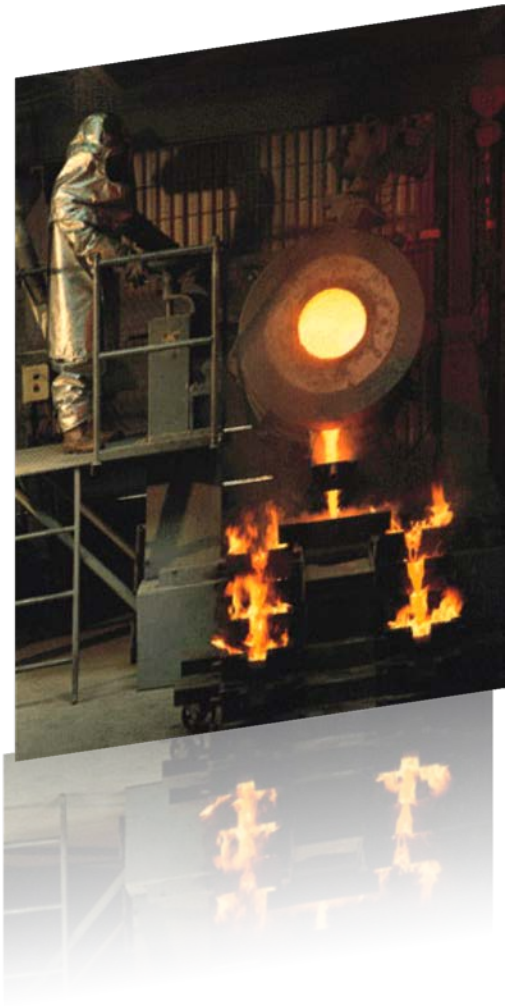
Precious Metals & Rhenium Consortium
Brussels, 10 October 2012



Refinables

PM Refiners WG

Meeting

1. Welcome & Introduction

Edwin BROECKAERT

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Approval of the Agenda
- Approval of minutes of last meeting (28 Jun 2012) – including status of action points

Actions (1)

Action	Who?	Status
PMC surveys		
SURVEY 1: Non-waste, UVCB, intermediate status assessment	KA to circulate & collate / Members to complete	Oct 2012
SURVEY 2: Rigorous containment assessment		Oct 2012
SURVEY 3: Strictly controlled conditions assessment		Dec 2012
Substance identification		
Document non-waste status of each relevant Refinable	Members	Jul-Oct 2012
Document UVCB status of each relevant Refinable		
Document intermediate status of each relevant Refinable		
Adjust composition and concentration ranges of each ID Card based on composition information provided for classification assessment exercise	ARCHE	Jul-Oct 2012
Update ID Cards Refinables to reflect main outcomes of Survey 1 assessment and update registration strategy accordingly	KA	Oct-Nov 2012
Prepare input on substance identification of UVCB for Autumn ECHA workshop	Eurométaux (with PMC support)	Jul-Oct 2012
Classification & labelling		
Find out about progress of multi-metal UWM report	CB	Done
Update MeClas and re-circulate updated classifications considering PBT assessment/removal from water column of each metal	ARCHE	Done
Prepare "Classification assessment" document for each Refinable	ARCHE (with Eurométaux)	Jul-Oct 2012
Upload updated classifications & "Classification assessment" doc to IUCLID	WCA	Aug-Nov 2012
SCC advocacy		
Circulate SCC examples & outcome Eurométaux' advocacy on SCC with ECHA	KA	Done
Circulate Jun 2012 "*Update on ECHA's activities on intermediates*" paper	KA	Done

Actions (2)

Action	Who?	Status
First tier RiCo assessment		
Inform PMC Members when RiCoG becomes available	EBRC/KA	Done
Perform first tier RiCo determination with RiCoG and/or other tools and complete Survey 2	Registrants	Sep-Oct 2012
Compile answers to Survey 2 in order to list Refinables for which RiCo is demonstrated/RiCo has not been shown yet/upgrade will definitely be required	KA	Oct-Nov 2012
Eurométaux Multi-metallic (E-)TRV database		
Gather DNELs/OELs/PNECs and other relevant information for the effects, exposure and risk assessment of UVCB under REACH	Eurométaux	Jul-Oct 2012
Prepare simple data-sharing agreement format to be formally approved by all data providers	Eurométaux (with PMC support)	Aug-Oct 2012
Second tier RiCo assessment (HH Exposure assessment)		
Following 1-to-1 sessions and PM Ref WG meeting 27-28 June, send remaining exposure data to EBRC	Registrants	Jul-Aug 2012
Once all data are received and TRV are compiled in the EM multi-metallic data-base, prepare generic exposure assessment reports for discussion with Members	EBRC	Oct-Nov 2012
Consider need for site-specific exposure assessment	All	Nov 2012
Second tier RiCo assessment (ENV Exposure assessment)		
Following 28 Jun PM Ref WG meeting send remaining emission data to WCA	Registrants	Jul-Aug 2012
Measure total versus soluble boron emissions in aquatic effluents and provide dataset to WCA	Registrants	ASAP
Once all data are received and ERV are compiled in the EM multi-metallic data-base, prepare generic exposure assessment reports for discussion with Members	WCA	Oct-Nov 2012
Consider need for site-specific exposure assessment	All	Nov 2012

Actions (3)

