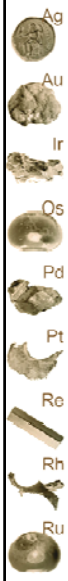


Precious Metal Refiners Work Group

Brussels, 5 December 2011
Metals Conference Centre – Room Aluminium
Rue du Duc 100, 1150 Brussels, Belgium

1. Welcome and introduction

Agenda

1. Welcome and introduction
   - Reminder on Confidentiality and Competition law
   - Tour de table & apologies
   - Approval of the agenda
   - Approval of the minutes last meeting (26-27 Sep 11) & status action points
2. Recap project strategy
   - Analysis Update vs. Upgrade
   - Questions & Answers
     - Authorisation of substances used in PM refining
3. Update on advocacy programme of Eurométaux: examples, information requirements UVCBs

   (including way forward on effects assessment and fulfilling Annex VII-X information requirements)

Agenda (2)

4. Workplace exposure assessment programme
   - Proposed general approach & tools
   - Updated version RiCoG with metal-specific adaptations
   - Status occupational exposure assessment – questionnaires
   - Feasibility pilot case for flue dust streams Johnson Matthey
5. Environmental emissions assessment programme
   - Proposed general approach & tools
   - Status environmental emissions assessment – questionnaires
   - Additional info needs & use of available site-specific environmental emission assessments of Ref constituents
6. Strategy to review the hazard classification of Refinables
7. AOB, next calls, meetings, and closing remarks

List of participants

1	**Angela Alderman**	Johnson Matthey	UK	
2	**Katrien Arijs**	Arche Consulting	Belgium	Project Manager
3	**Dave Boyd**	Johnson Matthey	UK	
4	**Caroline Braibant**	EPMF	Belgium	Secretariat
5	**Roland Brasch**	Heraeus	Germany	
6	**Edwin Broekaert**	Umicore	Belgium	Chairperson
7	**Philippe Cettou**	Metalor	Switzerland	
8	**Daniela Cholakova**	Aurubis	Germany	
9	**Paul Frost**	Britannia Refined Metals	UK	
10	**Michael Huber**	Wieland Edelmetalle	Germany	
11	**Mari Jarvikivi**	Norilsk Nickel	Finland	*By conference call*
12	**Joachim Kralik**	Heraeus	Germany	

List of participants (2)

13	**Claire Massey**	WCA environment	UK	Expert
14	**Mohammed Moukassi**	SFPZ	Morocco	
15	**Agnieszka Piechota**	KGHM	Poland	
16	**Giovanni Prelazzi**	Chimet	Italy	
17	**Manfred Probst**	C. Hafner	Germany	
18	**Mike Shepherd**	Vale Europe	UK	
19	**Ed Stutt**	WCA environment	UK	Expert
20	**Mika Toivola**	Boliden	Finland	
21	**Frederik Verdonck**	Arche Consulting	Belgium	Expert - *Afternoon only*
22	**Daniel Vetter**	EBRC	Germany	Expert
23	**Hugo Waeterschoot**	HW Consult	Belgium	Expert

Pending actions of 26-27 Sep meeting

	Action	Who?	Status
1	Circulate minutes of Hydrazine TF kick-off meeting	CB	Done
2	Find out consequences of intermediate constituent(s) being listed on the Candidate List and/or prioritised for Authorisation	KA + CB	Done (on agenda)
3-5	Advocacy programme EM: finalise PM examples demonstrating RiCo to be sent to ECHA	CB + PM Refiners	Done (on agenda)
6	PM Refiners to provide comments on RiCoG beta-version & EBRC to update RiCoG as appropriate	PM Refiners + EBRC	Ongoing (on agenda)
7	Ask companies that have not submitted exposure questionnaires yet, to do so by 7 Oct	KA	Ongoing
8	Check composition of UVCB streams and make sure all constituents are included, whether they are recovered or not	PM Refiners	Done?
9	Check how non-metallic constituents present in the UVCB are addressed during exposure assessment in the REACH text and guidance and by other metals consortia/Eurométaux	KA + HW	Ongoing
10	Collect DNEL and other TRV and supporting rationale on all human health relevant constituents and apply/update in workplace exposure assessment tools	Eurométaux	Ongoing
11	Provide legal reference to define & distinguish cold & hot processes	P. Frost	Done
12	Prepare feasibility project for all flue dust streams declared by Johnson Matthey	JM + EBRC	Draft done (on agenda)
13	Issue data submission form for occupational exposure data	EBRC	Ongoing

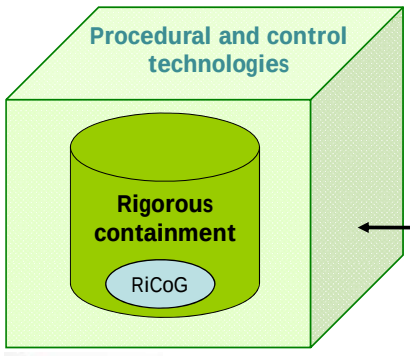
Pending actions of 26-27 Sep meeting (2)

	Action	Who?	Status
14	Outline the assessment procedure for occupational settings, e.g. in the form of a decision tree, by assigning tasks	PMC + EBRC	Done
15	Update questionnaire to include: • Info on non-PM Refinable streams which are also manufactured/used on site and may contribute to environmental emissions • Clarification on whether emissions to water refer to total or soluble	PM Refiners	Done?
16	Collect PNEC and other ERV on all environm. relevant constituents and apply/update in environmental emissions assessment tools	Eurométaux	Ongoing
17	Finalise update of SPERCs for low emissions sectors	ARCHE	Done
18	Calculate first tier RCR for all PM Refiners	WCA	Ongoing (on agenda)
19	Perform a pilot/feasibility cluster analysis on the basis of composition for all flue dust streams and propose classification categories/groups of flue dusts based on transport, packing and labelling as well as on-site handling/permitting needs	ARCHE (With support of A. Alderman, D. Boyd, P. Frost & M. Järvikivi)	Done (on agenda)
20	If you put the worst-case classification in the registration dossier, check whether you are allowed / obliged to put the worst-case classification in the MSDS or you have to classify the Refinable as it is	HW	Ongoing (on agenda)
21	Prepare an analysis reflecting Update vs. Upgrade	KA + CB	Done (on agenda)
22-24	Prepare FAQ/Q&A to address questions which arise at PM Refiners WG meetings	KA + CB + experts	Done

2. Recap project strategy

Relationship RiCo and SCC

All conditions of Article 18(4) (a) to (f) shall apply and be met at the same time



Trained and authorised personnel

Special procedures before entering the system

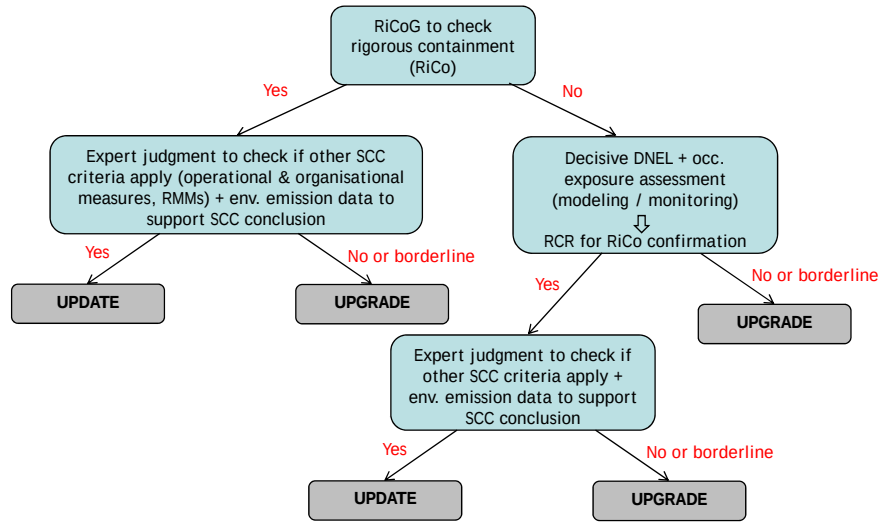
Well-documented procedures

Assessment of SCC for the workplace and the environment: Similarities and differences

Assessment step	WORKPLACE	ENVIRONMENT
Tier 0: SCC screening	Qualitative assessment of rigorous containment: RiCoG + expert judgment	Qualitative assessment of rigorous containment & RMMs: Expert judgment
Tier 1: Exposure assessment - modeling	MEASE	
Tier 2: Exposure assessment - measured	Monitoring data	
SCC validation*	Check modeling/monitoring with DNEL	Check measured emission concentrations with PNECs

* *SCC validation simulates an RCR calculation which is normally used to demonstrate safe use in a full risk characterisation/assessment*

