Precious Metals & Rhenium Consortium
Brussels, 6 February 2014

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 (5 November 2013) – including status of action points

Agenda

1. Welcome and introduction
2. Update on activities Eurométaux REACH intermediate task force: Feedback from workshop with ECHA on inorganic UVCB assessment
3. PM Refinables – scope, composition, classification
4. Splitting of PM slags and slimes & sludges
5. CSR human health and occupational sections
6. CSR environmental sections
7. CSR generic and other sections
8. Timing of submission upgraded PM Refinables dossiers
9. Next steps, AOB, next meetings/calls and closing remarks

Actions (1)

Action	Who?	Status
Classification		
Produce and distribute guidelines to ensure a consistent completion of IUCLID 5 files, including classification information, by all inorganic UVCB Registrants	EM	Ongoing
Review classifications of the PM Refinables and submit updated classifications if necessary	ARCHE/LRs	Ongoing
Substance identification		
Check correlation previously identified classification clusters and newly identified sub-groups	PMC Sec/ARCHE	Ongoing
Produce two new ID Cards for slags and circulate for comment/finalization	PMC Sec	Ongoing
Once the scope of each registration is agreed upon, inform EBRC and WCA, identify and launch the phys-chem testing needs, and produce separate registration dossiers	PMC Sec/EBRC & WCA	Ongoing
Once dossiers finalized, review LoA price to reflect additional work done since first submission in 2010	PMC Sec	Q2 2014
After separate dossiers submitted, inform SIEF, together with LoA Agreement/price announcement	PMC Sec	Q2 2014
Circulate 5 sub-groups for slimes & sludges to PM Ref WG so they can re-assign their slimes & sludges	PMC Sec	Done
Re-assign their slimes & sludges to proposed sub-groups	PM Ref WG	
Determine the composition/classification boundaries of the slimes & sludges sub-groups	PMC Sec/ARCHE	
Discuss outcome slimes & sludges splitting exercise and decide on registration strategy	PM Ref WG	To discuss today
Check source and process information currently in ID cards for all Refinables	PMC Sec	Ongoing
CSR HH and occupational sections		
Confirm gender of workers for which blood levels have been reported	EBRC	Done
Review/comment draft methodology section for Section 9 of the CSR (cf. Annex 5.1)	PM Ref WG	
Produce 1st draft company-specific ES and distribute to relevant companies for comment	EBRC	
Review/comment 1st draft company-specific ES	PM Ref WG	
Produce 2nd draft company-specific ES and distribute to relevant companies for finalization	EBRC	By 17 Feb 2014
Review/comment 2nd draft company-specific ES	PM Ref WG	By 3 Mar 2014
Produce final draft company-specific ES	EBRC	By Mid Mar 2014
Finalise mapping exercise and check approach is consistent across consortia	PMC Sec	Ongoing
Decide on best approach for the ES (in general or per company, or Refinable)	PM Ref WG	To discuss today
Discuss need to supply customers with the extended SDS for the Refinables	PMC Sec with other consortia	Q2 2014
Indicate whether info in company-specific ES can be coded and compiled into a unique appendix to the CSR or whether they prefer to submit their ES separately in their individual registration dossier	PM Ref WG	To discuss today
Check speciation assumptions used for MeClas classification and send to EBRC for their information	PMC Sec	Done

Actions (2)

Action	Who?	Status
Send survey on speciation of constituents in Refinables, including a request to specify the level at which exposure control is implemented by companies for constituents where there is no REACH DNEL available	EBRC	Done
Companies to confirm form of relevance in EBRC survey, distinguishing form present in the Refinable versus form present in occupational air to which workers may be exposed during the process	PM Ref WG	
Check whether Hg is present in any Refinable and inform EBRC and WCA accordingly so it can be added to the scope of data needs if relevant	PMC Sec	Done (Hg not present)
Agree on the best way forward regarding predicted data gaps (e.g. qualitative assessment using publicly available OELs, etc.)	PMC Sec with other consortia	Ongoing
CSR Environmental sections		
Finalise generic and site-specific exposure assessment based on information available to date and revert with updated assessment and monitoring recommendations	WCA	Done
Check the CSR of Pb, Zn, Cr, As, Cd and Cu and find a way to refine the generic ES Msafe exercise on the basis of the exposure assessment approach/principles that were used for each metal (e.g. bio-availability correction), as reported in the relevant CSR	WCA	Done
Obtain access to CSR for As, Pb, Cr, and possibly others (tbc by WCA)	PMC Sec with input WCA	Ongoing
Check whether a local indirect exposure via stack emissions ES would be relevant for Refinables	EBRC & WCA	Done
CSR generic and other sections		
Generate CSR template and coordinate LR input into generic segments	PMC Sec	Ongoing
Liaise and agree on how to start completing tox and ecotox general and specific portions of the CSR	EBRC & WCA with PMC Sec	
Phys-chem testing		
Send expert statement on waiving of oxidising properties for flue dust	A. Alderman	Done
Send expert statement on waiving of auto-flammability, flammability, and oxidizing properties and provide granulometry data for Pb bullion	Pb bullion LR	
Provide granulometry data for Materials for reclaim, PM in bricks, crucibles, and trays	Vale	
Contact each LR and check whether they can perform the phys-chem tests in-house / have test data available / have justifications for waivers	PMC Sec	

2. Feedback from ECHA workshop on inorganic UVCB assessment

Refinables WG Meeting

Brussels

06 February 2014

Daniel Vetter
EBRC Consulting
Hannover, Germany

Outline

- Introduction: setting the scene for inorganic UVCBs CSA
- Substance composition, SID, Classification:
  - Main principles
  - Illustration pilot case
- Hazard assessment: environment, human health
  - Main principles
  - Illustration pilot case

Outline

- Exposure assessment: environment, human health
  - Main principles
  - Illustration pilot case
- Risk Characterisation: environment, human health
  - Main principles
  - Illustration pilot case
- Uncertainty analysis
- Combined toxicity

HH hazard assessment: Reporting

- **For effect assessment (threshold derivation)**:
  - **Derivation of DNELs for the UVCB as such is meaningless**
  - Review of the hazard sections of all relevant constituents and assessment (data-sharing via the MMD):
    - On relevant endpoints and exposure routes:
      - Local –systemic, acute- chronic
      - Inhalation – dermal route (if intermediate, used exclusively at the workplace)
      - Hazard for the eye
    - Is there a DNEL or DMEL available?
  - DNEL summaries

How are the U and the V addressed in effect assessment?

Elemental constituent	Speciation constituent	Variability
Known (close to 100%) but variable	Largely known, some unknown	Low to high variability on elemental concentrations Medium variability on speciation concentrations

Solutions:

If unknown, species with worst-case DNEL/PNEC is selected by default (usually expressed as elemental ion)

Considered in exposure assessment

How are the U and the V addressed in exposure assessment?

Elemental constituent	Speciation constituent	Variability
Known (close to 100%) but variable	Largely known, some unknown	Low to high variability on elemental concentrations Medium variability on speciation concentrations

+ additional known metals in workplace/ environmental releases not part of the UVCB

Solutions:

If unknown, species with worst-case DNEL/PNEC is selected by default

Considered in selection of RWC percentile of representative elemental monitoring data

Exposure assessment HH: sources of information

- The assessment for the substance is therefore intrinsically conservative (i.e. precautionary) with respect to legal REACH requirements

  Tools

  - **Modelling tools:** MEASE
  - **Analogous data:** need to include a justification for the extrapolation

- Use of bio-monitoring data for e.g. Pb: bio-monitoring data already reflect uptake through all routes of exposure

Risk characterisation HH: main principles

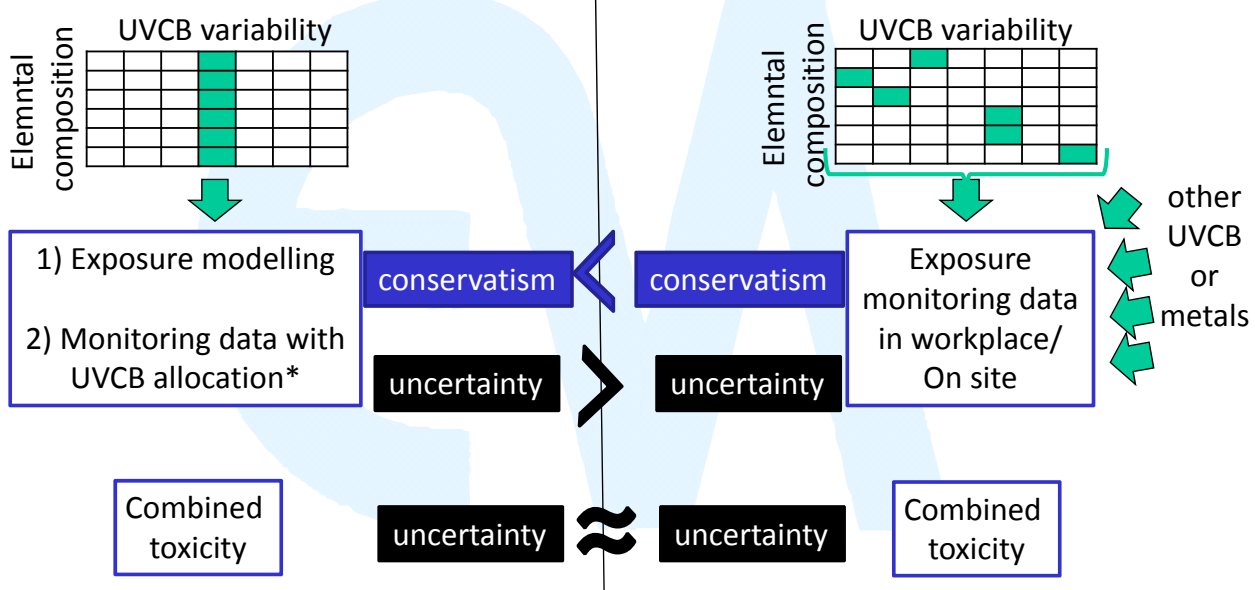
Hazard Conclusion	**Explanation**	**Subsequent Exposure assessment and risk characterisation**
DNEL	When DNEL is available (and data sharing agreement) and relevant exposure is present	Quantitative
	When DNEL is available, e.g.: - at ECHA dissemination website but no data access - and/or no or low exposure, hazard and risk expected	Qualitative assessment of emission and hazard potential
Other threshold (OEL,…)	When no DNEL is available but hazard is identified, relevant exposure is present and alternative threshold is available (e.g. OEL)	Semi-quantitative
Qualitative (no threshold)	When no DNEL is available but hazard is identified (low – medium –high)	Qualitative
No hazard identified	When no hazard	Not needed