Action	Who?	Status
Final tier SCC compliance assessment		
Perform final tier SCC compliance assessment and complete Survey 3	Registrants	Nov-Dec 2012
Compile answers to Survey 3 in order to list Refinables for which update/upgrade will be needed Report update/upgrade scope to Members and consultants	KA	Dec 2012 Jan 2013
Updates		
Circulate example of Article 36 Letters from ECHA	D. Cholakova	Done
Prepare SCC supporting evidence in the form Appendix 2 & 3 (using Eurométaux examples) and submit Appendix 3 as an update of individual Registration Dossier	Registrants	ASAP
Check IUCLID 5 files for each Refinable to make sure they contain the updated information listed below and send to each LR for inclusion of Appendix 3 and submission to ECHA: ✓ Updated ID Card ✓ Updated classification ✓ Classification assessment document ✓ Appendix 3 Attach Appendix 3 to section 13 of IUCLID 5 and submit updated joint Registration Dossier to ECHA	KA Lead Registrants	Oct-Nov 2012
Upgrades / Risk Assessment of UVCB under REACH / ECHA Autumn workshop		
Circulate minutes of 21 May 2012 ECHA + EM meeting to PMC	KA	Done
Develop test cases to demonstrate applicability of tools and models and ideally arrive at common approach to risk assess (inorganic) UVCB under REACH	Eurométaux	Jul-Oct 2012
Prepare input on risk assessment of UVCB for Autumn ECHA workshop	Eurométaux (with PMC support)	Sep-Oct 2012
Due diligence / Compliance without undue delay		
Document steps taken and use Eurométaux Roadmap on intermediates to demonstrate due diligence and compliance of Registration requirements without undue delay	Registrants	ASAP

2. Recap project strategy

Katrien ARIJS
Caroline BRAIBANT

Summarised work programme

SCC determination & Decision	REACH text + Guidance + RiCoG + exposure/emission assessment + expert judgement + view of authorities + risk assessment
Updates preparation	- Appendix 2 (in-house) - Appendix 3 (section 13 of IUCLID 5)
Risk assessment of UVCB	- UVCB identification - Effects assessment - Exposure assessment - Risk characterisation - CSA/CSR + ES
Classification	- MECLAS - ATPs to CLP

Summary of Steps

Demonstrate non-waste UVCB substance status

- Demonstrate intermediate status
- Demonstrate SCC
- Update individual Registration Dossier by adding Appendix 3 to section 13

- Demonstrate intermediate status
- Demonstrate Due Diligence
- Contribute to develop approach to risk assess UVCB under REACH

Timeline work programme

	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Substance identification • Non-waste/UVCB/intermediate status (factsheets) • Updated composition & concentration ranges				Survey 1	EM/ECHA workshop ?		
Classification & labelling • Classification assessment doc • Upload updated classifications & assessment doc							
First tier RiCo assessment • RiCoG and/or other tools • List Ref RiCo/not RiCo/upgrade				Survey 2			
Second tier RiCo assessment • Exposure assessment				EM MM database?			
Final tier SCC compliance assessment • Factsheet SCC • List Ref update/upgrade						Survey 3	
Updates • SCC supporting evidence in Appendix 2 & 3 • Submission updated dossiers							
Upgrades / Risk assessment • Provide input to Eurométaux guidance • Demonstrate due diligence		EM REACH intermediate TF mtg		EM REACH intermediate TF mtg			

3. Demonstration of substance status of PM Refinables

Katrien ARIJS
Caroline BRAIBANT

3.1. Factsheets & survey 1

- Factsheets have been developed to check the **intermediate** status of the Refinables and to check handling/use under **SCC**

- Factsheets on **waste** and **UVCB** status are under development

- **Survey 1** will be circulated later this month to check:
    - Intermediate status
    - UVCB status
    - Non-waste status

  of the Refinables

  + to review scope of work

Intermediates

- Specific provisions under REACH
- Definition: aim is to be chemically transformed (intended process)
- **Chemical modification** must be demonstrated
  - List of use descriptors that ECHA considers incompatible with chemical modification
- Preparation for inspections
  - Information ECHA requests in their **Article 36** letters
- Proposal to organise a workshop with specific (anonymised) cases

3.3. ECHA screening of intermediate dossiers

- ECHA conducted an **IT-based screening** to check whether REACH intermediate registration dossiers contain information that put into question:
  - the **transformation** of the substance during chemical processing and/or
  - the **SCC** until its transformation.

  The tool screens the use descriptors (PROCs and ERCs) applied for the intermediate dossier submissions.

- Screening of 5500 intermediate dossiers:
  - 2388 included uses incompatible with intermediate definition/SCC conditions
  - Representing 760 intermediate substances
  - ECHA sent letters to 574 registrants

ECHA screening of Refinables dossiers

- Several PM Ref WG members received **letters** requesting them to review and update their dossiers within 3 months

- Challenged PROCs for the Refinables are **PROC 22** and **PROC 26**

PROC22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	This category is not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.
PROC26	Handling of solid inorganic substances at ambient temperature	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions. as set out in Article 17(3) and 18(4) of REACH.

- **Action PMC sec:** describe how these PROCs can be justified to be compatible with SCC together with Eurométaux/EBRC and check with Members

ECHA screening of intermediate dossiers – Eurométaux actions (1)

- Eurométaux sees this initiative as challenging the extensive work they perform on the updates of UVCB intermediate dossiers

- Initial clarification from ECHA:
  - The annotations that were received shall be considered as '**warnings**' and be seen as an opportunity to address these issues prior to being imposed in a more formal and binding action e.g. via an Article 36 letter.
  - ECHA has taken this approach in order to (i) communicate transparently about what is a serious issue of concern (ii) give registrants opportunities to assess their uses case by case and refine the use sections of the affected dossiers.
  - The ECHA REACH Forum intended to forward immediately **Article 36** letters which ECHA did not feel appropriate.