Assessment of SCC for the workplace and the environment



Update versus Upgrade

	Update	Upgrade
Appendix 2 (in-house)	X	-
Appendix 3 (for reg dossier)	X	-
Sections 1-3 of IUCLID 5 (ID, composition, classification & labelling, manufacture & use)	Updated if needed	Updated if needed
Sections 4-7 of IUCLID 5 (phys-chem properties, env fate & pathways, tox and ecotox data)	Reduced to already available data; only study summaries have to be submitted	X (dependent on tonnage band)
Section 8 of IUCLID 5 (Analytical methods)	-	-
Section 11 of IUCLID 5 (Guidance on safe use)	X	X
Section 12 of IUCLID 5 (Literature search)	-	-
Section 13 of IUCLID 5 (CSR)	-	X (for > 10 t/a)
Time	~ 2 months/file (FTE)	~ 3-4 months/file (FTE) (assuming non-testing/read-across approach accepted)
Registration costs	None in addition to original submission	Increased registration fee depending on tonnage level
Compliance check by ECHA	Likely	Likely
Evaluation by Member States	Possible	Possible
Authorisation and restriction	Exempted	Exempted

Update versus Upgrade

- **Update**
  - *Appendix 2* template (example/model provided by Eramet)
  - *Appendix 3*
  - *Exposure assessment* to support RiCo
- **Upgrade**
  - *Exposure assessment*
    - to assess exposure level allowing for risk characterisation
    - all relevant elements to be included
  - *Effects assessment* (REACH Annexes VII-X)
    - **Classical assessment** for > 1000 t materials not appropriate and too costly (1,2 – 2,5 mio €/joint registration dossier)
    - Alternative: **read-across** from elements composition (< 150 - 200.000 €/joint registration dossier)
  - *Risk characterisation*
    - CSR > 10 t/a if hazard identified in effect assessment

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Appendix 2 & 3 for Update

	Appendix 2	Appendix 3
Purpose	In-house (demonstrate SCC to national enforcement authorities)	In registration dossier (demonstrate SCC to ECHA)
Detail	Extensive (more detailed than appendix 3) but also helpful for other workplace obligations (chemicals or carcinogens at the workplace, Seveso, …)	Extensive and including exposure assessment if needed to complement statements
Workload	A couple of days	A couple of days + update of IUCLID
Company specific	Yes	Can be developed at "Consortium" level but requires in most cases refinement by company

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Important considerations for Upgrades

- Difference substance dossier (full assessment) and intermediate dossier (local assessment)
  ⟹ not the same workload!
- Registration preparation cost & registration fee is higher than updates but main cost will be testing cost
  ⟹ focus should be on read-across!
- Uncertainty about intermediate status in future legislation
  ⟹ update strategy might only be short-term solution!
- Workload slightly higher than updates, but less likelihood of being challenged

  ⟹ **upgrades may be preferred choice…**

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Exposure assessment for Refinables

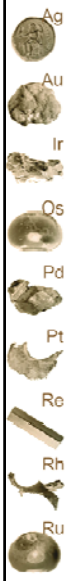
Aim is two-fold:

1. **Demonstrate RiCo for SCC assessment**
   no (significant) exposure = no release = good containment
2. **Prepare future Dossier upgrade needs**
   If SCC not met → Full intermediate dossier incl. Risk Characterisation (of which exposure assessment is a part)

Exposure assessment: Human health

- Collection of DNELs (or OELs) for all human health relevant constituents and identification of a '**decisive DNEL**' to define the most important risk driver and proceed with the occupational exposure assessment

1. If single decisive DNEL is sufficient for a refinable of variable composition (for a specific health endpoint)
   -> **consortia-wide** exposure assessment (sector-wide exposure scenario)
2. If decisive DNEL of one refinable varies considerably between different companies
   -> **company-specific** exposure assessment



Exposure assessment: Human health

- **Tier 1**: Exposure assessment using MEASE (modeling exposure)
- **Tier 2**: Exposure assessment using monitoring data (data generation)
- **Tier 3**: Further info / tests needed for refinements (particle size distributions, speciation analysis, …)

Next tiers will only need to be conducted if the risk assessment (as summarised in the RCR) does not demonstrate safe use.

Exposure assessment: Environment

- **Tier 1**: Development of Generic Exposure Scenario (GES) for each constituent, using default emission values (ERC or general metal SPERCs)
- **Tier 2**: Refinement of emission estimates using refined SPERC values
- **Tier 3**: Refinement of emission estimates using site-specific data (confidential)

EUSES will be used to model the env. exposure and resulting concentrations in each env. compartment.

Next tiers will only need to be conducted if the risk assessment (as summarised in the RCR) does not demonstrate safe use.

Monitoring will be needed where tier 3 modelling still identifies risk or where data are lacking.

Exposure assessment: differences between HH and ENV

	HH	ENV
Type of assessment	Workplace specific	Site specific
Expected data collection tiers	> 1	~ 1
Models/tools used	MEASE, Decisive DNEL	EUSES, SPERCs
Expected exposure assessment tiers	Minimum 3	2
RCR aimed at	< 1 for upgrades < 0.1 for updates (to be clarified by ECHA)	< 1 for upgrades To be clarified by ECHA for updates

Effects assessment – Read-across

- **Decisive DNEL**: aim is two-fold:
  1. To prioritise (define the most important risk driver for modelling/monitoring) and proceed with the occupational exposure assessment
  2. For effects analysis:

Define decisive DNEL per endpoint

⇩

Identify constituent of concern or read-across source (representative of all others)

⇩

Calculate RCR per endpoint (protective for all constituents)

Effects assessment – Read-across

- **Decisive DNEL - concerns**:

1. Potentially access will be needed to a lot of registration dossiers of individual constituents
   -> number of LoA's high (high cost)
2. Worst case approach: assuming 100% bioavailability
   -> bio-elution tests might be needed for refinement
   -> representative sample?

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Effects assessment – Read-across

ENVIRONMENTAL ENDPOINT

Assessment based on

- –Effects data constituents
  - •Most but probably not all available (can be checked on ECHA dissemination website and MECLAS)
- –Environmental Classification (see MECLAS)
  - •Updated for tox references and chronic endpoint
- –TDP test on Refinable
  - •Available: given based on the Representative samples selected / tested under the Registration program

Validation to check for "mixture effects"

- –Possibly toxicity test on most sensitive organism

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Effects assessment – Read-across

HEALTH ENDPOINT

Assessment based on

- –Effects data constituents
- –Health Classification (see MECLAS)
  - •Updated for tox references and new DNEL's
- –Selected Bio-elution tests to support "read-across"

Validation to check for "mixture effects"

- –Possibly (short term?) toxicity test or testing plan identification

To be further discussed

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Effects assessment – Read-across

Two pilot cases proposed:

1. Flue dust (oxides)
   ⟹ A lot of info available; "easy"
2. Metallic
   ⟹ Many corrections needed + bio-elution tests; "more difficult"

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Risk Characterisation

- Calculate RCR for human health and the environment
  - HH: compare exposure data with DNELs
  - ENV: compare modelled or site-specific exposure data with PNECs
- Updates: RCR used as qualitative supporting evidence of SCC
- Upgrades: RCR used in CSR to demonstrate safe use in registration dossier in IUCLID 5

Authorisation of substances used in PM refining

Authorisation of substances: process

- **Step 0:** "Registry of Intentions" (by ECHA)
- **Step 1:** Identification of Substances of Very High Concern (SVHC) (by authorities) -> 1st public consultation
  -> "Candidate list"
- **Step 2:** Prioritisation process (by authorities)
  -> on the basis of PBT/vPvB properties, wide dispersive uses, or high volumes + regulatory effectiveness
  -> 2nd public consultation
  -> "Authorisation list"
- **Step 3:** Applications for authorisation (by industry)
- **Step 4:** Granting of authorisations (by the European Commission)

Exempted from Authorisation: intermediates

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Authorisation – relevance to PM Refinables

- Although intermediates are not subject to Authorisation obligations under REACH, there may be
  - direct consequences if refining or reagent agents would be included in the Authorisation list (Hydrazine, Pb oxide, borax …)
  - indirect consequences if any of the Refinable constituents should require Authorisation, as uncertainties about security of supply might occur (suppliers might be denied Authorisation, requiring phase-out of supply).
- A clear longer-term strategy seems justified given several Refinable constituents are and can in the coming years be listed on the Candidate List and/or are prioritised for Authorisation.

