



## Precious Metals & Rhenium Consortium Management Committee meeting



Brussels, 24th of February 2010

Metals Conference Centre - Copper room  
Rue du Duc 100, 1150 Brussels





## Agenda

1. Welcome and introduction
2. Scope of activity of the PMC
3. Progress of PMC projects
4. Lead Registrants
5. Revision of Consortium Agreement
6. Letter of Access
7. IUCLID 5 Hosting System
8. AOB, next meetings, closing remarks

## 1. Welcome and introduction

## Actions of the last Assembly meeting

	Action	Who?	When?
1.	Identify the risks involved in not meeting the registration deadline with a complete Dossier	C. Braibant	Feb 2010
2.	Circulate guidance document to Members as soon as it becomes available	C. Braibant	Feb 2010?
3.	Contact potential candidates to identify a potential Lead Registrant for all substances in scope	C. Braibant	Jun 2010
4.	Clarify and strengthen Appendix 5 of the Consortium Agreement	C. Braibant	Jun 2010
5.	Circulate an updated list of uses covered by the Ag project	T. Hird	Mar 2010
6.	Devise a classification notification strategy with EBRC and WCA	C. Braibant	Early Q2 2010
7.	Add column for budget tracking in all project plans	T. Hird	Mar 2010
8.	Obtain clarification on the following aspects of the OECD Programme: <ul style="list-style-type: none"> <li>□ How would confidentiality and ownership rights apply in the event a Commodity shares (part of the content of) its Registration Dossiers with the OECD countries?</li> <li>□ Are all Dossiers concerned or only the Ag metal one (only High Production Volume)?</li> <li>□ Are Intermediates Dossiers of interest to the OECD Programme?</li> <li>□ Will extracts of the Registration Dossier be required or a full version of it?</li> <li>□ When are Commodities expected to provide the required information?</li> <li>□ What is the timeline to confirm interest in this Programme?</li> </ul>	T. Hird	Mar 2010
9.	Clarify any open issue (e.g.: security, IT set-up, etc.) before signing any contract commissioning the implementation of WCA's IUCLID 5 Hosting System	C. Braibant + MC	Feb 2010

Precious Metals and Rhenium Consortium - MC meeting 24 Feb 2010 All on track!



## Chairmanship of Mgmt Cttee

- Article 4.2.1.1: Elections of the Management Committee shall take place every 3 (three) years.
- Article 4.2.1.2: Elections of the Chairman of the Management Committee shall take place every 2 (two) years.
- Options:
  - Re-elect A. Griffiths for 2010 (have it approved by the Assembly in June 2010, and proceed to a new election in Dec 2010), or
  - Elect a replacement for Andrew today (candidate will be then be elected in June 2010 for the period of 2010-2012)



## 2. Scope of activity of the PMC



## Indicative lists

- In Sep 2009 'scope' of the Consortium was officially closed
- In Dec 2009, changes to the scope were requested:
  - Ag: Disilver oxide
    - Decrease of tonnage band from 100-1000 to 10-100
    - Pushes back Registration deadline to 2018 (originally 2010)
    - [Proposal](#): Prepare a 10-100 t/a Dossier for submission in 2010
  - PGM:
    - Removal of 5 substances/intermediates
    - Addition of 1 intermediate
    - Decreases in tonnage band
    - Changes of status from substance to intermediate
  - Re: One new intermediate



## Indicative lists (cont.)

- No *ad hoc* work has been done on any of the removed materials (collected information can be used for read-across)
- 'Past' work to be performed on newly added substances and intermediates only relates to Phase I (literature search)
- Only major change is re disilver oxide



## Cost implications and agreed approach

### Proposal:

- Work performed on removed materials or those materials having been subject to a decrease of tonnage or change of status will not be charged back to concerned companies
- 'Past' work performed on newly added materials will be charged to relevant companies (*ad hoc* invoices)



## Provisional position on nanosilver

- Presented at 3 Dec 2009 Assembly meeting
- PMC continued participating to RIP-oN1 exercise
- RIP-oN1 generally agrees with separation of silver and nanosilver for the purpose of Registration
- Position remains unchanged



### 3. Progress of PMC projects



### Progress report Ag



## Current status of Ag project


Phase	Status
I & IIa: Literature search	✓
IIb: Enabling Tests	✓
IIc: Refined literature review & data gap analysis	✓
IId: Test derogations/ & Integrated Testing Strategy	✓
III: Testing programme	Ongoing
IV: CSA/CSR (including ES)	Ongoing
V: IUCLID 5 preparation	Ongoing

