimes from electrolysis processes with sludges from hydro-metallurgical processes
    - In the BRef these are described as hydro-metallurgical processes overall
    - Existing EINECS entry groups slimes and sludges (but: we have generated new, separated entries for other Refinables like the electrolytes…)
    - **ECHA stated electrolysis is a separate process justifying separate UVCB registrations**
  - ECHA insisted that the variability of each Refinable, and possible approaches to decreasing the variability by splitting would need to be described in detail in each CSR
    - Done by PMC secretariat + check by LRs
    - Now: further refine using SID decision tree to prepare for further questions from/discussion with ECHA

ECHA service to change identifiers

- **New service ECHA**: registrants can **change the EC number** in their registration if the substance has been incorrectly identified
  - New EC number can only refine the identity of the substance initially concerned (cannot correspond to totally different substance)
  - 'Administrative' fee (min. 445 € / registrant requiring correction)
  - ECHA encourages companies to use the service before a compliance check is done
- For joint registration: LR to submit **joint submission plan**
- Action 30 June Ref WG call: PMC Sec to start preparing a joint submission plan for PM slags once further clarification is received from EM/ECHA.
  - ECHA website still mentions '*More information about the service will be available on ECHA's website in the near future*'
  - EM suggested we contact Mike Rasenberg (Head of Unit Computational Assessment & Dissemination) rather than going through the ECHA helpdesk
- Finalise SID check and then contact ECHA before next update of dossiers?

ECHA SCC guide

New practical guide 16 released by ECHA

- "How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID"
- http://echa.europa.eu/documents/10162/13655/pg16_intermediate_registration_en.pdf
- EM has identified possible differences / similarities with the ECHA guidance on intermediates published in 2010 (cf. EM assessment background doc): conditions to meet SCC have not changed: REACH Articles 17 and 18 remain key

ECHA Substance Identification and Sameness Workshop 6-7 Oct (1)

- Focus on SID and substance sameness of UVCB
- ± 60 participants: 1/3 MSCA, 1/3 stakeholders and 1/3 ECHA staff
- Presentations from ECHA, MSCA and industry (chemical, petroleum, metal) + discussion in breakout groups (different industry groups) on how to assess sameness of UVCBs
- EM was asked to present their view on substance sameness at the workshop:
  - Presentation prepared by Katia Lacasse, Violaine and Katrien (sent to Ref WG on 15 Sep)
  - (Fictitious) metals UVCB case presented at break-out session

ECHA Substance Identification and Sameness Workshop 6-7 Oct (2)

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UVCB substances – EINECS inconsistencies

- EINECS was not required to consist of a list of single substances
- The limits of EINECS for the identification of substances covered by the inventory has been recognised

Guidance on substance identification
"It is important to note that for some EINECS entries, the description of a substance is relatively broad and could potentially be considered to cover more than one substance"

CARACAL paper on Q&A regarding the role of EINECS (2010)
"One EINECS entry may also correspond to several substances or several EINECS entries may correspond to one and the same substance"
"In case of doubt, it is recommended to share data as widely as possible [...] and, at the same time, to interpret the substance definition narrowly"

- Recital 45 indicates that multiples substances may be covered by the same EINECS entry
- Uncertainties on substance sameness still to be resolved regardless of whether a substance is covered by EINECS or not!

ECHA Substance Identification and Sameness Workshop 6-7 Oct (3)

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Proposed substance sameness criteria

1) Identify the parameter(s), if any, allowing a structural representation of the substance
2) Identify any additional necessary parameter(s) necessary to represent the substance by the reaction scheme
3) Identify any additional necessary parameters necessary to represent the substance by the process

The combination of these parameters set the criteria for substance sameness

ECHA Substance Identification and Sameness Workshop 6-7 Oct (4)

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Structural representation

- Starting point: structural representation of well-defined substances
  - Achieved by the "80% rules"
    - 80% rule (mono-): No need to go beyond representing 80% of the composition of a substance
    - 80-10% rule (multi-): When it is not possible to define 80% of the composition by a unique structural depiction, a structural (qualitative) representation of the composition based on the identity of the main constituents is considered
- The structural depiction of well-defined substances is normally sufficient to determine if substances can be registered together
  - Same structural depiction → substances can be registered together
  - Different structural depiction → substances cannot be registered together

ECHA Substance Identification and Sameness Workshop 6-7 Oct (5)

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UVCB substance depicted as the output of a process

