



Precious Metals & Rhenium Consortium Plenary Meeting

Antwerp, 14 June 2012
Radisson Blu Park Lane Hotel



1. Welcome & Introduction

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Guy ETHIER
Umicore



- Reminder on confidentiality and Competition Law
- Actions agreed at the last meeting (6 Dec 2011)
 - o Cf. paper circulated in advance:
 - All actions done, on-going or addressed today
 - Pending:
 - o Legal review of Evaluation preparation strategy
 - o LR for PM CN- and PGM
- Approval of the minutes of the last meeting
- Approval of the Agenda
 - o Cf. following slides



1. Welcome & Introduction

- a) Confidentiality & Competition Law
- b) Approval of the Agenda
- c) Actions agreed & Approval of the Minutes of the last Meeting (Brussels, 6 December 2011)

2. Status & Progress of PMC Projects

- a) Ag: Reporting under US EPA's TSCA 8^e, Pending Registrations, Non-Member LR, Territorial Toxicity and Classification Update Work, Watch List (New Article 8b of Water Framework directive), Evaluation, Nano TF, Timeline
- b) Au: Testing Programme, CSA/CSR, Timeline
- c) PM CN-: Testing and Modelling Programme, CSA/CSR, Link with CuCN-, Project Management and Timeline



- d) PGM: Fast-track Substances, Overall Testing Programme, Exposure Data Collection (including Project Manager), Data-sharing with IPA, Chinese Regulations, Timeline
- e) Re: Testing Programme, IUCLID 5 Filling, Project Management and Timeline
- f) PM Refinables: Advocacy on SCC, Update vs Upgrade, Pilot Cases, Classification Update, Cost-sharing, Timeline
- g) Hydrazine: Task Force, Intermediate Status, Likelihood for Prioritization, Proposed Way Forward

3. **PMC Organization**

- a) PMC Membership
- b) PMC Management Committee and (Co-)Chairmanship
- c) Sample Management Protocol
- d) Revised LoA Costs (for internal reference)



4. **Expenses, Reserves, Budget Forecasts & Invoicing**

- a) Final 2011 Accounts & Reserves
- b) Deviations to the Original 2012 Budget and 2nd 2012 Invoices
- c) 2013 Budget and Simplified Invoicing Approach

5. **Presentation from Cu Consortium: REACH is here to stay**

6. **AOB, Next Meetings & Closing Remarks**

- a) AOB
- b) Next Meetings:
 - Next PMC Assembly Meeting: Brussels, 5 December 2012
 - Next PMC Plenary Meeting: Stockholm, 13 June 2013



2.1 Status & Progress of PMC Projects Ag

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Klaus ROTHENBACHER - EPMF
&
Caroline BRAIBANT - EPMF



Ag: Overview

- o Project scope
- o Testing programme
- o Dossier update
- o Preparation for Evaluation phase
- o Regulatory (non-REACH)



Ag: Scope



Ag: Adjusted Scope

Registration by	Name	Status	Tonnage Band (t/a)	N° of PMC registrants	Lead Registrant
2010	Silver	Substance	> 1000	33	Aurubis
	Silver nitrate	Substance	100-1000	10	Ames Goldsmith
	Disilver oxide	Substance	10-100	6	Ames Goldsmith
2012 (done)	<i>Disilver (1+) sulphate</i>	<i>Substance</i>	<i>1-10</i>	<i>2</i>	<i>Johnson Matthey</i>
	<i>Silver carbonate</i>	<i>Substance</i>	<i>1-10</i>	<i>3</i>	<i>Johnson Matthey</i>
ASAP	<i>Silver chloride</i>	<i>Substance</i>	<i>100-1000</i>	<i>5+4</i>	<i>Agfa Gevaert</i>
	<i>Silver bromide</i>	<i>Substance</i>	<i>100-1000</i>	<i>+4</i>	<i>Agfa Gevaert</i>
	<i>Silver iodide</i>	<i>Substance</i>	<i>1-10</i>	<i>+3</i>	<i>Agfa Gevaert</i>

Ag sulphide now out of scope

Ag iodide (re-)added to scope

Ag halides now required for Registration without undue delay



Ag: Remaining Registrations

Collaboration with I&P

- Following several changes in Members' declarations, AgS, AgI and AgBr no longer required by PMC Members
- AgCI ready for submission
- Following T/D testing and expert review, Imaging and Printing Association (I&P) have Registration obligations under REACH
- I&P have approached PMC to collaborate on Dossier preparation:
 - Substances previously in scope
 - Common data set (Ag ion)
 - Common work programme (AgCI, waste ES)
- Mgmt Cttee supported collaboration proposal as long as minimum PMC resources required
- Quotes requested from EBRC and WCA → ~ 92 000 € work excl. testing
- LoA price re-calculated:
 - At least 3*Generic costs LoA → 3*38.500 € = 115.500 €
 - At least 4*100-1000 t/a LoA → 4*22.000 € = 88.000 €
 - At least 2*1-10 t/a LoA → 2*8.000 € = 16.000 €
- I&P ready to sign LoA upfront
- Afga Gevaert (Belgium) ready to act as LR and sign PMC's Declaration of Commitment

As a minimum covers actual work!



