


# Precious Metal Refiners Work Group

Brussels, 6 June 2011
Metals Conference Centre






# 1. Welcome and introduction

# Agenda

1. Welcome and introduction
   - Reminder on Confidentiality and Competition law
   - Tour de table and apologies
2. Reminder to main aims of next phase of Refinables project and overall strategy
   - Aim , overall strategy, and info requirements
3. Status of Eurometaux/NMF Consortia Activities
   - Political review of the SCC criterion for intermediates
   - Guidance on « upgrade » or « update »
   - Development of a technical approach to facilitate « upgrades »
   - Review of cost sharing for refinables program
4. Review of Refinables categories/groups
   - Review of existing Refinable groups
   - Identification of needs for upgrades



# Agenda (2)

5. Exposure assessment programme
   - Objectives, relevance and importance
   - Outline of needs for upgrades
6. Strategy to improve/refine the hazard classification of Refinables
7. Status of dissemination files on PM Refinables (info)
8. Recap of the action points and review of timing
9. AOB, next calls, meetings or workshops
   - Refinables project manager
   - Next session

# List of participants

| | | | | |
|---|---|---|---|---|
| *1.* | **Angela Alderman** | Johnson Matthey | United Kingdom | |
| *2.* | **Dave Boyd** | Johnson Matthey | United Kingdom | |
| *3.* | **Caroline Braibant** | EPMF | Belgium | |
| *4.* | **Roland Brasch** | Heraeus | Germany | |
| *5.* | **Edwin Broekaert** | Umicore | Belgium | |
| *6.* | **Helena Byrdziak** | KGHM Polska Miedz | Poland | |
| *7.* | **Daniela Cholakova** | Aurubis | Germany | |
| *8.* | **Paul Frost** | Britannia Refined Metals | United Kingdom | *By teleconference* |
| *9.* | **Teodoro Garcia** | Sempsa | Spain | |
| *10.* | **Gerhard Gutekunst** | Wieland Edelmetalle | Germany | |
| *11.* | **Mari Jarvikivi** | Norilsk Nickel | Finland | |
| *12.* | **Erin Logan** | WCA | United Kingdom | |



# List of participants

| | | | | |
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| *13* | **Dawn Maycock** | WCA | United Kingdom | |
| *14* | **Agnieszka Piechota** | KGHM Polska Miedz | Poland | |
| *15* | **Giovanni Prelazzi** | Chimet | Italy | |
| *16* | **Heinz-Günter Schenzel** | C. Hafner | Germany | |
| *17* | **Mike Shepherd** | Vale Europe | United Kingdom | |
| *18* | **Nafisa Teladia** | Vale Europe | United Kingdom | |
| *19* | **Ruediger Thiele** | Heraeus | Germany | |
| *20* | **Michael Turner Jones** | Lonmin | South Africa | |
| *21* | **Mika Toivola** | Boliden | Sweden | |
| *22* | **Daniel Vetter** | EBRC | Germany | |
| *23* | **Chantre Viviers** | Heraeus | Germany | *By teleconference* |
| *24* | **Hugo Waeterschoot** | EPMF | Belgium | |




## 2. Reminder to main aims of next phase Refinables project, overall strategy and info requirements






## Reminder to main aims of next phase Refinables project and overall strategy

### Main aim

Prepare "*update*" or "*upgrade*" of Refinables files (intermediate) in a *cost effective* but robust way, to ensure that dossier/substance evaluation will lead to *acceptance by ECHA and MSC*

# Original PM Refinables programme: 4 phases

- *Inventory re-scoping phase:*
  - Identify which Refinables registrations need an "update" or an "upgrade" to comply with the Dec 2010 SCC interpretation
- *Planning phase* :
  - Prepare review of identity and sameness, classification and dossier content
- *Execution phase* :
  - Generation, evaluation and validation of effects, exposure and emission data

Exposure and emission data useful both to demonstrate scc and prepare update/upgrade

- *Conclusion phase* :
  - Preparation of IUCLID 5 files and submission to ECHA



# Updates

## Tasks to prepare updates:

- Companies to update **in house documentation**
- EM/PMC Secretariat to provide support on "**reporting format**" (Appendix 2?) and "**example**"
- Organise **collection of exposure and emission data** to prove "rigorous containment"
- Consider what **additional info** needs to be included **in IUCLID** registration (e.g. Classification)

# Upgrades

**Tasks to prepare upgrades:**

In addition to those required to "update", prepare upgrade:

- **In a tiered** approach
- Using/distiguishing when necessary **Reference** and **Company-specific** material
- In line with programs of **other Consortia**
- Emphasis on "**exposure and emission assessment**" to avoid non-predictive testing
- Including **validation** where needed