Illustration: Cu slime case
Scope of assessment

Route	Type of effect	Cu	Pb	As	Ni	Cd	Sb	H_2SO_4	Se	Sn	Mn	Zn	Te
Inhalation	Systemic Long Term	Not relevant due to internal DNEL	Not relevant due to biomonitoring	SemiQuantitative	Quantitative	Quantitative	Qualitative	Qualitative	Qualitative	Quantitative	Quantitative	Quantitative	Qualita
	Systemic Short term	Quantitative	Qualitative	Qualitative	Quantitative	Qualitative	Qualitative	Qualitative	Qualitative	Quantitative	Qualitative	Qualitative	Qualita
	Local Long Term	SemiQuantitative	Qualitative	Qualitative	Quantitative	Qualitative	Quantitative	Quantitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualita
	Local Short term	Qualitative	Qualitative	Qualitative	Quantitative	Qualitative	Qualitative	Quantitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualita
Dermal	Systemic Long Term	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualita
	Systemic Short term	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualita
	Local Long Term	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualita
	Local Short term	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualita
Internal (biomonitoring)	Systemic Long Term	Quantitative	Quantitative	Semiquantitative	Semiqualitative	Semiquantitative	Not available	Not available	Not available	Not available	Not available	Not available	Not ava
Eye	Qualitative												

Uncertainty analysis: main outcomes
Risk Assessment

- Standard substance approach
- Inorganic UVCB constituent approach/monitoring



* Not common practice

Proposed way forward on **human health** combined toxicity: Tier 0

Tier 0:

- Assess and review literature data: locate/identify existing data for inorganic UVCB constituents:
  - Target organs
  - Information on modes of action

- We could use the sum of RCRs of all constituents as first filter…

Proposed way forward on human health combined toxicity: Tier 1 – non CMR effects

Tier 1 step depends on the endpoint:

- **Acute toxicity** is generally associated with huge margins of safety:
  - Systemic: add RCRs, if threshold available
  - Local: add RCRs, if threshold available, or address via RMMs if peak exposures are expected
- **Sensitising / corrosive / irritating effects** are addressed by considering the applied strict RMMs on a qualitative basis (at the UVCB level)
- **Repeated dose, systemic effects/local effects**:
  - If same target organ: add RCRs
  - Otherwise: no combined toxicity assumed

Proposed way forward on human health combined toxicity: Tier 1 – CMR effects

- **Reproductive effects**
  - ➢ to be summed up
- **Mutagenic effects:**
  - ➢ strict application of RMMs
  - ➢ can only be addressed on a qualitative basis
- **Carcinogenic effects:**
  - ➢ to be summed up by target organ, without distinguishing mode of actions

3. PM Refinables – scope, substance identification, classification

Katrien ARIJS

3.1. Scope

Refinable	Nr of companies	Nr of updates	Nr of upgrades	Highest status	Highest tonnage band
1. Doré	8	4	4	Non-SCC intermediate	≥ 1000
2. Matte, PM Refining	4	0	4	Non-SCC intermediate	100-1000
3.1. Slags, PM Refining - sub-group 1	3	2	1	Non-SCC intermediate	≥ 1000
3.2. Slags, PM Refining - sub-group 2	5	0	5	Non-SCC intermediate	≥ 1000
4. Slimes & sludges, PM Refining	9	3	6	Non-SCC intermediate	≥ 1000
5.1. Matte leaching residues	3	0	3	Non-SCC intermediate	≥ 1000
5.2. Speiss leaching residues	0	-	-	REACH exempt	-
6.1. Ag electrolyte	3	3	0	SCC intermediate	≥ 1000
6.2. Au electrolyte	1	1	0	SCC intermediate	10-100
7. Flue dust, PM Refining	6	1	5	Non-SCC intermediate	100-1000
8. Residues, PM cementation and reduction	8	2	6	Non-SCC intermediate	100-1000
9.1. Materials for reclaim - PM w/ or w/o support	5	0	5	Non-SCC intermediate	100-1000
9.2. Materials for reclaim - PM in bricks, crucibles, trays, etc.	5	0	5	Non-SCC intermediate	100-1000
9.3. Materials for reclaim - PM production by-products	3	0	3	Non-SCC intermediate	100-1000
10. Pb bullion PM Rich	1	0	1	Non-SCC intermediate	10-100

Split?

z12 dossier upgrades

3.2. Composition of PM Refinables (1)

- Composition is reported in IUCLID section 1.2
  - LE specific + Generic composition (+ classification specific compositions if relevant) with LE specific reported first
  - Typical + concentration ranges for all compositions
  - Typical composition should add up to 100%

- Before: concentration ranges in the ID cards based on min of min and max of max of the LE specific compositions, in order to make sure all registrants are covered

3.2. Composition of PM Refinables (2)

- Now: Approach Cu intermediates presented to ECHA:

  - **Legal entity (LE) specific composition = across year(s)**, for each elemental constituent:
    - LE Typical concentration = +/- average concentration
    - LE Minimum concentration
    - LE Maximum concentration (without "outliers")
  - **Generic composition = across industry** (used to derive verified classification), for each elemental constituent:
    - Typical concentration = average of LE typicals
    - Minimum concentration = minimum of LE typicals
    - Maximum concentration = maximum of LE typicals or (generic/specific) concentration limit

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- Suggest to use the same approach to be harmonised

3.2. Composition of PM Refinables (3)

- ID cards are being updated accordingly
- E.g. Doré

Name of the element	Symbol	Species present *(one line per species)*	Usual concentration range (%)
Silver	Ag	Metallic	0-100
Gold	Au	Metallic	0-80
Iridium	Ir		0-12
Palladium	Pd		0-10
Platinum	Pt		0-5
Rhodium	Rh		0-7
Ruthenium	Ru		0-20
Aluminium	Al	Al2O3	0-0,4
Antimony	Sb	Metallic	0-2
Arsenic	As	As2O3?	0-1
Barium	Ba	Metallic?	0-0,4
Bismuth	Bi		0-6
Cadmium	Cd	Metallic?	0-0,1
Copper	Cu	Metallic	0-99
Chromium	Cr		0-2
Lead	Pb	Metallic	0-35
Iron	Fe	Metallic	0-50
Magnesium	Mg	MgO	0-4
Nickel	Ni	Metallic?	0-15
Selenium	Se	Metallic?	0-5
Tellurium	Te	Metallic	0-16
Tin	Sn	Metallic	0-2
Zinc	Zn	Metallic	0-10

Name of the element	Symbol	Species present *(one line per species)*	Typical concentration (%)	Concentration range (%)
Silver	Ag	Metallic	70,5	20-99
Gold	Au	Metallic	4,2	0-40
Iridium	Ir		1,0	0-12
Palladium	Pd		0,79	0-5,1
Platinum	Pt		0,52	0-2,6
Rhodium	Rh		0,70	0-7,1
Ruthenium	Ru		1,7	0-20
Aluminium	Al	Al2O3	0,03	0-0,4
Antimony	Sb	Metallic	0,08	0-1,1
Arsenic	As	As2O3?	0,08	0-0,5
Barium	Ba	Metallic?	0,03	0-0,4
Bismuth	Bi		0,42	0-3,1
Cadmium	Cd	Metallic?	0,004	0-0,05
Copper	Cu	Metallic	8,0	0-50
Chromium	Cr		0,11	0-1,5
Lead	Pb	Metallic	0,81	0-5,0
Iron	Fe	Metallic	1,9	0-25
Magnesium	Mg	MgO	0,20	0-2,5
Nickel	Ni	Metallic?	0,60	0-7,8
Selenium	Se	Metallic?	0,41	0-2,5
Tellurium	Te	Metallic	1,7	0-16
Tin	Sn	Metallic	0,08	0-1,1
Zinc	Zn	Metallic	0,47	0-5

3.3. Classification of PM Refinables

- Since last PM Ref WG meeting
  - MeClas: Improved output sheet based on ECHA recommendation (showing 'in-between-calculations') -> to be included in IUCLID section 13
  - New cluster analysis for PM slimes & sludges
- To do:
  - Revision of existing classifications using latest information in MeClas: keep existing clusters but check composition boundaries
  - Update ID cards accordingly + IUCLID

4. Splitting of PM slags and slimes & sludges

Katrien ARIJS

4.1. Splitting of PM slags: status and way forward (1)

- 2 sub-groups agreed at last meeting

Sub-group	Description	Composition	Highest tonnage band	Dossier needed	Nr of companies
1	Slags produced as by-products in the production (smelting, reduction, converting, and refining processes) of doré	• relatively high Ag, As, Cu, Ni, Pb, Sb, Se, Te • relatively low Ca, Co, Mn, P	>1000 t/a	Art. 10	3
2	Slags produced as a by-product in the smelting of PM bearing feeds to produce a PM containing material other than doré subject to further refining	• relatively high Al, Ca, Co, Mg, Mn, P • relatively low Cu, Pb	>1000 t/a	Art. 10	5

- ID cards ongoing, LR being identified
- Phys-chem data gaps identified & testing to start shortly

4.1. Splitting of PM slags: status and way forward (2)

- EC number and name needed for 2 registrations
- Current registration:
  - EC Number: 308-515-5
  - EC Name: Slags, precious metal refining
- Similar substances:

Name	EC number	CAS number	Description (EC inventory)
Slags, silver-smelting	308-315-8	97926-95-9	Product resulting from the smelting of silver and its alloys obtained from primary and secondary sources and including recycled plant intermediates. Consists primarily of SiO2 and other gangue constituents and may contain other residual non-ferrous metals and their compounds.
Slags, dore furnace	266-975-1	67711-98-2	Slag produced as a by-product in the furnace smelting of metal wastes rich in gold and silver. Principal components are usually tellurium, selenium and copper with minor amounts of lead, antimony and other metals.
Slags, precious metal recovery lead refining	273-826-4	69029-85-2	Inorganic slags produced from treatment of calcined scrap metals and oxides with borax, litharge and sodium carbonate followed by fusion.

