Precious Metal Refiners Work Group

Hannover, 26-27 September 2011
EBRC Consulting GmbH
Raffaelstr. 4, D-30177 Hannover, Germany

1. Welcome and introduction

Agenda

1. Welcome and introduction

- Reminder on Confidentiality and Competition law
- Presentation PM Refinables Project Manager: Katrien Arijs
- Tour de table & apologies
- Approval agenda
- Approval minutes last meeting (6 Jun 11) & status action points

2. Interpretation of SCC: impact on and challenges for (precious) metals industry

- Current state
- Demonstrating rigorous containment: LEV, PPE and other metal specificities
- Preparing dossier upgrades: hazard assessment, mixture toxicity rules, full CSR, etc.

Agenda (2)

3. Exposure assessment programme

- Brief introduction to exposure assessment of UVCB
- Assessment of workplace exposure & environmental emissions:
  - Proposed general approaches and tools
  - Similarities and differences
- Status of environmental exposure assessment
- Status of occupational exposure assessment
  - Data needs (e.g. dustiness, bio-elution)

4. Strategy to review the hazard classification of Refinables

- The use of pick-lists and examples
- Defining groups and relevant boundaries

5. 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	**Rodger Battersby**	EBRC	Germany	Expert, *will join later on 26th*
4	**Dave Boyd**	Johnson Matthey	UK	
5	**Caroline Braibant**	EPMF	Belgium	Secretariat
6	**Roland Brasch**	Heraeus	Germany	
7	**Edwin Broekaert**	Umicore	Belgium	Chairperson
8	**Helena Byrdziak**	KGHM	Poland	
9	**Paul Frost**	Britannia Refined Metals	UK	*Will only attend on 27th*
10	**Daniel Glowacki**	KGHM	Poland	
11	**Peter Grohnert**	Heraeus	Germany	*Will only attend on 26th*
12	**Mike Halhead**	Anglo Platinum	South Africa	
13	**Michael Huber**	Wieland Edelmetalle	Germany	
14	**Mari Jarvikivi**	Norilsk Nickel	Finland	

List of participants (2)

15	**Claire Massey**	WCA environment	UK	Expert
16	**Giovanni Prelazzi**	Chimet	Italy	
17	**Hendrik Roth**	Aurubis	Germany	
18	**Jutta Schade**	EBRC	Germany	Expert
19	**Heinz-Gunter Schenzel**	C. Hafner	Germany	
20	**Mike Shepherd**	Vale Europe	UK	
21	**Hege Stubberud**	Xstrata Nickel	Norway	
22	**Ed Stutt**	WCA environment	UK	Expert
23	**Nafisa Teladia**	Vale Europe	UK	
24	**Mika Toivola**	Boliden	Finland	
25	**Ruediger Thiele**	Heraeus	Germany	
26	**Daniel Vetter**	EBRC	Germany	Expert
27	**Hugo Waeterschoot**	HW Consult	Belgium	Expert

Pending actions of 6 Jun meeting

	Action	Who?	Status
1	Obtain more info on RiCoG & inform Members Check whether maintenance & cleaning are considered as reasonably acceptable breaching occasions in RiCoG	CB EBRC	Done
2	Circulate draft Oct 2010 Guidance on intermediates	CB	Done
3	Develop a PM Refinable example to illustrate Industry's arguments wrt Dec 2010 ECHA Guidance on intermediates	HW, chairs, CB, KA	Ongoing (cf. Item 2 on Agenda)
4	Circulate Eurométaux Appendices 2 & 3 template examples	CB	Done
5	Develop a PM Refinable Appendix 2 & 3 example & agree on whether to keep in-house or submit as part of Dossier update	PM Refiners	Postponed (according Euro-métaux progress)
6	Launch collection of info on processes with Members and clusters analysis with ARCHE	CB	Ongoing
7	Collect most up to date DNEL, DMEL & PNEC for all PM Refinables constituents	Eurométaux	Ongoing
8	Meet with EBRC & WCA to prepare questionnaire & quality criteria/cover note	HW, CB, Chairs, KA	Done
9	Consider splitting some of the Refinable to result in narrower composition ranges and narrow down some of the largest composition ranges where possible/relevant	PM Refiners	Oct-Nov 2011 (based on cluster analysis)
10	Check whether any of the PM Refinables files has already been published on the ECHA website & inform Members	AR	Done
11	Contact Borax Consortium	CB	Sep 2011

2. Interpretation of SCC: impact on and challenges for (precious) metals industry incl. PM examples for advocacy of SCC towards ECHA

Meeting with ECHA

- Several industry representatives met with very high level delegates from ECHA on 27 Aug 2011
- Outcome of meeting was presented to EM Members at 5 Sep EM meeting on SCC
- ECHA recognises industry's difficulties in implementing existing Guidance on intermediates
- ECHA can't change the guidance but can "interpret aspects" as long as fitting with objectives
- ECHA agreed to continue discussion with industry on the basis of specific examples

Aim of examples

Illustrate specificities of UVCB intermediates in NFM, proving that Rigorous containment can be obtained in different ways recognising that:

- *Overall complexity and variability* of material streams and processes
- *Co-existence of different physico-chemical forms*, including very massive forms
- UVCB are more V than U: *hazard effects of UVCB 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

Type of examples

- Ideally 2 – 4 examples
- From different metal sectors
- Reflecting one ore more of the previously listed specificities
- One process step in the life-cycle of the intermediate if possible
- Using Appendix 3 of ECHA Guidance on intermediates as template

Examples : further info from ECHA

Recent info obtained from ECHA staff :

- ***Appendix 3***: but keep it simple & focussed (2 pages ?)
- ***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 autumn (don't come with final proposal : engage us !)

PM examples

Two examples proposed:

- Initial smelting phase of mix of complex streams
  - Demonstrates complexity (both in terms of composition and varying physical forms) of streams handled simultaneously and continuously in the same work area + interlinkages between several refining streams (Cu, Pb, PM, etc.)