✓ Completed phase



## Phase III: Testing Programme (Ends February 2010)

Phase IIIA: PhysChem testing (EBRC)	
Oxidising properties AgNO <sub>3</sub> (Siemens) - inconclusive need for repetition	✓
Oxidising properties Ag <sub>2</sub> O (Siemens) - inconclusive need for repetition	✓
Water solubility Ag <sub>2</sub> SO <sub>4</sub>	✓
Water solubility Ag <sub>2</sub> CO <sub>3</sub>	✓
Flammability tests (Siemens)	✓
Propose C&L requirements	✓ 1 month late
Repeat oxidising properties Ag <sub>2</sub> O - respirable & inhalable (BAM)	Feb
Repeat oxidising properties AgNO <sub>3</sub> (BAM)	Mar




**Phase III: Testing Programme (Ends February 2010)**

**Phase IIIB: Human Health - Tox testing (EBRC)**

Sensitisation Ag2SO4 - LLNA (inconclusive, requires repetition with other test material)	✓
<i>In vitro</i> skin corrosivity AgNO3	✓
Acute tox inhalation Ag2O - waiver statement being drafted	✓
<i>In vitro</i> micronucleus Ag2SO4 - OECD 487 (Covance)	✓
<i>In vitro</i> gene mutation Ag2SO4 - OECD 476 (Covance)	✓
Repeat Sensitisation test (as per method recommended by ECHA, as per response to inquiry)	Mar
90-day oral RDT - on hold pending data holders confirmation to provide (report received)	Mar
Propose C&L requirements	Feb

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**Phase III: Testing Programme (Ends February 2010)**

**Phase IIIC: Environmental - Ecotox testing (WCA/BIBRA)**

No requirement identified to date	
Potential need for long term soil test (Annex IX & X)	
Potential need for bird test (Annex IX & X)	
Need for further discussion on environmental testing requirements	April
Propose C&L requirements	✓ 1 month late

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## Phase IV: Chemical Safety Assessment/Report (Ends June 2010)

<b>Phase IVA: Collection of information on uses, emissions and exposure (EBRC &amp; WCA)</b>	
Evaluate existing information and perform preliminary assessment	✓
Preparation of uses, emissions and exposure questionnaire	✓
Circulation of questionnaire to primary manufacturers and downstream users	✓
Questionnaires collected & forwarded to consultants	✓
123 Responses (29 not in required format)	June 2009 Nov 2009
Collation and analysis of responses and preparation of tier 1 exposure scenarios (ES) (default table values)	Oct -WCA Nov- EBRC
Propose approach for ES building	Meeting Dec 2009
<b>Phase IVB: Uses</b>	
Identify uses and confirm to PMC Members	Dec 2009 Feb 2010



## Phase IV: Chemical Safety Assessment/Report (Ends June 2010)


<b>Phase IVC: Exposure &amp; DNEL Derivation (EBRC)</b>	
Tier 1 Exposure Scenario (default table values)	✓ 1 month late
ES format to be established	Jan
DNEL availability	Jan
Update & propose RCR subject to DNEL availability	Jan
Refined Tier 1 Exposure Scenarios subject to DNEL availability	Jan
Additional data collection from Members/DSU + site visits	Feb-Mar
Full evaluation & report on monitoring data for occupational exposure	✓ On time
Tier 2 ES (from site visits)	Mar > Apr
Tier 3 ES	Apr > May
Tier 4 ES + final DNEL	May/Jun > July
Discussion, exchange of ESs with industry, finalisation	Jun > Sep



## Phase IV: Chemical Safety Assessment/Report (Ends June 2010)

Phase IVD: Emissions & PNEC Derivation (WCA)		
BLM - Ag bio-availability correction model test programme (scoping)		✓
BCM interim report		✓
BCM evaluation		✓
Peer review of WCA BLM report - to be revisited once more data available from monitoring programme		✓
SSD > part of EQS report		✓
i) Background routine testing at 111 sites		Jan-Jun
ii) Site specific sampling - 5 sites		Feb-Jun
Revised PNEC available		✓

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## Phase IV: Chemical Safety Assessment/Report (Ends June 2010)