ECHA screening of intermediate dossiers – Eurométaux actions (2)

- Expert dialogue on the challenged **use descriptors**:
  - Some of the PROCs have been used to describe **pre-steps** of the chemical transformation and do not refer to the chemical transformation of the intermediate itself.
  - Agreement that some of the (metal) PROCs are indeed not 'compatible' with SCC in particular when the definition of the PROC mentions opportunity for contact/exposure/low or no degree of containment.
  - Other PROCs where the PROC taken on its own does not allow to draw a clear-cut conclusion on SCC/not SCC. E.g. **PROC 22**, where the level of containment in the definition of the PROC is not clearly defined ("*potentially closed*").
  - In the context of PROC 22, but also PROCs 26 and 27 a and b, the assessment of SCC should rely not only on the PROCs but also on the justification that will basically be provided in Appendix 3.
  - **Importance to send appendix 3 for those that have concluded their SCC assessment!**

ECHA screening of intermediate dossiers – Eurométaux actions (3)

- Eurométaux will write a letter to ECHA explaining that:
  - They understood the purpose of the letters and seriousness of the issue
  - They are currently updating/upgrading a number of dossiers and in discussion with the Substance ID units and Evaluation Units on the upgrade methodology
  - They have some issues with the table of PROCs included in the annotation letters, linked to specificities in the metals PROCs/justification and they welcome the possibility to have a technical discussion with the ECHA experts on this
  - They will bring back the outcomes of this discussion with ECHA to their dossiers and correct the PROCs where needed in the context of updates/upgrades
  - EM commits to the fact that the sector will integrate the updating of use description into the other mentioned revision activities and ask whether ECHA's follow-up on this issue (after 3 months) could be put 'on hold' temporarily

To ensure maximum impact of such a letter, it was recommended to write this letter as EM and to refrain from sending consortia-specific letters

- Eurométaux will organise a meeting on PROCs-discussion back-to-back with Substance ID discussion

UVCBs

- Substances of Unknown or Variable composition, Complex reaction products or Biological materials
  - The number of constituents is relatively large and/or
  - The composition is, to a significant part, unknown and/or
  - The variability of composition is relatively large or poorly predictable.

- Sufficiently **variable and poorly predictable composition** at registrant level and across registrants to be considered as true UVCB under REACH

- Grouped based on similar origin or source and/or similar processes or process steps
  - ➢ Sameness confirmed by similar hazardous properties and classification

3.2. Reviewed composition ranges

- Composition and concentration ranges of each ID Card are being adjusted based on composition information provided for classification assessment exercise + following disclaimer:

  "In a UVCB substance, the number of constituents is relatively large and/or; the composition is, to a significant part, unknown and/or; the variability of composition is relatively large or poorly predictable. Hence, concentration ranges outside the ones given above do not exclude sameness"

- ID Card of each Refinable will be updated to reflect main outcomes of UVCB and intermediate assessment (responses to Survey 1)

Example reviewed composition ranges - Doré

Type	Name of the element	Symbol	Species present *(one line per species)*	Usual concentration range (%)	Usual concentration range (%) REVIEWED
Precious metals	Silver	Ag	Metallic	25-99,55	0,3-99,7
	Gold	Au	Metallic	0-99	0-80
	Platinum Group Metals	PGM	Metallic	0-20	0-19,7
Other metals	Antimony	Sb	Metallic	0-12	0-3
	Arsenic	As	As2O3?	0-1	0-3
			As2O5?		
	Bismuth	Bi		0-6	0-8
	Cadmium	Cd	Metallic?	0-1	0-0,1
	Copper	Cu	Metallic	0-35	0-99
	Lead	Pb	Metallic	0-10	0-75
	Iron	Fe	Metallic	0-5	0-50
	Magnesium	Mg		0-4	0-4
	Nickel	Ni	Metallic?	0-15	0-15
	Selenium	Se	Metallic?	0-5	0-5
	Tellurium	Te	Metallic	0-8	0-15,7
	Tin	Sn	Metallic	0-7	0-2
	Zinc	Zn	Metallic	0-6	0-10

Waste vs REACH

2010 ECHA Guidance on intermediates

< 2010	2010	> 2010
REACH or Waste ?	REACH and/or Waste ✓	REACH or Waste ?

A business decision!

Each company to put pros and cons next to each other for each 'material'

Ideally sharing of test cases across Members at dedicated workshop?

	REACH legislation	Waste legislation
Scope	Phase-in and non-phase-in substances (EC Inventory and more)	EU Waste Catalogue (under review)
Enforcement	MS	MS
Administrative burden	Joint + individual	Individual
Cost	Dossier submission + labelling, packaging, and transport (depends on classification of substances)	Packaging, transport (depends on classification of waste)
Material access	Administratively simpler	Administratively more complicated (Basel Convention's aim is to reduce transboundary movements of waste)
Future	Review…?	Review…?

4. Classification & labeling: status updated classifications

Katrien ARIJS
Claire MASSEY

Status & next steps

- Updated classifications presented at the last PM Ref WG meeting (28 June)
- Minor modification for Doré (env & HH endpoints integrated)
- Removal from water column results for Ag not considered, as interpretation of these results are currently still under discussion (both within Eurométaux and within the Ag group) -> classifications left unchanged (currently worst case)
- Review when we have more final decisions on the UWM results for Ag and other metals
- WCA:
  - Enter classifications into IUCLID and attach the document describing the approach – Oct 2012
  - Supply the updated IUCLID file to the Lead Registrants for submission – Nov 2012

5. First tier Rigorous Containment (RiCo) assessment

Katrien ARIJS
Daniel VETTER

5.1. RiCoG

- Members were informed on availability RiCoG on EBRC website some weeks ago

  www.ebrc.de/ricog.html

- Invitation to give feedback/ask technical questions related to the tool

5.2. Survey 2 for RiCo assessment

- **Survey 2** will be circulated later this month to check RiCo of the Refinables