- Loading of Doré in converting furnace
  - Demonstrates uselessness of physical containment of massive forms which liberate no dust and which are manipulated in a semi-automated manner

Aimed at demonstrating state-of-the-art practice in PM industry to ECHA:

- Higher chances of acceptance by ECHA
- Still, not sure how MS will use ECHA's views/flexibility

Aspects related to Update and Upgrade

- *Eurometaux consequence analysis*
- Aims of Exposure assessment: RC proof

Upgrade versus Update : *Eurometaux consequences analysis*

Eurometaux conducted overview assessment on potential consequences. **Main conclusions :**

Update :

- ***Appendix 2*** template (provided by Eramet)
  - "Extensive" but as helpful for other workplace obligations (chemicals or carcinogens at the workplace, Seveso, ...)
  - Workload : couple of days
- ***Appendix 3***
  - "Extensive" and requiring "exposure assessment" to complement statements
  - Can be developed at "Consortium" level but requires in most cases refinement by companies on an individual basis
  - Workload : couple of days + update of IUCLID
- ***Exposure assessment*** program to support validate RC conditions
  - Can be focussed toward "open steps" but must incl. all relevant elements

Upgrade versus Update : *Eurometaux consequences analysis*

Eurometaux conducted overview assessment on potential consequences. **Main conclusions :**

Upgrade :

- ***Exposure assessment*** :
  - to assess exposure level allowing risk characterisation
  - "Extensive": but as useful for other workplace obligations (chemicals agents at the workplace, ...)
  - All relevant elements to be included
- ***Effects assessment*** :
  - ***Classical assessment*** for > 1000 t materials not appropriate and too costly (1,2 – 2,5 mio €)
  - Alternative : ***read across from elements composition*** (< 150-200.000) may need validation assessments to avoid cumulative (See Ni)

Upgrade versus Update : *Eurometaux consequences analysis*

- Cost Factors for upgrades :
  - Increased registration fee (1 versus 10 k€)
  - Testing cost (1,2-2,5 mio)

- 200-400 “registrations” of intermediates expected for the sector
- 25-75 % of upgrades depending on interpretation of RC

Conclusion: Costs reducting achieved with relevant Read Across methodology for 1 to 2 UVCB’s balances out all costs for increased legal fee. Focus should consequently be on Read Across.

Preparation of upgrades

- Dossier upgrade (with corresponding proportionate cost-sharing) foreseen if at least one PMC Member cannot demonstrate rigorous containment (and SCC) for one Refinable
- Based on existing assessment of rigorous containment by PMC Members and rigid interpretation of MS, (some) upgrades will likely be required

Exposure Assessment for REFINABLES

Aim is two-fold:

1.Demonstrate rigorous containment = no (significant) exposure = no release = good containment

2.Prepare future Dossier upgrade needs… If not rigorously contained, if not SCC → Full intermediate dossier based on Risk Characterisation:

Challenges related to upgrades :

-All ***REACH Annexes*** 7-8-9-10

- No benefit for authorities, workers' or environment's safety to perform all REACH tests on UVCB!
- EM fighting for reasonable hazard assessment approach on the basis of read-across, mixture toxicity rules, etc. instead

-***Chemical Safety Report*** = Effects assessment + exposure assessment + risk characterisation + exposure scenario (in several refining tiers)

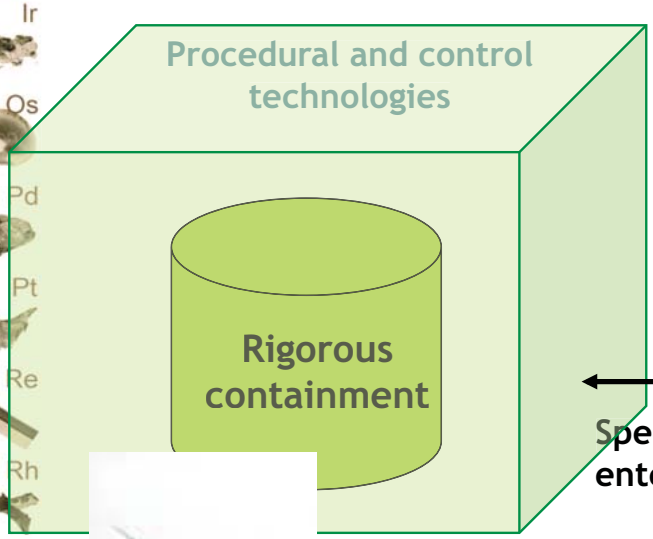
-***Registration*** (update) fee?

-***Upgraded dossier*** submitted with undue delay – 6 mo, 1 y, 2 y?

Demonstration of rigorous containment

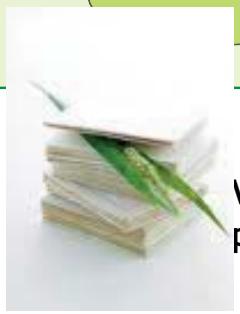
- Critical point when doing a SCC-check
  - If Rigorous Containment assessment fails → SCC fails
- Done differently for HH and ENV
  - **ENV:** on the basis of exposure data
  - **HH:** on the basis of Hirst et al. validated by exposure data
    - For metals, Hirst et al. 'translated' into a tailor-made tool: RiCoG

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

Rigourous Containment reference

Containment systems - A design guide', edited by Hirst et al. 2002 to determine a suitable containment strategy

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

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

3. Exposure assessment programme

Differences between ENV and HH assessments

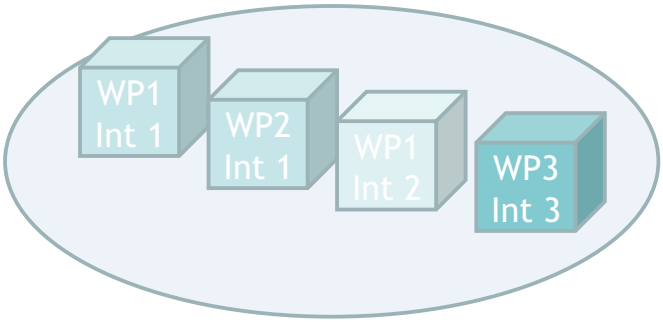
	ENV	HH
Type of assessment	Site-specific	Workplace-specific
Demonstration of rigorous containment	Environmental emission data	RiCoG + Occupational exposure data
Expected data collection tiers	~ 1	> 1
Models/tools used	SPERCS, exposure monitoring (data generation)	MEASE, Decisive DNEL, exposure monitoring (data generation)
Expected exposure assessment tiers	2-3	Minimum 3
RCR aimed at	< 0,1	To be clarified by ECHA