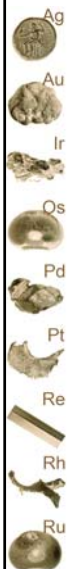
Phase IVD: Emissions & PNEC Derivation (WCA)		
Tier 1 ES (default table values)		✓
ES format to be established		Jan
Feedback on draft PEC/PNEC ratios		Jan
Update & propose RCR		Jan
Tier 2 ES (taking account of responses)		Feb
Identify waste emissions and assess		Feb/Mar
Peer review of EQS Report		Mar
Meeting with WCA to discuss above and which studies & AF to use		Apr
Additional data collection from Members/DSU + site visits		Feb/Mar
Tier 3 ES (from above task)		Apr > May
Tier 4 ES + final PNEC		Apr/May > Jun
Discussion, exchange of ESs with industry, finalisation		June-Sept

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## Phase IV: Chemical Safety Assessment/Report (Ends June 2010)

Phase IVE: CSA/CSR (final dnels, pncecs, exposure scenarios)	
Perform CSA, carry out RA, prepare CSR and extended SDS	Jun
Circulate extended SDS & CSR for adjustment / approval amongst PMC and other joint registrants as relevant	July
Final extended SDS & CSR for submission	Aug

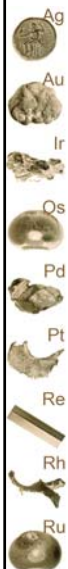
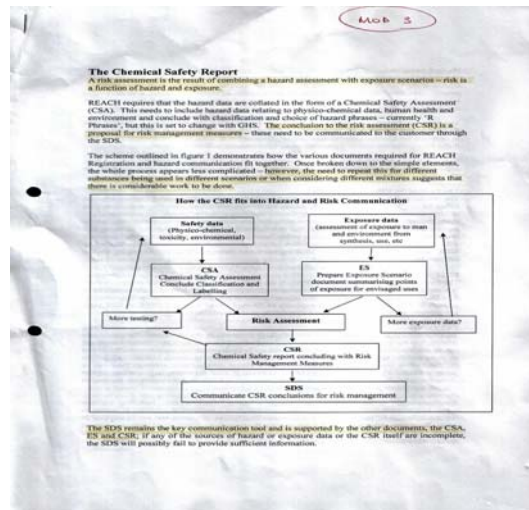


## Phase V: Compilation of IUCLID 5 file & Registration Dossiers

		2009												2010											
		A	M	J	J	A	S	C	N	D	J	F	M	A	M	J	J	A	S	C	N	D			
Phase IVE	CSA/CSR (final dnels, pncecs, exposure scenarios)	[Timeline grid for Phase IVE]																							
	Perform CSA, carry out RA, prepare CSR and extended SDS	[Timeline grid]																							
	Circulate extended SDS & CSR for adjustment / approval amongst PMC and other joint registrants as relevant	[Timeline grid]																							
	Final extended SDS & CSR for submission	[Timeline grid]																							
Phase V	Compilation of IUCLID 5 file & Registration Dossiers	ORIGINAL OVERALL TIMEFRAME OF PHASE V																							
	WCA Proposal >	[Timeline grid]																							
	EBRC Proposal >	[Timeline grid]																							
	Identify IUCLID 5 sections and fields to be filled by WCA, PMC, EBRC	[Timeline grid]																							
	Set-up of IUCLID5 templates & individual files	[Timeline grid]																							
	Agree on centralised IUCLID5 hosting system	[Timeline grid]																							
	IUCLID 5	[Timeline grid]																							
	Section 1 General Information	[Timeline grid]																							
	Section 2 Classification & Notification	[Timeline grid]																							
	Section 3 Manufacture, Use & Exposure	[Timeline grid]																							
	Section 3.5 Identified Uses	[Timeline grid]																							
	Section 4 Physical & Chemical Properties	[Timeline grid]																							
	Section 5 Environmental Fate & Pathways	[Timeline grid]																							
	Section 6 Ecotoxicological Information	[Timeline grid]																							
	Section 7 Toxicological Information	[Timeline grid]																							
	Section 8 Analytical Methods	[Timeline grid]																							
	Upload final CSR into REACH dossier (IUCLID5)	[Timeline grid]																							
	Send complete IUCLID 5 files to PMC	[Timeline grid]																							
	Perform overview of IUCLID 5 content with PMC	[Timeline grid]																							
	Complete IUCLID 5 files with LR information	[Timeline grid]																							
	Send LR full IUCLID 5 file ready for submission	[Timeline grid]																							
	Provide each legitimate joint submissioner with a copy of the non-confidential sections of the IUCLID 5 file	[Timeline grid]																							