4.2. Splitting of PM slimes & sludges – status and way forward

Katrien ARIJS

Takeaways EM/ECHA meeting 22 Jan (1)

- Identification of the substance must give a solid handle to the registrant and to regulatory authorities so that they can ensure the safe use of the substance in all its grades and in all its uses

A UVCB is identified by means of its name and its description

The **UVCB description** depends on:

- the starting materials it originates from,
  - i.e. the mineral sources (described in generic terms such as primary material, secondary feeds, etc.);
- the production process step(s) from which it results,
  - i.e. the type of refinement step (described in a generic way, e.g. smelting, refining, precipitation, etc.); and
- the "known" main constituents of the UVCB

Takeaways EM/ECHA meeting 22 Jan (2)

Four **parameters** of variability :

- **Elemental** (chemical) composition
  => mainly driven by the sources
- **Speciation** of the (chemical) elements
  => mainly driven by the processes
- **Concentration** ranges of elements/constituents:
  => driven by sources and processes
- Physical **appearance**:
  => driven by sources (e.g. concentrate) and processes

Large variability in speciation within 1 UVCB -> difficult to defend; indication that different processes are grouped?

Takeaways EM/ECHA meeting 22 Jan (3)

Relevance of process and source

- Substances with variability in composition and/or unknown constituents
  - Process and source are then integral to the identification
  - Why: process and source fix the composition and thus the identity of the substance
  - Where process and/or sources are varied, composition variation is unknown and generic (e.g. 0-73 % Copper)
  - Identity of the substance is poorly defined which makes it impossible to ensure its safe use
  - Intrinsic variability in source for a given process acceptable (e.g. ores from different regions for copper smelting)

Takeaways EM/ECHA meeting 22 Jan (4)

- Sources and processes are not independent variables
- Processes cannot be overly generic (e.g. Flue dust)
- Sources cannot be overly generic (e.g. an ore is not the same source as scrap metal)
- Composition is reported per LE
- Elemental analysis alone is not sufficient for the composition
- Broad concentrations ranges are a flag that more than one substance is being registered
- EINCES/ELINCS entries are fixed – SID cannot be redefined and still keep the EINECS/ELINCS entry
- EINECS descriptions cannot be revised.

EM has planned a site visit for ECHA at Boliden Harjavalta on Feb 14 to improve common understanding on UVCB intermediates processes and variability

Outcome TF meeting 27 September – PM slimes & sludges (1)

- 5 sub-groups proposed:
  1) Slimes obtained/produced during the electrolytic refining of Ag.
  2) Slimes obtained/produced during the electrolytic refining of Au.
  3) Slimes obtained/produced from hydro-metallurgical upgrading of PM containing solid materials including non-PM sources (i.e. removal of base metals or solvent, producing an upgraded/enriched residue).
  4) Slimes obtained/produced from the hydro-metallurgical leaching of PMs from PM containing solid materials (i.e. dissolution of PMs leaving a lower grade residue).
  5) Slimes obtained/produced by precipitation from solutions containing PMs.

Outcome TF meeting 27 September – PM slimes & sludges (2)

- Keep slimes obtained/produced during the electrolytic refining of Ag and Au separate -> composition and source very different (process similar)!
- We might have to split other sub-groups/Refinables according to source as well (e.g. Ag/Au) -> why use different splitting/grouping criteria for different Refinables?
- Check if slimes always result from hydro-metallurgical processes
- Check if members fit within the proposed sub-groups
- Following the sub-grouping of slimes & sludges, more Refinables that were originally in the slimes and sludges group may end up in the Ref group 'Residues, PM refining cementation and reduction', resulting in an over-grouping there
- We might **group sub-group 3, 4 and possibly 5 (even if different classification)**, but we need to prove first that we did not over-group and they cannot be distinguished from each other. Ideally, the sub-groups should allow refining the compositions/reducing the variability.

Outcome TF meeting 27 September – way forward

ID & sameness

- PMC secretariat to circulate revised sub-groups to the PMC Members
- PMC Members to assign their Refinable(s) to sub-group(s)

Define boundaries

- Determine composition and classification of sub-groups

Registration strategy

- Split registrations or register as sub-groups of 1 registration (or combination of both)?
- Determine availability of other EC numbers applicable to PM refining slags + slimes & sludges if separate registrations considered

Splitting of PM slimes & sludges: Input received

- PMC Members were asked to assign their slimes & sludges to sub-groups
  - Response received from 8/9 registrants
  - 36 compositions reported in total under 5 sub-groups (some companies reported multiple compositions) – good dataset
  - Most registrants declared slimes & sludges in 3 or 4 sub-groups (4/8 only declared sub-groups 3-4-5)

Sub-group	Highest tonnage band	Type of dossier needed	Nr of companies	Nr of compositions for exercise	Remarks
1	100-1000 t/a	Art. 10	4	5	
2	1-10 t/a	Art. 17/18	1	1	Sole registrant declared SCC
3	> 1000 t/a	Art. 10	6	10	Pyro-metallurgical processes reported (roasted slime)
4	100-1000 t/a	Art. 10	6	8	
5	100-1000 t/a	Art. 10	6	12	

Splitting of PM slimes & sludges: Speciation sub-groups

- Differences in speciation between the different sub-groups?

Sub-group	Speciation reported by registrants
1	metallic + oxides
2	? metallic + oxides
3	metallic + oxides + chlorides + sulfates
4	metallic + oxides + chlorides + sulfates
5	metallic + oxides + chlorides + sulfates

- Very variable; no distinct differences in speciation between the sub-groups -> worst-case speciation used to derive classifications for the sub-groups
- Speciation has a big impact on classification (e.g. chlorides and sulfates more irritating) -> **define different grades/sub-groups allowing to refine speciation?** E.g. different sub-groups for different acid treatments (hydrochloric/sulphuric) used? Sometimes mixture of acids used in same process!
- Difficult to defend large variability in speciation for 1 UVCB (indication of multiple processes being grouped)! Explanation as to why speciation so variable?

Splitting of PM slimes & sludges: Composition boundaries (1)

- Min, max and avg. of typical
- Constituents > 10% avg. + constituents driving classification

	Sub-group 1 (n=5)			Sub-group 2 (n=1)			Sub-group 3 (n=10)			Sub-group 4 (n=8)			Sub-group 5 (n=12)		
	Min	Max	Avg (typ)	Min	Max	Avg (typ)	Min	Max	Avg (typ)	Min	Max	Avg (typ)	Min	Max	Avg (typ)
Ag	30,5	84	45,6	11,3	18,1	14,1	0,1	47	9,52	0,57	67	13,7	0,07	84	9,69
As	0	0,1	0,05	0	0	0	0	5,2	1,72	0	3	1,05	0	2	0,56
Au	0,4	46	28,4	75,2	82,7	78,7	0	2,3	0,48	0	95	13	0	40	4,45
Ba	0	0,01	0,002	0	0	0	0	16	3,07	0	1	0,22	0	1	0,11
Ca	0	0,016	0,003	0	0	0	0	3,5	0,58	0	3	0,66	0	10	1
Cd	0	0	0	0	0	0	0	0,1	0,015	0	0,2	0,025	0	0,1	0,025
Cl	0	17,4	3,48	0	0	0	0	16	3,63	0	57,5	18,5	0	60	12,7
Co	0	0,004	0,001	0	0	0	0	0,2	0,036	0	3,73	0,6	0	0,6	0,1
Cu	0	14,1	4,14	0	0	0	0,7	21,5	7,29	0	9	2,14	0,02	33	7,51
Mn	0	0,004	0,001	0	0	0	0	0,1	0,031	0	0,5	0,076	0	0,1	0,016
Ni	0	0,004	0,001	0	0	0	0	2,4	0,81	0	2	0,57	0	10,2	1,97
Pb	0	2,5	0,55	0	0	0	0	11	4,23	0	7	1,09	0	13,6	2,26
Pd	0,015	12	4,7	0,2	0,7	0,5	0,01	27,7	5,12	0	14	3,56	0	88	15,5
Pt	0	1,2	0,48	0,35	0,5	0,45	0	60	11,5	0,3	20,7	5,55	0,01	7,2	2,45
Rh	0	0,1	0,02	0,05	0,15	0,1	0	20,5	4,07	0	5,95	1,41	0	16,55	3,47
Ru	0	0	0	0	0	0	0	28,5	7,17	0	7,6	2,18	0	15,07	1,95
S	0	0	0	0	0	0	0	26	4,38	0	1,5	0,31	0	2,4	0,48
Se	0	0,48	0,12	0	0	0	0	17,5	3,5	0	30	6,01	0	15	4,58
Te	0	1,5	0,42	0	0	0	0	10,9	2,63	0	7	2,25	0	15,7	2,84
Zn	0	0,004	0,001	0	0	0	0	4,5	0,52	0	0,43	0,13	0	4	0,45

Sub-group 1 (n=5):
- high Ag, Au (Ag > Au)
- relatively high Cu, Pd
- relatively low in other metals