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

SCC check

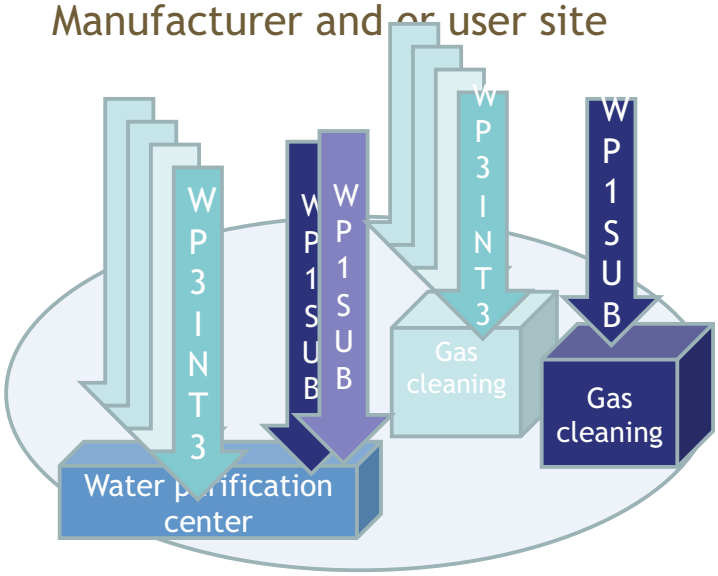
Workplaces

Manufacturer and/or User site



Environment

Manufacturer and/or user site



CHECK by INTERMEDIATE
(if possible)

COMBINED CHECK
and SPLIT if possible

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

Assessment step	WORKPLACE	ENVIRONMENT
SCC screening	Qualitative assessment of rigorous containment: RICOG + expert judgement	Qualitative assessment of rigorous containment & RMMs: Expert judgement
Exposure assessment: modeling	MEASE RCR Questionnaire DNEL?	
Exposure assessment: measured	Monitoring data	Emission data or Ambient data (modeling) Questionaire
SCC validation (by RCR)	Check monitoring with DNEL/DMELS	Check measured emission concentrations; cf with background, PNECS

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

Conclusions:

- Establish that the process(es) of concern are 'rigorously contained' is a common starting point (although this is most important for workplace exposure)
- The methodology, structure and aim of the exposure data assessment program is different between ENV and HH

- ENV :
  - Qualitative screening to establish sufficiently robust RMMs are in place (these will generally be required for other regulations e.g. IPPC, WFD) & emission/ ambient data collection
  - starts from GENERIC exposure scenario/assessment and REFINES were posible (ultimately to site-specific level)

- HH :
  - Tiered approach:
    - Screening (RiCoG)
    - Modeling (MEASE)
    - Exposure assessment based on monitoring data
  - Exposure modeling: selection of parameters based questionnaire information
  - Exposure assessm.: starts by workplace and "pools" data sets where applicable

PM Refiners WG meeting – Hannover, 26-27 September 2011
Precious Metals and Rhenium Consortium

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

Conclusions :

- BUT overall aim is identical between ENV and HH

- Proof/validate SCC conditions ➔ UPDATE
  - Selective focussed exposure monitoring

- Conduct Risk Characterisation ➔ UPGRADE
  - Conduct Exposure measurement according REACH guidance

Assessment of environmental exposure: Proposed general approaches and tools

Claire Massey
Ed Stutt
Adam Peters

Overview

- SCC and the environment
- Two approaches
  - Dossier updates
  - Dossier upgrades
- Questionnaires
- Modelling and risk characterisation
- Monitoring

SCC and the environment

- The environment appears to a secondary consideration
- Criteria primarily relate to process engineering and worker exposure
- Rigorous containment considered under human health assessment – no need to repeat for environment
- If not rigorous containment then not SCC
- If rigorous containment, possibly SCC depending on environmental RMM
- Need to demonstrate that any emissions are controlled by appropriate RMM

SCC and the environment

- Basis for compliance with SCC can possibly be based on:
  - company's IPPC licence or permit, as long as sufficient and adequate documentation of the compliance with the conditions of the permit 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.

SCC and the environment

- Waste gas incineration
  - complete destruction of waste gases at high temperatures for a specified minimum residence time (not so relevant for metals)
- Condenser
  - low temperature devices - waste vapours pass through and are liquefied for collection (again, not so relevant for metals)
- Scrubber
  - number of types available. The waste scrubber solution is then recycled or disposed of by incineration

SCC and the environment

- HEPA-filter
  - a filter designed to trap small particles. The contaminated filter is then disposed of by incineration…. Or recycled!

SCC and the environment

- WWTP
  - a biological and/or physical/chemical system to which the aqueous waste streams from a process and washing/cleaning solutions are sent. Traces of the substance are removed from the water before discharge into the environment.
- Cryogenic treatment
  - very low temperature condenser which traps all the condensable materials as a liquid or a solid. This liquid or solid is then disposed of by incineration.

SCC and the environment

- Biofilter
  - A bio-filter is a biological system where certain substances in vent streams are degraded by micro-organisms

SCC and the environment

- RMM are expected to demonstrate 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
  - Not used to calculate RCR (although this is being discussed)
  - Used qualitatively to demonstrate releases are negligible

Two approaches

- Dossier updates
  - SCC met
  - Company includes justification for this conclusion in dossier
  - Could include monitoring data to confirm SCC
- Dossier upgrades
  - SCC not met or business decision
  - Full substance hazard dossier required
  - Full exposure assessment required
  - Monitoring data likely to be required to demonstrate safe use

Questionnaires

- Useful for both updates and upgrades
- Captures information on:
  - Refinable composition
  - Tonnage
  - Potential emissions
  - RMM
  - Monitoring data
  - Confounding factors

Questionnaires

- One questionnaire for each site
  - Potentially several refinables and other materials with similar components
- Process diagram gives us a much better understanding of your site
- 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

- Will focus on refinable's components that have an environmental classification
  - Ag, As, B, Cd, 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
- Environmental concentrations modelled in EUSES

Modelling and risk characterisation

- Tier 1
  - Develop Generic Exposure Scenario "Manufacture and use as an intermediate in the recovery of precious metals"
  - Use maximum or 90th percentile tonnage at a typical site, typical RMM and default emission values
  - One GES for each component (9 in total)
  - These GES used for all refinables
    - *reduce the resource and time*
    - *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 Generic Exposure Scenario
  - One GES for each component (9 in total)
  - Use SpERC values to refine emission estimates
    - *Compare these to 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
  - Same Generic Exposure Scenario
  - One GES for each component (9 in total)
  - Use site specific data to refine assessment
    - *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 (monitoring)

Monitoring

- Useful for both updates and upgrades
- Most important for upgrades where Tier 3 modelling still identifies RCR above 1 or where data are lacking
- Similar process for both situations though