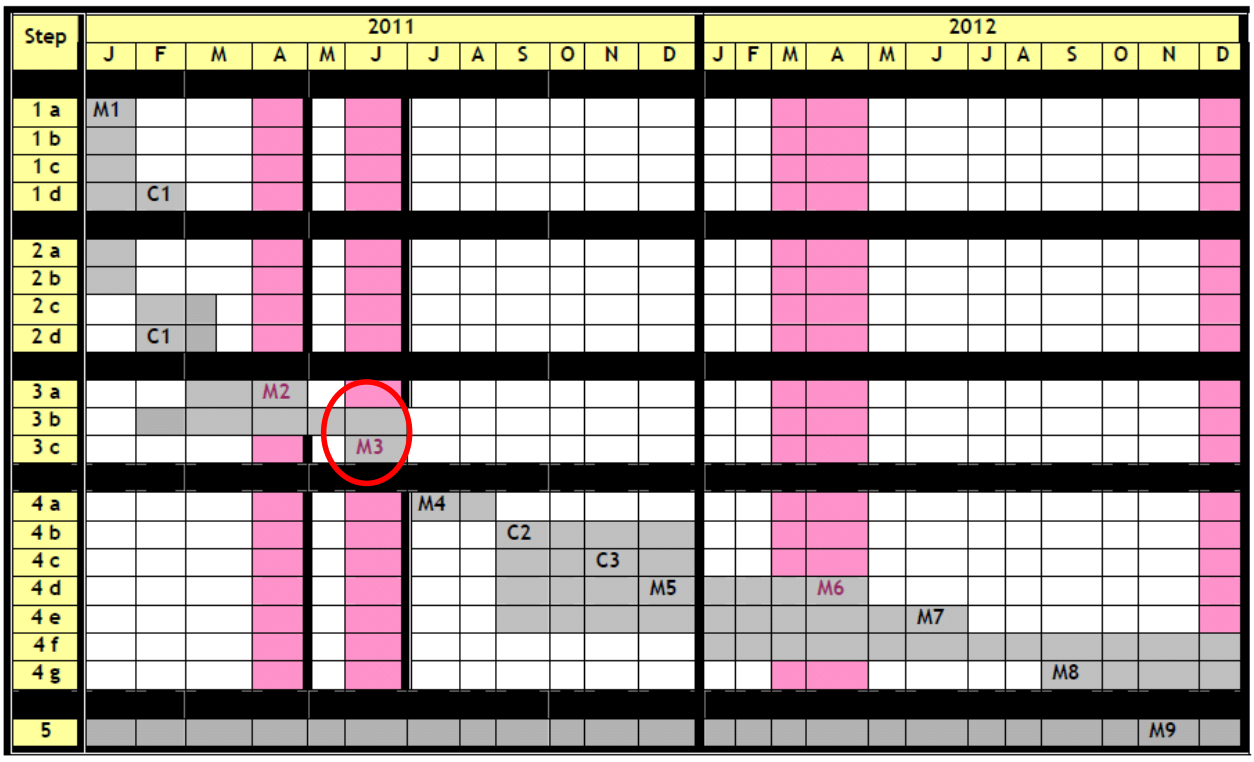
# Key milestones

| | Key Milestone/Decision point | Justification | When? |
|---|---|---|---|
| a. | Agreement on "sameness" | Impacts design of execution phase | April 2011 |
| b. | Acceptance of Read Across approach by ECHA and exposure collection needs by PMC Members | Impacts design of execution phase | June 2011 |
| c. | Finalisation of effects, emission and exposure data collection (two tiers) | Delay could strongly paralyse/delay CSA and subsequent CSR drafting/validation | Late Q1/Early Q2 2012 |
| d. | Finalisation of Appendix 3 and updated Registration file | Key for successful submission | Dec 2012 |

**Changes :**

| | |
|---|---|
| a) Agreement on sameness : | this meeting |
| b) Acceptance of Read Across methods | Q3 |
| b) Exposure data collection needs : | this meeting |
| c) Finalisation for exposure : | Q1 2011 |
| c) Finalisation for effects : | Q2 2011 |
| d) Update of Appendix 3 and registrations | Dec 2011 |

# Timing




# 3. Status of Eurometaux/NFM Consortia activies regarding « SCC » and intermediates

# Reminder:
## *Registration requirement for Intermediates*

- REACH Title II, Chapter 3:
  - « any manufacturer of an on-site isolated or transported intermediate > 1tonne/year shall submit a Registration to ECHA »
- Article 17 (2) and 18 (2):
  - Registrants of on-site or transported intermediates can provide reduced registration information if they can confirm that the substance is manufactured or used under Strictly Controlled Conditions (SCC) as described in Article 17 (3) and 18 (2)-(4)

**BUT : No definition in REACH for SCC** !!!

Only a brief description « *rigorous containment by technical means during whole lifecycle* »



# SCC according to
## *Feb 2008 ECHA guidance*

- Need to evaluate if following conditions are in place?
  - Rigorous containment by technical means
  - Procedural and control technologies to minimize emissions
  - Handling by properly trained and authorized personnel
  - Set up of special procedures for cleaning and maintenance
  - If accident and/or generation of waste, procedural and control technologies to minimize emissions
  - Substance-handling procedures well documented
  - **N.B.:** PPE – not a primary role – only under certain circumstances (e.g.: sampling and maintenance)

SCC = combination of **technical measures (adapted to the nature / composition / form / behaviour of the intermediate),** supported by **management system**




# How to document SCC

## *under Feb 2008 Guidance*

- In Registration dossier:
  - Limited set of data
  - No specific format: using section 3.5. and 11 was appropriate

- In-house documentation:
  - Documentation confirming « rigorous containment »
  - 2008 guidance included examples providing a high level of flexibility






# SCC according to

## *Dec 2010 ECHA guidance*

- Mechanical barriers and procedural control TOGETHER are the elements of an SCC strategy (combination of measures operating simultaneously)

- Achieved by technical design of a process and equipment aiming at preventing releases

- No reference anymore to relevance of *Hazard and/or Physical Form* to define SCC and Rigorous containement

- Dec 2010 Guidance refers to 'Containment systems - *A design guide', edited by Hirst* et al. *2002' to determine suitable containment strategy based on control banding approach (cf. two next slides)*




| | |
|---|---|
| **Strategy 1: Controlled general ventilation**  | No special engineering requirements; adequate control is achieved by general ventilation of the process area. (This strategy is not covered further in this guide) |
| **Strategy 2: Local exhaust ventilation**  | A Local Exhaust Ventilation (LEV) system is used to contain the contaminants within a defined area and draw airborne contaminants away from the operators' breathing zone. This can involve either:<br>• a good point exhaust ventilation; or<br>• a unidirectional air-flow booth.<br>This can achieve significant reductions in operators' exposures to the concentrations of airborne dusts and vapours generated during open transfer operations of hazardous materials. |
| **Strategy 3: Open handling within isolator**  or **High-integrity closed coupling without external containment** | Open transfer or handling of hazardous materials takes place within an isolator.<br>Typically this might involve surrounding the transfer operation with a fixed or flexible air-tight barrier. Containers of process material may be placed in or removed from the isolator only in a way that does not compromise the integrity of the containment it provides. The operator uses a glove-port to effect the transfer of material to or from the open container and to clean empty containers.<br>This Containment Strategy can also cover transfers effected by means of a high-integrity coupling between closed containers without an external isolator. |
| **Strategy 4: Closed handling within isolator**  | Closed transfer or handling of the hazardous material takes place within an isolator.<br>This is similar to the preceding strategy except that open transfer is not permitted even within the enclosure. The operator, again using a glove-port or similar device, attaches the closed container directly to the access port for the process to form a closed connection and then opens the valve to effect the transfer of material. |
| **Strategy 5: Robotic handling, contained system**  | This strategy is adopted for materials so hazardous that even with a closed transfer system the use of a glove-port represents an unacceptable risk because of the possibility that the gloves could rupture. The transfer therefore has to be effected by a fully automated enclosed process. The strategy requires highly specialized training and should be prepared and implemented only after consultations with experienced health and safety professionals and the HSE. |