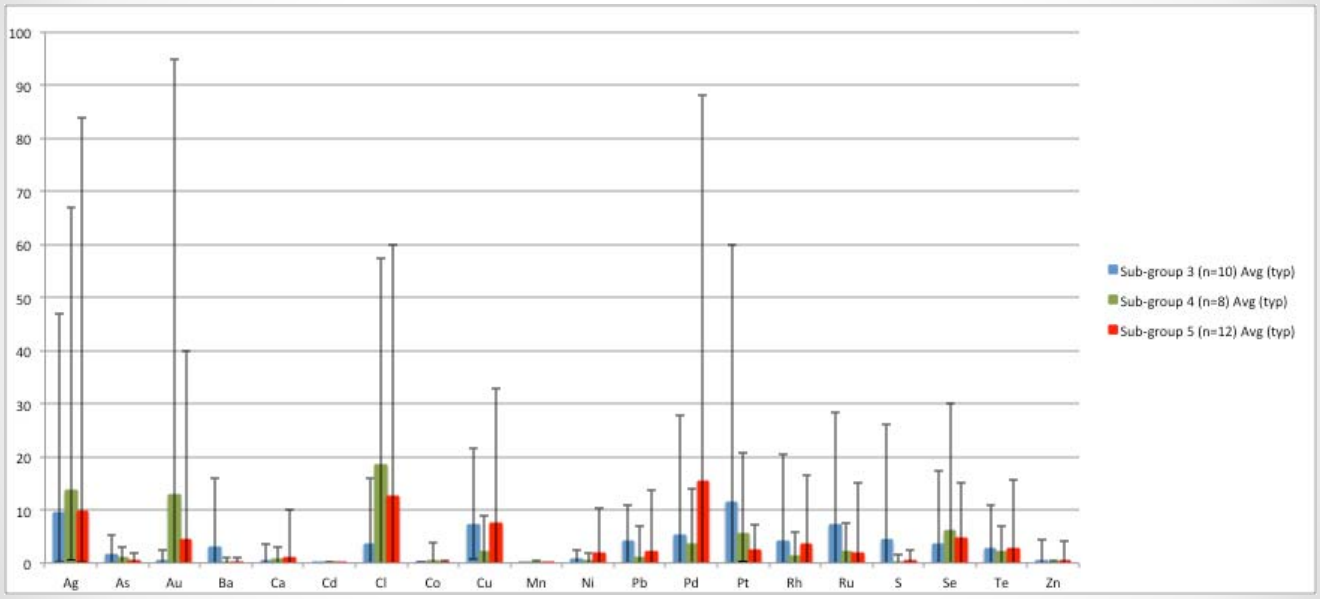
Sub-group 2 (n=1!):
- high Au, Ag (Au > Ag)
- relatively low in other metals

Sub-group 3-4-5 (n=30):
- relatively low Ag, Au (compared to sub-group 1 & 2)
- Relatively high in other metals

Different from chemical point of view

No significant differences in composition

Splitting of PM slimes & sludges: Composition boundaries (2)



Sub-groups 3-4-5: inter-sample variability in composition is larger than inter-sub-group variability in composition

Splitting of PM slimes & sludges: Classification boundaries

- MeClas used to derive classification; Tier 1
- Classification checked for max of typical
- Speciation:
  - o New in MeClas: H_2SO_4, $NiCl_2$, $CdCl_2$
  - o Need to differentiate between chlorides and oxides?

Splitting of PM slimes & sludges: Classification sub-group 1

(electrolytic refining of Ag)

Endpoint	Classification max of typical	Classification company-specific slimes & sludges (typical)				
		11	12	13	14	15
Acute toxicity-oral	Cat. 4; H302	NC	v	v	v	NC
Acute toxicity-dermal	Not classified	v	v	v	v	v
Acute toxicity-inhalation	Not classified	v	v	v	v	v
Skin corrosion/irritation	Not classified	v	v	v	v	v
Serious eye damage/eye irritation	Not classified	v	v	v	v	v
Resp. or skin sensitisation	Skin Sens. Cat. 1; H317	v	v	v	v	NC
Germ cell mutagenicity	Not classified	v	v	v	v	v
Carcinogenicity	Cat. 1A; H350	NC	v	v	NC	Cat. 2
Reproductive toxicity	Cat. 1A; H360	NC	NC	NC	NC	v
Specific target organ toxicity - single exposure	Not classified	v	v	v	v	v
Specific target organ toxicity - repeated exposure	Cat. 1; H372	NC	NC	Cat. 2	Cat. 2	v
Aspiration hazard	Not classified	v	v	v	v	v
Hazardous to aquatic environment - ACUTE	Acute Cat. 1; H400	v	v	v	v	v
Hazardous to aquatic environment - CHRONIC	Chronic Cat. 1; H410	v	v	v	v	v
		↓ non CMR			↓ non CMR	

Splitting of PM slimes & sludges: Classification sub-group 2

(electrolytic refining of Au)

Endpoint	Classification typical (20)
Acute toxicity-oral	Not classified
Acute toxicity-dermal	Not classified
Acute toxicity-inhalation	Not classified
Skin corrosion/irritation	Not classified
Serious eye damage/eye irritation	Not classified
Resp. or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive toxicity	Not classified
Specific target organ toxicity - single exposure	Not classified
Specific target organ toxicity - repeated exposure	Not classified
Aspiration hazard	Not classified
Hazardous to aquatic environment - ACUTE	Acute Cat. 1; H400
Hazardous to aquatic environment - CHRONIC	Chronic Cat. 1; H410

Splitting of PM slimes & sludges: Classification sub-group 3

(hydro-metal. upgrading of PM cont. solid materials incl. non-PM sources)

Endpoint	Classification max of typical	Classification company-specific slimes & sludges (typical)									
		31	32	33	34	35	36	37	38	39	395
Acute tox-oral	Cat. 3; H301	v	v	Cat. 4	v	Cat. 4	Cat. 4	v	NC	Cat. 4	v
Acute tox-dermal	Not classified	v	v	v	v	v	v	v	v	v	v
Acute tox-inhal.	Cat. 4; H332	v	v	NC	v	NC	NC	NC	NC	v	v
Skin corr./irritation	Cat 1A; H314 (H_2SO_4)	v	v	NC	Cat. 2	Cat. 2	NC	v	NC	v	Cat. 2
Serious eye damage/eye irritation	Cat 1; H318	v	v	NC	Cat. 2	v	NC	v	NC	v	Cat. 2
Resp. or skin sens.	Resp./Skin Sens. Cat. 1; H334/H317 ($NiCl_2$)	v	v	NC	v	v	v	v	NC	v	v
Germ cell mutagenicity	Cat. 1B; H340 ($CdCl_2$)	Cat. 2	Cat. 2	NC	Cat. 2	v	Cat. 2	Cat. 2	NC	Cat. 2	Cat. 2
Carcinogenicity	Cat. 1A; H350	v	v	NC	v	v	v	v	v	v	v
Reproductive tox	Cat. 1A; H360	v	v	NC	NC	v	NC	v	NC	v	v
STOT - single exp.	Not classified	v	v	v	v	v	v	v	v	v	v
STOT - repeated exp.	Cat. 1; H372	v	v	NC	Cat. 2	v	Cat. 2	v	NC	v	v
Aspiration hazard	Not classified	v	v	v	v	v	v	v	v	v	v
Hazardous to aq. env. - ACUTE	Acute Cat. 1; H400	v	v	v	v	v	v	v	v	v	v
Hazardous to aq. env. - CHRONIC	Chronic Cat. 1; H410	v	v	v	v	v	v	v	v	v	v

↓ non CMR

Note: 1 company reported pyro-metallurgical processes (roasted slime)

Splitting of PM slimes & sludges: Classification sub-group 4

(hydro-metal. leaching of PMs from PM cont. solid materials)

Endpoint	Classification max of typical	Classification company-specific slimes & sludges (typical) 41	42	43	44	45	46	47	48
Acute tox-oral	Cat. 3; H301	NC	NC	Cat. 4	Cat. 4	v	v	v	Cat. 4
Acute tox-dermal	Not classified	v	v	v	v	v	v	v	v
Acute tox-inhal.	Cat. 4; H332	NC	NC	NC	NC	v	v	v	NC
Skin corr./irritation	Cat. 1B; H314 (H_2SO_4)	NC	NC	NC	NC	Cat. 2	Cat. 2	Cat. 2	NC
Serious eye damage/eye irritation	Cat. 1; H318	NC	NC	NC	NC	v	v	v	NC
Resp. or skin sens.	Resp./Skin Sens. Cat. 1; H334/H317 ($NiCl_2$)	NC	NC	v	v	v	v	v	v
Germ cell mutagenicity	Cat. 1B; H340 ($CdCl_2$)	NC	NC	Cat. 2	Cat. 2	NC	Cat. 2	v	Cat. 2
Carcinogenicity	Cat. 1A; H350 ($NiCl_2$)	NC	NC	v	v	v	v	v	v
Reproductive tox	Cat. 1A; H360	NC	NC	v	v	Cat. 1B	v	v	NC
STOT - single exp.	Not classified	v	v	v	v	v	v	v	v
STOT - repeated exp.	Cat. 1; H372	NC	NC	Cat. 2	v	Cat. 2	v	v	Cat. 2
Aspiration hazard	Not classified	v	v	v	v	v	v	v	v
Hazardous to aq. env. - ACUTE	Acute Cat. 1; H400	v	v	v	v	v	v	v	v
Hazardous to aq. env. - CHRONIC	Chronic Cat. 1; H410	v	v	v	v	v	v	v	v

non CMR non CMR

Splitting of PM slimes & sludges: Classification sub-group 5

(precipitation from solutions containing PMs)