- This assessment can be done using RiCoG or other tools/expert judgment

6. Update on activities Eurométaux REACH intermediate task force and how these affect the Refinables project

Caroline BRAIBANT
Katrien ARIJS

6.1. Data-sharing

- Science programme progresses slowly due to lack of clear and final data-sharing principles between:
  - Consortia involved in the preparation of complex UVCB Article 10 Dossiers, and/or
  - Consortia holding relevant information on constituents driving the risk assessment of these UVCB
- Action list:
  - Understand, explain, agree context
  - Agree on basic or minimum principles, frame and rules
  - Prepare unique LtU Agreement

Data-sharing → data rights → right to use → licence to use

Context	Rules	LtU

• > 2010 data-sharing for 'simple' multi-constituent substances; now complex UVCB
• > 2010 data-sharing for entire Dossier; now individual (R)SS
• > 2010 data-sharing for first time registrations; now for registration updates
	• Definitions
	• Scope:
	  ○ UVCB Article 10 registrations or more?
	  ○ Driving constituents? which?
	• Property / ownership rights retained by owner
	• Confidentiality ensured
	• Liability
	• Law
	• Etc.
		• Inspired from existing models (Ni, Pb, PMC, etc.)
		• Two parts:
		  ○ Generic (cf. previous rules)
		  ○ Data owner-specific (e.g. LtU cost)
		• Between Data owner and:
		  ○ Each registrant?
		  ○ Consortium?

6.2. Status multi-metallic (E-)TRV database

- Multimetallic Database: the complete database on effects assessment outcomes
  - ✓ What for? E.g.
    - × Intermediate & mixture assessments
    - × Mixtures eSDS
  - ✓ Why?
    - × Allow access to reliable/relevant data generated by consortia, 1 location
    - × Allow the appropriate use of the data
    - × Enable consistent approach & use of the data
  - ✓ Where?
    - × Reach Metals Gateway (members only section)

→ *The mmdb excercise was launched in May*

The multimetallic database

- ✓ Who:
  - × Cu, Sb, Se, Al, B, Mo, Iron Oxides, Be, Ni, Pb, Co, As, Cd, Zn

Complete set of information

- ✓ Additionally from the ECHA website,e.g.
  - × Si: little data available
  - × Te: intermediate use only
  - × Br: Br2 dossier, PNECs aq & DNELs workers
  - × Ba, Hg, Ca, Cr…

Limited set of information

Main issues

- Timing was a critical issue for consortia!!
  - Reach agreement to develop the database
  - Developing the database

- This exercise goes hand in hand with the development of appropriate methodology to register complex intermediate UVCB (EM REACH Intermediate TF)
- Important to demonstrate to ECHA that industry shares relevant information

NOTE: Agreement has been reached to share effect assessment data, thus allowing industry to clarify its registration needs

Next steps

- Retrieving remaining Me data (ca. 25%)
- Final merge of all the data sets
- Publish on the Reach Metals Gateway (members only section) as excel table
- Collecting further updates from specific metals (i.e. classification)

- When: October, **asap!**
- Data are crucial for intermediate UVCB assessment

6.3. Substance identification and characterisation

Identification of UVCB substances

- Source
  - Not necessarily only one
  - Primary, secondary materials, pure substance (reagent or precursor)
- Process
  - Not necessarily only one
  - Smelting, refining, precipitation, purification, incineration, etc.
- Composition
  - All constituents matter
  - Variability within sameness boundaries

New, splits and mergers of SIEFs

Characterisation of UVCB substances

- Identity
  - Elemental composition
- Nature and proportion of composition
  - Metallic species,
  - soluble and sparingly soluble compounds,
  - mineral, and
  - Metallic species in alloys
- Physical form and morphology
  - Fine powder to massive
  - Macroscopic and microscopic structure

Assessment and classification profiles

6.4. Human health risk assessment

- **Eurométaux** REACH intermediate TF subgroup

- Members:
  - Katrien Arijs (ARCHE/EPMF – Belgium)
  - Steve Binks (ILA – UK)
  - Caroline Braibant (EPMF – Belgium)
  - Daniela Cholakova (Aurubis – Germany)
  - Evert Hamblok (Metallo-Chimique – Belgium)
  - Federica Iaccino (ARCHE/Eurométaux – Belgium)
  - Jutta Schade (EBRC – Germany)
  - Violaine Verougstraete (Eurométaux – Belgium)
  - Daniel Vetter (EBRC – Germany)

Human health risk assessment: principles

- The risk assessment of a UVCB is based on the available effects/exposure/risk information of the **individual constituents**.
- Relative relevance of constituents will depend a.o. on the concentration and form in which they are present in the UVCB, the nature and extent of their effects, and on the potential they have to participate in synergistic or antagonistic effects.
- In order to develop a targeted risk assessment, a **prioritisation tool** is needed to identify the driving constituent(s).

Human health risk assessment: prioritisation tool (1)

- '**Risk drivers**': will scope the exposure and effects data collection and/or generation.

- Selection of the risk drivers could be/has been performed in **different ways** depending e.g. on the degree of complexity/variability of the UVCB and on the amount and type of available information on the UVCB's composition, behaviour during processing, exposure data etc. (tiers/methods still under discussion)

- Proposed approaches and their underlying principles should be validated by assessing one or several **UVCB examples** via each approach and comparing the outcome.