- According to the EINECS reporting rules, the depiction essentially consists of
  - Identity of the precursors
  - Technology
  - 'typical' composition
- Outputs from processes relying on different sources or process technologies would in principle not refer to the same substance
- 'Typical' composition is taken care of at the level of the structural depiction according to the proposed methodology

ECHA Substance Identification and Sameness Workshop 6-7 Oct (6)

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Note on the depiction of the technology

- The depiction must be proportionate
  - Different process parameters (e.g. reaction temperature 100°C vs. 120°C, pressure) do not necessarily mean that the technology depiction will be different
- If the inherent variability does not allow the definition of a technology parameter, such parameter should not be used as a substance sameness criteria
  - Example: identity of secondary sources

→ Focus on the parameters that matter!

→ Definitions of EINECS-listed UVCB substances as a reference for the technology depiction

ECHA Substance Identification and Sameness Workshop 6-7 Oct (7)

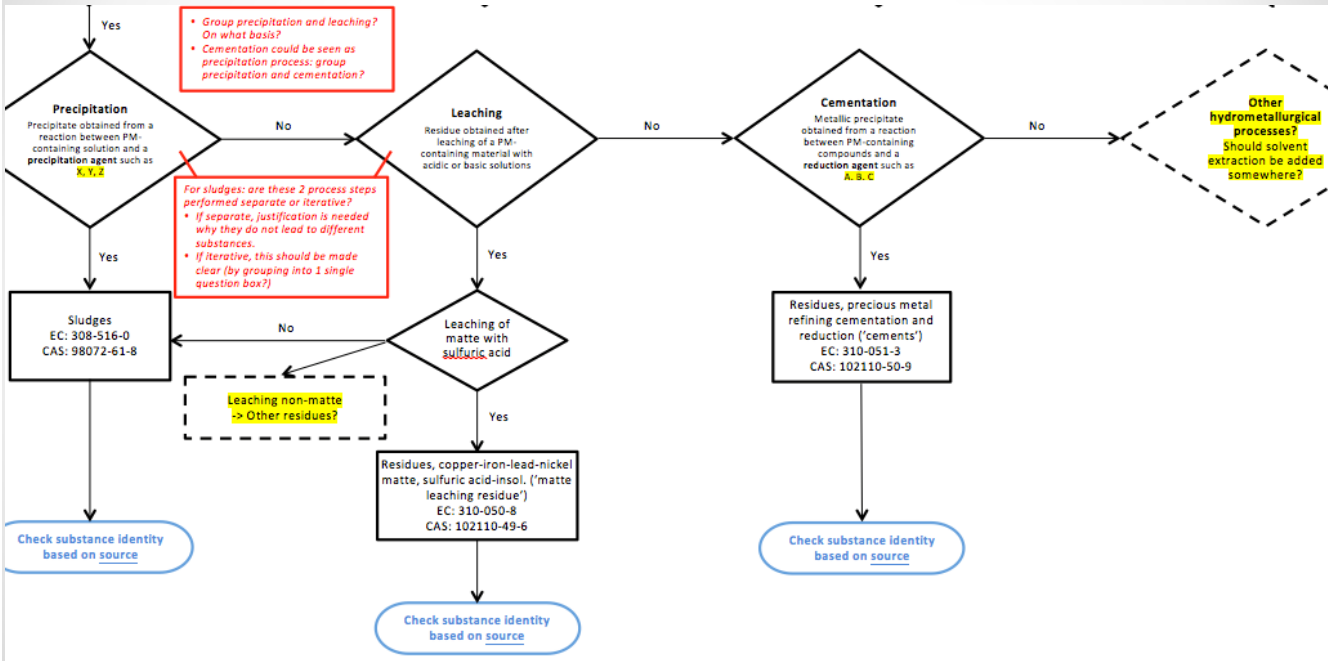
Key messages:

- Both the different industry sectors and the MSCA are still struggling with SID of UVCBs.
- There was general support to explore the applicability of the proposed 3-step sameness methodology (structural representation/reaction scheme/process output) further, but there were still quite some questions on how it will work in practice. ECHA doesn't have answers to all these questions and recognises there will always be a 'grey zone' for SID of UVCBs.
- In the 'grey zone', after using the proposed methodology, it is important to **make the argumentation that the chosen SID approach is sound**.
- Some informal feedback from our break-out session: ECHA does not expect us to revise our SID approach completely but thinks some further work is needed from industry's side to rationalise and document our approach so that it is transparent.