Endpoint	Classification max of typ	Classification company-specific slimes & sludges (typical) 51	52	53	54	55	56	57	58	59	60	61	62
Acute tox-oral	Cat. 3; H301	NC	v	Cat. 4	v	Cat. 4	Cat. 4	v	Cat. 4	Cat. 4	v	Cat. 4	v
Acute tox-dermal	Not classified	v	v	v	v	v	v	v	v	v	v	v	v
Acute tox-inhal.	Cat. 3; H331	NC	NC	NC	Cat. 4	NC	Cat. 4	Cat. 4	NC	Cat. 4	Cat. 4	Cat. 4	Cat. 4
Skin corr./irr.	Cat. 1B; H314 (H_2SO_4)	NC	Cat. 2	NC	Cat. 2	NC	NC	Cat. 2	NC	NC	Cat. 2	Cat. 2	Cat. 2
Serious eye dam./eye irr.	Cat. 1; H318	NC	Cat. 2	NC	v	NC	NC	Cat. 2	NC	NC	v	Cat. 2	Cat. 2
Resp. or skin sens.	Resp./Skin Sens. Cat. 1; H334/H317 ($NiCl_2$)	NC	v	v	v	v	v	v	v	v	v	v	v
Germ cell mutagenicity	Cat. 1B; H340 ($CdCl_2$)	NC	NC	v	Cat. 2	NC	NC	Cat. 2	NC	NC	v	v	Cat. 2
Carcinogenicity	Cat. 1A; H350 ($NiCl_2$)	NC	v	Cat. 1B	v	NC	v	v	v	v	v	v	v
Reproductive tox	Cat. 1A; H360	NC	NC	v	v	NC	NC	NC	Cat. 1B	NC	v	v	v
STOT - single exp.	Not classified	v	v	v	v	v	v	v	v	v	v	v	v
STOT - repeated exp.	Cat. 1; H372	NC	Cat. 2	v	v	NC	Cat. 2	Cat. 2	NC	Cat. 2	v	v	v
Aspiration hazard	Not classified	v	v	v	v	v	v	v	v	v	v	v	v
Hazardous to aq. env. - ACUTE	Acute Cat. 1; H400	v	v	v	v	v	v	v	v	v	v	v	v
Hazardous to aq. env. - CHRONIC	Chronic Cat. 1; H410	v	v	v	v	v	v	v	v	v	v	v	v

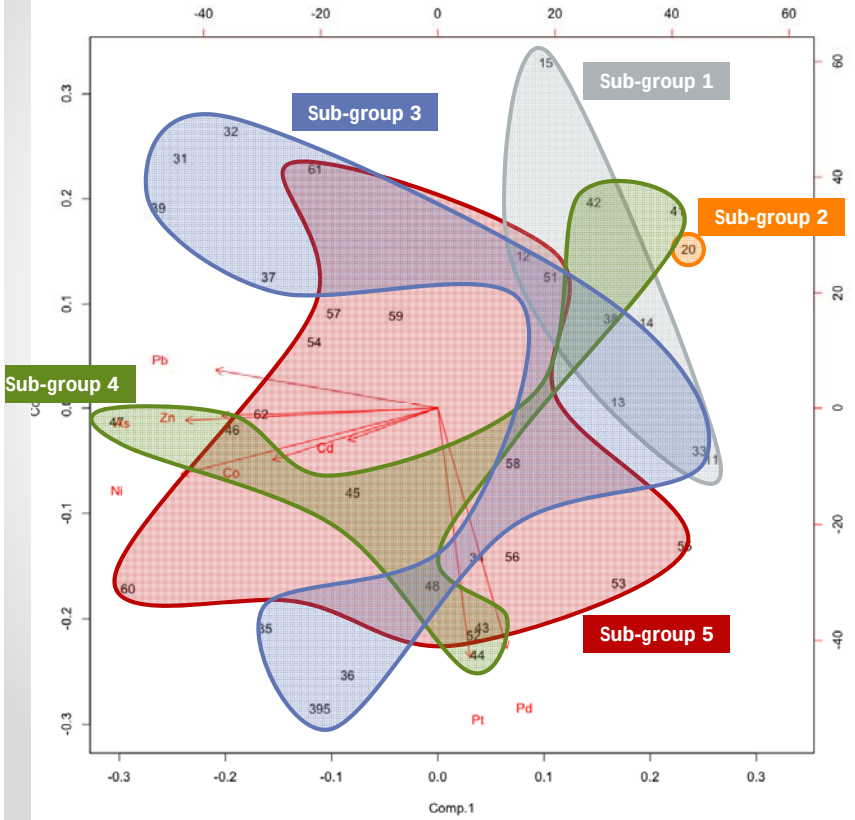
non CMR non CMR

Splitting of PM slimes & sludges: Classification sub-group 1-5

Endpoint	Sub-group 1	Sub-group 2	Sub-group 3	Sub-group 4	Sub-group 5
Acute tox-oral	Cat. 4	NC	Cat. 3	Cat. 3	Cat. 3
Acute tox-dermal	NC	NC	NC	NC	NC
Acute tox-inhal.	NC	NC	Cat. 4	Cat. 4	Cat. 3
Skin corr./irr.	NC	NC	Cat 1A	Cat. 1B	Cat. 1B
Serious eye dam./eye irr.	NC	NC	Cat 1	Cat. 1	Cat. 1
Resp. or skin sensitisation	Skin Sens. Cat. 1	NC	Resp./Skin Sens. Cat. 1	Resp./Skin Sens. Cat. 1	Resp./Skin Sens. Cat. 1
Germ cell mutagenicity	NC	NC	Cat. 1B	Cat. 1B	Cat. 1B
Carcinogenicity	Cat. 1A	NC	Cat. 1A	Cat. 1A	Cat. 1A
Reproductive tox	Cat. 1A	NC	Cat. 1A	Cat. 1A	Cat. 1A
STOT - single exp.	NC	NC	NC	NC	NC
STOT - repeated exp.	Cat. 1	NC	Cat. 1	Cat. 1	Cat. 1
Aspiration hazard	NC	NC	NC	NC	NC
Hazardous to aq. env. - ACUTE	Acute Cat. 1	Acute Cat. 1	Acute Cat. 1	Acute Cat. 1	Acute Cat. 1
Hazardous to aq. env. - CHRONIC	Chronic Cat. 1	Chronic Cat. 1	Chronic Cat. 1	Chronic Cat. 1	Chronic Cat. 1

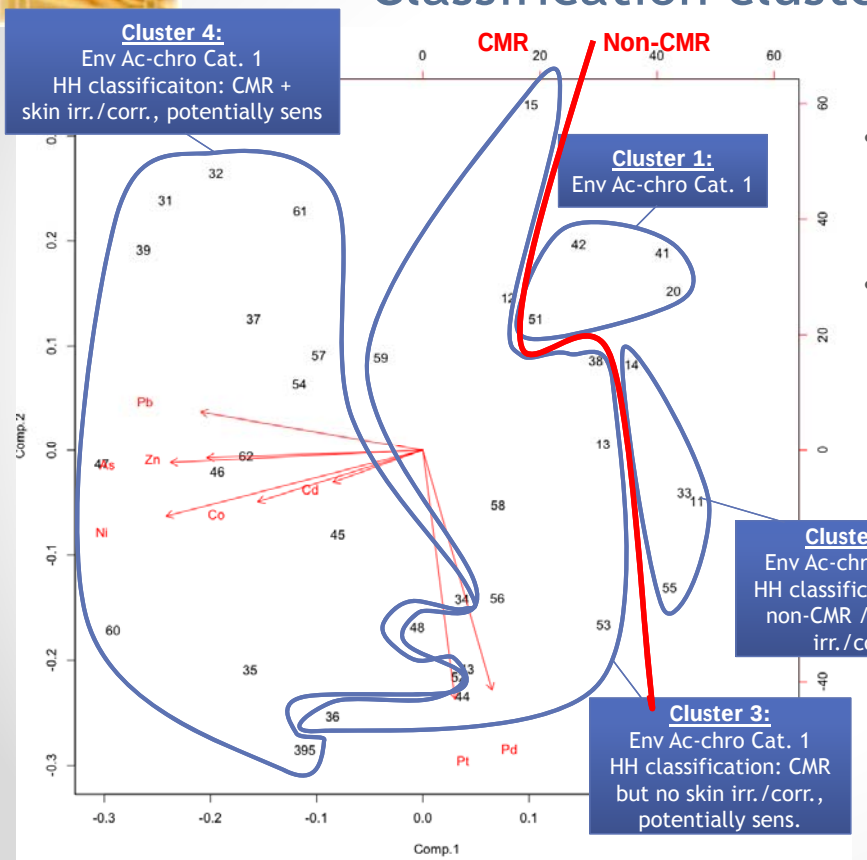
- Based on max of typical
- Sub-groups 3-4-5: no significant differences in classification + inter-sample/company variability > Inter-sub-group variability
- Sub-group 1 vs. sub-groups 3-4-5: some differences in classification
- Sub-group 2 vs. sub-groups 3-4-5: significantly different but only 1 sample!

Splitting of PM slimes & sludges: Sub-group analysis



- Analysis reduced to classification drivers
- 2 principal components:
  - Pt/Pd
  - As/Cd/Co/Ni/Pb/Zn
- Sub-groups **3-4-5**:
  - clearly overlapping
  - heavily classified but large inter-sample/company variability (low to high classification)
- Sub-group **1**:
  - low As/Cd/Co/Ni/Pb/Zn
  - low to high Pt/Pd
  - chemically different
  - classification not significantly different
- Sub-group **2**:
  - low As/Cd/Co/Ni/Pb/Zn
  - low Pt/Pd
  - chemically different
  - classification different

Splitting of PM slimes & sludges: Classification cluster analysis



- Classification cluster analysis redone with new composition data
- 4 clusters identified
  - Sub-group 1: 3 clusters
  - Sub-group 3-4-5: 4 clusters

Splitting of PM slimes & sludges: Way forward

Conclusions:

- UVCB identity should be based on process/source/main constituents
- 5 sub-groups were proposed based on different process/(source)
  - Sub-group 1: chemically different, classification not significantly different
  - Sub-group 2: chemically different, classification different (but only 1 sample)
  - Sub-groups 3-4-5 overlapping in terms of composition & classification

Recommendation TF:

- Current proposed sub-grouping does not allow to refine the composition / reduce the variability
  - Register slimes & sludges, PM refining as 1 UVCB by end of April (incl. results new classification cluster analysis)
  - Await outcome site visit ECHA
  - Look at other possibilities to split slimes & sludges (and inform ECHA accordingly)
  - Come up with general rules for Refinables identification to ensure consistency (i.e. same criteria are used across all Refinables)