Human health risk assessment: prioritisation tool (2)

	1: Qualitative approach	2: Constituents' hazard classification approach	3: Decisive DNEL approach
ID of driving constituents	Qualitative assessment/expert judgment is used to select the driving constituent(s)	Hazard-based selection of driving constituents for each endpoint or effect and exposure route	Risk-based selection of driving constituents for each relevant endpoint or effect, exposure route & exposure duration
Description/principle	Selection of most hazardous constituent(s) based on e.g. hazard classification results and those which are most likely to release from the UVCB during handling, processing, or use	Based on the assumption that more dangerous substances have more severe classifications and that classified constituents will drive the risk	Selection of most critical DNEL by reflecting actual workplace conditions, i.e. exposure conditions
Operational conditions / combined effects	OCs and mode of action and possible synergies and antagonisms are not taken into account.	OCs and mode of action and possible synergies and antagonisms are not taken into account.	OCs are taken into account Work in progress: how to address potential combined effects and non-threshold-related effects?
Data requirements	Expert judgment, information on hazard classification of constituents, process knowledge	• CLP classification entries of UVCB constituents • Bio-available concentration of the constituent in the UVCB • Classification cut-off value to identify the driving constituent for each endpoint of effect and exposure route	• DNELs for UVCB constituents (+ info on derivation of these DNELs) for each relevant exposure route, nature of effect & exposure duration to which the effect refers (if any of these DNELs were not derived -> justification) • Info on UVCB constituents (e.g. % of the constituent in UVCB, mp) • Additional info on processes is required (e.g. handled physical form & process t°)

Human health risk assessment: prioritisation tool (3)

	1: Qualitative approach	2: Constituents' hazard classification approach	3: Decisive DNEL approach
Derivation of RCR / UVCB risk assessment	By performing RA on the selected driving constituent, safe use can be demonstrated and assumed for all constituents and the UVCB as a whole if the RCR of the driving constituent is acceptable	• RCR derived separately for all selected constituents identified above by comparing the exposure to each constituent to its respective DNEL for every endpoint or effect and exposure route • How to integrate these RCRs?	The DNEL having the lowest rank is designated as the decisive DNEL and will be used for risk assessment. It is currently assumed that safe use of the UVCB can be demonstrated if the RCR in consideration of the decisive DNEL is acceptable.
Example	For 'simple' UVCBs with a limited number of constituents	Approach used for Cu slags	Approach to be used for PM Refinables (case study on Flue Dus?)

Occupational Exposure

Inhalation exposure assessment

Refinables WG Meeting

Brussels

10 October 2012

Daniel Vetter
EBRC Consulting
Hannover, Germany

Proposed general approach & tools

- Tiered approach & tools:
  - Screening of RiCo with e.g. RiCoG by companies →outcome?
  - Important for the scope of exposure assessment
  - If SCC cannot be demonstrated for PMRs
    - Identification of decisive DNEL → database not yet available
    - EA with MEASE → will lead to high exp. estimates
    - EA with inhalation monitoring data
    - Further refinements

Recapitulation of previous project activities

- Approach:
  - Low DNELs require exposure assessment based on monitoring data → modelled exposure levels are far too high
  - Exposure assessment to cover each site and refinable
  - Pooling of monitoring data required to enlarge database for specific exposure situations (strict requirements in R.14)
  - “Pooled exposure assessments” = Pooled workplaces in ES
  - Last meeting: 1-to-1 discussions to inform/clarify
    - follow up: clarifications via email
    - submission of additional measured data

Update of inhalation exposure data base

- Status of exposure data base:
  - Additional measured data: 315 measurements
  - Total amount: 1,025 (778) measurements
  - Leading to 11,310 (9,723) data points for individual constituents
  - Number of data submitters: 8
  - 222 measurements not yet included (some parameters need clarification, e.g. sampling duration, fraction)
- Status of questionnaire data base:
  - Number of questionnaires: 50
  - Thereof additionally included/modified since last meeting: 17