Monitoring

- Identify components of relevance
  - For upgrades this is components still showing RCR>1
  - For updates this may be all components of interest
- Identify compartments of relevance
  - Water, sediment, air, soil
- Design monitoring scheme
  - in line with ECHA 2010 R16 Environmental Exposure Estimation

Monitoring

- For upgrades
  - Monitoring data collected will be used to update exposure modelling
- For updates
  - Monitoring data can be used by companies to support their SCC justification

EBRC

Strategy for the Assessment of Rigorous Containment of Refinables

Refinables WG Meeting
Hannover
26/27 September 2011

Daniel Vetter
EBRC Consulting
Hannover, Germany

Outline and initial considerations

- On-going technical discussions, e.g. RCR based assessment vs. general dust limit
- BETA-version of RiCoG released, no comments received yet
- Questionnaire has been issued and responses were received
- Site visits have been conducted
- Intermediates to be nominated for exposure assessment, for example, not RiCoG-compliant
- Update vs. upgrade and implications of each for assessment

Tiered approach for RiCo assessment

Tier zero	• **Assessment of rigorous containment using RiCoG conducted by companies**
1st Tier	• **Exposure assessment using MEASE (modelling)**
2nd Tier	• **Exposure assessment using monitoring data obtained from relevant workplaces**
3rd Tier	• **Further information/tests needed for refinements**

Tiered approach: Tier Zero

Tier zero	• **Assessment of rigorous containment using RiCoG conducted by companies**
1st Tier	• Exposure assessment using MEASE (modelling)
2nd Tier	• Exposure assessment using monitoring data obtained from relevant workplaces
3rd Tier	• Further information/tests needed for refinements

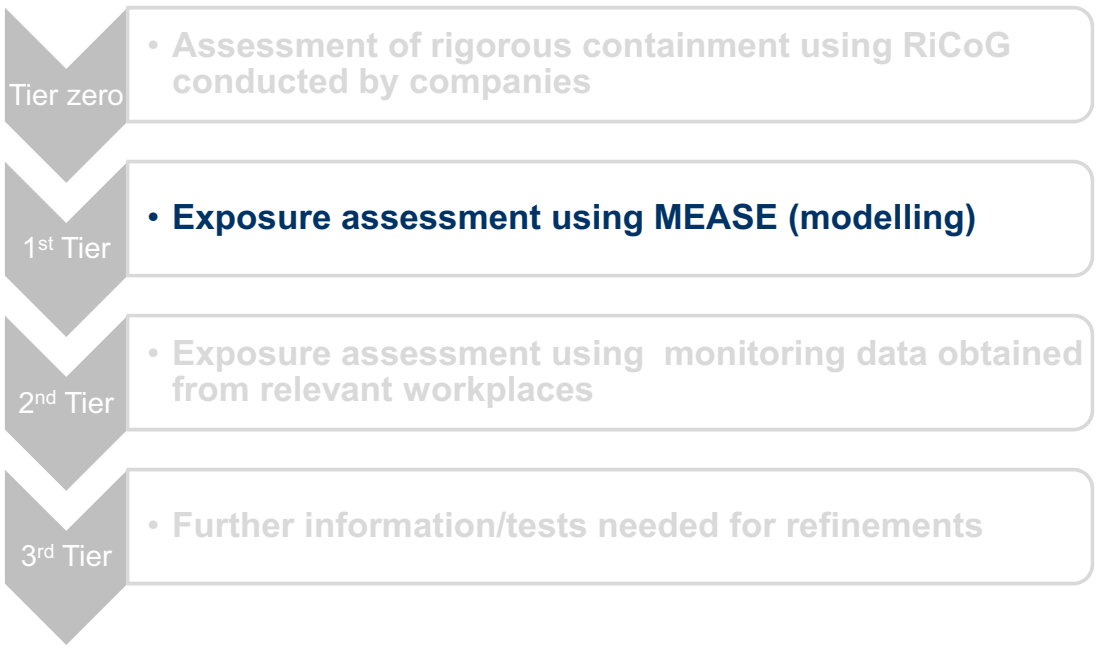
Tier zero: Rigorous Containment Guide

- Use of RiCoG is of course voluntary!
- No obligation to report results of RiCoG assessment
- RiCoG meant to be **qualitative screening tool** for RiCo
- Compliant with current ECHA-guidance (and regulation)
- As the use of measured data can be omitted, it is meant to provide conservative assessments, however:
- Metal-specific adaptations will provide (not yet included!) more flexibility to reflect specific measures of RiCo
- Industry input urgently needed to implement adaptations

Tier zero: RiCoG live session

- BETA-Version available from:
  http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/downloads/RiCoG-0.02.05-BETA.xls
- Commenting form available from:
  http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/downloads/RiCoG-ContainmentStrategies.docx
- Please send any comments to: dv@ebrc.de

Tiered approach: 1st tier



Tier 1: Exposure assessment (MEASE)

- To be kept in mind: on-going technical discussions:
  - RCR requires toxicological reference value
  - Level of general dust currently discussed is at 50 µg/m³
- To be conducted for nominated refinables
- Questionnaire data are needed:
  - as input parameters for MEASE
- Additional data needed: dustiness data (if applicable)
- Site visits will help to understand the submitted information
- Format for use of exp. data in RiCo assessment to be developed