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Ag: On-going scientific work



Ag: Terrestrial Testing

Background

- 2-year project, with CSIRO (Prof. Mike McLaughlin)
- Started June 2011
- Reported range-finder results in Reach dossier update
- Testing proposal submitted to ECHA for full work

Status

- Project on track
- All soils collected and characterised
- Most range-finding tests completed
- Liability/ leaching experiments started
- First results look promising (s. next slide)



Ag: Terrestrial Testing Example results

E value = available metal pool

- Available Ag is not equal to Ag amounts added
- Some Ag becomes fixed and is no longer available (ageing, reductive precipitation, etc.)

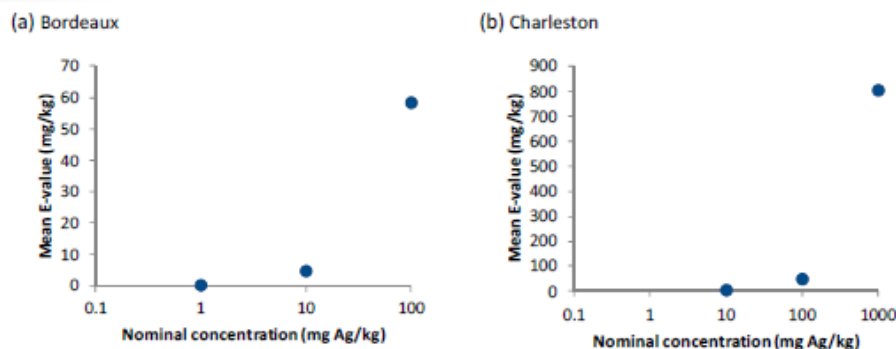


Figure 12. Mean E values for (a) Bordeaux and (b) Charleston over the nominal concentrations used for the silver spike rate range in the root elongation study. Error bars indicate standard deviations and $n = 4$. E values were not determined at 0.1 mg Ag/kg in the Bordeaux soil or 0.1 and 1 mg Ag/kg in the Charleston soil since silver concentrations were below detection limits for ICP-MS analysis.



Ag: Terrestrial Testing



Time line/ Milestones

Task	2012										2013									
	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	
Microbial N transformation																				
conduct testing																				
soil digests																				
data analysis																				
Root elongation																				
conduct testing																				
soil solutions																				
soil digests																				
data analysis																				
Plant emergence & growth																				
conduct testing																				
soil solutions																				
soil digests																				
plant digests																				
data analysis																				
Earthworms																				
conduct testing																				
soil/worm digests																				
data analysis																				
Aging Experiment																				
spike/leaching aging soils																				
Ag lability determination																				
spike/leach non-aging soils																				
conduct toxicity testing																				
soil digests																				
plant digests																				
data analysis																				
Milestone reports																				
Soil properties																				
Ag lability/prelim plant & microbial toxicity																				
Ag toxicity to soil microorganisms																				
Ag toxicity and accumulation in plants																				
Ag toxicity to earthworms/aging results																				

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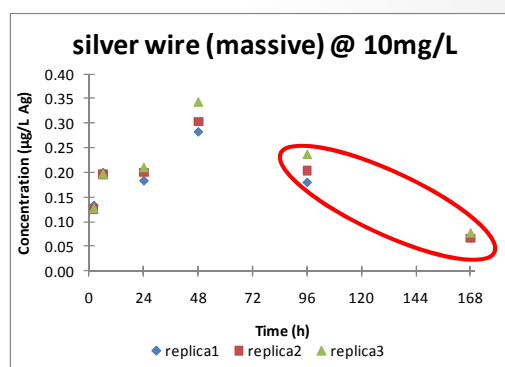
Ag: Classification T/D testing massive Ag

Background

- Massive Ag not classified, but open questions remain on our TD tests
- Currently clarifying questions in additional experiments

Status

- Testing ongoing at ECTX
- Pre-test shows
 - no significant influence from pH, light, filtration
 - significant influence from the resin, probably through absorption of Ag to the resin
- Possible corrosion through residual chloride ions
- Currently evaluating other resins (tests ongoing)