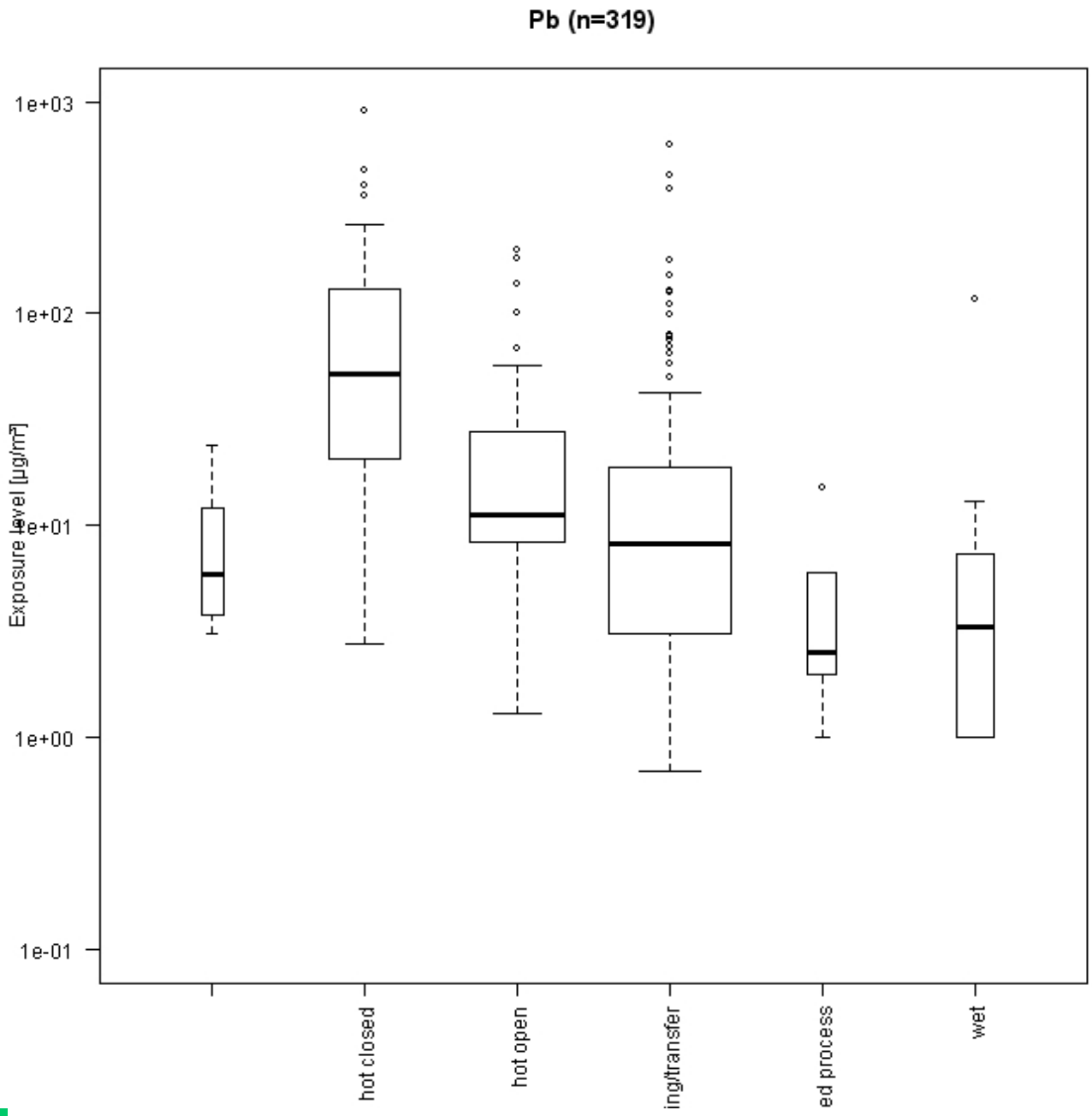
Analysis of inhalation exposure data

- Main objectives
  - to support a sector-wide demonstration of rigorous containment
  - to determine correlations between several exposure modifiers and exposure levels
  - to define similar exposure groups
  - to facilitate exposure assessments required for exposure scenarios
- Pre-requisites
  - implementation of rigorous containment
  - clear and unique assignment of exposure modifiers to measured data
  - inclusion of all relevant exposure modifiers
  - specific amount of measured data for individual SEGs
  - data base to cover the associated complexity

Analysis of inhalation exposure data

- Initial findings
  - Exposure levels for some impurities e.g. Pb, Ni are high comparing to their OELs/DNELs, huge inter-company variation
  - Cd levels are generally low, however sometimes also exceeding levels 100 µg/m³
  - As levels are generally controlled at low levels, however maximum levels occur at 90 µg/m³
  - Co, Hg levels are controlled below their DNELs
    → Hg was not nominated as constituent, Co only up to 12%
  - Cr, Au levels are overall quite low < 24 µg/m³
  - Ag, Pd levels are measured up to 440 µg/m³