## The Chemical Safety Report




## Remaining Milestones

- Establish the IUCLID5 hosting service (crucial in the preparation of the CSR)
- Repeat oxidising properties (launched) & sensitisation to conclude C&L
- Obtain the right to refer to silver thiosulphate study to negate the need for 90 day oral RDT study
- Establish environmental testing requirements (meeting March)
- Ensure the Ag monitoring sub-project remains on track
- Keep up the pressure on all tasks which feed into the Exposure Scenarios building as this is critical to completing the CSR (4-5 week process)
- Communication to members and other joint registrants



Ag  
Au  
Ir  
Os  
Progress report Au  
Pd  
Pt  
Re  
Rh  
Ru



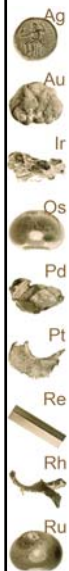
Ag Au  
Au  
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Ru

- WCA started work in January
- DKC Phase I report reviewed
- Satisfied with literature search on Au metal
- Further literature searches required on other substances
- Some out of scope substances were looked at for purposes of read across
- Development of waiver statements for some end points
- Project plan now developed around WCA proposal
- Published and proprietary data held by PMC forwarded to WCA
- Now awaiting data with DKC already paid for by PMC
- On receipt forward to WCA
- Final review to identify data gaps and report to PMC
- Teleconference between WCA & PMC to discuss development of Phase II

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## Progress report PM CN-





## Precious Metal Cyanides


- WCA have reviewed DKC Phase I report
- Additional literature search needed
- Project plan now developed around WCA proposal
- Published and proprietary data held by PMC forwarded to WCA
- ECETOC JACC reports received from PMC
- Now awaiting data with DKC already paid for by PMC
- On receipt forward to WCA
- Final review to identify data gaps and report to PMC
- Teleconference between WCA & PMC to discuss development of Phase II





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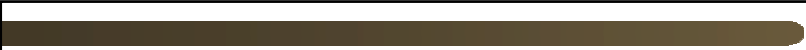
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## Progress report PGM





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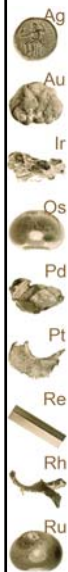
 Rh

 Ru

## Status of PGM project

Phase	Status
I: Literature search	✓
II.1: Pilot project for grouping approach	✓
II.2: Test derogations & Integrated Testing Strategy, tier 1 (water solubility & T/D)	✓
II.2: Test derogations & Integrated Testing Strategy, tier 2 (physico-chemical and ecotox)	✓
II.2: Test derogations/ & Integrated Testing Strategy, tier 3 (tox)	In preparation
III: Testing programme	Starting in 2010
IV: CSA/CSR (including ES)	Not yet commenced
V: IUCLID 5 preparation	Ongoing

✓ Completed phase



## Testing programme

- Tier 1 (agreed): water solubility and transformation/dissolution tests
- Tier 2 (on hold): Other physico-chemical tests and ecotox tests (agreed in principle but awaiting results of tier 1)
- Tier 3 (tbd): Tox tests (in preparation)
- No start before Q2 to allow focus of resources on Ag & refinables



## Current State of Play

- Phase II ITS report (covering Pt, Pd, Rh, Ru & Ir) now available mid March - delayed due to 2x changes in scope and issues around anhydrous vs hydrated forms
- Report will contain reference to category building and the rationale behind the proposed testing programme on PhysChem, Ecotox & Tox (BIBRA)
- T/D recommendations to establish read across strategy
- Proposal for T/D testing ahead of Phase II ITS report in Jan (insufficient rationale for circulation & discussion)
- Slot reserved at CANMET in April for T/D testing but slot not yet reserved for H<sub>2</sub>O solubility at Wildlife International
- April now probably too early




## Current State of Play


- Teleconference on Friday 26 February to discuss approach eg T/D testing on metals in April + further testing in June?
- T/D testing on the metals is an industry approach and is likely to be more acceptable to ECHA + starting position for read across
- Addition of the new substance meant no delays in the overall project plan
- There will be an update of the Phase I report
- Phase II work was adjusted so the data gap analysis, category building and ITS design reported takes account of new substance





## To Conclude


- The remainder of Phase III testing depends on the recommendations of the Phase II ITS report - mid March
- Decide if we proceed with T/D metals testing in April
- Map out with WCA the timing of the individual tasks in Phases IV & V
- Early start on collection of information on uses, emissions and exposure
- Next PGM WG Meeting 20 April
- Registration deadline is May 2013
- Project plan currently reflects having everything wound up by Q1 2012
- Time is on our side but lab space will become at a premium as we move through 2010
- Albania Grosso the WCA Project Manager is moving on but will be accessible to WCA