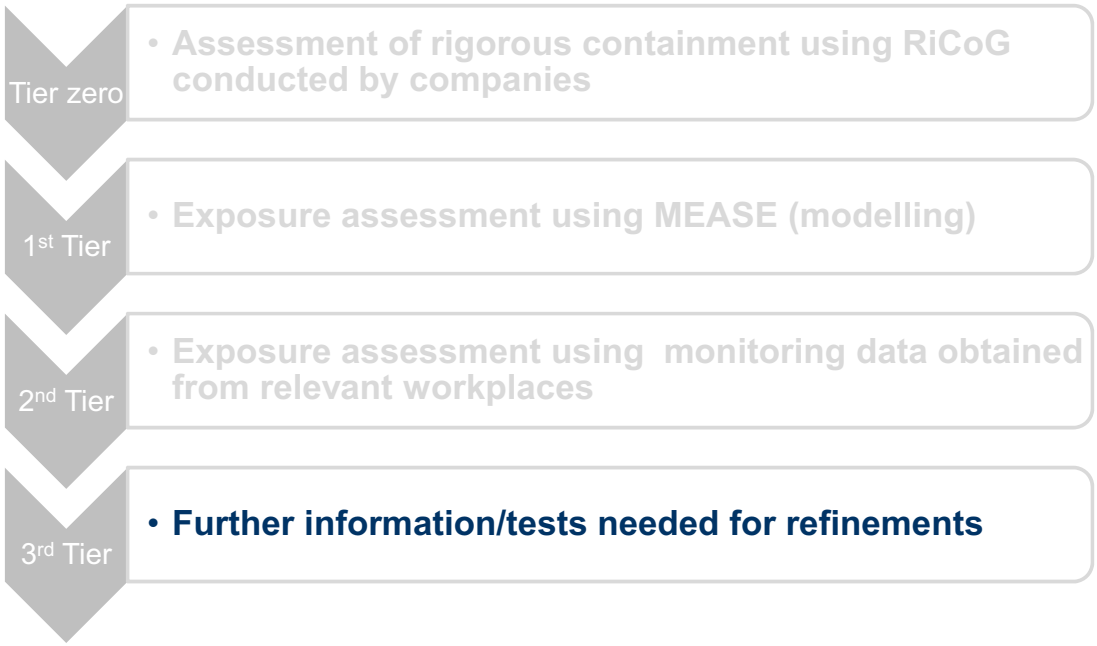
Tiered approach: 2nd tier

Tier zero	• Assessment of rigorous containment using RiCoG conducted by companies
1st Tier	• Exposure assessment using MEASE (modelling)
2nd Tier	• **Exposure assessment using monitoring data obtained from relevant workplaces**
3rd Tier	• Further information/tests needed for refinements

Tier 2: Data-based assessment

- To be kept in mind: on-going technical discussions:
  - RCR requires toxicological reference value
  - Level of general dust currently discussed is at 50 µg/m³
- To be conducted for refinables failing 1st tier assessment
- Questionnaire data are needed:
  - as information to be used for data submission form
- Strict quality criteria will be applied to measured data (according to R14)
  - for example, number of data points, percentile and GSD
- Site visits will help to pool/group submitted data

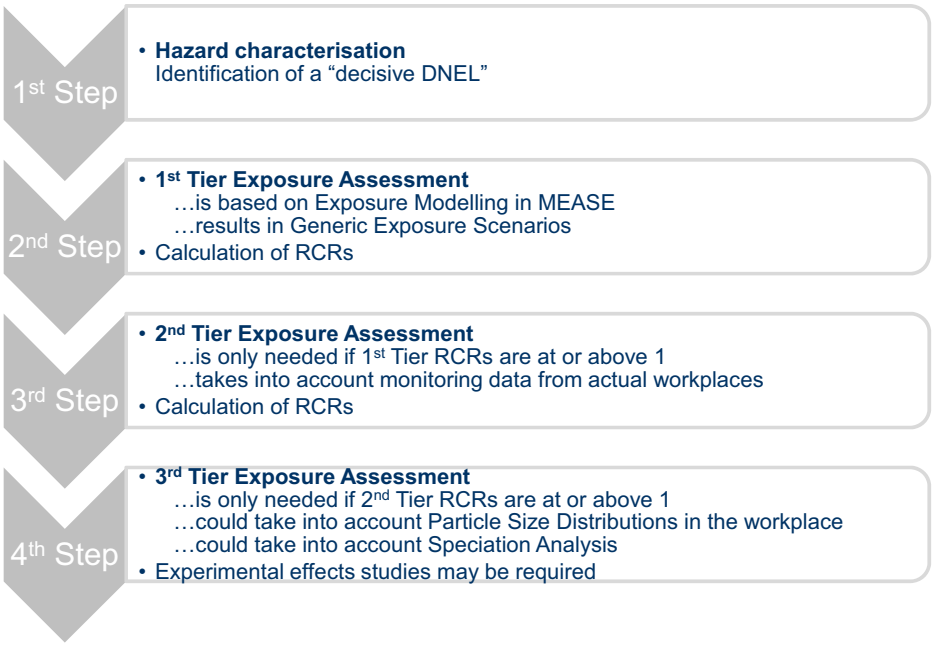
Tiered approach: 3rd tier



Tier 3: Update or upgrade?

- Refinements of exposure assessment may be possible based on:
  - Bio-availability
  - Particle size distributions of dust in the workplace
  - Speciation analysis
- Or does this already constitute a full registration?
  - All generated exposure data could be used in a dossier upgrade for the generation of exposure scenarios
  - Toxicity data are available from dossiers of “pure” constituents, read-across could be applied
  - Companies have legal certainty for the prod./use of their refinables
  - Contra: registration fees, time to complete technical dossiers…

Exposure assessment for **upgrades**



Decisive DNEL

- REACH registration dossiers have been/are prepared for all of the involved constituents (assumption)
  - → Read-across to dossiers instead of generating experimental data *de novo*
  - → Extensive and complex ES for each constituent (different hazard profiles, exposure routes, etc.)
- Pragmatic and pre-cautionary approach needed to avoid extensive assessments!
- First step: Identifying a "decisive DNEL"

Decisive DNEL - Inhalation 1

- Essential to define a single critical DNEL for each refinable constituent
  - Identifying most important risk driver to propose measures for adequate protection of workers
  - This works for all threshold related effects
- Derivation of a "decisive 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 highest rank is designated as "decisive DNEL"

Decisive DNEL - Inhalation 2

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

Decisive DNEL - Inhalation 3

- Common 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 each refinable for "homogenous" mixtures of constituents for given "cold" processes
- 4) could be used to weight DNELs for their relevance as risk driver

Decisive DNEL – Justification (cold)

- Generally RCR < 1
  (1) RCR = EXP / DNEL (highest RCR means highest risk)
  (2) EXP < DNEL
- For a 1st tier assessment in ECETOC TRA or MEASE:
  (3) $EXP = EXP_{initial} * MF_{percentage} * MF_{EPhot,\ EPcold} * MF_{RMMs}$
- $EXP_{initial}$ and MF_{RMMs} are constant for each constituent
- Cold processes
  - EP_{cold} is constant (e.g. homogenous powder mixture)
  - Impact on RCR exclusively comes from $MF_{percentage}$ considering (1) and (3)

Decisive DNEL - Inhalation 4

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

Percentage of constituent	Exposure reduction in MEASE	DNEL ranking weights
<1 %	90 %	10.0
1 % - <5 %	80 %	5.0
5 – <25 %	40 %	1.7
25 % - 100 %	0 %	1.0

Decisive DNEL – Example (cold)