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Authorisation strategy

Action ECHA	Action PMC Refinables WG	Comments
	Eurométeaux regularly checks the registry of intentions published by ECHA	ROI allows interested parties to be aware of the substances for which the authorities intend to submit Annex XV dossiers.
Hypothesis 1: Constituent of PM Refinable is published in the Registry of Intentions - Proposal for SVHCs and an Annex XV dossier is submitted.	• Check possibility of categori-sation as intermediate-type use. • If intermediate-type use cannot be confirmed: possibility to submit a dossier within the deadline set for comments	If intermediate-type use can be confirmed, then the use is exempt from Authorisation.
Hypothesis 2: Constituent of PM Refinable is published in the Candidate List for Authorisation	Verify communication obligations along the supply chain (Article 33). None for confirmed intermediate!	As soon as a substance is listed in the Candidate list, duty of communication applies.
Hypothesis 3: Constituent of PM Refinable is prioritised for Annex XIV inclusion (Authorisation List) and ECHA's draft Annex XIV recommendation is published on the ECHA website	If intermediate-type use cannot be confirmed: possibility to submit comments via webform within 3 months of the date of publication, in particular on uses that should be exempt from the Authorisation requirement.	Article 58(2) of REACH: possible to exempt from the Authorisation requirement some uses or categories of uses provided that based on existing specific EU legislation imposing min requirements for protection of human health & environment the risk is properly controlled.

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Authorisation strategy (2)

Action ECHA	Action PMC Refinables WG	Comments
Hypothesis 4: Constituent of PM Refinable is included in Annex XIV (Authorisation List)	If constituent use is not intermediate-type and not exempt from Authorisation: • Send a notification of intent to ECHA • Prepare and submit an Application for Authorisation. a) based on CSR, show that risks are adequately controlled, that tonnage is not of high concern, that there is no wide dispersive use and env=no PBT/nor=vPvB; b) analysis of alternatives; c) if there are alternatives, submit a substitution plan; d) based on more socio-economic evaluation, show that there are no alternatives, benefits outweigh the cons (socio-economic analysis or SEA).	• There is no tonnage threshold for a substance to be subject to Authorisation. • Authorisation will be granted if the registrant can show: a) Adequate control of risks or b) Social economic benefits outweigh the risks and no substitution is possible. • If suitable alternatives are available, the application for Authorisation is unlikely to be granted. • A fee has to be paid for each Authorisation application. • All Authorisations will be reviewed after a certain time-limit which will be set on a case-by-case basis, and industry must re-apply (with the appropriate fee).

Takes a long time!

Base fee: 50.000 €

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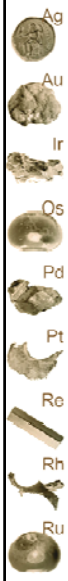


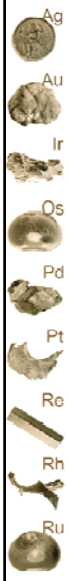
3. Update on advocacy programme of Eurométaux: examples, information requirements UVCBs

Status SCC-Intermediates discussion

As a reminder !

- Political action (at Caracal level) allowed to reopen the discussion
- Meeting with senior executives at ECHA :
  - Focus on guidance interpretation
  - Cases on "level 2" of the Hirst scheme can be SCC and RC, IF clearly demonstrated why "conditions are strictly controlled".
  - Develop case examples and discuss them with ECHA (CEFIC-EUROMETAUX-CONCAWE)

Type of examples



- Ideally 2 – 4 examples
- From different metal sectors
- Demonstrating:
  - *Overall complexity & variability* of material streams & processes
  - *Co-existence of different physico-chemical forms*, incl. massives
  - UVCB are more V than U: *hazard effects of constituents* are known
  - *LEV functions properly to remove all exhausts* from workplace
  - *Wearing of PPE* not a primary mean of workers' protection
  - *Availability of exposure data* to demonstrate rigorous containment and safety of workers and environment
- One process step in the life-cycle of the intermediate
- Using template of Appendix 3 of ECHA Guidance on intermediates

Examples: additional info from ECHA

- *Focus to HIRST 2 conditions* and demonstrate Rigorous Containment is complementary achieved through:
  - "Physical form" contribution
  - LEV's : creating "physical or chemical" barier
  - "Effects can not occur" on basis of effects knowledge
- Preparedness to *discuss read across approach* in late autumn (don't come with final proposal: engage us !)

Examples: what happened (1)

- 4 examples were submitted by Eurometaux
- CEFIC submitted also examples
- CONCAWE did not

- Review discussion along MSC mtg November and RAC last week.

Examples: further info from ECHA

Generic comments :

- Examples are step forward
  - CEFIC's examples were less comprehensive
- BUT still require further technical update:
  - More focus on "issue only"
  - More demonstration of RiCo
  - Less reference to aspects like IPPC, OEL, …
  - …

- Feeling that comments of ECHA reviewers
  - Did not fully recognise specificities of the metals sector !!!
- **Opening towards** a simplified approach for using **existing evidence for "test waiving"** (they even did not call it Read-Across)

Examples: further info from ECHA

Next steps:

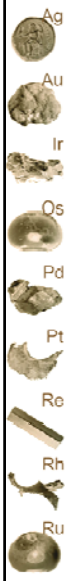
- Slight review and Cosmetic update
- Technical review/discussion with ECHA staff

- BUT
  - CEFIC stops working on examples
    - Difficult to achieve internal agreement
    - More focus on training national inspectors

- Eurometaux:
  - Will conduct the updates before Dec 14
  - Check ECHA's reaction

CONCLUSION

- "**Last try**" on the examples (Dec-Jan)
- Each **company should settle** on what they feel SCC and defendable vis-a-vis national authorities
  - using RICOG-decisive DNEL/MEASE check,
  - and own judgement…
- Growing momentum for **upgrades**
  - Given simplified test waiving approach
  - Exposure assessment anyway relevant for the two options
  - Longer term considerations
  - Tiered approach for ENV enough for full dossier
  - …



4. Workplace exposure assessment programme

Occupational Exposure

Way forward, questionnaire & pilot study

Refinables WG Meeting

Brussels

5 December 2011

Daniel Vetter
EBRC Consulting
Hannover, Germany

Proposed general approach & tools

- Tiered approach & tools:
  - Screening of RiCo with e.g. RiCoG by companies
  - If SCC cannot be demonstrated for PMRs
    - Identification of decisive DNEL
    - EA with MEASE
    - EA with inhalation monitoring data
    - Further refinements

→ Feasibility to be checked with the pilot study!
→ Refinement of approach required?

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Updated version of RiCoG I/II

- Feedback received
  - Internal and external comments of varying extent
- Some critical points:
  - Metal specific issues to be better reflected
    - Physical forms
    - Containment strategies
    - CS2+
    - Process steps

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Updated version of RiCoG II/II

- Metal-specific adaptations:
  - Additional physical forms:
    - molten metal/slag, metal in liquid mixture, slurry, wetted filter cakes
  - “Liquid substances” not relevant, disabling vapour pressure
  - Replacement of quantity determinant with process determinants
  - Inclusion of CS0+ and CS2+
  - Metal-specific adaptation of CS characteristics (not yet complete)
- Further amendments
  - Process step specific assessment
  - Descriptive data fields included
  - Glossary to be amended

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RiCoG - Live session

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Status of occ. exposure survey

- 11 individual questionnaires from 11 sites
  - 3 of these sites will provide further information (additional questionnaires and/or additional process steps are expected)
- 3 companies with multiple (2 - 8) questionnaires

→ total of 24 returned questionnaires (22 included into database so far), no feedback received from 1 company

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Status: 29/11/2011

Availability of exposure monitoring data

- Inhalation monitoring data received from 7 companies (1 provided data in own format, 6 used the EBRC-format), some minor issues to be solved…
- Biomonitoring data are available as well at some companies (not yet addressed)
- Dermal exposure data were not available at all

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Status: 29/11/2011

Availability of DNELs

- No DNEL-reports received yet
- Some DNELs available from the dissemination database (but information on these DNELs is very limited → critical for the development of "decisive-DNEL-tool")

→ Trying to get further information on DNELs

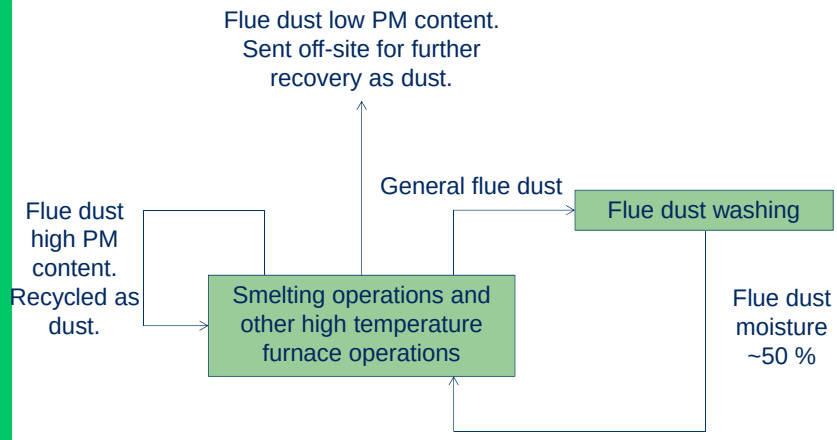
→ Work-around: OELs for flue dust provided by JM