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## Progress report Re





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## Status of Re project

Phase	Status
I: Literature search	✓
II.1: Pilot project for grouping approach	✓
II.2: Test derogations & Integrated Testing Strategy, tier 1 (physico-chemical and ecotox)	✓
II.2: Test derogations & Integrated Testing Strategy, tier 2 (tox)	In preparation
III: Testing programme	Commenced
IV: CSA/CSR (including ES)	Uses identified
V: IUCLID 5 preparation	Ongoing

✓ Completed phase

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## Test Derogation & Testing Programme

- Phases II & III of the project plan
- Draft Phase II report made available for discussion in Sept 2009 giving Tier 1 & Tier 2 testing proposals
- Final Phase II report available end February 2010
- Testing started in December 2009 before receipt of above because of the tiered approach proposed in the draft report
- Tier 1 tests completed on UV vis & pH and are being reported in draft form at the same time as the Final Phase II report
- Planned visit to AQura 8 March with WCA to assess T/D testing capabilities
- Lab space immediately available in March & April for this, H<sub>2</sub>O solubility & ecotox tests



## Test Derogation & Testing Programme

- Draft report in May to be reviewed by WCA, Re WG & Dr Mitchell
- Tier 2 tests (physico-chemical + human health + environment ) will be launched after Tier 1 results have been reviewed
- Scheduled for Sept-Oct 2010
- Teleconference to discuss inhalation tests on APR relating to particle size
- Potassium Perrhenate literature search has been completed, sent to BIBRA for comment and will be included in the Final Phase II report



## Phases IV & V

- Phase IV work (CSA & CSR) has started with uses of Re already having been identified, now to be followed by preparation of a questionnaire to collect information on uses, emissions and exposure
- Phase V which is IUCLID5 population will continue to build as more data becomes available from the testing programmes
- Earliest opportunity for registration based upon the current project plan is Feb 2012



## Progress report Refinables



## Refinables Project

Other PMC projects usually follow a phased approach covering:

- I. Literature search and data gap analysis
- II. Intelligent testing strategy
- III. Testing programme
- IV. CSA/CSR and C&L
- V. IUCLID 5 completion

For complex intermediates, this had to be adjusted to dedicate available resources to key aspects



## Refinables Project

Based on experience from Cu, Ni, Zn, Eurometaux and others, for complex intermediates (type UVCB):

Less emphasis on:

- Literature search - expensive and not conclusive
- Testing - expensive and difficult to conduct

Focus on:

- Speciation: to allow for substance ID+ sameness check, grouping, read across, and classification
- Replace testing, based on read-across (T/D, Bio-elution, etc.)
- Classification requirements (phys-chem testing)



## Proposed Way Forward

	New Phasing	Status/Comment
1	Identification/Analytical work/speciation	Partially done through grouping; may need to be slightly re-visited/completed
2	Preliminary classification	Partially done by "additivity" principle; will be repeated using classification matrix tool
3	Evaluation of available information	Information collection launched; work in Progress
4	Read-across possibilities/potential	To be started
5	Testing programme A) Annex VII B) Classification needs	To be started
6	Refined classification	After Phases 1 to 5
7	UCLID 5 compilation	In parallel with phases 3 to 6
8	Dossier submission (training)	In parallel with phase 7



## Phase I: Identification & Analytical Work

- All refinables identified and organised into 10 groups
- ID cards prepared, being refined for circulation to pre-SIEFs
- 7 samples being tested for speciation at Outotec March
- Report not before April
- Chosen because of experience in characterisation in UVCB metals
- 11 samples 24hr screening T/D at ECTX Consult March
- Help to refine and confirm preliminary classifications and support the grouping approach
- Adequate ID is required under REACH, Eurometaux drafting a paper on the type of analysis that should be used



## Phase II: Preliminary Classification

- Indicative classifications derived from assumed compositions
- Preliminary classification & sub-grouping derived by PMC & WG from data provided by members
- TRVs received from WCA on PM Refinable specific constituents
- Tier recommendation derived from ARCHE & Cu Consortium classification tool
- HW to derive potential classification based on TRV data and speciation results (April)



## Phase III: Literature Search & Data Gap Analysis

- Information on Refinables sent by members to PMC
- WCA currently identifying information on PMC & NFM refinables
- Report on data gap analysis possibly by end of March (early)

## Phase IV: Read-Across & Testing Strategy

Read-across possibilities reported end of March (early)

Intention is to have Phases I-IV completed by the end of Q1 and no later than early Q2