# SCC according to

## *Dec 2010 ECHA guidance*

| *Level / Strategy* | *SCC compatible?* |
|---|---|
| 1 | NO |
| 2 | Generally NO but LEV can be an integrated part of the containment strategy 3, requiring partial or full mechanical enclosure in addition |
| 3 | YES |
| 4 | YES |
| 5 | YES |

# How to document SCC

## *under Dec 2010 Guidance*

- Measured **exposure data can be used** to demonstrate that rigorous containment is achieved.
- **Hazard info can not be used** to reduce the requirements for rigorous containment
- **Risk Characterisation info can not be used** to reduce the requirements for rigorous containment



# How to document SCC

## *under Dec 2010 ECHA Guidance*

- In Registration dossier:
  - Appendix 3 of new ECHA guidance defines *type of information* for complying and *proposes a structured format* to be attached to Section 13 of IUCLID (cf. next slide)

- In-house documentation:
  - Documentation confirming the rigorous containment
  - Template provided in **Appendix 2** of ECHA guidance
    - (Example in Eurometaux guidance → Appendix 2 allows limited flexibility)

## APPENDIX 3: Format for documenting information on risk management in a registration dossier for isolated onsite and transported intermediates

*This format can be used by the registrant of an isolated intermediate (the manufacturer or importer) to provide a basic indication to which conditions his conclusion refers that SCC are in place. To be attached into 13 of the IUCLID dossier with the file name _RMM detail*

*Note: This information is not to be published on ECHA's website.*

1. **Brief description of technological process applied in manufacture of the intermediate**

*Provide an overall technical description (no details). A simple overview scheme may support understanding. Ensure that all relevant activities (unit operations) are covered in this description, such as synthesis, purification steps, cleaning and maintenance, sampling and analysis, loading and unloading, storage and waste treatment*

2. **Brief description of technological processes applied in use of the intermediate.**

*Provide an overall technical description. A simple overview scheme may support understanding Ensure that all relevant activities (unit operations) are covered in this description, such as synthesis , purification steps, cleaning and maintenance, sampling and analysis, loading and unloading, storage and waste treatment*

3. **Means of rigorous containment and minimisation technologies applied by the registrant during the manufacturing and/or use process**

- Description of the technical means to rigorously contain the substance. *Make reference to different activities (unit operations) and life cycle stages as appropriate (see Appendix 1)*
- Identification of residual emissions to:
  - Workplace
  - Environment (air, onsite water streams)
- Description of the procedural and control technologies in place to minimise emission and resulting exposure. *A rough quantification of the releases and information on effectiveness of control techniques may be useful to demonstrate that the technologies ensure rigorous containment and minimization of releases. .*
  - Workplace
  - Environment (air, waste water, discharge from site)
- Specify the management means and training that particularly contribute to the



# In-house documentation (Appendix 2)



- Description of the process and equipment used
- Description of the technical means and conditions to minimize exposure at different life cycle stages
- Document for compliance with other legislative frameworks
- Justification for the assignment of use as an intermediate (including customer statement)
- Relevant operating conditions
- Risk Management Measures implemented within the companies and recommended to DU
- Exposure considerations
- Derivation of any relevant threshold values and relevant data on phys-chem, tox and ecotox data




# ECHA Communication on Intermediates & Strictly Controlled Conditions

**RECENT ECHA communication** :

- 80 % of Intermediate files incomplete
- Documentation on SCC or absence/controlled exposures, often lacking or insufficient
- Warning to industry to update/upgrade

# BUT

- % based on experience with early submissions
- No examples (yet) on inorganic files






## Eurométaux' programme

## Need for a PRAGMATIC solution !!!

**EUROMETAUX-CONSORTIA-COMMODITY-NATIONAL FEDERATIONS combined programme for:**

- **A more reasonable approach**
- **More recognition of metal specificities**

# Eurométaux' programme (1)

3 main tracks:

**Political advocacy:** aiming at obtaining a more reasonable interpretation of SCC

**Technical path**: develop read-across tools / strategy to facilitate upgrades (where relevant)

**Communication**: update of internal guidance and development of examples







# Eurométaux' programme (1.1)

## Timing and progress

**Political advocacy** aiming at obtaining a more reasonable interpretation of SCC

**LAUNCH : MAY**

- Agreement on goal and aim
- Drafting of Position paper & intro letter
- Advocacy plan
- Launch Advocacy network

**IMPLEMENTATION JUNE-SEPT**

- Advocacy contacts in key countries
- Aim: recognition for reopening debate on SCC
- Caracal mtg June : put issue on agenda for Oct !

**FINISH : OCT**

- Advocacy contacts in key countries
- Briefings with ECHA/Comm.
- Aim : discussion at Oct. Caracal meeting

# Eurométaux' programme (1.1)

## Advocacy strategy:

- **Return to compromise reached at Nov. PEG** mtg between Industry and ECHA
  - Benefit: Recognition of physical form and knowledge on hazards
  - But: Exposure should still be minimal and controlled !
- Arguments:
  - Process after PEG was not transparent
  - Pragmatism! and focus on relevant issues

**Aim:** ensure SCC issue can be re-opened and discussed at Oct 2011 Caracal mtg - requires issue to be tabled at June mtg



# Eurométaux' programme (1.2)

## Technical path:

- **Examples collected**: Cu and Ni
- Need for **further guidance/strategy** on:
  - **Exposure assessment models** (SPERCS-MEASE) and use of exposure assessment data
  - Application of **Bio-elution/TDp data** for risk evaluation or test waiving
  - How to handle **Combined toxicity**

Meeting scheduled to review experience and discuss technical way forward: **23 & 24 June 2011**

# Eurométaux' programme (1.3)

## Communication/Support:

- Eurometaux SCC **guidance** updated in Dec 2010
- (Detailed) **explanations** on SCC provided to several Consortia or Companies, on request
- Still somewhat unclear on **how many** "Updates" versus "Upgrades"
- Need to develop **additional examples**
- Format to demonstrate "**in-house documentation**" made available by Eramet
- Electronic assessment tool to support assessment of SCC conditions (**RiCoG**) (cf. next slide)