Status: 29/11/2011

Pilot study: Flue Dust

- Flue dust example:
  - Johnson Matthey volunteered
  - Provided information:
    - Process flow chart
    - Composition profile
    - Process description
    - Operational conditions and risk management measures
    - Inhalation monitoring data

Flue Dust: Process overview



→ Flue dusts with different PM content, depending on input materials

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Flue Dust: Composition

- Large variation of concentrations of constituents:
  - Often 0-15%
  - Sometimes factor of 18 from min to max
  - Even a factor of 37 from min to max possible

→ Implications for the development of the Decisive-DNEL-Tool

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Flue Dust: Process description

- 4 process steps:
  1. high temperature operations (PROC 22)
  2. sealing of drums (PROC 26)
  3. flue dust washing (PROC 26, 4)
  4. furnace loading (PROC 26) when furnace is cooled down
- Different physical forms:
  - Molten metal/UVCB
  - Powder (high dustiness?)
  - Wetted powder (low dustiness)

→ Emission potential depends on physical forms of the material used

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Flue Dust: Monitoring data

- One of the critical DNELs/OELs is for Platinum (e.g. 2 µg/m³ for soluble platinum compounds) → monitoring predominantly aimed at compliance checking for Pt (not distinguishing between soluble/insol.)

→ High number of data points available for Pt

- But, content of Pt varies between different Flue dusts:
  - High PM flue dust: 2 - 2.5%
  - Low PM flue dust: 0.029%
  - General flue dust: 0.1 – 0.276%
  - Composition profile (up to 15% PGMs) was broad to include flue dust imported from other companies

→0.018 – 17 µg/m³ measured in personal measurements (mean=1.6 µg/m³), strongly depending on the input materials

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Critical points in pilot study I/II

- Composition:
  - Varying PM content in individual flue dust streams (low PM, high PM, general flue dust)
  - DNELs only available for a few ingredients
- Process:
  - Furnaces sealed during operation, loading of furnaces when cooled down
    - → Dustiness of the refinables, not temperature of the process, is exposure driver → two steps for RiCoG
    - → Dustiness testing strongly suggested

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Critical points in pilot study II/II

- Monitoring data (specific to flue dust):
  - Inhalation monitoring aimed at demonstration/checking of compliance with most sensitive OELs (Pt, Rh)
  - Number of observations (personal + static) for individual substances vary between 0 and 8 with Pt having 21 values

→ Varying extent of data sets for different substances for 2009/2010 (additional (older) data will be submitted once available)

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Example: RiCo of Flue dust

- Demonstration of rigorous containment with RiCoG:
  - Classification was provided to us (same classification result for maximum concentrations and typical concentrations):
    - H301, H332, H314, H318, H334, H317, H341, H350, H360, H372, H410
    - → All groups of H-statements need to be selected in RiCoG
    - → Result: Hazard group E

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Example: RiCo of Flue dust – Live session

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Example: Decisive DNEL for Flue dust

- Ranking of DNELs in consideration of different percentages:
  - Performed with available OELs
  - Cold processes only
  - Without consideration of different effects (long-term, short-term, …)
  - Lowest ranks would be for rhodium and platinum (soluble compounds): 0.001 mg/m³ and 0.002 mg/m³ respectively
  - Next highest ranks would be for selenium, silver and tellurium

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Example: EA of Flue dust (MEASE)

- Exposure assessment with MEASE (long-term, inhalation):
  - Lowest initial exposure estimate in MEASE for massive object
    = 1 µg/m³ (PROC 1 and PROC 2)
    (without consideration of PPE)
  - For high dusty substances
    = 10 µg/m³ (PROC 1)
    = 1 mg/m³ (PROC 2)
    (without consideration of PPE)

→ Outcome strongly depends on physical form

→ Many of the DNELs are relatively low…

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Example: EA of Flue dust (measured data)

- Exposure assessment (measured data):
  - **Rh:** 8 data points, 0.01-4 µg/m³ (mean = 0.8 µg/m³), comparing to an OEL of 1 µg/m³
  - **Pt:** 19 data points, 0.018 – 17 µg/m³ measured in personal measurements (mean = 1.6 µm/m³), comparing to an OEL for soluble Pt compounds of 2 µg/m³
  - **Ag:** 5 data points: 2-200 µg/m³ (mean = 46 µg/m³), comparing to an OEL/DNEL of 100 µg/m³/10 µg/m³
  - **Se:** 5 points: 4-160 µg/m³ (mean = 44 µg/m³), comparing to an OEL of 100 µg/m³
  - **Te:** 5 points: 3-60 µg/m³ (mean = 17 µg/m³), comparing to an OEL of 100 µg/m³

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Conclusions / discussion points

- Hazard information is not complete:
  - DNELs are not complete for known constituents
  - Unknown constituents
  - Varying content of constituents
  - Implications for decisive DNEL / read-accros → OELs?
- Exposure data will not yet cover risk driver for each refinable for each company
- Process information for development of ES was gathered
- Dermal exposure is not yet considered

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Way forward

- Exposure data base will include:
  - Conducted processes including OC and RMMs at process step/activity level
  - With assigned refinable streams incl. composition
  - With assigned measured data (inhalation)
- Exposure data base will allow:
  - To develop exposure scenarios at the process (step) level
  - the generation of a data gap matrix (DGM)
- DGM to develop monitoring strategy to fill data gaps
- Strategy for dermal exposure monitoring to be developed

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Thank you for your attention!

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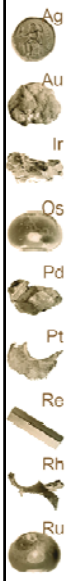

5. Environmental emissions assessment programme

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Assessment of environmental exposure: Proposed general approaches and tools

Ed Stutt, Adam Peters, Claire Massey,

REACH Ready Approved Supplier
ISO 9001 REGISTERED FIRM
ISO 14001 REGISTERED FIRM

Overview

- SCC and the environment
- Two approaches
  - » Dossier updates
  - » Dossier upgrades
- Responses to survey questionnaires
- Modelling and risk characterisation

SCC and the environment

- Rigorous containment primarily considered under human health assessment
  - » criteria primarily relate to process engineering and worker exposure
  - » generally no need to repeat for environment.... but may need to assess storage conditions when environmental hazards are the only concern
- If not rigorous containment then not SCC
- If rigorous containment, possibly SCC depending on environmental RMM and other factors

SCC and the environment

- Need to demonstrate that any emissions are controlled by appropriate Risk Management Measures (RMMs)
- Basis for compliance with SCC can possibly be based on:
  - » company's IPPC license or permit, as long as adequate documentation and evidence of compliance are available
  - » relevant IPPC (Directive 2008/1/EC): Best Available Technique Reference Document (BREF) to demonstrate the effectiveness of procedural and control technologies from the perspective of minimisation of emissions

SCC and the environment

- Use of appropriate **RMMs** is required to demonstrate compliance with SCC
  - » Opposite to worker assessment!
- Compliance with other regulatory schemes (IPPC) can be used as evidence
- Monitoring data can also be used to support conclusion of SCC
  - » Used qualitatively to demonstrate releases are negligible
  - » It is currently being discussed by Member States whether RCR could be used as evidence of SCC

Two approaches to Registration

- Dossier updates
  - » SCC criteria met
  - » Company includes justification for this conclusion in dossier
  - » Potential to include monitoring data to confirm SCC
- Dossier upgrades
  - » SCC not met or company opts to complete upgrade
  - » Full substance hazard dossier required
  - » Full exposure assessment required
  - » Adequate monitoring data (and modelling) required to demonstrate safe use (i.e. RCR <1)

Survey Questionnaires

- Useful for both updates and upgrades
- Captures information on:
  - » Refinable composition
  - » Tonnage
  - » Potential emissions
  - » Risk Management Measures (RMMs – type & efficiency)
  - » Monitoring data
  - » Confounding factors

Questionnaires

- One questionnaire for each site
  - » Potentially several refinables and other materials with similar components on site
- Process diagram gives us a much better understanding of your site and processes involved
- Site visits appreciated for further understanding of processing
- May come back to you with specific questions as we review the questionnaires and process diagrams