3.2. UVCB identification rules: decision tree for SID (1)

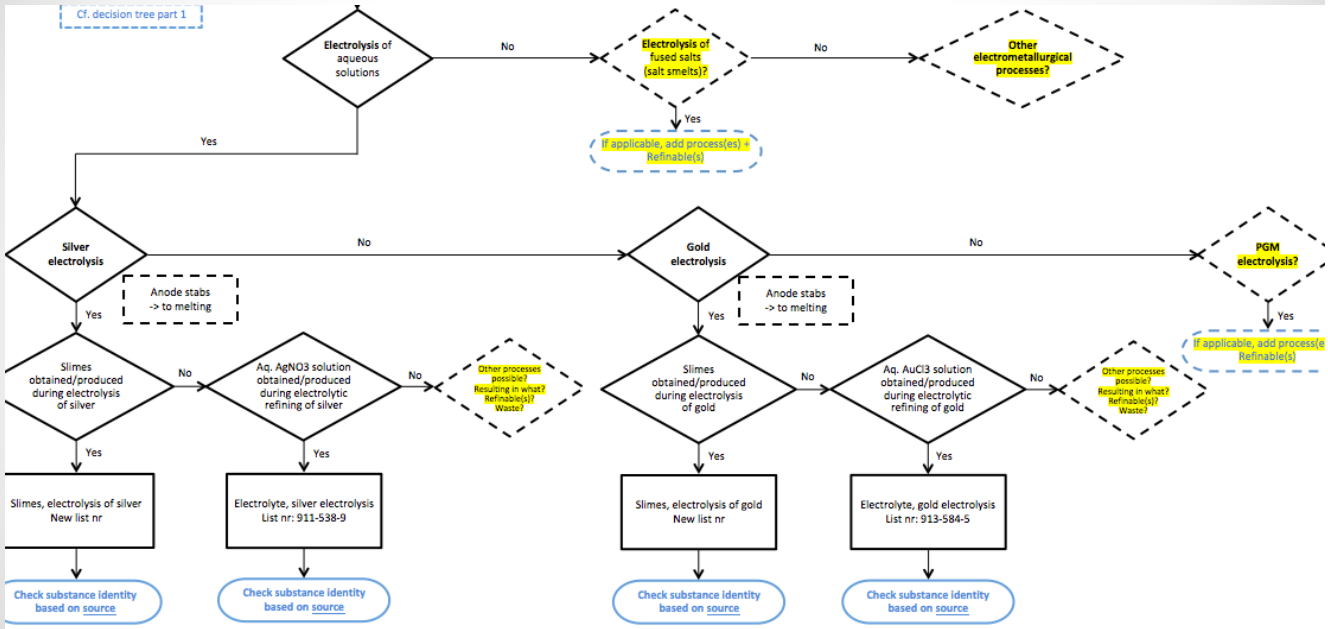
- New version of decision tree circulated: 'try-out' of the previous decision tree on all Refinables, mentions the Refinables per process
- Consists of 4 parts with references to the various parts as applicable
- Processes are split in hydro-, electro- and pyro-metallurgical processes (part 1-3). **Other processes in PM refining?**
- Part 4: SID checked for all Refinables based on the source -> SID validation step rather than an SID determination step (justification why we are grouping several sources for the same Refinable)