## RiCoG: Rigorous Containment Guide

- No matter how ECHA Guidance evolves, "***Hirst* et al. *(2002) scheme***" (see next slide) will remain reference of scc
- RiCoG constitutes excel-based ***assessment tool*** based on Hirst scheme
- RiCoG provides an objective indication as to whether strict control is or not achieved; this indication together with additional evidence supports decision-making by leaving final judgement/interpretation to user
- ***Investment***: Total 20.000-25.000 € individual cost depends on n° of Consortia/Companies that join (probably < 5000 €). Members of contributing consortia will have possibility of using the tool for no additional cost

**Strategy 1: Controlled general ventilation**



No special engineering requirements; adequate control is achieved by general ventilation of the process area.
(This strategy is not covered further in this guide)

**Strategy 2: Local exhaust ventilation**



A Local Exhaust Ventilation (LEV) system is used to contain the contaminants within a defined area and draw airborne contaminants away from the operators' breathing zone. This can involve either:

- a good point exhaust ventilation; or
- a unidirectional air-flow booth.

This can achieve significant reductions in operators' exposures to the concentrations of airborne dusts and vapours generated during open transfer operations of hazardous materials.

**Strategy 3: Open handling within isolator**



Open transfer or handling of hazardous materials takes place within an isolator.

Typically this might involve surrounding the transfer operation with a fixed or flexible air-tight barrier. Containers of process material may be placed in or removed from the isolator only in a way that does not compromise the integrity of the containment it provides. The operator uses a glove-port to effect the transfer of material to or from the open container and to clean empty containers.

or

**High-integrity closed coupling without external containment**

This Containment Strategy can also cover transfers effected by means of a high-integrity coupling between closed containers without an external isolator.

**Strategy 4: Closed handling within isolator**



Closed transfer or handling of the hazardous material takes place within an isolator.

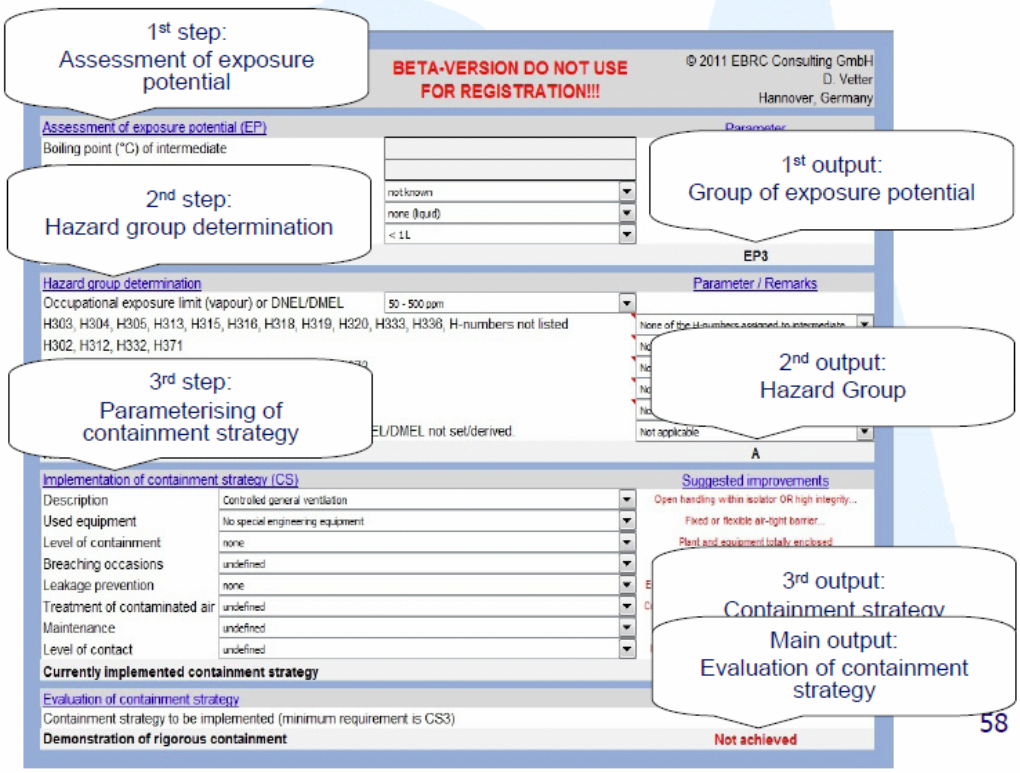
This is similar to the preceding strategy except that open transfer is not permitted even within the enclosure. The operator, again using a glove-port or similar device, attaches the closed container directly to the access port for the process to form a closed connection and then opens the valve to effect the transfer of material.

**Strategy 5: Robotic handling, contained system**



This strategy is adopted for materials so hazardous that even with a closed transfer system the use of a glove-port represents an unacceptable risk because of the possibility that the gloves could rupture. The transfer therefore has to be effected by a fully automated enclosed process. The strategy requires highly specialized training and should be prepared and implemented only after consultations with experienced health and safety professionals and the HSE.

# Rigorous containment guide (RiCoG)



## RiCoG

- → ...integrates the Hirst *et al.* approach in an easy to use tool
- → ...is based on Dec 2010 ECHA guidance
- → ...will help assessing rigorous containment
- → ...will help demonstrating good housefather handling
- → ...provides an objective and standardised yet flexible source of information to be added to in-house documentation
- → ...will include metal specific guidance and adaptations
- → ...could be issued relatively quickly (Summer 2011)
- → ...will be peer-reviewed
- → ...will be accompanied by scientific documentation
- → ...will not produce miracles
- → ...






# BE REALISTIC !!!



### ADVOCACY: FOCUS CARACAL

- Requires extensive effort by IND and support by several countries!
- Success is not guaranteed...