Modelling and risk characterisation

- Focussing on refinables components that have an environmental classification
  - » Ag, As, B, Cd, Co, Cr, Cu, Ni, Pb, Zn
- Difficult to assess risk from UVCB as a single substance
  - » Different properties, environmental behaviour and toxicity
- Model each component separately
- Local environmental concentrations estimated according to R16 guidance

Modelling and risk characterisation

- Environmental exposure information for sites
  - » Tonnage, emission characteristics (days/yr, flow rates), emission conc., dilution factor, etc…
- Local environmental concentrations
  - » Air, freshwater (with and without further treatment at a municipal STP) and marine waters as receiving environment
  - » Regional background not considered at this stage
- Most sites lacking some necessary information
  - » A few sites have provided all the required information

Modelling and risk characterisation

- Tier 1
  - » Developing Generic Exposure Scenario for "Manufacture and use as an intermediate in the recovery of precious metals"
  - » 'Reasonable worst case scenario' using maximum or 90th percentile tonnage (from all sites), typical RMMs, emission characteristics and default emission values (e.g. SpERCs)
  - » One GES for each component (9 in total)
  - » These GES used for <u>all refinables</u>
    - o *practical and reduces the resource and time*
    - o *reduce issues of commercial confidentiality (as specific component and refinable combinations will not be identified)*

Modelling and risk characterisation

- If RCR are above 1 for any component move to Tier 2
  - » Same GES emissions data and exposure characteristics
  - » Basis of GES remains constant but it is individually quantified with emission factor for each component (9 in total)
  - » Also review latest SpERC values to refine emission estimates
    - o *Compare these to emission factor based on data provided by companies to ensure that they are representative for the refinables sector*

Modelling and risk characterisation

- If RCR are above 1 for any component move to Tier 3
  - » Site specific assessment
  - » 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 will be confidential and only shared with the respective companies***
  - » Will identify those sites which can demonstrate safe use, and those sites which need additional refinement to demonstrate safe use (i.e. more information or monitoring)

Environmental Exposure Questionnaires

- Questionnaire developed to capture all of the available data that is relevant to environmental exposure resulting from processing of refinables
- A questionnaire needs to be completed for each site
- Data on:
  - *- Tonnage (of refinables as opposed to specific metal constituents)*
  - *- Composition of refinables (range and mean)*
  - *- Risk Management Measures (RMMs) and efficiencies*
  - *- Quantified emissions to air and aquatic environment*
  - *- Characteristics of receiving environment*

Summary of responses so far

- 12 questionnaires received to date (9 contained 'reasonable' amount of information).....so still more to come.
- Good level of information on stack emissions and waste-water output (and receiving environment)
- Composition of refinable materials shown to be HIGHLY variable (so we need tonnage values and typical or average concentration of constituents to calculate total input)

Summary of responses so far

9 responses:

Parameter	No. Questionnaires providing data
Tonnage	7
Composition	7
Water sol of constituents	1
Emissions to air	8
RMM & efficiency	7 + 4
Emissions to water	8
RMM & efficiency	6 + 4
Waste	7

Questionnaire Survey

- Keep responses coming over next few weeks
- We are happy to receive revised versions of the questionnaire (.....up to agreed cut-off point)
- We are happy to discuss and answer your questions
- We have be in touch to request additional data and will do so again

Generic Exposure Scenario

- 3 scenarios required for discharge to aquatic environment
  - » (freshwater with/without STP & marine)
- Provisional GES developed based on 6 sites providing most complete datasets ..... to be expanded!
  - o *Maximum or 90th percentile tonnage value for each constituent*
  - o *Description of RMMs and range of efficiencies*
  - o *Maximum or 90th percentile emission factors (EFs) to air and water (after RMMs) calculated across all constituents and for individual constituents (cf. SpERCs)*
  - o *Median or 10th percentile emission days (under review)*
  - o *Median or 10th percentile effluent flow rate and dilution factor (under review)*

GES parameters – Emission Factor (EF)

- EF is a very important parameter for GES
- EFs (air and water) calculated on annual basis as % or g/T from

$$\frac{\text{amount discharged}}{\text{tonnage used/produced}}$$

- SpERCs have been produced detailing EFs for various sectors of the metals industry

Refinables EFs vs Metals SpERCs

SpERC	Emission Factor (AIR)
Manufacture of massive metal, metal powder	0.03% (90P of 111 sites)
Formulation of massive metal, metal powder	0.03% (90P of 145 sites)
Use of refinable intermediates	0.017-2.7% (Values for 9 metals from 5 sites) Overall 90P = 0.096% (26 values from 5 sites) *[0.03% IF we exclude 2 apparent outliers]*

Refinables EFs vs Metals SpERCs

SpERC	Emission Factor (WATER)	Emission Days
Manufacture of massive metal, metal powder	0.002-0.03% (90P of 142 sites)	218 days/yr (10P of 110 sites)
Formulation of massive metal, metal powder	0.001-0.2% (90P of 201 sites)	182 days/yr (10P of 168 sites)
Use of refinable intermediates	0.006-2% (Values for 9 metals from 5 sites) Overall 90P = 0.04%	? 10P = 282 days for water 10P = 99 days for air

Further work on emission factors (EFs) and SpERCs

- More data ⟶ more statistically robust EF values (reduce effect of outlying values on 90P/10P calc)
- Assess use of latest (metal specific) SpERC values for emissions to aquatic environment (modfied by partition coefficient, K_d)

Emission Factors - Important Issues

- For calculation of emission factors it is essential that we are comparing <u>like with like</u>
- Currently we have been provided with refinables input and total site emissions (conservative!)
- Where possible, for each metal component we need total produced/used and emitted to environment <u>due to refinable processing</u>
  - estimate proportion of total
- Also need site total input per metal if other activities on site using these substances

Provisional Exposure Modelling

- Undertaken initial site-specific modelling (only local air and freshwater without STP possible at present)
- Additional parameter values are still required, e.g.
  - *Kd, STP removal rate*
  - *PNECs & DNELs*
- *All GES parameters to be revised on receipt of complete datasets, initial results detailed below:*

Constituent	Air	Freshwater (no STP)
Silver	NO RISK (RCR<1)	NO RISK (RCR<1)
Nickel	RISK (RCR>1)	NO RISK (RCR<1)
Chromium	RISK (RCR>1)	NO RISK (RCR<1)

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6. Strategy to review the hazard classification of Refinables

PM Refiners WG meeting – Brussels, 5 December 2011
Precious Metals and Rhenium Consortium

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ASSESSING RISKS OF CHEMICALS

Pilot study:
Cluster analysis on PM Flue Dust

Frederik Verdonck

Stepwise approach in pilot study

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Statistical cluster analysis on **composition**

Support from: Dave Boyd

Manual cluster analysis based on **impact classification**

Support from: Mari Jarvikivi, Angela Alderman, Paul Frost

Define profile groups

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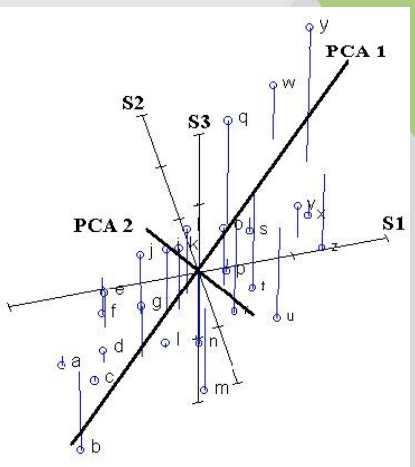
Methodology

94

- Principal Component Analysis
  - Converts possibly correlated elemental concentrations into a set of values of uncorrelated variables called **principal components**
  - Multidimensional data set reduced to 2 dimensions



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Methodology

- Cluster Analysis: various methods
  - **Partitioning algorithms**: method divides a priori into k clusters and algorithm carries out clustering (k-means + pam)
  - **Hierarchical algorithms**:
    - **Agglomerative methods** start with every stream as separate cluster and then successively merges
    - **Divisive methods** start with whole data set as one cluster and then splits up until each stream is separate cluster.