Decision tree: Hydro-metallurgical processes

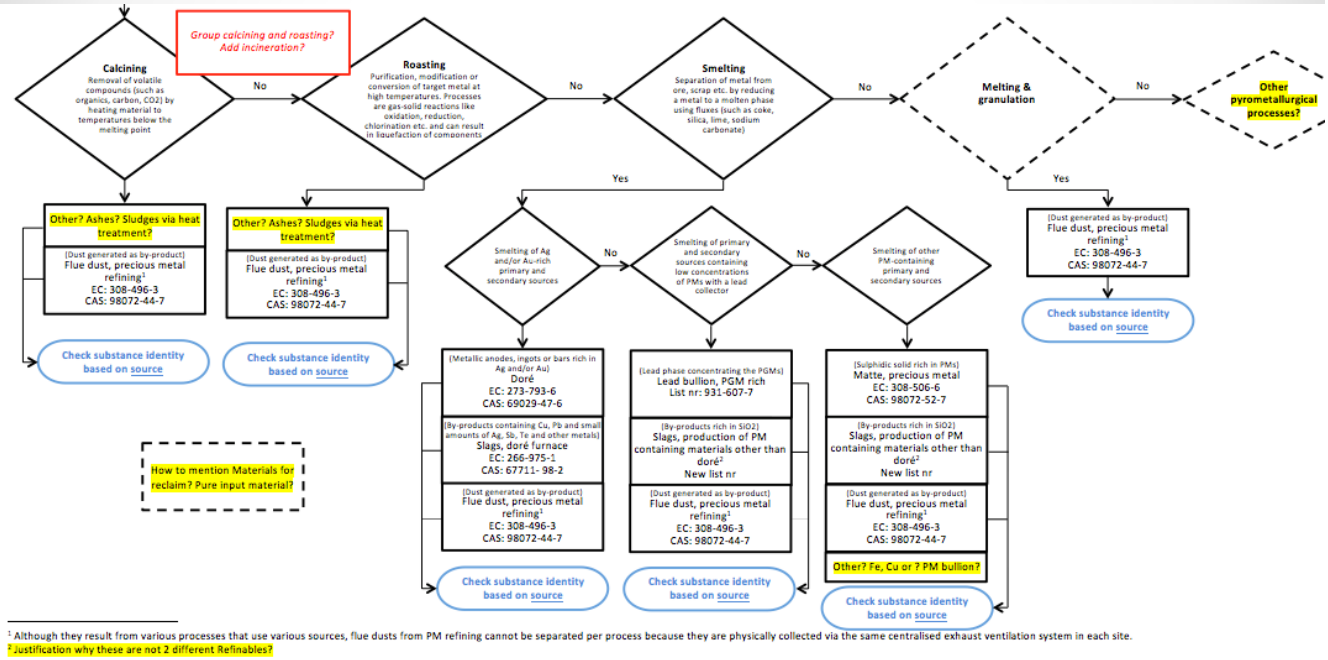


Can precipitation, leaching or cementation of PM-containing materials lead to other substances than the ones mentioned here? If so, what is its name and where does it go? Waste for discarding? Concentrated PMs for further refining?

Decision tree: Electro-metallurgical processes



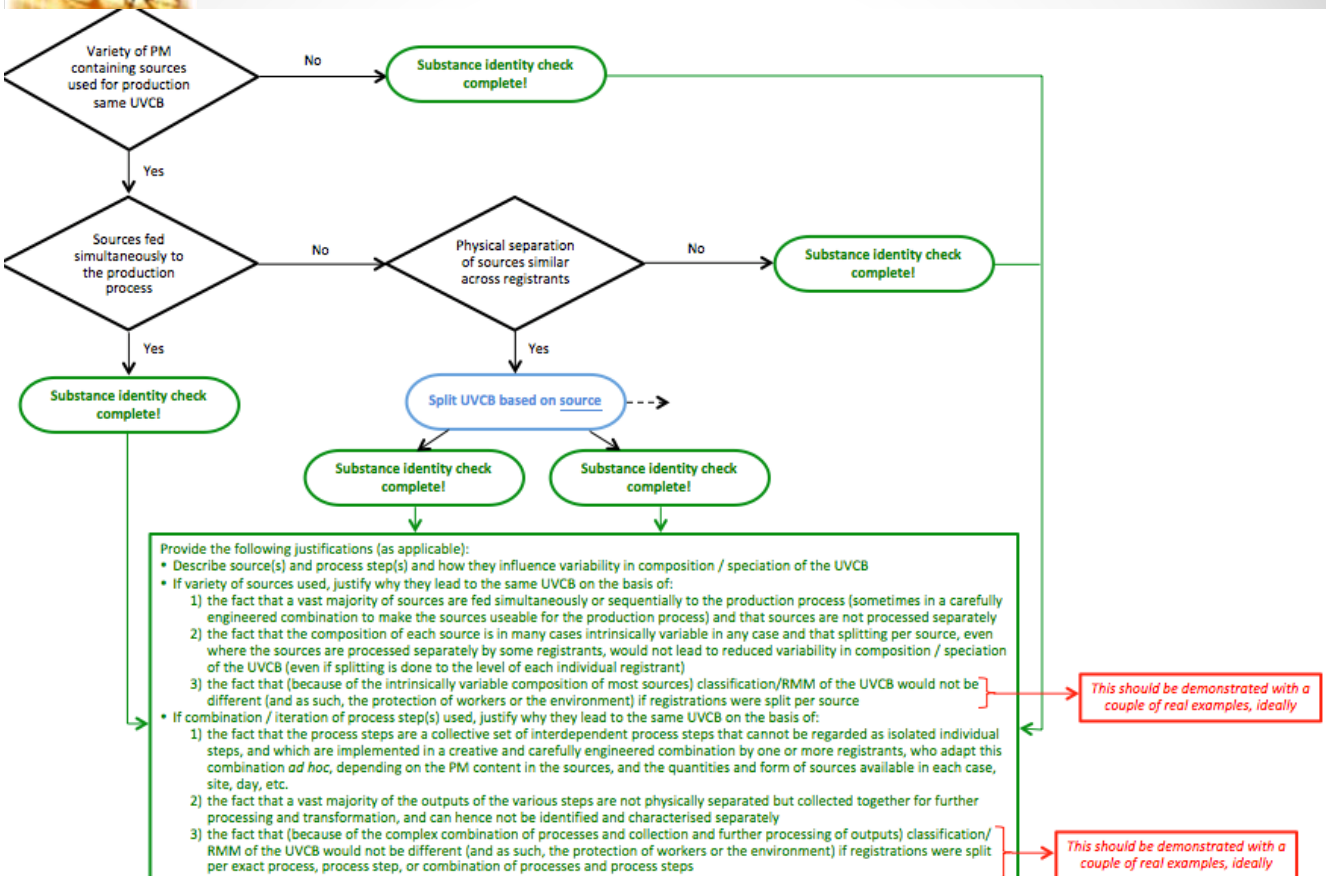
Decision tree: Pyro-metallurgical processes