- Number of (hazardous) constituents: 6

	Percentage [%]	Ranking weight	DNEL [mg/m³]	Ranking value (concentration)	Rank
Constituent A	1.2	5	0.07	0.35	5
Constituent B	3	5	0.5	2.5	2
Constituent C	0.53	10	0.03	0.3	6
Constituent D	12	1.7	1	1.7	3
Constituent E	0.5	10	0.6	6	1
Constituent F	4	5	0.15	0.75	4

Decisive DNEL - Inhalation 5

- Common 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 refinables for given "hot-metallurgical" processes
- 1) also to be considered according to the PT/MP ratio of the individual constituents for weighting of DNELs
- 4) could be used to weight DNELs for their relevance as risk driver

Decisive DNEL – Justification (hot)

- Generally RCR < 1
  (1) RCR = EXP / DNEL (highest RCR means highest risk)
  (2) EXP < DNEL
- For a 1st tier assessment in ECETOC TRA or MEASE:
  (3) $EXP = EXP_{initial} * MF_{percentage} * MF_{EPhot,\ EPcold} * MF_{RMMs}$
- $EXP_{initial}$ and MF_{RMMs} are constant for each constituent
- Hot processes
  - Impact on RCR comes from $MF_{percentage}$ and MF_{EPhot} considering (1) and (3)

Decisive DNEL - 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	2.0	7	1
PROC 23 (open furnace operations)	0.5	4	1.5	1.3	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	2.9	10	1

Decisive DNEL – Example (hot)

- Number of (hazardous) constituents: 6
- PROC 22 (furnace operations), 450℃ process temperature

	Melting point [℃]	Emission class	Ranking weight temperature	Ranking value (concentration & temperature)	Rank
Constituent A	250	high	1	0.35	6
Constituent B	690	low	7	17.5	2
Constituent C	750	low	7	2.1	3
Constituent D	190	high	1	1.7	4
Constituent E	1200	low	7	42	1
Constituent F	380	medium	2	1.5	5

Decisive DNEL – Inhalation 7

- Input & Output:
  - Consideration of variations in the content of individual constituents
  - Selection of individual concentrations of constituents (and associated ranking factors) on a worst-case basis
  - This concept allows assessment of occupational exposure on company-by-company basis
  - Development of a tool for the correct identification of a “ranked DNEL” to be provided to individual companies
  - Any company could characterise their risk by comparing their ranked DNEL with their specific exposure estimate derived from a “generic exposure scenario”

Decisive DNEL - 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 om risk characterisation for most metals)

Decisive DNEL - Further aspects

- Bio-monitoring:
  - Before mentioned approach: Assumption that relevant DNELs are all derived as external exposure levels
  - BUT: 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)

Assessment of environmental exposure: Current status

Ed Stutt
Claire Massey & Adam Peters

Environmental Exposure Questionnaires

- Questionnaire developed to capture all of the available data that is relevant to the 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 (mean and range)*
  - *- Risk Management Measures (RMMs) and efficiencies*
  - *- Quantified emissions to air and aquatic environment*
  - *- Characteristics of receiving environment*

Summary of responses so far

- 9 completed questionnaires received to date.....

.....so plenty 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 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 will be in touch to request additional data

Important Issues

- For calculation of emission factors it is essential that we are comparing like with like
- 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 due to refinable processing
  - estimate proportion of total
- Also need site total input per metal if other activities on site using these substances

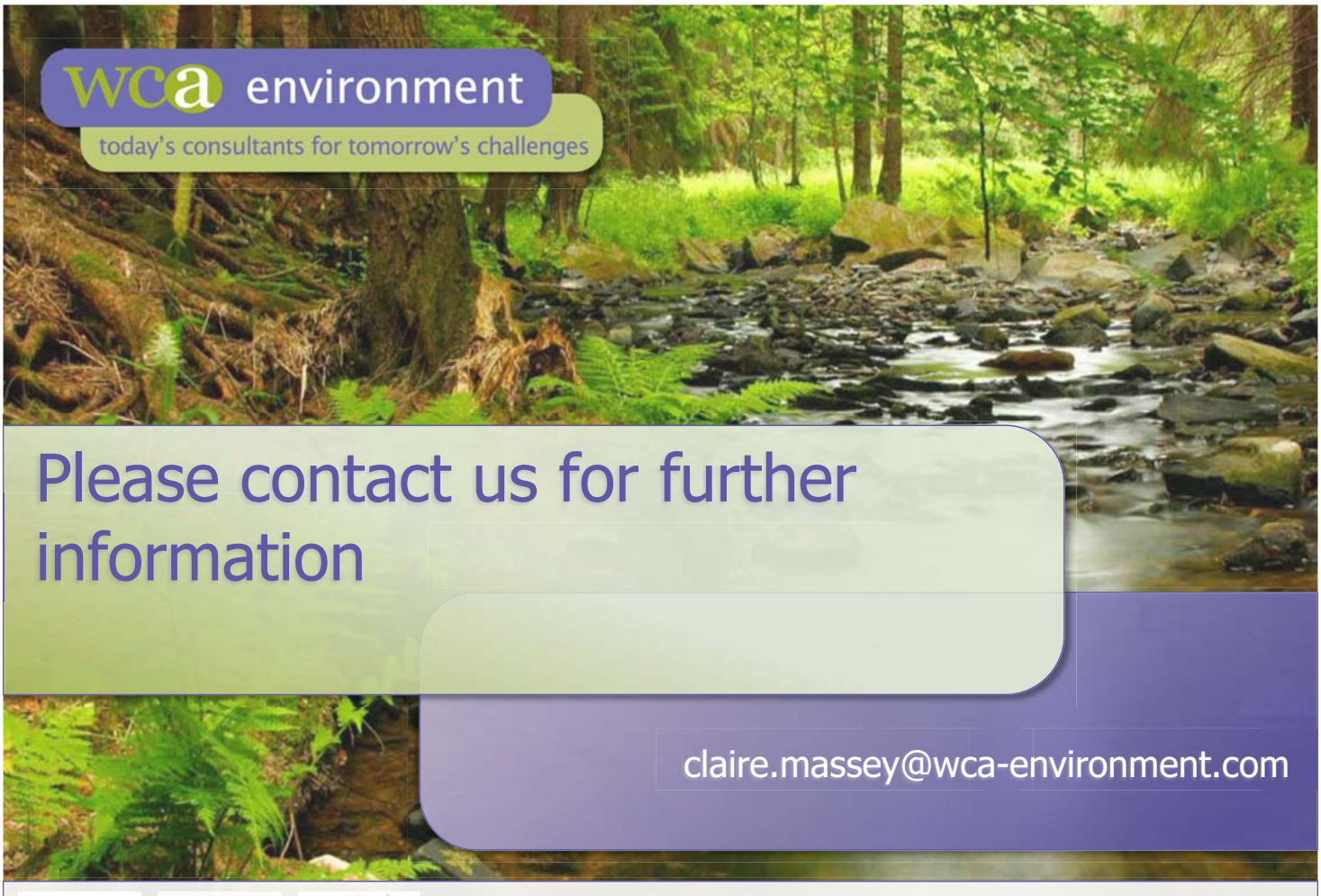
Important Issues

- Where limit values are presented options are

  i) no emissions ii) emissions at LoD iii) 50% LoD

- Are stack emission and waste-water testing undertaken for all hazardous components listed in the composition – this does appear to always be the case from the responses so far

- Any questions?