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Methodology

- Cluster Analysis
  - **Measure of similarity or dissimilarity**: Euclidean distance, Manhattan distance, nearest or furthest neighbor method,…
  - Various methods gave similar results for 1-2-3 clusters but more differences occur for >3-4 clusters, therefore, **3-4 clusters is considered maximum for robust assessment**

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Methodology

97

- Database used for company classifications in 2010 + 2 company updates
- Nondetects: DL/2 is taken
- Absence of concentrations is assumed as “0”
- Scenarios:
  - Maximum elemental conc. (vulnerable to sum >100% !)
  - Mean of elemental concentration range
  - Elemental concentrations “as such”
  - Rank-transformed elemental concentrations

Methodology

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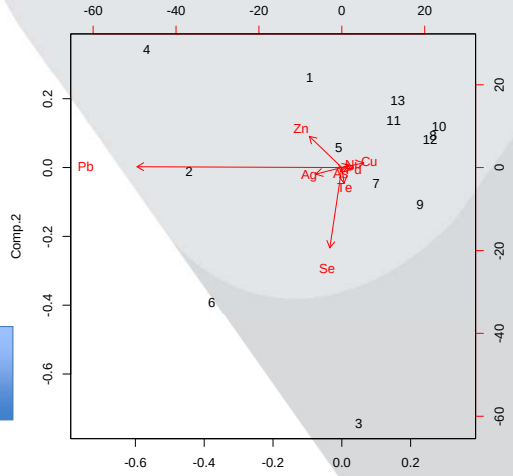
- Need pre-selection of elements to avoid that number of variables > number of observations

Elements driving classification selected

For flue dust: **As, Ni, Pb**, Se, Cu, Te, Zn, Ag, Pd

Results
Principal Component Analysis

Scenario
Typical
Untransformed



Se dominated second component (due to 1 Cie!)

Pb dominated first component

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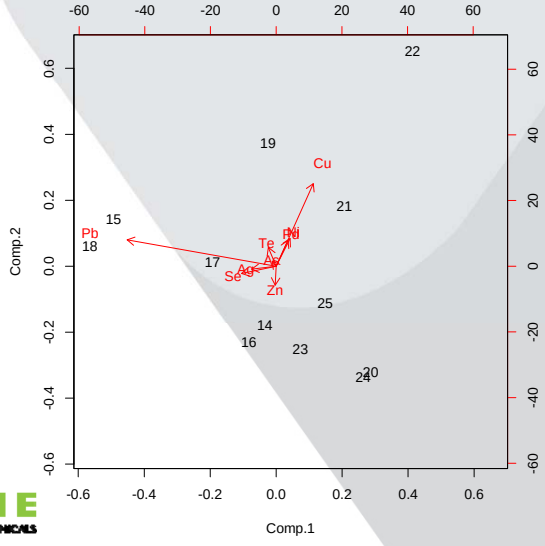
Results
Principal Component Analysis

Scenario
Maximum
Untransformed



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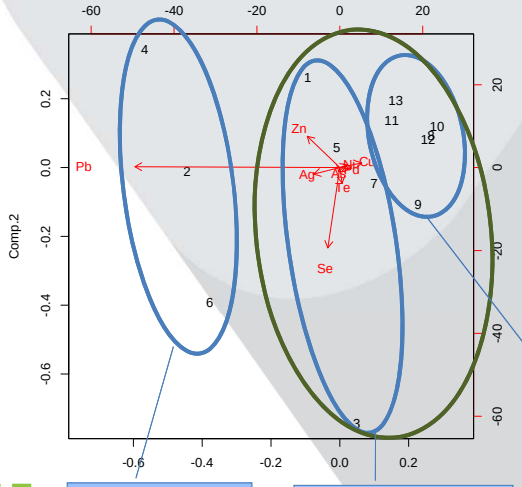
Results cluster analysis
Partitioning: pam

101

Scenario
Typical
Untransformed



High Pb cluster

Medium Pb cluster

Low Pb cluster

Results cluster analysis
Partitioning: k-means

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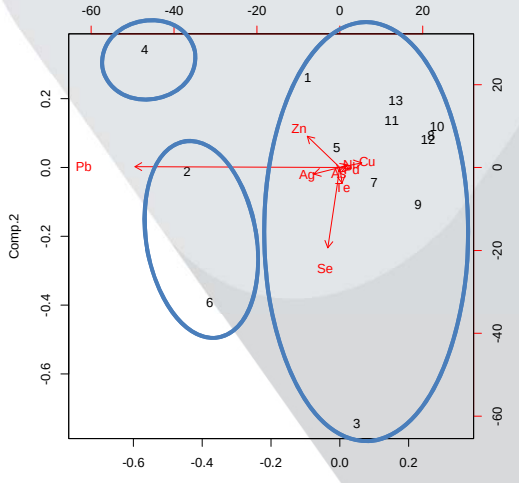
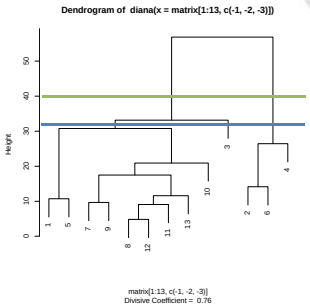
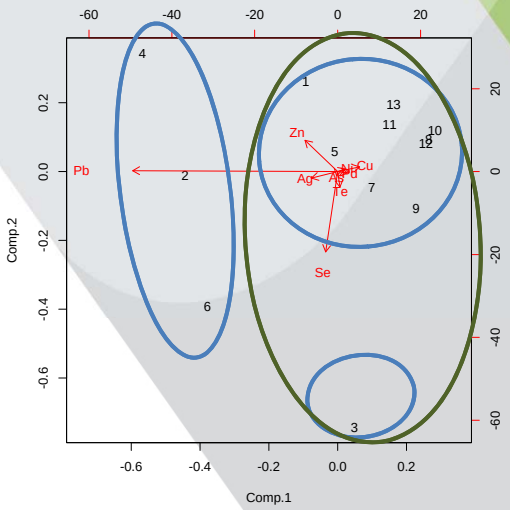
Scenario
Typical
Untransformed



Results cluster analysis
Hierarchical: agglomarative+divisive

Scenario
Typical
Untransformed





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Discussion

- Principal component and cluster analysis driven by
  - Pb because largest in absolute value
  - Se (in case of typical sc) or Cu (in case of max sc) because of one company (outliers)
- More relevant to use rank-transformation because:
  - All metal concentrations are normalised to same scale
  - More robust analysis (minimizes effect of outlier Cies)

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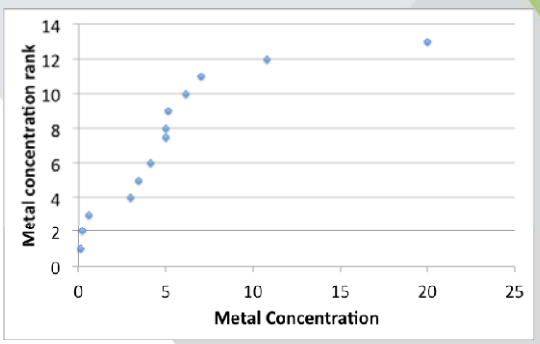
Methodology

- Rank transformation

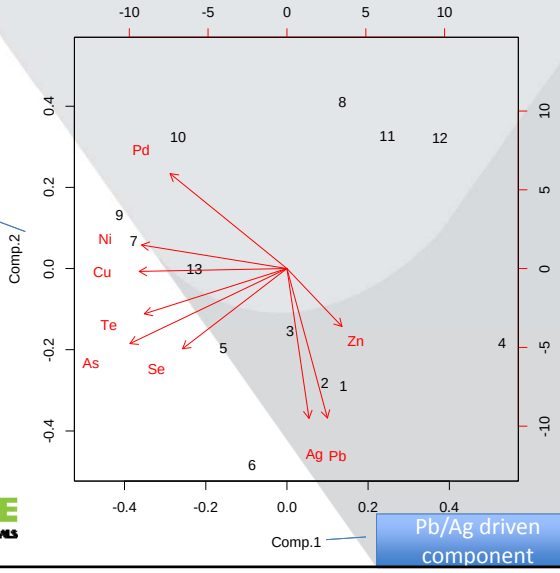
Metal Conc	Rank
10,8	12
6,15	10
4,1	6
5,125	9
7	11
20	13
3,45	5
0,2	2
2,985	4
0,585	3
0,119	1
5	7,5
5	8