[1] Although they result from various processes that use various sources, flue dusts from PM refining cannot be separated per process because they are physically collected via the same centralised exhaust ventilation system in each site.

[2] Justification why these are not 2 different Refinables?

Decision tree: Sources



3.3. Way forward

- Further commenting round needed for SID decision tree?
- Deadline?

4. Classification of PM Refinables

Katrien ARIJS

4.1. Collection updated LE specific compositions

- Will be done Q4 2014
- Current data are from 2009-2011 (except for slags and slimes & sludges)
- Good data for some companies, others only provided composition up to 20%

4.2. Revision of classification-related compositions

For the purpose of classification, the compositions of the PM Refinable clusters are defined by means of formulas

-> agreed at last Ref WG meeting to change these formulas into elemental compositions (max of typical) where possible for next update

Tasks:

- Collect updated compositions from members
- Enter into MeClas and derive classifications
- Group samples per classification and derive composition ranges per classification

5. Future work programme

Katrien ARIJS

5.1. Action list & timing for next update (1)

	Action	Who?	Timeline
Substance identification (SID)			
1.	Collect updated LE specific compositions to further refine SID (composition + speciation)	PMC Sec	Q4 2014
2.	Refinement SID / finalization SID decision tree	PMC Sec	Q4 2014
3.	Perform further speciation analysis where needed	PMC Sec	Q1 2015
4.	Update ID cards and IUCLID files/CSRs following refinement SID	PMC Sec/EBRC/WCA	Q1/Q2 2015
Classification			
5.	Perform 28d TDP test on Doré to refine the classification	PMC Sec	Q1 2015
6.	Change the formulas in the classification-related compositions into elemental compositions (max of typical) where possible and update IUCLID files	ARCHE	Q4 2014
CSR - human health and occupational sections			
7.	Inform EBRC/the PMC secretariat if new monitoring data are available	All registrants	As appropriate
8.	Inform EBRC/the PMC secretariat if additional compounds need to be taken into account for occupational assessment	All registrants	As appropriate
9.	Changes/additions for the next update: • Suggest monitoring campaign to overcome weaknesses in current data base (i.e. suggest workplaces/activity classes) • Include additional activity class (AC4) for some companies • Close current data gaps (data access, exposure estimates, DNELs) and issue questionnaires if needed (e.g. species refinement) where missing information becomes available • Include additional PROCs (4 and 27b) for some ACs • Editorial/language/content improvements of ES documents (methodology and assessment part) • Include company-specific refinements where requested (i.e. base assessment on individual company data sets instead basing on sector data base for data owning companies) • Include additional information on assessment of typical dermal exposure levels in methodology paper • Include organisational measures as suggested in Pb dossier • Improve/extend uncertainty analysis • Improve/extend consideration of combined toxicity • Develop ES for SCC companies (as requested by the companies) • Include MvE assessment • (Editorial) error corrections and inclusion/reflection of additional information in IUCLID files/CSRs	EBRC	Q1 2015 for editorial and textual updates Q2 2015 for revision and update of monitoring data base