Next WG meeting on 21 April to discuss outcomes of speciation, data gaps, read-across and testing programme



## Phase V: Testing Programme (Phys-Chem Annex VII)

- Testing strategy to be based on reduced number of reference samples subject to results of 24hr screening T/D
- PMC providing test guidelines for granulometry test which is required for particles <1mm
- HW identified Refinables where phys-chem tests can be run in parallel with speciation & 24hr screening T/D
- WCA have secured a timeslot at Harlan UK to perform phys-chem tests



## Phase VI: Preliminary Classification

- No tasks due to be completed until April
- The intention is to have all classifications confirmed in Q2
- Section 2 of IUCLID 5 requires a classification submission either at Registration and no later than Jan 2011
- WCA/HW working on a classification notification strategy Q2



## To Conclude

- The project is on track
- There is no time for slippage
- Tremendous progress has been made in a relatively short period of time

BUT.....

Bottlenecks exist:-

- Sample selection, preparation & shipping and testing house capacity
- Potential delay in ECHA responding to our questions on clarification for substances needing new EINECS numbers, or name or description changes, and on how to submit classification notifications
- Discussions needed for example in discussing the outcome of Phases I, II, III & the 24hr screening T/D which will be used to identify end points that can be waived by reading across from existing information



## 4. Lead Registrants



## Official designation, commitment and duties

- PMC Agreement + support document outline designation and duties of Lead Registrants
- Liability is limited to wilful misconduct, fraud, and gross negligence
- Actual commitment still rather “loose”
- **Proposal:** see template in handouts (Declaration of Commitment - to be included in LoA contract)



## 5. Revision of the Consortium Agreement



## Integration of addendum, clarification and other *ad hoc* notices

- Version 2 (dd 6 June 2008) of Consortium Agreement includes:
  - Consortium Agreement and its appendices
  - Addendum (20 Jun 2008)
  - Clarification on Signature folio and Article 3.4 (dd 1 Sep 2008)
  - Notice to new Members (29 Oct 2008)
- Assembly approved above documents and agreed to have these included in the event of a revision of the Consortium Agreement

✓ Done (cf. draft version 3)



## Clarify Members' commitments after Registration

- From the 106 Substances and Intermediates that are being prepared for Registration by the Consortium, only 16 will be registered by the first REACH Registration deadline (1 Dec 2010):
  - Ag metal dossier
  - Ag nitrate dossier
  - Ag disilver oxide dossier
  - 13 Refinables dossiers
- The Ag metal dossier constitutes the "sole" PMC dossier to be submitted for eight PMC Members
- Proposal (first part): Need to clarify that REACH obligations continue after Registration: aim of Consortium Agreement strengthened Done (cf. draft version 3)



## Clarify Members' commitments after Registration (cont.)

- In addition to “legal frame”, Members must be re-assured that future costs will be limited/controlled
- Proposal (second part): After expenses predictions are discussed and approved (by MC + after Accountant's feed-back), C. Braibant will calculate the likely annual share of each Member as from 2011
  - To cover for minimum maintenance needs (Generic costs)
  - Dossier specific costs will be less predictable (Metal-specific costs)
  - This 'basic' annual amount shall be reasonable (e.g.: 1000-5000 €/year per Member)



## Appendix 5: Clarification of working structure and decision-making

- Appendix 5 addresses working structure of Consortium
  - At 3 Dec 2009 Assembly meeting working structure and decision-making across work groups was clarified
  - It was agreed to incorporate updated working structure and decision-making flowchart to Consortium in the event of an update
- ✓ Done (cf. draft version 3)



## Inclusion of intermediates in cost-sharing formula

### Background:

- Current cost-sharing formula allocates the budget according to:
  - n° of Members,
  - n° of Substances in any tonnage, and
  - n° of Transported Isolated Intermediates in the > 1000 t/a tonnage band
- However, other Intermediates represent in some projects a significant part of the scope of work and in average 30%
- Originally agreed that work performed on intermediates would be charged at the end of the registration process to the concerned companies, on the basis of work actually performed for each intermediate (~ 5000 €/intermediate dossier split across interested companies)



## Inclusion of intermediates in cost-sharing formula (cont.)

Originally agreed way forward is difficult to implement

### Options considered:

- 1: include intermediates in the first part of the Metal-specific costs only (f2)
- 2: include intermediates in the second part of the Metal-specific costs only (f3)
- 3: include intermediates in both parts of the Metal-specific costs (f2 and f3)