Pros and cons analysis of 1 versus multiple registrations

Registration option	Pros	Cons
One registration for identified sub-groups	• Lower registration costs • No additional phys-chem testing needed	• Risk to be challenged by ECHA/considered 'over-grouped'
Multiple registrations for identified sub-groups	• Risk to be challenged by ECHA/considered 'over-grouped' lower • Possibly simpler effects and exposure assessment (as the variability of each sub-group could be less than for the group as a whole)	• Higher registration costs for companies who have multiple sub-groups (depending on tonnage) • Risk to be considered as 'escape route' if sub-grouping results in lower tonnage/no need for registration • Additional phys-chem testing needed (impact on time/cost line) • Additional EC numbers needed (process to be checked)

4.3. UVCB identification rules for other Refinables

- Recommendation TF: come up with general rules for Refinables identification to ensure consistency (i.e. same criteria are used across all Refinables)
- Check source and process information currently in ID cards for ALL Refinables
- Further refinement/completion might be necessary

5. Occupational exposure scenarios

Refinables WG Meeting

Brussels

06 February 2014

Daniel Vetter, Jutta Schade, Torsten Grewe, André Schäfer

EBRC Consulting

Hannover, Germany

First draft occ. ESs

- End December 2013: company specific EA were sent to companies requiring “upgrades” in April 2014
- Occ. ESs are company-specific:
  - Information taken from companies directly: e.g. composition profiles, workplaces, operational conditions and risk management measures (where not overwritten by activity)
  - Available inhalation monitoring data were pooled for all companies
  - Extrapolation to specific company settings (e.g. for higher content of a specific constituent or different RMMs) was required in some cases
  - Extrapolation to be addressed in uncertainty assessment

Occ. ESs – Methodology I/IV

- Approach taken for the UVCB hazard and exposure assessment, incl. considerations of
  - impact of varying content of constituents, varying process conditions and varying risk management measures
  - contribution of other substances handled in parallel
  - ACs based on tasks, physical appearance of handled substances and modifying factors such as process temperature or containment
  - ACs assigned to monitoring data (1 AC per measurement) and WPs of companies (multiples ACs possible per WP)
  - → ES on workplace-by-workplace basis, providing specific information on RMMs for different tasks/activities (= ACs) in a workplace
  - → ES currently taking into account all constituents classified for HH and handled in a workplace

Occ. ESs – Methodology II/IV

- Inhalation exposure assessment
  - based on inhalation monitoring data provided by companies
  - explorative data analyses performed with the programme R
  - "significant" exposure modifiers were identified
  - monitoring data from different companies pooled according to sameness of exposure settings (incl. conc., OCs, RMMs)
  - reasonable worst-case (RWC) estimates were derived for different exposure situations based on GSD and number of data points → generic exposure assessment table (GEA table)
  - GEA table amended by extrapolated estimates for situations for which data are currently not available
  - exposure estimates in GEA table represent full-shift values

Occ. ESs – Methodology III/IV

- Bio-monitoring data (blood lead)
  - bio-monitoring data reflect uptake through all routes of exposure
  - internal exposure levels already take PPE into account (in contrast to external inhalation monitoring data)
  - not possible to assign data to ACs, in most cases not possible to assign data to WPs
  - risk assessment conducted on industry-wide scale, assessed to be representative for involved European companies
  - 90th percentile values for all provided data: well below the DNEL for lead

Occ. ESs – Methodology IV/IV

- Dermal exposure assessment
  - based on exposure estimation tool MEASE
  - relevant parameters for dermal exposure assessment:
    - pattern of use (wide-dispersive use, non-dispersive use, inclusion into/onto matrix, closed system without breaches)
    - pattern of exposure control (direct handling vs. non-direct handling)
    - contact level (extensive, intermittent, incidental, none)
    - composition of handled materials
    - use of PPE
  - parameters may be defined by AC definition or are company-specific
  - exposure estimates represent full-shift values

Occ. Exposure Scenario I/III

- Company-specific occ. ESs
  - workplaces as being defined by companies represent contributing ESs for worker exposure
    - overall composition profile considered as provided for workplaces
    - indication provided if refinements based on species were made
  - ACs represent sub-scenarios taking into account specific OCs and RMMs, based on
    - company-information for a specific workplace: e.g. availability of LEV during handling of dusty materials (AC1), or
    - AC-definition (e.g. separation of workers during smelting operations (AC 5 or 6)
  - derivation of exposure estimates for each AC in a workplace

Occ. Exposure Scenario II/III

- Personal protective equipment (PPE) – respiratory protective equipment (RPE):
  - whenever inhalation exposure estimates are above the DNEL, RPE is required to protect workers‘ health
  - specific assigned protection factors (APFs) are available in e.g. BS EN 529:2005
  - in some cases, high APFs (200) are currently required (way forward to be discussed on a case-by-case basis)
  - required RPE based on exposure assessment, taking into account:
    - worst-case species (if refinement not possible)
    - extrapolation factors (read-across concept)
  - RPE as currently used in the workplace additionally provided in brackets (for reasons of comparison/communication)

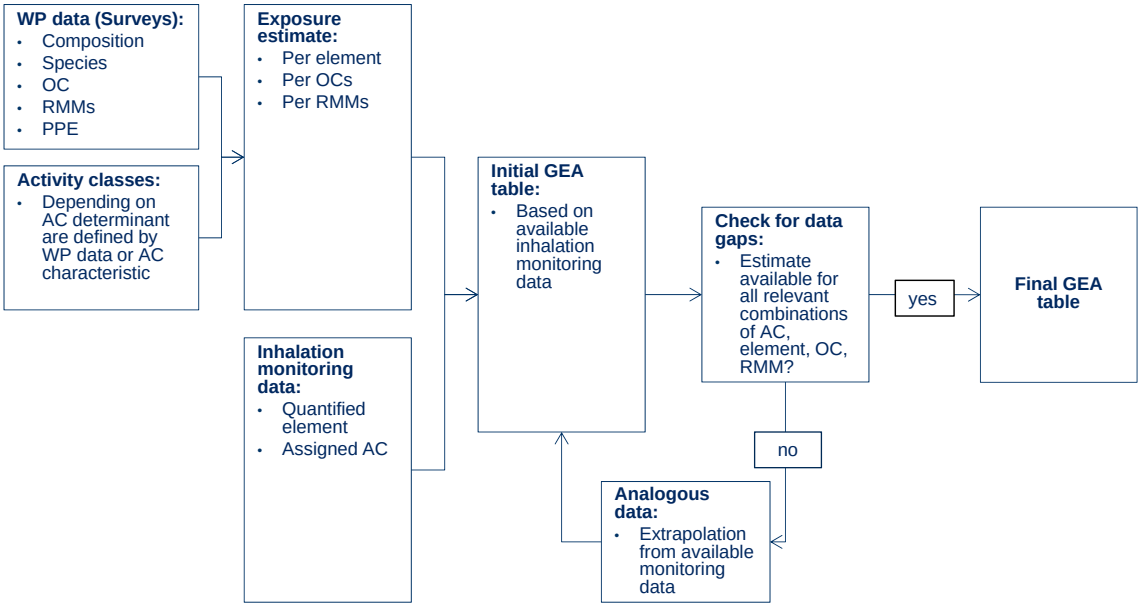
Occ. Exposure Scenario III/III

- PPE – dermal protection:
  - appropriate protective gloves (e.g. acid-resistant or gloves protecting for mechanical damage) have to be worn (unless skin contact with any of the substances can be excluded) in each ES
- PPE – eye protection:
  - eye protection has to be worn (unless contact with any of the substances can be excluded) in each ES
- Further PPE:
  - general good occupational hygiene practices to be followed (further information provided in introduction)

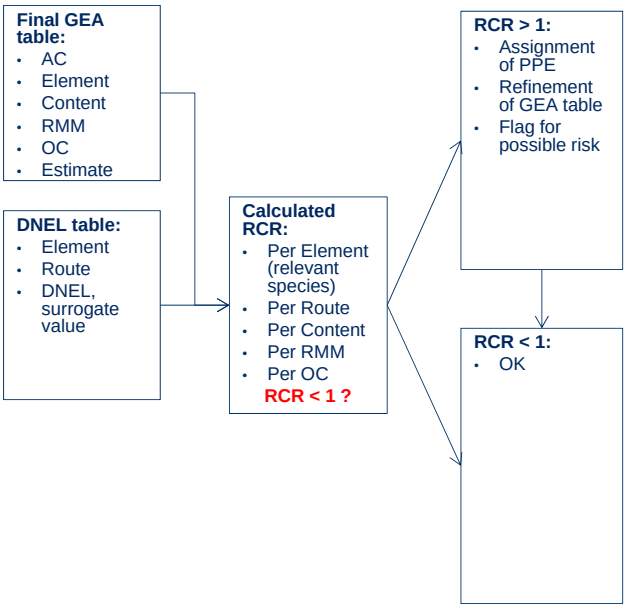
Occ. Risk Characterisation

- Exposure estimates provided for
  - each relevant activity class
  - each relevant element/species
  - each endpoint (inhalation vs. dermal, local vs. systemic, long-term vs. acute)
- Risk characterisation taking into account
  - exposure estimates
  - (assigned) protection factors
  - corresponding DNELs
- To be significantly shortened (expected max. 2 pages)

Summary: Generation of GEA table



Summary: Generation of RC table



To do list (regarding data base):
- Routes for which no hazard is identified, are not to be reported
- DNEL list to be completed
- Combined toxicity for systemic effects of the same element and different routes to be reflected

Section 10 - combined exposure/toxicity

- Qualitative assessment or clarification for:
  - simultaneous exposure to the same constituent at a workplace via different exposure routes
  - aggregated exposure resulting from the applicability of more than just a single contributing worker scenario in a single work shift
  - for different constituents (only interim solution)
  - workers who are members of other sub-populations are considered to be covered in the assessment

Required amendments

- further hazard data
- further information on worst-case species
- further information on extrapolation factors
- uncertainty analysis
- Section 10 – combined toxicity → according to roadmap only at qualitative level for April deadline
- Minor issues:
  - PPE to be adapted for some exposure situations (e.g. use of eye protection in control room)
  - Risk characterisation table to be shortened