Results
Principal Component Analysis

Scenario
Typical
Rank-transformed

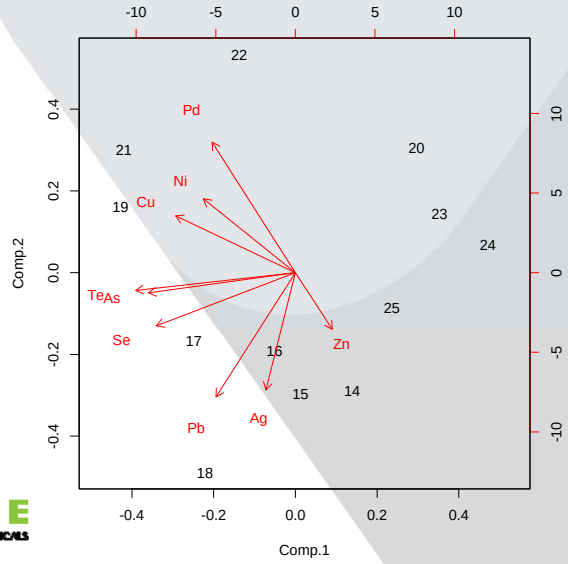
Ni/Cu/Te/As driven component



Pb/Ag driven component

Results
Principal Component Analysis

Scenario
Maximum
Rank-transformed



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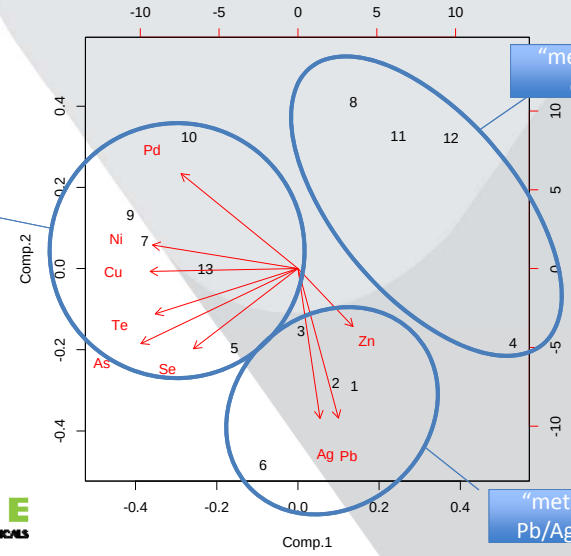
Results: Cluster analysis
Partitioning: k-means + pam

Scenario
Typical
Rank-transformed



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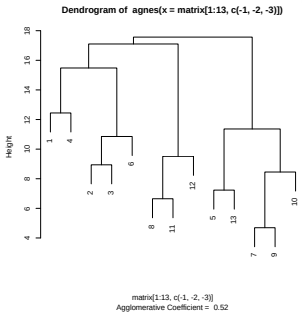
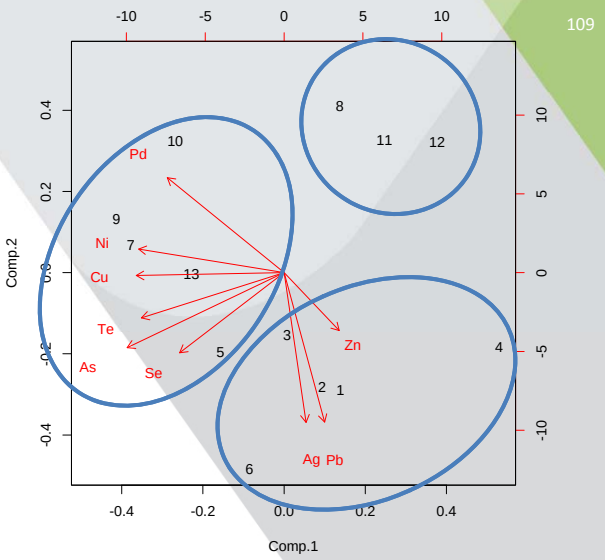
Results: Cluster analysis Agglomarative

Scenario
Typical
Rank-transformed





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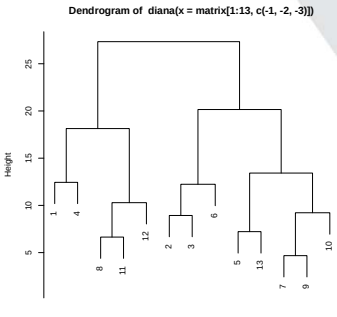
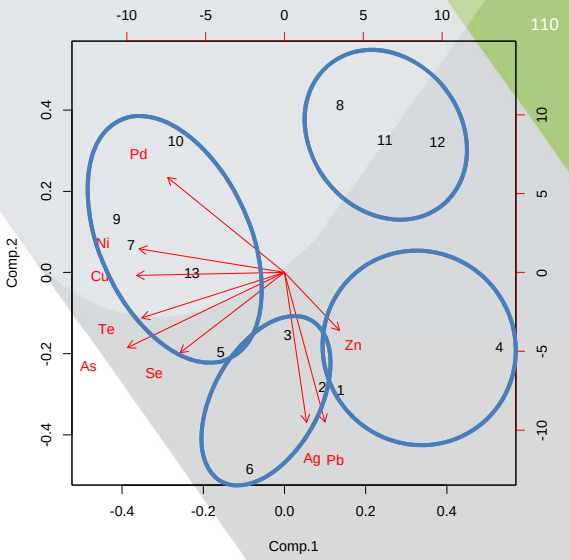
Results: Cluster analysis Divisive

Scenario
Typical
Rank-transformed





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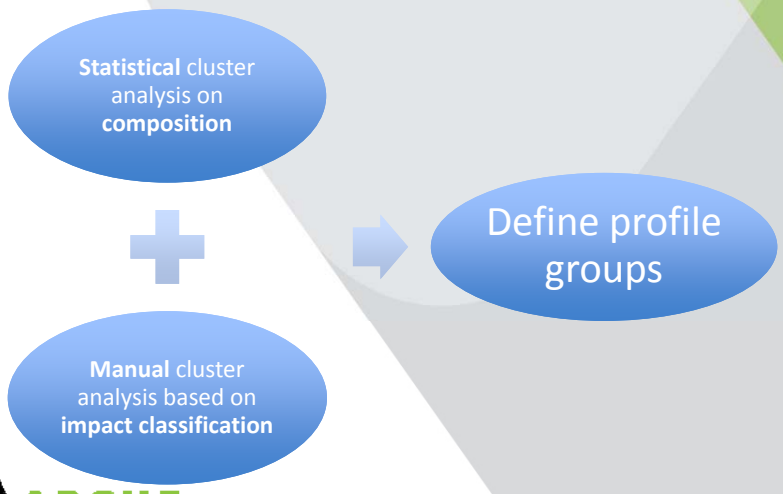
Discussion

- Principal component and cluster analysis gives
  - similar clusters
  - Depending on method, Cie can be allocated to different cluster
- Rank-transformation gives more robust assessment
- Results not much different for typical versus maximum scenarios

Stepwise approach in pilot study



Impact classification

		Transport & packing	Permits	SEVESO
Hazardous to the aquatic environment -	Acute Cat 1, Chronic Cat 1,2	YES		YES
	Cat 3,4	NO		NO
Hazardous to the ozon layer		NO		NO
Acute Toxicity	Cat 1,2,3	YES	YES	YES
	Cat 4	NO		NO
Skin corrosion/irritation	Cat 1 (1A, 1B, 1C)	YES	YES	NO
	Cat 2, 3	NO		NO
Serious eye damage/eye irritation	Cat 1, 2A, 2B	NO		NO
Respiratory or skin sensitization	Cat 1	NO		NO
Germ cell mutagenicity	Cat 1A, 1B, 2	NO	YES	NO
Carcinogenicity	Cat 1A, 1B, 2	NO	YES	NO
Reproductive toxicity	Cat 1A, 1B, 2	NO	YES	NO
Specific target organ toxicity single exposure	Cat 1, 2, 3	NO		NO
Specific target organ toxicity repeated exposure	Cat 1, 2	NO		NO
Aspiration hazard	Cat 1, 2	NO		NO

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ASSESSING RISKS OF CHEMICALS

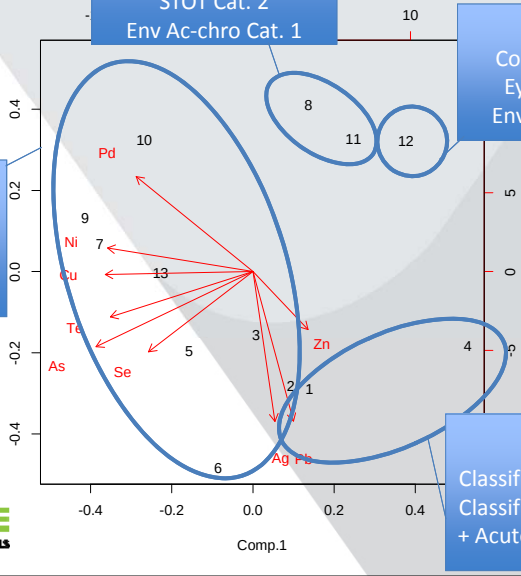
Results Typical

Cluster 2
Skin sens. Cat. 1
Carc. Cat. 1
Repr. Cat. 1
STOT Cat. 2
Env Ac-chro Cat. 1