## Inclusion of intermediates in cost-sharing formula (cont.)

### Preferred option/Proposal: 2

Impact: Different cost-share increases:

- Ag: ~ 70 €/intermediate
- Au: ~ 470 €/intermediate
- PGM: ~ 620 €/intermediate
- Re: ~ 880 €/intermediate

Always < than originally  
foreseen 5000 € per  
intermediate dossier



## 6. Letter of Access



## Joint submission/OSOR principles

### Background

- One Dossier shall be submitted for each substance/intermediate
- All entities having interest in same substance/intermediate are part of this unique joint submission, meaning:
  - One “complete” dossier submitted by LR
  - One small dossier (containing company-specific info only) submitted by others
- The above implies that “others” have a right to refer to the LR dossier
  - As per existing Consortium Agreement
  - If non-Member → Letter of Access (LoA) proposed



## Rights granted through a LoA

- When a LoA is proposed, it may give a right to:
  - Refer to the LR’s dossier, and/or
  - Use the LR’s dossier (Licence to Use, LtU)
- Proposal: PMC LoA grants a right to refer only



## REACH principles when calculating LoA price

- Fairness
- Transparency
- Non-discrimination
- Non-profit

Allows complying with Competition Law and avoids being accused of forming an exclusive 'cartel'



## Supporting principles when calculating the price of a PMC LoA

Proposal: In addition to REACH/Competition Law principles, the following principles are proposed:

- PMC Membership remains open to any joint registrant
- Price of a LoA is reasonably attractive to promote LoA route
- LoA is purchased per:
  - Legal entity
  - Substance/Intermediate
- A legal entity purchasing a LoA:
  - has no obligation towards the PMC (only those in LoA contract)
  - pays its share of Generic costs only once
  - has no co-ownership right on the information contained in the dossier
  - does not receive a copy of the dossier submitted to the ECHA (if it does, need to purchase a LtU)
- No reduction or premium applied on a LoA purchased earlier or later
- Price of LoA reviewed every year as the PMC expenses predictions are confirmed or refined



## Calculation of the PMC LoA price

- Expenses are calculated to cover the period of 2007-2020.
- Confirmed expenses of the period of 2007-2009 are taken as a baseline to make 2010-2020 predictions.
- Two scenario:
  - 1) Include meeting & telcon costs
  - 2) Exclude meeting & telcon costs



## Calculation of the PMC LoA price (cont.)

Scenario 1 not recommended:

- Members' costs and not PMC costs
- Costs have been incurred by some Members, to a different extent
- If PMC wishes to charge for these costs:
  - Each company would have to charge the PMC for such costs
  - PMC would have to account for each company's "participation rate" when calculating future shares
- Hence:
  - Administratively cumbersome
  - Decreases transparency of calculation method

### Proposal:

- Follow scenario 2, and
- Include contingency that "covers" for these parallel costs: 10%, 15%, 20%?
  - Example calculated with 10%
  - Example calculated with 20% (typical contingency applied by PMC since start)



## Calculation of the PMC LoA price (cont.)

- After expenses have been predicted, need to distribute these across potential joint registrants, i.e.:
  - PMC Members, and
  - Potential LoA purchasers (cf. responses to survey - 20%)
- Once distribution is done, extract the cost of a LoA for a substance/intermediate in each tonnage band and project



## Calculation of the PMC LoA price (cont.)

- Following scenario 1.2 with 20% contingency applied to expenses predictions, LoA are derived:
  - Provided in handouts
  - Pending adjustment after confirmation of 2009 expenses by Accountant (mtg on 15 March)
- Proposal:
  1. MC to discuss, comment, improve and approve method of calculation
  2. C. Braibant to adjust calculations (arrive to "round number" and justification document accordingly)
  3. C. Braibant to prepare legal frame (with support of Legal Work Group)
  4. "Full package" circulated to MC again for approval (telcon?) before presentation to the Assembly in June 2010
  5. Official circulation of LoA proposal through REACHsuite in July 2010



## Management of "incomes" due to LoA

- Selling of LoA can not aim at producing profit to the PMC or its Members
- Calculation method implies that more entities will share the overall costs
- This means that PMC Members' invoices for years after Registration will be lighten
- Where an "excess" is produced - Options:
  1. Reimbursement to Members (profit?)
  2. Store on an *ad hoc* fund to re-invest in risk assessment-related research



## 7. IUCLID 5 Hosting System



## IUCLID 5 Hosting System - What is it?

IUCLID 5 = software used to create REACH dossier - All data inputted into it  
IUCLID 5 Hosting System = tool that centralises access to IUCLID 5 file