### TECHNICAL SUPPORT: FOCUS ECHA

- Acceptance for pragmatic solution will require recognition and examples
- Acceptance presently **NOT guaranteed** (neither for submitted dossiers)

### INDUSTRY:

- Apply RiCoG and prepare dossier updates
- Devise strategy towards dossier upgrades (if needed, whatever its form, it may be very time-consuming)
- Meanwhile: exposure and emission data collection to fill-in existing requirements and demonstrate responsibility/good faith towards authorities




# 4. Review of cost-sharing for PM Refinables

C. Braibant, EPMF






# PMC cost-sharing formula

- Generic costs distributes evenly
- Metal-specific costs distributed proportionately:
  - Number of substances
  - Tonnage band of each substance
  - Application of “weights”
    - Intermediates = 1 (assumed to be handled under SCC)
    - Transported intermediates > 1000 t/a = 5
    - Substances 1-10 = 5
    - Substances 10-100 = 20
    - Substances 100-1000 = 100
    - Substances > 1000 = 1000

## Recently…

- Dec 2010 ECHA Guidance on Intermediates → adjusted interpretation of "strict control"
- PMC Members submitted updated substance and tonnage band declarations (8 pending!)
- Consolidation into updated inventories showed following scenarios:
  1. Material "A" as substance and as intermediate
  2. Material "A" as SCC and non-SCC intermediate
- Scenario 1 already foreseen in existing PMC cost-sharing formula
- Scenario 2 not…



## Proposed cost-sharing for simple intermediates

- Substances and non-SCC simple intermediates have same information requirements → same weight
- Substances/Non-SCC simple intermediates and SCC simple intermediates have different information requirements → different weight




## And for Refinables…?

- Advocacy strategy aims at bringing detail of information requirements to a reasonable/realistic level
- Assuming it succeeds, what would be the difference (in information requirements) between a scc Refinable, and a non-scc Refinable?
  - R/ None → Proposal to keep the PMC cost-sharing formula for Refinables unchanged






## 5. PM Refinables categories and groups






## SSC or non-SCC for some Refinable groups?

1. Doré: pure or impure?
2. Matte:
3. Slimes and sludges: high variability
4. Slags: which one, only one?
5. Leaching residues
6. Electrolytes
7. Flue dusts : high variability
8. Cementation and reduction
9. Materials for reclaim: which ones?
10. PGM rich Pb bullion: consistency with Pb Consortium








## Main conclusions from preliminary survey

- Most members but **not all reacted** so far on the questionaire (8 are still lacking)
- **Declaring**:
  - Re-direction to waste
  - Remain REACH Intermediate:
    - But requiring full registration
    - Rigorous containment and SCC achieved
    - Working towards SCC by end of 2011
  - Are not sure




















# Main conclusions from preliminary survey

## Generic conclusions :

- **Redirect to waste**: only one single company for one material (4: Slimes and sludges)
- Most companies identified that all Refinables would **remain intermediates** and:
  - **All Refinable groups** received a majority **requiring an "upgrade"**
  - 2 companies confirmed **SCC conditions** on the basis of rigorous containment for 7-8 and 9
  - Limited number of companies (2) indicated working on rigorous containment conditions to assure **SCC by the end of 2011**
  - Limited n° of companies responses indicated that they **were still unsure** about the status of their Refinables. Arguments were quite different ranging from : *lets see and wait what the others do, lets see what Eurometaux decides, until if enough companies conduct an "upgrade" we will follow by precaution*.






















# 6. Exposure assessment programme

# Occupational Exposure Assessment and Risk Characterisation

**PMC Meeting**
**Brussels**
**6 June 2011**

Daniel Vetter
EBRC Consulting
Hannover, Germany

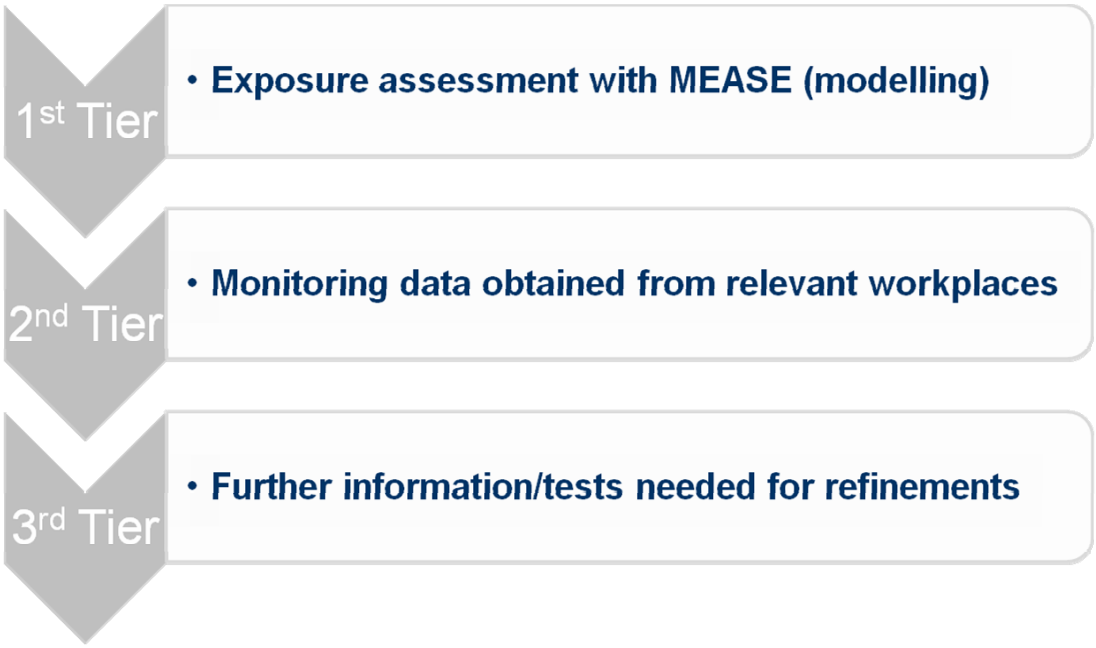
Dr. Maren Bode



## Introduction 1

- It has been questioned that all refinables are handled under strictly controlled conditions
- Exposure assessment to demonstrate “safe use” and to prepare “full registration” of intermediates
  - Requiring risk assessment (calculation of RCR) for which DNELs are needed
  - The proposed tiered approach for exposure assessment therefore requires an initial hazard characterisation step
  - Tier of exposure assessment has also consequences for content of exposure scenarios (ES)