→ Impurities/PM lead to similar exposure levels


Pb (n=319)
Exposure level [µg/m²]
1e+03
1e+02
1e+01
1e+00
1e-01
hot closed
hot open
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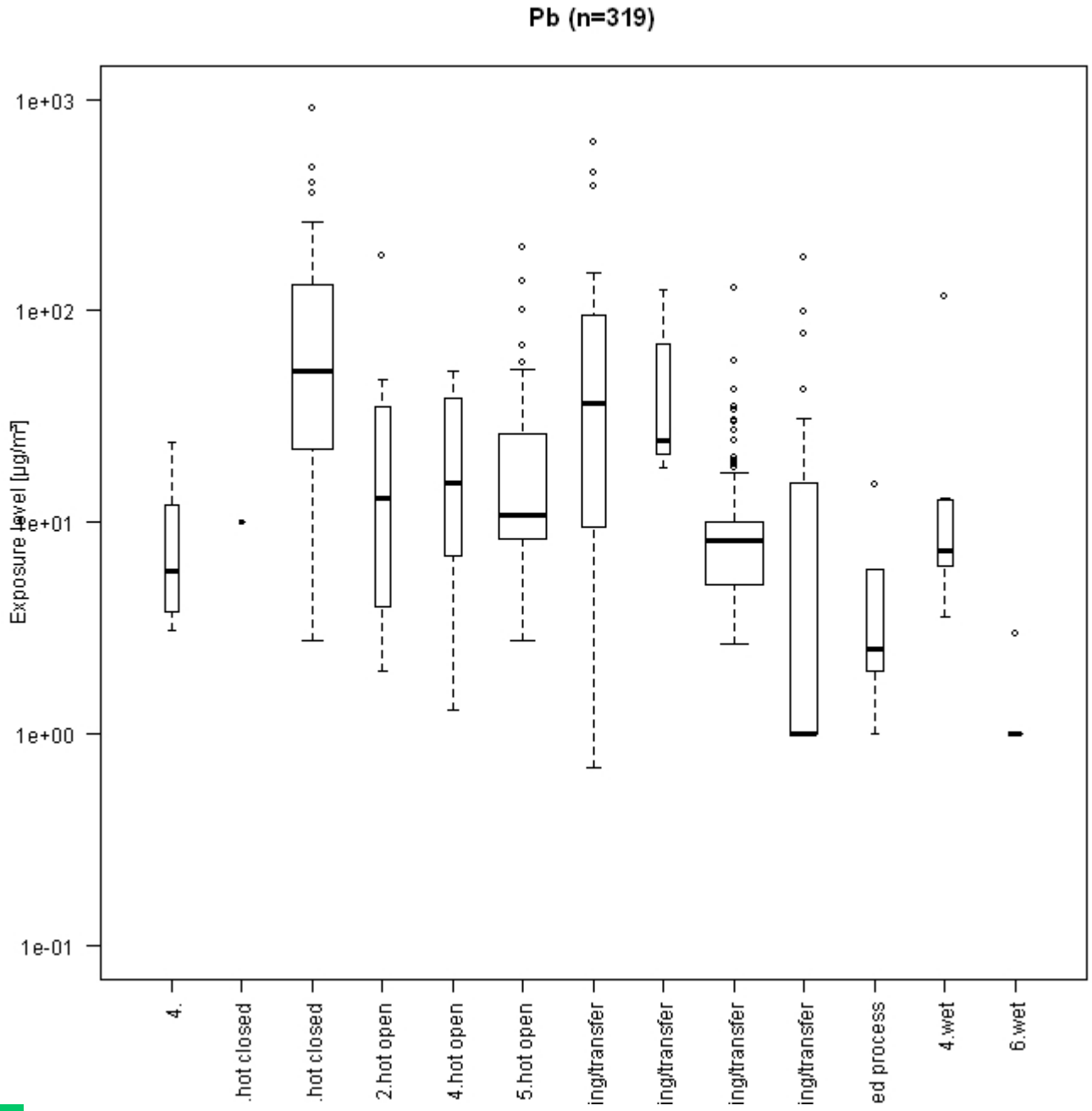
Pb (n=319)
Exposure level [µg/m³]
1e+03
1e+02
1e+01
1e+00
1e-01
4.
.hot closed
.hot closed
2.hot open
4.hot open
5.hot open
ing/transfer
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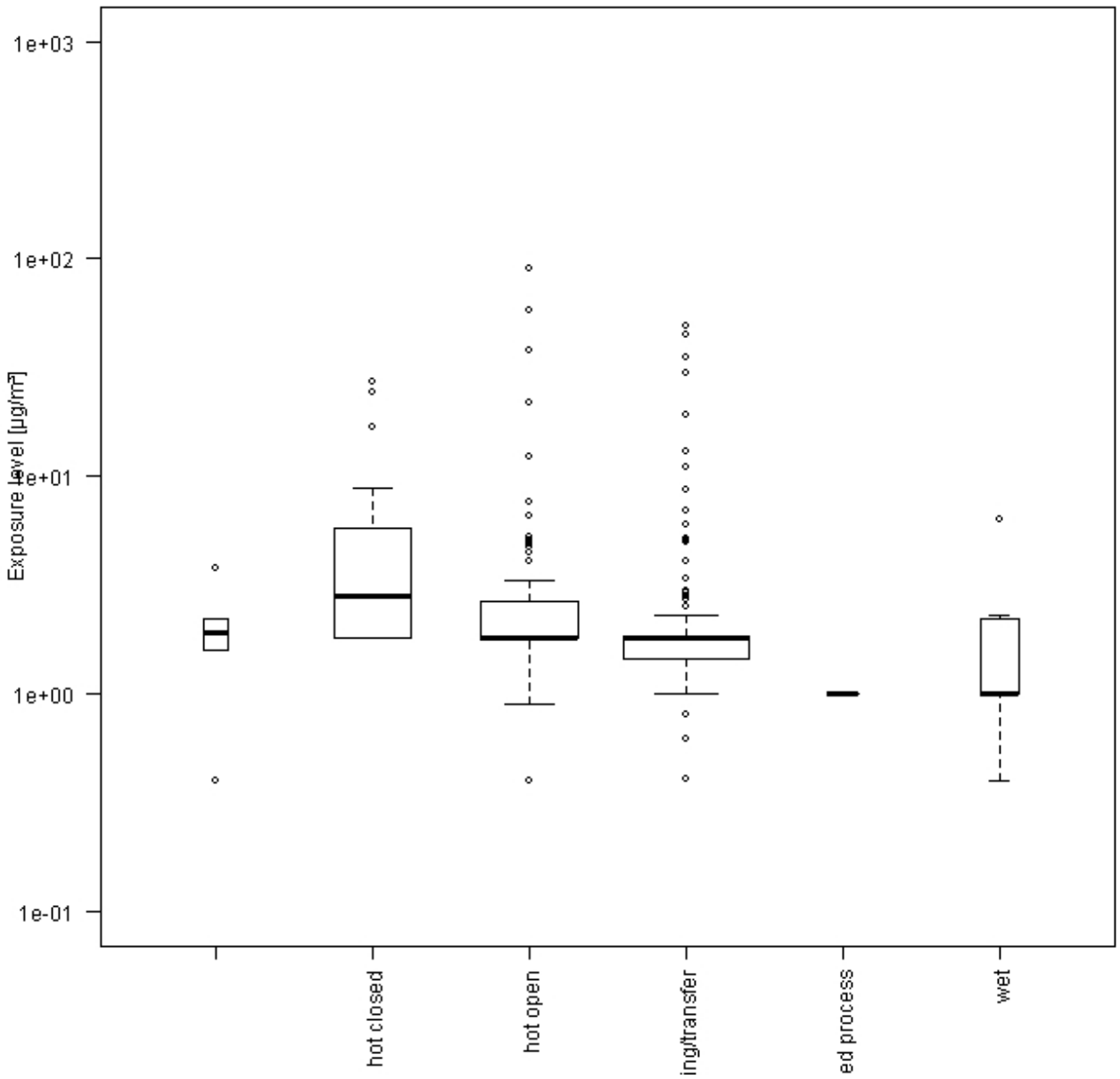
ing/transfer
ed process
4.wet
6.wet


As (n=295)
Exposure level [µg/m³]
1e+03
1e+02
1e+01
1e+00
1e-01
hot closed
hot open
ing/transfer
ed process
wet

Consequences of exposure analysis

- Findings do not allow:
  - to support “rigorous containment” on a sector-wide basis
  - to find statistically significant exposure modifiers
  - to attribute exposure to composition “exact” levels

→ Further support for “rigorous containment” assessment only possible at company level

- Findings do allow:
  - to derive exposure levels on a sector-wide basis for specific
  i. processes and classes of emission potential,
  ii. constituents and
  iii. composition categories.