External comments to first draft ESs I/II

- Feedback received that the approach is appropriately summarised in the methodology section
- Received company-specific proposals for different AC assignments to workplaces
- Communication regarding further grouping of workplaces
- Refinements of the reported overall composition profiles may be required for some companies

External comments to first draft ESs II/II

- Questions were asked regarding
  - worst-case species used for prescribed RPE
  - same exposure value provided for a constituent used at different concentrations (<10%, <1%, <0.1%)
  - use of substances not yet included in composition profiles (e.g. boron fluxes)
- Some errors were identified (RCR>1, typos, missing values)
- High protection factors need to be refined

Proposed timing (from last meeting)

- Closing of remaining data gaps: 6 Dec 2013 → some remaining questions for companies **NOT** requiring upgrades
- Delivery of 1st draft company-specific ES: 18 Dec 2013 → 1st draft sent to companies requiring upgrades
- Comments on 1st drafts: 8 Jan 2014 → comments received from most companies
- 2nd draft company-specific ES: 15 Feb 2014 → 17 Feb 2014
- Comments on 2nd drafts: 1 March 2014 → 3 March 2014
- Final draft occ. ES: Mid March 2014

CSR/IUCLID human health

Refinables WG Meeting

Brussels

06 February 2014

Torsten Weil, Melanie Horzella
EBRC Consulting
Hannover, Germany

IUCLID/CSR current status HH

- “Shopping list” has been forwarded to PMC
- Updated IU5-template was submitted by EUROMETAUX in the meantime
- Comments and questions were forwarded to EUROMETAUX
- Currently adaptation of the template for the individual UVCBs is ongoing

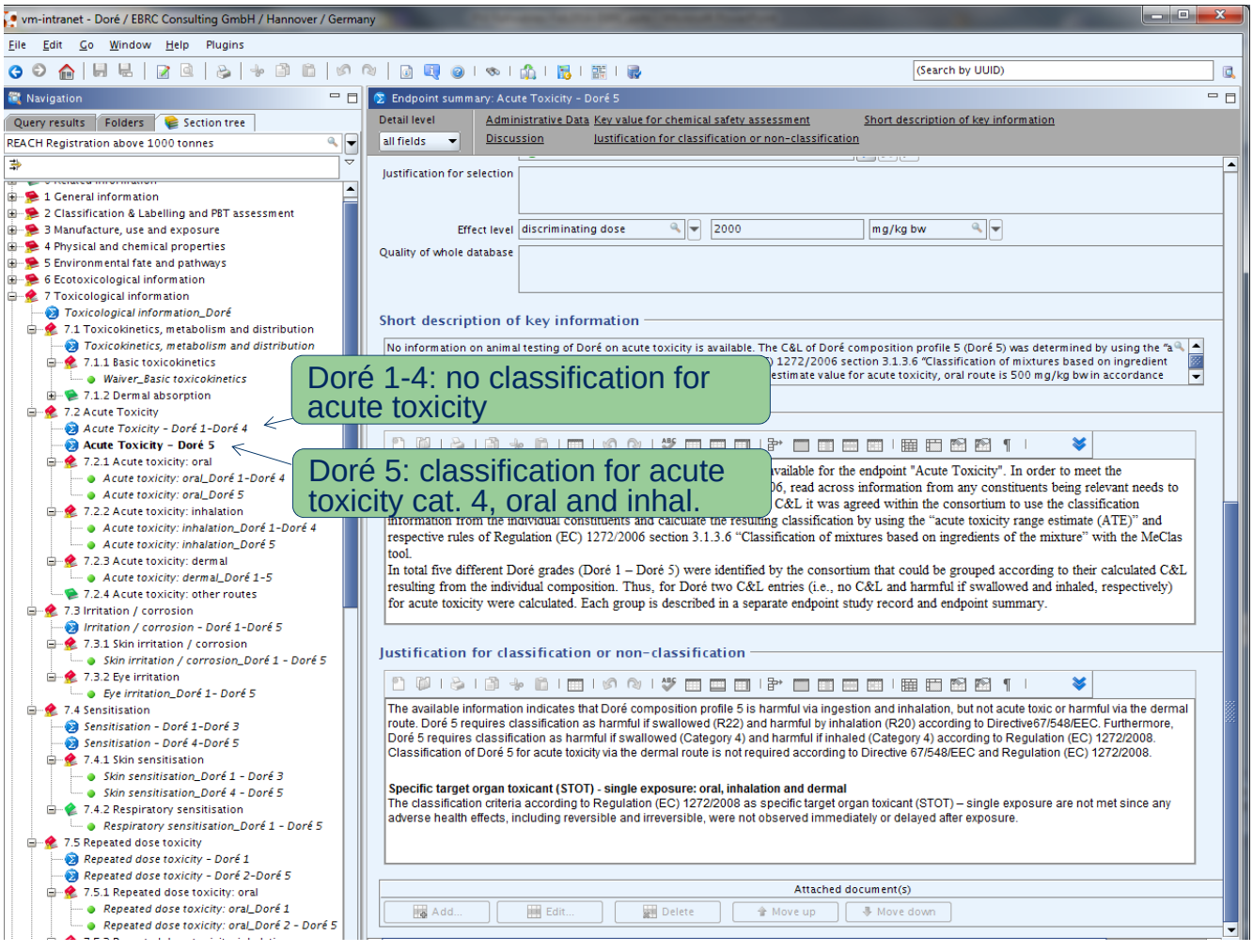
Shopping list – formal data requirements

- 3 “levels” of required data access:
  1. Constituents present in the UVCBs and classified for e.g. HH
     + Not classified constituents but present in significant amounts
     → **Need for LoA and inclusion in dossier**
  2. Constituents that may be generated during processing (not required for IUCLID but for EA)
     → **Need for LoA and inclusion in CSR**
  3. Constituents that are not related to the UVCB but present in the workplace
     → **No formal data access required**

IUCLID/CSR – Example: Doré

- Endpoint study records and respective endpoint summaries for the example UVCB Doré are prepared
- Different grades of Doré were grouped based on resulting classification
  - One endpoint study record and one endpoint summary per group in IUCLID
  - Contrary to initial strategy: Endpoint summaries will be completed with constituent specific information (all constituents).
  - Why? Constituent specific information will presumably only be available for the overall HH summary (DNEL section)

    → For discussion!



IUCLID/CSR – Example: Doré

- Constituent specific information in the overall summary will be included when all data-sets are available
- Draft-CSR for the HH part has been generated as a first example...
- ...see Word document!

Questions – composition UVCB substances

Name of the element	Symbol	Species present *(one line per species)*	Usual concentration range (%)
Silver	Ag	Metallic	0-100
Gold	Au	Metallic	0-80
Iridium	Ir		0-12
Palladium	Pd		0-10
Platinum	Pt		0-5
Rhodium	Rh		0-7
Ruthenium	Ru		0-20
Aluminium	Al	Al2O3	0-0,4
Antimony	Sb	Metallic	0-2
Arsenic	As	As2O3?	0-1
Barium	Ba	Metallic?	0-0,4
Bismuth	Bi		0-6
Cadmium	Cd	Metallic?	0-0,1
Copper	Cu	Metallic	0-99
Chromium	Cr		0-2
Lead	Pb	Metallic	0-35
Iron	Fe	Metallic	0-50
Magnesium	Mg	MgO	0-4
Nickel	Ni	Metallic?	0-15
Selenium	Se	Metallic?	0-5
Tellurium	Te	Metallic	0-16
Tin	Sn	Metallic	0-2
Zinc	Zn	Metallic	0-10

Composition profile “Doré”

- Composition as attached to IUCLID section 13 “Doré” (As2O3?)
- It appears possible to split into multiple individual dossiers
- ECHA may ask why “residues, silver-refining” and “black metal, copper electrolytic slime smelting” belong to the “Doré” group?

IUCLID generation – questions

- Generation of phys-chem data: composition of most representative sample
- Need to clarify on specific potential issues regarding C&L
  - For example, were bioaccessibility data taken into account?

CSR generation – questions/remarks

- Timing for
  - Review/Commenting
  - Merging
- Proposal for generic CSR format:
  - Section 5: generic for all LE but UVCB specific (including all grades)
  - Section 9.0.X: generic for all LE and all UVCB
  - Section 9.1.X: specific to LE but generic for all UVCBs
  - Section 10: Originally for combined exposure i.e. generic but will include aspects for combined toxicity, i.e. potentially LE specific

IUCLID – CSR Timeline

- Based on information available:
  - IUCLID: HH part available mid of March 2014
  - CSR: draft for „Doré“ mid February 2014 (depending on provided data)
  - CSR: finalisation of all CSRs: Mid of March 2014

Thank you for your attention!