1 Cie Carc. Cat. 2
1 Cie no Repr. class.

Cluster 1
Corrosion Cat. 1B
Eye Dam. Cat. 1
Env Ac-chro Cat. 1

Cluster 4
Classification Cluster 3
+ Acute oral+inh Cat. 3
Muta. Cat. 1B
STOT Re Cat. 1



Most Cie Acute inh Cat. 4
1 Cie skin corr. Cat. 2
2 Cie no Resp/skin sens
3 Cie Mut. Cat. 2
3 Cie STOT Re. Cat. 2

1 Cie no Acute oral
1 Cie no Skin sens
1 Cie Carc. Cat. 2

Cluster 3
Classification Cluster 1
Classification Cluster 2
+ Acute oral+inh Cat. 4

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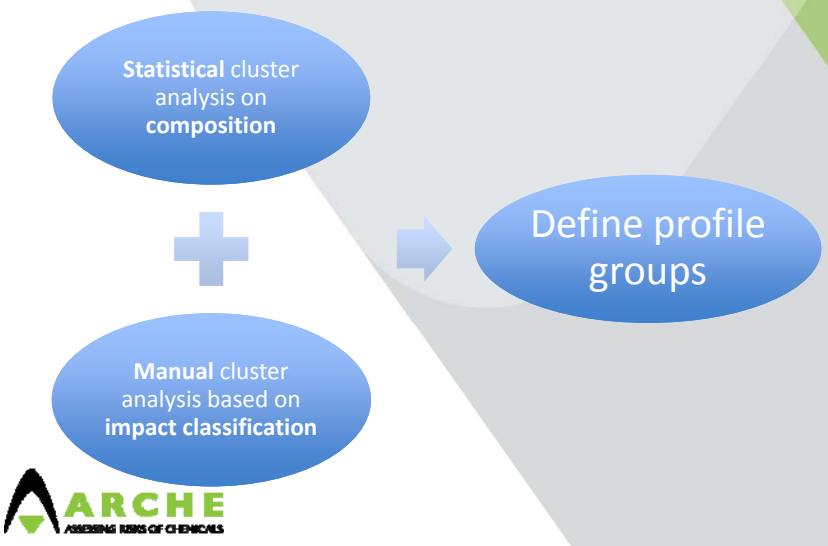
Discussion

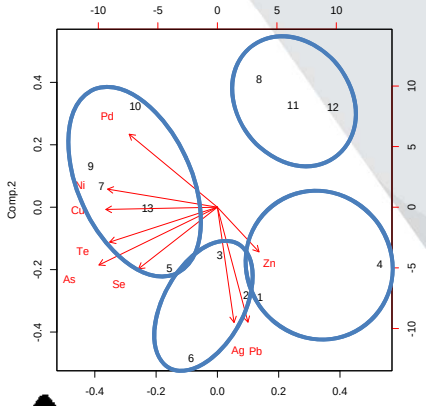
- Relatively “easy” to define clusters for flue dust
- More differentiation in “metal-poor” cluster and less differentiation in “metal-rich” cluster
- Suggests cluster analysis based on elemental concentrations divided by their classification cut-off

Stepwise approach in pilot study

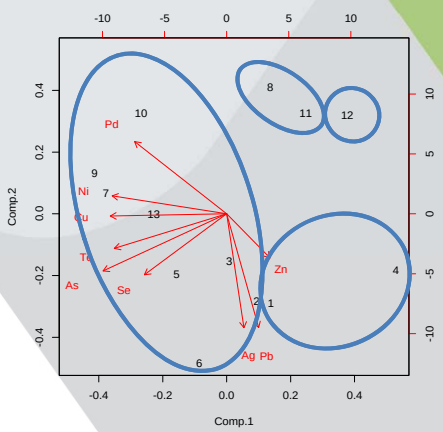


Results for typical

Cluster Analysis
Hierarchical: Divisive



Cluster Analysis
Impact classification



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Discussion

- Discussion clusters for flue dust
  - Weight of chemical clustering
  - Weight of classification clustering
- Recommendations for slags, slimes & sludges, materials for reclaim:
  - Keep overall approach
  - But reduce number of cluster analysis methods, main message is in principal component analysis
  - Focus on rank-transformed (and typical?)

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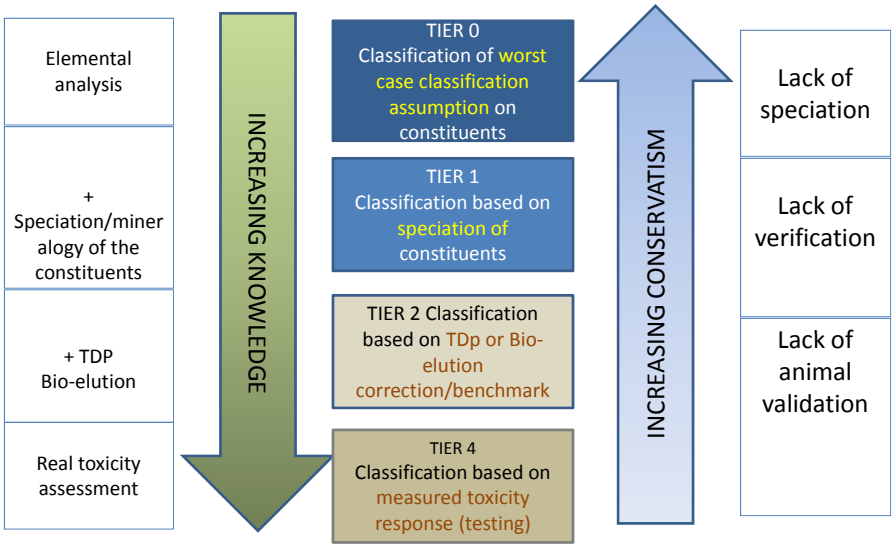
ASSESSING RISKS OF CHEMICALS

SCHEMATIC OVERVIEW of the TIERED CLASSIFICATION APPROACH FOR COMPLEX MATERIALS

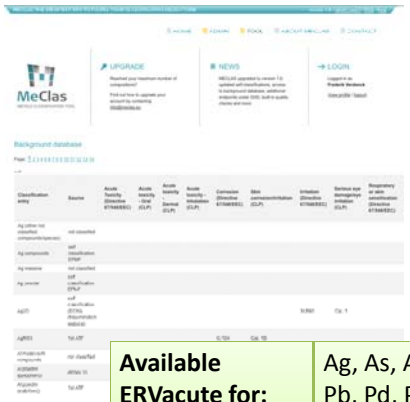


MeClas

2nd ATP Implementation Mixture rules

	Summation method	**Additivity method**
TIER 0: Classification of worst case classification assumption on constituents	MECLAS v1.6 (1st ATP) → **MECLAS v2.0beta (2nd ATP)**	
TIER 1: Classification based on speciation of constituents	MECLAS v1.6 (1st ATP) → **MECLAS v2.0beta (2nd ATP)**	
TIER 2: Classification based on TDp or Bio-elution correction	To do: **MECLAS v2.0beta (2nd ATP)**	MECLAS v1.6 (1st ATP) → **MECLAS v2.0beta (2nd ATP)**

2nd ATP Implementation Background database



Implemented in beta version

- Acute & chronic environmental classification
- Acute & chronic M-factor

Available ERVacute for:	Ag, As, Au, Ba, Cd, Ce, Co, Cr, Cu, La, Mn, Nb, Ni, Pb, Pd, Pt, Rh, Sb, Se, Ta, Te, Ti, W, Zn
Available ERVchronic for:	Ag, As, Au, Ba, Cd, Co, Cr, Cu, Mn, Ni, Pb, Pt, Sb, Se, Zn

Classification in registration dossier vs. SDS

Question to be submitted to ECHA helpdesk

"The Precious Metals and Rhenium Consortium members have in 2010 registered several UVCB intermediates – complex metal containing substances with variable composition.

The Consortium has derived several classifications by grouping composition profiles based on combination of constituents driving classification entries. Individual composition of the substance at registrant company may trigger "lighter" classification due to presence of one or several constituents below the classification cut offs.

Although the hazard classifications in the REACH dossiers reflect "worst case" hazard identification and corresponding classifications, it is our understanding that each registrant needs to use the actual hazard classification of the material manufactured or imported on its SDS. This would mean that there could in some cases be a discrepancy between the classifications appearing in the dossier (more worst cases since covering the variability for all registrants the joint registration applies) and those appearing in the company specific SDS (worst cases or not) of the relevant intermediates; but the intermediates would bare the appropriate classification during manufacture and use.

Can the ECHA helpdesk confirm this reasoning?"

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5. AOB, next calls, meetings, and closing remarks

- **Refinables project 2012 budget and cost-sharing**

PM Refiners WG meeting – Brussels, 5 December 2011
Precious Metals and Rhenium Consortium

Thank you!