→ Exposure assessment to be used in exposure scenarios

Exposure scenarios

- Data base will be used for the generation of a GES including
  - all mentioned process (types)
  - operational conditions (OCs)
  - composition ranges
  - as nominated by submitters of exposure data
- Processes and OCs nominated by non-data submitters will be covered by read-across where possible
- Company specific exposure scenarios will be based on
  - risk driver for each endpoint
  - composition category for risk driver

→ Tool to be developed for the selection of risk driver and exposure estimate

From GES to company ES - overview

- Example for a single process step: Smelting
- GES provides exposure estimates for all constituents for hot process (semi-closed) for different exposure categories
- Company X identified Pb as being the most important risk driver for this process step
- Pb content of individual refinable to be used to select exposure estimate
- To be done and reported for all refinables of Company X

→ Potentially resulting in conflicting company-specific ES

→ “Generic company specific ES” will include most restrictive RMMs for Company X for smelting

→ Submission or in-house filing of “Generic company specific ES”

Thank you for your attention!

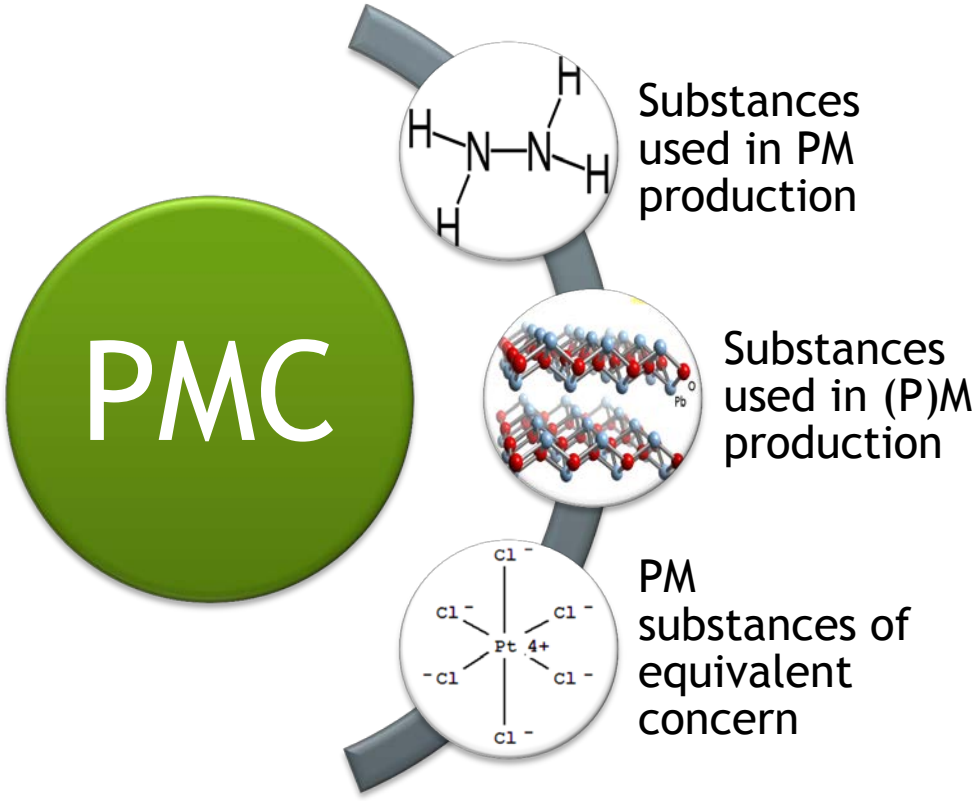
6.5. Environmental risk assessment

- Work in progress:
  - **Eurométaux** REACH intermediate TF subgroup will present draft guidance at the 12 Oct meeting
  - **WCA** will progress the environmental exposure assessment of the Refinables once the Eurométaux multi-metallic database is available

7. Authorisation - substances on SVHC list of relevance to the PM sector

Caroline BRAIBANT

Authorisation



Authorisation

PMC Member 1,
SVHC 1 and 2

PMC Member 2,
SVHC 1

PMC Member 3,
SVHC 2

Notification of interest to PMC

Task Force for SVHC 1
PMC Members 1, 2

Task Force for SVHC 2
PMC Members 2, 3

PMC only made aware via PMC Members!

PMC not always source of Task Force

Timeline work programme

	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Substance identification • Non-waste/UVCB/intermediate status (factsheets) • Updated composition & concentration ranges				Survey 1	EM/ECHA workshop ?		
Classification & labelling • Classification assessment doc • Upload updated classifications & assessment doc							
First tier RiCo assessment • RiCoG and/or other tools • List Ref RiCo/not RiCo/upgrade				Survey 2			
Second tier RiCo assessment • Exposure assessment				EM MM database?			
Final tier SCC compliance assessment • Factsheet SCC • List Ref update/upgrade						Survey 3	
Updates • SCC supporting evidence in Appendix 2 & 3 • Submission updated dossiers							
Upgrades / Risk assessment • Provide input to Eurométaux guidance • Demonstrate due diligence		EM REACH intermediate TF mtg		EM REACH intermediate TF mtg			

8. AOB, Next Meetings/Calls & Closing Remarks

Edwin BROECKAERT

Thank you!