# Introduction 2 - Tiered approach






# Introduction 3

- The tiered approach can only be applied if sufficient information to characterise the hazard is available!
- In addition, information on physico-chemical properties may be needed:
  - Melting point (1st tier)
  - Dustiness testing (1st tier)
  - Particle size distribution (2nd or 3rd tier)
  - Solubility and speciation analysis (3rd tier / technical dossier)
  - Relative density (technical dossier)
  - Analytical information (technical dossier)

# Hazard characterisation

- REACH registration dossiers have been/are prepared for all of the involved constituents (assumption)
- → Referencing to dossiers instead of generating experimental data *de novo*
- → Extensive and complex ES for each refinable (different hazards, exposure routes, etc.)
- Pragmatic and pre-cautionary approach needed to avoid extensive assessments!
- Initial step: Identifying a “ranked DNEL”



# Hazard characterisation - Inhalation 1

- Essential to define a critical DNEL for each refinable
  - Identifying most important risk driver to propose measures for adequate protection of workers’ health
  - This works for all threshold related effects
- Identification of a “ranked DNEL”
  - DNEL value and percentage in refinable/contribution to overall exposure to be taken into account
  - To be identified for each exposure pathway, nature of effect and exposure duration to which the effect refers

  → DNEL with the lowest rank is designated as “ranked DNEL”

# Hazard characterisation - Inhalation 2

- If threshold- and non-threshold-related effects are involved for a specific ranked DNEL:
  - → Careful toxicological evaluation of the available information is needed: are non-threshold effects covered by the ranked DNEL?
- Use of bioaccessibility data for a ranked DNEL?
  - Variation in concentration of each constituent
  - Different chemical speciations of the constituents
  - → Worst-case assumption for ranking of DNELs currently proposed: 100% bioaccessibility



# Hazard characterisation - Inhalation 3

- Available exposure assessment tools (1st tier) consider:
  1) Substance intrinsic emission potential
  2) Process related emission potential
  3) Additional operational conditions & risk management measures
  4) Concentration of constituent in refinable
- 1), 2) and 3) are constant for individual refinables representing “homogenous” mixtures of constituents for given “cold” processes
- 4) could be used to weight DNELs for their relevance as risk driver

# Hazard characterisation - Inhalation 4

- Cold metal processes:
  - proportional contribution of each constituent to the overall exposure has to be assessed separately

| Percentage of constituent | Exposure reduction in MEASE | DNEL ranking weights |
|---|---|---|
| <1 % | 90 % | 10.0 |
| 1 % - <5 % | 80 % | 5.0 |
| 5 – <25 % | 40 % | 2.5 |
| 25 % - 100 % | 0 % | 1.0 |



# Hazard characterisation - Inhalation 5

- Available exposure assessment tools (1st tier) consider:
  1) Substance intrinsic emission potential
  2) Process related emission potential
  3) Additional operational conditions & risk management measures
  4) Concentration of constituent in refinable
- Only 2) and 3) are constant for individual refinables for given "hot-metallurgical" processes
- 4) could be used to weight DNELs for their relevance as risk driver
- 1) also to be considered according to the PT/MP ratio of the individual constituents for weighting of DNELs

# Hazard characterisation - Inhalation 6

- Hot-metallurgical processes
  - Emission potential based on ratio PT/MP

| Hot-metallurgical process category | Emission potential and related initial MEASE estimates for inhalation exposure and associated ranking weights | | | | | |
|---|---|---|---|---|---|---|
| | low | | medium | | high | |
| | estimate | weight | estimate | weight | estimate | weight |
| PROC 22 (partly closed furnace operations) | 1.0 | 7 | 3.5 | 3.5 | 7 | 1 |
| PROC 23 (open furnace operations) | 0.5 | 4 | 1.5 | 3.0 | 2 | 1 |
| PROC 25 (other hot metallurgical processes) | 0.5 | 4 | 1.0 | 2.0 | 2 | 1 |
| PROC 27a (hot metallurgical powder production processes) | 1.0 | 10 | 3.5 | 3.5 | 10 | 1 |



# Hazard characterisation – Inhalation 7

- Variations in the content of individual constituents:
  - Either: selection of “representative” concentrations (and associated ranking factors) on a worst-case basis
  - Or: selection of company-specific concentrations of individual constituents
  - Any company could characterise their specific risk by comparing their ranked DNEL with their specific exposure estimate derived from a “generic exposure scenario”
  - Development of a tool for the correct identification of a “ranked DNEL” to be provided to individual companies

# Hazard characterisation - Dermal

- Ranked DNEL for dermal effects:
  - Basically the same ranking approach
  - Justification: exposure expected to occur to the same dust
- This aspect is not developed further (lack of relevance of risk characterisation for most metals)



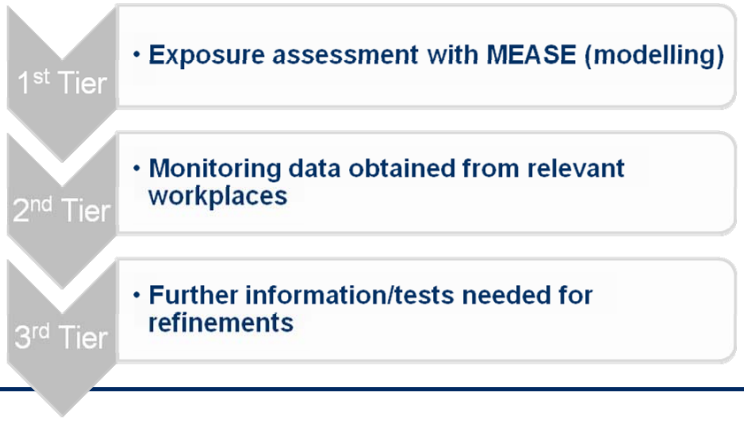
# Further aspects

- Bio-monitoring:
  - Intrinsic assumption that relevant DNELs are all derived as external exposure levels
  - However, DNELs for some constituents are based on internal exposure (monitored in a specific physiological medium such as lead in blood, or cadmium in urine)

  →Such constituents either would have to be assessed separately or the associated DNEL would have to be converted to an external exposure value
- Combined toxicity of different constituents:
  - not yet considered (due to lack of toxicological information and lack of appropriate guidance)

# Exposure Assessment - Introduction

- "Upgrade" or "Update" of UVCBs
  - Need for exposure assessment
  - Potential use of RiCoG-tool (Rigorous Containment Guide)
- Tiered approach for exposure assessment:






# Exposure Assessment – 1st Tier

- MEASE could be used to assess exposure
- Required information includes:
  - physical form of the refinable
  - concentrations (or ranges) of constituents/impurities
  - generic type of conducted processes (scale of process)
  - process temperatures of the conducted processes
  - generic information on operational conditions and risk management measures (level of containment, use of PPE)
  - scale of operation, exposure duration
- Development of occupational exposure scenarios
- Generic exposure scenarios based on the above information

# Exposure Assessment – 2nd Tier (i)

- Required if the RCR is ≥1 in 1st tier assessment
- Need for minimum information as requested for 1st tier
- Exposure estimates based on monitoring data
  - Such data have to fulfil strict quality criteria in addition to requirements resulting from good monitoring practice!