- Each substance requires its own technical dossier and therefore its own IUCLID 5 file
- Hosting system allows to give Lead Registrants (read-only) access to their IUCLID 5 files so they can follow the build of the file 'live' - *confidentiality*
- Other Consortia Members would have access via PMC
- Main advantage is that all data is held in one place/centralised (put in by the contractors)
- Allows consultants to work together more easily
- PMC can follow up and supervise the work done by the consultants
- Reduces the possibility of errors due to more efficient handling of files
- More secure than e-mailing IUCLID5 export files around (still some) - *time- and cost-efficient*
- Finalised copies can be stored in REACHSuite giving ease of access/traceability



## IUCLID 5 Hosting System - Conditions

- At 3 Dec 2009 Assembly meeting proposed to use IUCLID 5 Hosting System provided by WCA as follows:
  - One single/separate hosting instance (licence) per project
  - 6 projects (Ag, PGMs, Re, Au, PMCNs & Refinables) = 6 instances
  - Set-up cost (once) of 250 £
  - Hosting cost (monthly) of 200 £
- Before "signing up" to this tool - need to check security *et al.*

~ 3000 € per project  
or instance per year



## IUCLID 5 Hosting System - Q&A


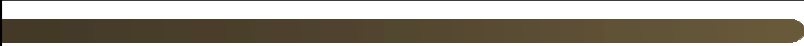
	Question	Answer	Status
1.	How secure is the system? Anti-virus softwares, back-ups (frequency, storage), data repair/recovery, physical protection	Virus Scan software on all servers Back-ups: daily, kept 7 days, in same building and overwritten afterwards (128bit EAS Encryption)	OK
2.	How is confidentiality guarded in the system? Login/passwords, general encryption/software	Encryption: SSL Access: Through HTTPS session One Database and Website per instance Database and Website on two separate servers Servers hosted by 1and1 (cf. <a href="http://www.1and1.co.uk">www.1and1.co.uk</a> ) Servers cannot be accessed directly from internet (only through IUCLID 5 application) Login/passwords: One per user and 2-fold (one for Hosting facility, one for IUCLID Application)	OK
3.	Is the server hosting the Hosting System used for other customers as well?	Database server: up to 3 instances Website server: up to 5 instances (PMC = 6 instances)	OK (cf. 1 and 2)
4.	What is the maximum n° of users in each instance? Which roles exist?	Unlimited Roles: from 'Read-only' to 'Administrator'	OK
5.	What is the maximum amount of files that can be stored on one instance?	Unlimited	OK



## IUCLID 5 Hosting System - Q&A (cont.)


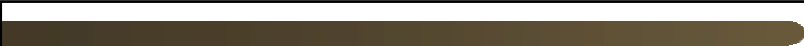
	Question	Answer	Status
6.	How easily can a IUCLID 5 file pre-populated in another system be exported to this Hosting System?	Easily, importing one file at a time	OK
7.	How easily can each IUCLID 5 file be uploaded back onto a non-centralised system (after Dossier submission)?	Easily, exporting one file at a time	OK
8.	How easily is a IUCLID 5 file hosted on such a system evaluated by the TCC and transferred through REACH IT?	No problems identified/envisaged	OK
9.	Is there any advantage in waiting for IUCLID 5.2 to become available?	Could be	OK
10.	What are the administrative/support costs involved in the set-up and overall functioning of the Hosting System?	Mainly during set-up: User set-up: 20 min File migration and template set-up: 30 min	OK

**Proposal:** Purchase IUCLID 5 Hosting System with WCA



Ag  
Au  
Ir  
Os  
Pd  
Pt  
Re  
Rh  
Ru

8. AOB, next meetings, closing remarks



Ag  
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AOB?



## Next meetings

- Re WG teleconference: 26 February 2010, 3 pm CET
- Exposure Scenario meeting: Brussels, 1st week of March 2010
- TAP+Ag WG meeting with EBRC: Brussels, 18 March 2010
- TAP+Ag WG meeting with WCA: UK, 6 or 7 April 2010
- PM Refiners WG meeting: Brussels, 21 April 2010
- IUCLID 5 training session: Brussels, 22 April 2010
- Re WG meeting: Brussels, 23 April 2010
- TH+CB+EBRC+WCA meeting: Brussels, week 26 April 2010
- MC teleconference: tbd
- PMC Plenary Meeting: Hamburg, 18 June 2010

PGM WG tbc



## Closing remarks

Thank you for your participation!