Please contact us for further information

claire.massey@wca-environment.com

Occupational Exposure

Questionnaire & demonstration of rigorous containment

Refinables WG Meeting

Hannover

26/27 September 2011

Jutta Schade
EBRC Consulting
Hannover, Germany

Number of completed questionnaires

- 7 individual questionnaires from 7 sites
- 2 sites with multiple questionnaires (3 for one site, 8 for another site)

→ total of 18 completed questionnaires

Availability of measured data

- 5 sites indicated availability of measured inhalation exposure data
- Of these, 4 sites indicated to also have biomonitoring data available as well

Use of refinables in questionnaires

- 1 refinable in 1 questionnaire
- Different refinables in 1 questionnaire
- Physical form of refinables:
  - Massive, powder, solution, …
  - Often different compared to questionnaire from 2009 (e.g. from blocs to powder)
  - Need to determine the dustiness of powders

Nominated PROCs

PROC	Description	Number of nominations
1	Use in closed process, no likelihood of exposure	2
2	Use in closed, continuous process with occasional controlled exposure	7
3	Use in closed batch process (synthesis or formulation)	8
4	Use in batch and other process (synthesis) where opportunity for exposure arises	4
8a (may be covered by 8b or 26)	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	2
8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	21
9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	1
22	Potentially closed processing operations with minerals/metals at elevated temperature; Industrial setting	7
23	Open processing and transfer operations with minerals/metals at elevated temperature	9
25 (may be covered by 22)	Other hot work operations with metals	1
26	Handling of solid inorganic substances at ambient temperature	13
27b	Production of metal powders (wet processes)	1
PROC not selected		5

Example - RiCoG

- Demonstration of rigorous containment
- Refinable X:
  - Low dusty substance
  - Containing 7 different metals
  - DNEL: 10 – 100 µg/m³ (80 µg/m³)
  - Being classified with:
    - H301 (Toxic if swallowed)
    - H312 (Harmful in contact with skin)
    - H320 (Causes eye irritation)

Example - RiCoG

	A	B	C	H	I
1					
2		**RiCoG 0.02.05 (BETA)** **Rigorous Containment Guide for Intermediates** **Based on Hirst et al. (2002)**	**TEST-VERSION - DO NOT USE FOR REGISTRATION!!!**	© 2011 EBRC Consulting GmbH	
4		Assessment of exposure potential (EP)		Results of EP assessment	
5		Physical form of intermediate at process temperature	low dusty	low dustiness (as reported)	
6		Vapour pressure at process temperature (not considered)	not known		
7		Boiling point of intermediate in °C (not considered)			
8		Process temperature in °C (not considered)			
10		Quantity of intermediate handled per task/operation	> 100 kg	large	
11		**Exposure potential (long term)**		**EP3**	
13		Hazard group determination		Results of hazard group determination	
14		Occupational exposure limit or DNEL/DMEL	10 - 100 µg/m³	C	
16		H-statements			
17		303, 304, 305, 313, 315, 316, 318, 319, 320, 333, 336, all not listed	At least one of the H-# assigned to intermediate	C	
18		302, 312, 332, 371	At least one of the H-# assigned to intermediate		
19		301, 311, 314, 317, 318, 331, 335, 370, 373	At least one of the H-# assigned to intermediate		
20		300, 310, 330, 351, 360, 361, 362, 372	None of the H-numbers assigned to intermediate		
21		334, 340, 341, 350	None of the H-numbers assigned to intermediate		
23		Conclusive classification not possible due to lack of data	Not applicable	Data allow conclusive classification.	
24		**Hazard group (determined by threshold value and worst case classification)**		**C**	

Example - RiCoG

4	**Hazard group (determined by threshold value and worst case classification)**			**C**
6	Implemented containment strategy (CS)			Suggested improvements
7	Description	Local exhaust ventilation		Open handling within isolator OR high integrity closed ...
8	Used equipment	Closed containers within fixed or flexible air-tight barrier (e.g. glove-port)		none
9	Level of containment	Process totally enclosed with specially designed equipment		none
10	Breaching incidents	Contamination minimised by LEV		Only limited breaching permitted (e.g. sampling)
11	Leakage prevention	LEV prevents contamination of general working area		Enclosures are maintained under negative pressure
12	Treatment of contaminated air	Contaminated air is passed through a HEPA filter before exhausted outside the building		none
13	Maintenance scheme	Regular certification and testing of the filtration system		none
14	Level of contact	Operators do only prepare containers for transfer of substance		none
15	**Currently implemented containment strategy**			**CS2**
17	Evaluation of containment strategy			
18	Containment strategy to be implemented (minimum requirement is CS3)			CS3
19	**Demonstration of rigorous containment**			**Not achieved**

developed by EBRC on behalf of EuroMetaux

Disclaimer
Report bugs to author
GNU General Public License
Download most recent RiCoG-Version

Example – RiCoG failed

- Refinable X:
  - Containment strategy to be implemented: CS3
  - Currently implemented containment strategy: CS2

  → Rigorous containment not demonstrated based on RiCoG

  → Way forward:
    - → Implement additional containment measures as recommended
    - → Justify deviations (or own CS) in a qualitative way
    - → Proceed with exposure assessment