  → measurements of personal exposure, and

  → exposure estimates based on a specific minimum number of data points
  - a multitude of auxiliary information required (e.g. sampling duration, measured fraction of dust, used sampling equipment,...) to ensure sufficient data quality



# Exposure Assessment – 2nd Tier (ii)

- Current situation:
  - monitoring data are assumingly not available in sufficient extent and/or quality
- Monitoring campaigns should deliver adequate results at short notice!
- Monitoring data should
  - demonstrate a safe use for the conducted processes
  - reflect the associated OC and RMM for the relevant processes
  - be representative/specific for the individual exposure scenario

  → **It is therefore necessary to identify relevant workplaces and to obtain monitoring data in a standardised way!**

# Exposure Assessment – 2nd Tier (iii)

- Site visits should be conducted
  - to identify relevant workplaces
  - at sites representative for specific types of processes and workplaces
- Any information reported in ES does not focus on process details!
  - Instead, focus is given to the exposure settings (containment of process, installed RMMs, tasks conducted by workers,...)
- Information will be summarised in a site-visit report, already including an ES in the standard REACH format



# Exposure Assessment – 2nd Tier (iv)

- Site-visit report
  - First draft to be reviewed period by the visited site (check reported information, delete any confidential information)
  - Circulation of report amongst industry
  - Agreement on the identified workplaces, discussion of differences in the conducted processes and implemented RMMs if needed
  - Development of sampling strategy based on the final workplace definitions (including recommendations on workplaces to be monitored and sampling equipment to be used)
  - Distribution of “monitoring guidance sheet” (prior to sampling)
  - Distribution of standard submission form (facilitating an assignment to workplaces, asking for the necessary additional information for each individual data point

# Exposure Assessment – 2nd Tier (v)

- Development of occupational exposure scenarios
- Compared to 1st tier generic ES, these 2nd tier ES are highly specific to the conducted processes, OCs and RMMs as relevant for actual sites
- Therefore, high level of knowledge is required (most easily and efficiently be obtained by conducting site visits)



# Exposure Assessment – 3rd Tier

- Required if the RCR is ≥1 in 2nd tier assessment
- Further refinements may be:
  - particle size investigations,
  - speciation analyses or
  - *toxicity testing* (not in the scope of this proposal)
- Refinements could already be required during monitoring (2nd tier level):
  - for example, if DNELs are driven by particle size, generation of monitoring data should already investigate particle size distributions of dust present in the workplace atmosphere

# Overall Timing

**during June 2011:** Gathering of information required for the first tier occupational exposure as described above (EPMF)

**at short notice after providing all required information to EBRC:** First tier exposure assessment using MEASE (EBRC)

**July 2011:** Selection of representative production sites for site visits (EPMF & EBRC)

**July - September 2011:** Conduction of site visits (EBRC)

**October 2011:** Development of detailed sampling guidance for each refinable (EBRC)

**October – December 2011:** Conduction of sampling campaign (Individual companies/external institute/EBRC)

**February 2012:** Review and second tier assessment

**later in 2012:** Higher tier assessments (if required)



# Summary - Step-wise approach

**1st Step**
- **Hazard characterisation**
  Identification of a "ranked DNEL"

**2nd Step**
- **1st Tier Exposure Assessment**
  …is based on Exposure Modelling in MEASE
  …results in Generic Exposure Scenarios
- Calculation of RCRs

**3rd Step**
- **2nd Tier Exposure Assessment**
  …is only needed if 1st Tier RCRs are at or above 1
  …takes into account monitoring data from actual workplaces
- Calculation of RCRs

**4th Step**
- **3rd Tier Exposure Assessment**
  …is only needed if 2nd Tier RCRs are at or above 1
  …could take into account Particle Size Distributions in the workplace
  …could take into account Speciation Analysis
- Experimental effects studies may be required



**Thank you for your attention!**




# 7. Strategy to improve/refine hazard classification for refinables






# Classifications submitted in 2010

- Prepared on the basis of existing information, ad hoc tests performed at Harlan, and expert judgement
- MeClas was used to derive:
  - Classification for typical streams
  - Pick-lists for streams where number of typical streams exceeded number of individual classification endpoints
- All done in an accelerated manner considering complexity of deriving classifications for such complex UVCB in such a short time




## Classifications submitted in 2010

- Members have informed PMC secretariat that:
  - New information has become available (test data as well as updated (E-)TRV
  - Expert judgement sometimes not complete/correct
  - MeClas pick-lists not easy to understand/apply
  - In addition to pick-lists, should demonstrate application of pick-lists by adding examples of typical streams in each relevant Dossier






## Classification review in 2011

- PMC secretariat proposal:
  - Gather any new information that may have been generated after Dec 2010
  - Re-assess/update classifications in MeClas
  - Derive classification examples for each “pick-list menu”
- Perform the above in parallel with exposure and emission data generation and collection




## 8. Status on dissemination of PM Refinable Dossiers






## Dissemination of Registration Dossier content

First PMC Dossiers have been published on the ECHA dissemination website:

- **Disilver oxide** (EC No. 243-957-1) - http://apps.echa.europa.eu/registered/data/DISS-987664da-0ac8-0ffe-e044-00144f67d031/index.html
- **Residues, copper-iron-lead-nickel matte, sulfuric acid-insol.** - http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbbb86-a413-3fce-e044-00144f67d031/DISS-9fdbbb86-a413-3fce-e044-00144f67d031_DISS-9fdbbb86-a413-3fce-e044-00144f67d031.html