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6. Environmental exposure assessment of refinables & IUCLID entry

Ed Stutt, Rhiannon Smith & Becky Marks

Overview

- Recap of approach to environmental assessment
- Exposure assessment and risk characterisation
  - GES
  - SSRA
  - Secondary poisoning
- Filling in IUCLID
- Remaining steps
- Phys-chem endpoints

Environmental exposure and risk characterisation

- Focussing on refinables components that have an environmental classification ('driving constituents')
  - » Ag, As, B, Cd, Cr, Cu, Ni, Pb, Zn
- Assess each constituent separately (no consideration of additivity at present)
- Local environmental concentrations estimated according to R16 guidance (metal EUSES)
  - » Same approach for GES and SSRA

Generic Exposure Scenario(s)

- 2 environmental exposure scenarios for 'processing of refinables'
- Based on characteristics of aquatic emissions:
  - » ES1: Discharge to freshwater via STP
  - » ES2: Direct discharge (to freshwater and marine)
  - – Option of including discharge to marine waters via STP (?)
- GES covers all refinable substances and all aspects of refinables processing (i.e. production AND use)

Generic Exposure Scenarios (ES1 and ES2)

- GES based on Tier 3 exposure assessment
  - » **<u>90P tonnage for driving constituents from sector data</u> (where possible)**
  - » SpERCs for emissions to water and air (use of SpERCs justified on the basis of refinables sector exposure data)
  - » 50P values for flow rates etc & defaults for dilution etc
  - » Some RCRs>1 ⟶ Msafe tonnage for certain driving constituents under ES2
- *GES narratives prepared for inclusion in CSR (Sections 9 & 10), including justification for all assumptions and choices of parameter values*

Refinements to Exposure Assessment

➢ Changes since last draft of GES

- Refinement of exposure modelling (EUSES) by removing conservative assumptions
  - » Partitioning calculations more appropriate to metals (via calculation of unitless partition coefficient)
  - » Excluded partitioning to sediment from background water concentration when including regional background concentration for sediment

Refinements to Exposure Assessment

- Metal specific refinements

—Thanks for assistance from metal consortia and their consultants

  - » confirmation on use of added risk approach where appropriate (e.g. sediments and soil for Zn, sediments for Cd)
  - » choice of regional background concentrations
  - » metal-specific STP removal rates

Final Draft GES for ES1

- By incorporating exposure assessment refinements it is possible to use representative sector data for tonnage (rather than theoretical Msafe tonnage)
- RCR < 1 for all compartments (except stack emissions of Ni and Cr to air)

ES 1 (FW via STP)

Metal	Silver	Nickel	Lead	Zinc	Chromium
Tonnage (tpa)	1811	561	1408	647	329
RCR					
Discharge to STP	0.13	0.19	0.010	0.051	3.1E-05
Freshwater	0.36	0.94ǂ	0.20	0.17	0.081
Freshwater sediment	0.037	NA	0.59	0.0094	0.71
Terrestrial	0.16	0.48	0.13	0.0016	0.0018
Air (MvE)	0.013	8.2*	NA	7.6E-05	26*

* Based on worst case assumptions using 90th percentile tonnage, an emission factor defined by a SpERC and a basic algorithm from ECHA technical guidance. Most assessments on a site specific basis indicate an absence of risk

ǂ RCR largely attributable to regional background concentration (RCR local = 0.12)

ES 1 (FW via STP)

Metal	Arsenic	Boron	Cadmium	Copper
Tonnage (tpa)	222	60	396	1296
RCR				
Discharge to STP	0.11	0.020	0.088	0.21
Freshwater	0.0047	0.0087	0.61	0.41
Freshwater sediment	0.0047	NA	0.43	0.90ǂ
Terrestrial	0.062	0.65	0.50	0.39
Air (MvE)	0.033	NA	NA	3.6E-04

ǂ RCR largely attributable to regional background concentration (RCR local = 0.12)

GES for ES2

- CSR requires exposure scenario demonstrating no risk to the environment (i.e. RCRs<1)

— But GES based on sector specific values and max defaults for exposure assessment gives RCRs>1 for some driving constituents

  - » SpERCs & sector-specific exposure parameter values used in conjunction with PNECs to calculate the tonnage of each classifiable constituent that can be safely processed (manufactured or used) WITHOUT posing a risk to environment (**target RCR = 0.8**)

➢ Msafe approach for Ag, Ni, As, Cd, Cu

ES2 (direct discharge to FW and marine)

Metal	Silver	Nickel	Lead	Zinc	Chromium	Arsenic
Tonnage (tpa)	1120*	360*	1000	647	329	130*
RCR						
Freshwater	0.82	0.95‡	0.20	0.17	0.081	0.0055
Marine water	0.31	0.72	0.020	0.70	0.032	0.77
Freshwater sediment	0.034	NA	0.60	0.051	0.73	0.0056
Marine sediment	0.12	NA	0.58	0.14	0.023	0.77
Terrestrial	0.10	0.48	0.13	1.2E-05	6.9E-05	2.0E-04
Air (MvE)	0.0078	5.4**	NA	7.6E-05	26**	0.019

* Msafe tonnage

** Based on worst case assumptions and most assessments on a site specific basis indicate an absence of risk

‡ RCR largely attributable to regional background concentration (RCR local = 0.13)

Site specific risk assessment (SSRA)

- Sites falling within the operating conditions described by the GES are covered but, if the operating conditions at a site do not fit within the GES further information may be used to demonstrate that this site does not present an unacceptable risk to the environment.
  - » Use site specific data to undertake individual risk assessment for each constituent (maximum of 9 but only considering those discharged at the site)
    - o ***These assessments are confidential and have only been provided to the companies concerned***
  - » Will identify those sites which can demonstrate safe use, and issues at those sites which need additional refinement to demonstrate safe use (i.e. more information or monitoring)

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Summary of SSRA

- Provided to companies preparing upgraded submissions
- Based on monitoring data where available..... or SpERC release factors applied to estimated tonnage
- RCR < 1 for all constituents in all aquatic compartments (freshwater, marine water and sediments) and soil
- RCR>1 for MvE from stack emissions of Ni and Cr at some sites
  - » Can be resolved by higher tier air dispersion modelling (Tier 2 GPM model sufficient for some sites); or
  - » Need monitoring data, including Cr speciation (III v VI)

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Secondary Poisoning

- Some driving constituents have been identified as being potentially harmful to higher organisms (e.g. mammals) if exposed via their food
  - » As, Ni, Cd, Pb
- PEC_{oral} calculated for:
  - » freshwater – contaminant accumulated in fish eaten by aquatic bird or mammal (select most conservative or both)
  - » marine – accumulation in fish-eating predators and top predators
  - » terrestrial environment – accumulation in earthworm eaten by bird or mammal
- $RCR = PEC_{oral} / PNEC_{oral}$

Secondary Poisoning

Constituent	RCR		
	Freshwater	Marine	Terrestrial
Arsenic	0.148	0.672	0.48
Cadmium	0.181	0.801	0.41
Lead	0.088	0.009	0.23
Nickel (bird)	0.076	0.118	0.17
Nickel (mammal)	0.409		**11.95**

- Worst case (1st Tier) based on $C_{local} + PEC_{regional}$ ($C_{local} < PEC_{regional}$)
- Refinement available for Ni but need access to the CSR
- To be added to GES narrative for CSR

Eurometaux position on assessment of waste for intermediates

- Eurometaux agreed that waste life cycle stage is not applicable for UVCB intermediates.
- The refinables are used only as intermediates, chemically modified to become other substances.
- The refinables themselves are recycled as part of the manufacturing process.

Status of IUCLID entry

- IUCLID files are being upgraded to full substance files following the approach developed by Eurometaux
- For environmental endpoints data for all constituents with an environmental classification will be included in IUCLID:
- Ag, As, B (borates, possibly boric oxide) Cd, Cr (Cr III and Cr VI) Cu, Ni, Pb, Zn
- Endpoints to be filled using waivers, data on constituents shared by other Consortia or UVCB classification (MECLAS) entries
- Data access currently being obtained for all constituent data
- IUCLID dossiers for refinables will be compiled following receipt of constituent IUCLID data

Next steps

- Finalise GES narratives for all refinable substances going for upgraded submission
- SSRAs
  - » Incorporation of additional data and higher tier modelling if necessary at later date
- Data entry to IUCLID

7. CSR generic and other sections

Katrien ARIJS

CSR generic and other sections

Sections to be added manually for:

- Chapter 1: Substance identification: general introduction + explain difficulties in grouping/splitting the Refinables
- Chapter 2: Manufacture
  - Extract process descriptions from NFM BREF document Precious Metals chapter (generic, not mentioning each individual Refinable)
  - Input LRs to draft a comprehensive proposal of a description of:
    - ✓ How the manufacture of the Refinable occurs (Cf. CSR Cu slimes and sludges Chapter 2.1-2.2)
    - ✓ How the Refinable and its production process by-products are further processed/transformed
- Chapter 3: Classification & labelling: general introduction on use of MeClas + cluster analysis

8. Timing of submission upgraded PM Refinables dossiers

• • •

Katrien ARIJS & Caroline BRAIBANT

8.1. Status data-sharing agreements

- Data-sharing agreements signed with Pb, Cu, Ni, Zn, Cd and As
- Data-sharing agreement requests sent to B, Co, Mn, Mo, Sb, Se, Te
- Some further clarifications needed on other constituents
- Free exercise but anticipated that some consortia (e.g. Co) will charge at least an administrative fee

8.2. Status testing for PM refinables with phys-chem data gaps (1)

- Data waivers have been applied wherever possible
- Existing data has been requested from registrants and some tests are being conducted by companies in-house
- The following data gaps remain, and testing is being conducted at Harlan:
  - Flue dust, PM refining: Flammability, water solubility
  - Lead bullion, PM metal rich: Melting point, relative density
- Contracts have been signed, and testing will start in February
- Draft reports may not be available until April but draft results will be provided as soon as they become available in order to complete IUCLID files

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8.2. Status testing for PM refinables with phys-chem data gaps (2)

- It was agreed to split the registration for Slags, PM refining
- Physico-chemical testing was conducted for a sample from sub-group 1 in 2010 and therefore no further testing is required for this sub-group
- For sub-group 2 the following data gaps remain:
  - Melting point
  - Relative density
  - Auto-flammability
- A quote has been requested from Harlan to conduct tests to complete these endpoints

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8.3. Timing

Ref mtg or cc?

22 April

		Feb	Mar	Apr	May	Jun - ...
SID + classif.	• Slimes & sludges splitting					
	• Update ID cards all Refinables (composition/classif.)					
	• General rules for identification to ensure consistency					
Testing	• Phys-chem testing Flue dust, Pb bullion					
	• Phys-chem testing Slags sub-group 2					
	• Determine data gaps Slimes & sludges + testing if needed					
ES	• Revision of company-specific ES / GES					
	• Commenting round					
	• 'Final' company-specific ES / GES					
IUCLID/CSR	• Data-sharing agreements / data access					
	• IUCLID entry					
	• CSR generation					
	• Review CSR/IUCLID					
Submission	• Submission by LRs					
	• Submission by co-registrants					
Further updates						

Ultimate deadline!

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

Edwin BROEKAERT

Thank you!