Example - MEASE

Substance characteristics	Model parameters	R	Exposure modifier
Molecular weight (g/mol)			---
Melting point (°C)			---
Vapour pressure (Pa)			---
Physical form	Solid, low dustiness		Low fugacity (dustiness based)
Content in preparation (including alloys)	> 25%		100%
Operational conditions (OC)	**Model parameters**	**R**	**Exposure modifier**
Process category	2 - Use in closed, continuous process with occasional controlled exposure		---
Process temperature (°C)			---
Scale of operation	Industrial use		Industrial use
Duration of exposure (minutes)	> 240 minutes		100%
OCs used for dermal exposure assessment	**Model parameters**	**R**	**Exposure modifier**
Pattern of use	Wide dispersive use		High dermal exposure potential
Pattern of exposure control	Direct handling		High dermal exposure potential
Contact level	Extensive		High dermal exposure potential
Risk management measures (RMM)	**Model parameters**	**R**	**Exposure modifier**
Implemented RMMs	LEV (generic)		22%
RMM efficiency based on	Lower confidence limit		(as reflected in reduction factor above)
Respiratory protective equipment (RPE)	No RPE		100%
Use of gloves	No gloves		100%
Exposure estimate			**Exposure estimate**
Dermal exposure estimate			500 µg/cm²/day
Exposed skin area			480 cm²
Total dermal loading			**240 mg/day**
Inhalation exposure estimate			**0.002 mg/m³**

Example - MEASE

Substance characteristics	Model parameters	R	Exposure modifier
Molecular weight (g/mol)			---
Melting point (°C)			---
Vapour pressure (Pa)			---
Physical form	Solid, low dustiness		Low fugacity (dustiness based)
Content in preparation (including alloys)	> 25%		100%
Operational conditions (OC)	**Model parameters**	**R**	**Exposure modifier**
Process category	8b - Transfer of subst. or prep. from/to vessels/large containers at dedicated facilities		PROC 26 could be used
Process temperature (°C)			---
Scale of operation	Industrial use		Industrial use
Duration of exposure (minutes)	> 240 minutes		100%
OCs used for dermal exposure assessment	**Model parameters**	**R**	**Exposure modifier**
Pattern of use	Wide dispersive use		High dermal exposure potential
Pattern of exposure control	Direct handling		High dermal exposure potential
Contact level	Extensive		High dermal exposure potential
Risk management measures (RMM)	**Model parameters**	**R**	**Exposure modifier**
Implemented RMMs	LEV (generic)		22%
RMM efficiency based on	Lower confidence limit		(as reflected in reduction factor above)
Respiratory protective equipment (RPE)	No RPE		100%
Use of gloves	No gloves		100%
Exposure estimate			**Exposure estimate**
Dermal exposure estimate			500 µg/cm²/day
Exposed skin area			480 cm²
Total dermal loading			**240 mg/day**
Inhalation exposure estimate			**0.022 mg/m³**

Example – MEASE

- Demonstration of rigorous containment by MEASE:
  - PROC 2:
    - RCR = 0.025 (local exhaust ventilation installed)

  → Rigorous containment demonstrated by a RCR <0.1 for PROC 2 based on MEASE

  - PROC 8b:
    - RCR = 0.275 (LEV installed)

  → Rigorous containment not demonstrated (RCR >0.1) for PROC 8b based on MEASE, but safe use demonstrated (RCR<1)

→ Proceed with EA based on measured data

Summary

- Some questionnaires still missing (status 22/09/2011)
- 12 out of 29 PROCs nominated
- Use of RiCoG and MEASE to demonstrate rigorous containment
- Measured data for higher tier assessments available (no information on quality and extent yet)

Thank you for your attention!

4. Strategy to review the hazard classification of Refinables

Possible strategy to improve classifications registered for PM Refinables in 2010:

aiming mainly at replacing pick-lists by typical profile classification where possible

	Action	Who?
1	Perform clusters analysis on the basis of composition with focus on driving elements	ARCHE
2	Distinguish groups of similar profiles in each Refinable	ARCHE
3	Determine composition boundaries for each profile group	ARCHE
4	Associate composition boundaries to classification endpoints (limited to transport, packing, site-permit and similarly relevant classification endpoints)	ARCHE, HW, Chairpersons
5	Define profile groups for each Refinable	ARCHE, HW, Chairpersons
6	Derive a classification for each profile group	ARCHE
7	Circulate the proposed profile groups and associated classifications for each Refinable to Ref WG for discussion/approval	KA
8	Agree on profile groups and associated classification	Ref WG
9	Update the classification and labelling accordingly + GHS + new data in the IUCLID 5 file	WCA
10	Prepare CLP update guidance document	CB
11	Submit updated classification	All (PMC Members & non-Members)

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

Updated project timeline - Classifications

	Task	Who?	When?
1	a. Review composition ranges provided for each Refinable b. Discuss possibility of narrowing down composition ranges	Refiners WG	Summer 2011 Sep 2011 mtg
2	Review classifications based on new available data: a. Collect test results from Harlan b. Collect test results from Members and forward to WCA c. Develop updated classifications d. Agree on updated classifications	 WCA CB WCA Refiners WG	 Summer 2011 Dec 2011
3	Review the output of MeClas & make it more user-friendly: a. Collect updated DNEL, DMEL, acute & chronic (E-)TRV of the constituents b. Derive updated GHS classifications for all PM Refinables c. Calculate updated classifications for all PM Refinables streams d. Review/confirm classification profiles e. Refine output & classification boundaries / triggers to make these more user-friendly	 Eurométaux ARCHE ARCHE, PMC sec ARCHE, PMC sec ARCHE, PMC sec	 Summer 2011 Sep-Oct 2011 Oct 2011 Dec 2011 Jan 2012
4	Develop 1-2 examples for each Refinable where classification is provided in the form of a pick-list (if unsuccessful in generating classification profiles)	Refiners WG, ARCHE	Jan-Feb 2012
5	Prepare updated Registration Dossiers in IUCLID 5	WCA	
6	Submit updates to the Registration Dossiers where needed	LR	Mar 2012

Updated project timeline - HH and env data

	Task	Who?	When?
1	Questionnaire to collect workplace exp info & env emission info	EBRC & WCA Refiners WG	Aug-Sep 2011
2	Tier 0: RiCoG	EBRC Refiners WG	Sep-Nov 2011
3	Process descriptions per Refinable	Refiners WG EBRC & WCA	Sep-Nov 2011
4	Key constituents for modelling and monitoring	EBRC & WCA	Oct-Nov 2011
5	Tier 1: modelled/existing data	EBRC & WCA	Nov-Dec 2011
6	Tier 2: monitoring data	EBRC & WCA Refiners WG	Dec 2011 - Mar 2012
7	Tier 3: new data, refined	EBRC & WCA Refiners WG	Mar -Jul 2012

Thank you!