# Dissemination of Registration Dossier content

- The disseminated information is surprisingly extensive but in line with what ECHA published
- Publication is clearly administrative in nature and not really user friendly
- PMC secretariat will review Dissemination website regularly



# 9. Recap of Action Points and review of timing






# Information needs

The following information would (ideally) be required

- Detailed composition/speciation and hazard classification of the reference sample (available from the MECLAS input and output files)
- Description of the variability (available from group descriptions but require refining/updating)
- Detailed description of the physical form (during manufacturing, transport and use) (not available yet)
- DNEL, DMEL and PNEC for substances occurring in the composition of the Refinable (partly available, to be requested from other Consortia)
- Short Generic process description to estimate potential and type of exposure and identify relevant PROC (NOT available, will require some efforts)
- Physico-chemical and dustiness information (partially available for reference sample(s))
- Gather and evaluate existing monitoring data (partially available for some sites) in accordance to quality criteria



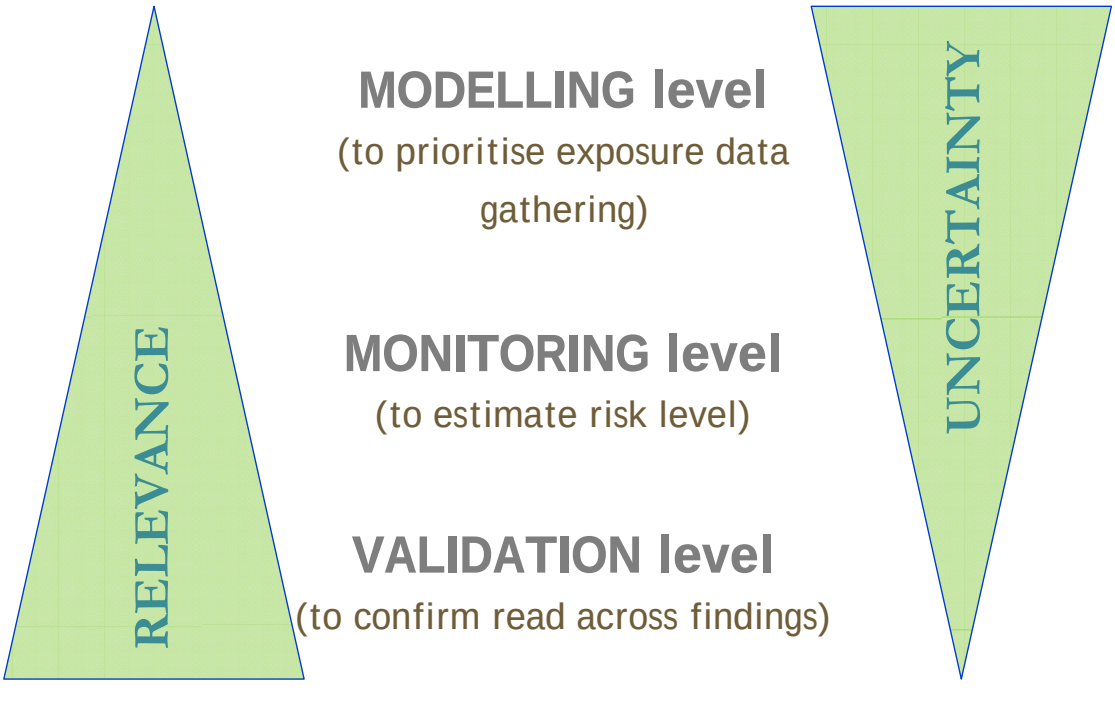





# Monitoring programme (cf. next slides)

- A detailed understanding of main process steps is required to design valid and cost-effective monitoring strategy and plan
- Following steps are suggested:
  - *Step 1*: selection of a representative site per Refinable so that a site visit can be assured to define monitoring needs and operational parameters that determine selection of modelling parameters
  - *Step 2*: monitoring campaign
    - Draft generic outline for a monitoring plan on Refinables
    - Prepare specific monitoring recommendations per Refinable where relevant
    - Build template/questionnaire for data collection
  - *Step 3*: investigate how to deal with combined exposures for metals with similar mode of action?

# Tiered way






# *TIER 1 : modelling approach using MEASE/SPERCS* **(updated)**

**Define reference samples**

- Check substance ID and validity of chem-specs in Registration file
- Collect exposure driver info for the reference samples (Dustiness info)
- Collect risk profile info from other Consortia if relevant/needed
- Collect generic info on operational conditions and PROC's
- Define relevance of conducting bio-elution tests (TDp data available)

Run first TIER for *the Reference* substances

**Company samples : (indicative)**

- Collect exposure driver info for the sample (Dustiness info)
- Check if read across can be applied based on speciation/classification info and would allow for test waiving
- Conduct Bio-elution tests in case read across would not be feasible

Run first TIER for *the company* substances




## TIER 2 : monitoring based approach

- **No distinction** between reference & company situation since monitoring data would be collected for all relevant workplaces.
  - Define relevant workplace steps that require exposure monitoring
  - Collect workplace/environmental exposure info for selected risk driving parameters (CMR's, sensitisers, aqua tox substances, …)

Run second TIER :

- based on monitoring evidence
- compare with modelled data using MEASE (updated) and EUSES for Environment and
- define level of PPE or ENV equivalent, to demonstrate safe use






## 10. AOB, next meetings, and closing remarks






# AOB: REACH Refinables project manager

- At 12 Jan 2011 Assembly meeting a request was put to the PMC secretariat to identify a Project Manager to support the Refinables project
- Job description was prepared and circulated among PMC Belgium-based consultancies
  - Described profile ideal/real
- One CV received from ARCHE (see handouts)
  - Good/long experience in project management
  - Decent technical/ecotox/environmental assessment skills
  - No metal-specific experience but can be facilitated by rest of ARCHE team
  - OK to work on a partial time basis








# Next meeting and calls

- PMC Secretariat, H. Waeterschoot, EBRC, WCA, etc. to meet to prepare questionnaire
- PMC Secretariat, H. Waeterschoot, ARCHE to meet to review/update MeClas
- PM Refiners WG to meet in Sep 2011 to review progress made and discuss next steps




# Thank you!