Action list & timing for next update (2)

CSR - environmental sections			
10.	Changes/additions for the next update: • Collect waste-water monitoring data for Se, Te, Co, Sn and PGMs to include in environmental risk assessment • Collect monitoring data of stack emissions • Improve/extend consideration of combined toxicity in line with the approach for UVCBs developed by Eurométaux • (Editorial) error corrections and inclusion/reflection of additional information in IUCLID files/CSRs	WCA	Q4 2014 - Q1 2015
Phys-chem testing			
11.	Check for which substances TDP testing may be needed	PMC Sec	After AP2
12.	Have TDP tests conducted at ECTX for Flue dust and other Refinables identified in AP11	WCA	After AP11
Updates			
13.	Update dossiers for Ag and Au electrolytes (SCC intermediates) as needed (for a transported SCC intermediate >1000 tonnes, the data requirements on the substance's intrinsic properties as specified in Annex VII must be included)	PMC Sec with WCA and EBRC	Q4 2014 - Q1 2015
14.	Finalisation of updates CSRs and IUCLID files	WCA, EBRC & PMC Sec	By end Q2 2015
15.	Produce generic (e-)MSDS contents	WCA	Q4 2014 - Q1 2015

Suggested timing: next update by Summer 2015

5.2. Project plan (1)

- As requested by the PMC Assembly in Bern (12 June 2014), and in order to have a basis from which consultants will be able to produce working proposals and invoice PMC, a project plan for the Refinables project has been developed.
- The project plan is entirely for the 'upgrade' registration programme, starting in 2011.
- Currently Excel version, will be imported into MS Project and will be circulated to the WG for approval.

Project plan (2)

- Phase 0 - Appointment of Consultant (CON)
- Phase 1 - Project (re-)scoping
- Phase 2 - Substance identification and characterisation
- Phase 3 - Effects assessment and classification (CLP + CLP ATP)
  - 3A - Physico-chemical properties
  - 3B - Human Health (HH)
  - 3C - Environment (ENV)
- Phase 4 - Exposure and risk assessment
  - 4A - Human Health
  - 4B – Environment
  - 4C - CSR and Annexes
- Phase 5 - Compilation of IUCLID 5 file & Registration Dossiers
- **Phase 6 - Post-registration work**
- Project Management

5.3. Budget update (1)

	(A) 2014 Budget*	(B) 2014 Spent by 31.08.14	Difference (A) - (B) = Reserves by 31.08.14
Refinables	612.064 €	307.876 €	304.188 €

* sold LoA (21.000 €) + use of the reserves as incomes (591.064 €)

Remaining costs for 2014: ?

- EBRC and WCA preparing proposal for remaining work by end October
- Some costs still anticipated in 2014 but no more than 10% of 2014 expenditures to date

Budget update (2)

Total Ref-specific costs under PMC (2010-2014)	Minimum reserve (7,5 % of total Ref)
1.501.156 €	112.587 €

Year(s)	Basis	Estimated budget/year
2015	SID refinement, validation testing, reducing uncertainties, etc.	366.300 €
2016-2018	= 50% of 2015	~ 175.000 €
2019	Assumes work finalised	0 €? Credit Members back?
2020	Assumes work finalised	0 €

	(A) Total Ref-specific reserves	(B) Remaining Ref-specific costs 2014	(C) Ref-specific costs 2015-2020	(D) Minimum reserve to be retained in-house	Delta (A) - [(B) + (C) + (D)]
Presented at June Plenary meeting	591.064 €		~ 175.000 €	73.059 €	343.004 €
Update /Correction	304.188 €	~ 30.000 €	~ 891.300 €	112.587 €	-729.699 €

6. Next steps, AOB, next Meetings/Calls & Closing Remarks

Edwin BROEKAERT

AOB, next meetings/calls and closing remarks

- AOB
  - 4 Borates on the Final 6th Recommendation List for REACH Annex XIV;
    - Public consultations (ECHA & COM) period running until Nov 30, 2014
    - PMC Secretariat communication will follow to better scope out the extent of the challenge for the PM sector
    - Response to public consultation left at each company's discretion
    - Secretariat will support by transmitting any information received from EBA and answering general questions on the Public Consultation process
- Appropriate time for next meeting / call:
  - Next meeting: Feb/Mar 2015 to discuss status next update?
  - Calls as needed

Thank you!