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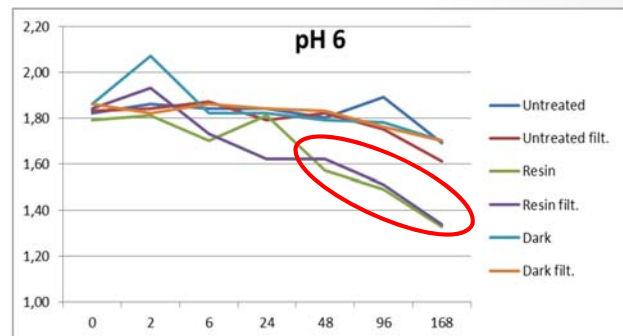
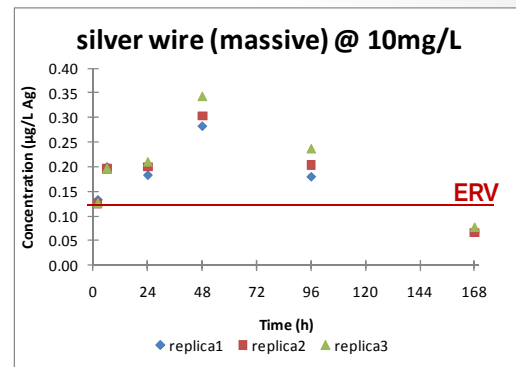
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Ag: Classification T/D testing massive Ag

Next Steps

- Validate resins
- Repeat TD test with inert resin

Timing

- Delay due to additional tests required
- Results by end Q3 2012
- Still in time for dossier update



Ag: Dossier update



Ag: Dossier Update - Background

- **November 2011:** ECHA rejects our testing proposals for Ag, AgNO₃, Ag₂O
 - o 90d oral study, with a suitable bioaccessible Ag compound + read across to other Ag compounds rejected => request testing all 3 substances
 - o Request inhalation route for Silver, not oral
 - o Soil testing rejected (tests on-going already)
- **12 December 2011:** technical discussion with ECHA
 - o Deadline for IND response extended to give time to evaluate newly available data
 - o Dossier update requested by 29th February 2012



Ag: Dossier Update – Background

Review of new data

- Third party studies reported to ECHA: valid for their original purpose but unsuitable to derive DNEL
- US NIEHS/FDA currently conducting under NTP a **13 wk oral feeding study** on soluble Ag compound (Ag acetate) = will fulfil Reach data requirements
 - Note: the same programme is also testing nano-silver
- New data on inhalation (Sung *et al.*) : 90d inhal. study on nano-silver

All data gaps addressed = no new (potentially expensive) studies required



Ag: Dossier Update - February 2012

Soil testing

- Withdrew Aecom testing proposal
- Reported Aecom results in dossier (plus expert assessment to put results in perspective) - PNEC left unchanged
- Reported initial CSIRO range-finder results (cf. previous slides)
- Submitted testing proposal for full CSIRO work

Repeated dose

- Withdrew testing proposal for 90d studies
- Reference to ongoing NTP 90d feeding studies (will need to update dossier once results are available)
- Inhalation : extrapolated Sung *et al.* 90d inhal. study from nano-silver to bulk silver (via “human equivalent concentrations” HEC)
- Retained waiver for 2 Gen study

Environmental Classifications

- Updated in line with new requirements from 2nd ATP



Ag: Substance Evaluation



Ag: Evaluation - Background

CoRAP

- “Community Rolling Action Plan” (CoRAP) selects substances for REACh Evaluation phase
- Silver listed for Substance Evaluation in 2013
- Rapporteur country: NL
- Rationale for inclusion “Initial Grounds for Concern: Substance characterization/ **Nanoparticles**, toxicity of different forms of the substance.”

Substance Evaluation

- Thorough review of dossier: scientific soundness, are all uses/ all grades covered, are conclusions logical and well documented, etc.
- CoRAP explicitly states that Evaluation not limited to “initial grounds for concern” = whole dossier will be reviewed
- Need to ensure silver dossier is as robust as possible (cf. next slides)



Ag: Evaluation - Preparation

Preparation strategy

- Dossier update Jan 2013
- Strategy document presented at previous Assembly Mtg
- Revised strategy document discussed with Ag WG in April
- Most issues already addressed in Feb 2012 dossier update, except
 - o Establish informal contact with rapporteur
 - Contacted in April, May and June
 - [NL open for exchange in 2nd half of 2012](#)
 - o Literature update
 - o Classification (work in progress)
 - o Update exposure scenarios 'man via env.' and waste scenarios
 - o Nano silver (following slides)



Ag: Evaluation - Preparation

Issue	Possible actions	Time line/ Budget	Priority
Literature search dated 2008 - New relevant data may have become available	Update literature search	2 months Ca 9 000 €	High
Update Exposure Scenarios	Update waste scenario, 'man via env.' scenario	3 months Ca 20 000 €	High
Prepare for potential nano discussion	See separate programme Nano TF	6-9 months Ca 75 000 €	High





Ag: Evaluation - NanoAg

	2009	2012
Definition	Under development	Definition available
Identification under REACH (Guidance)	On-going	On-going but progressed (some Guidance)
Testing protocols (OECD)	On-going	
Physico-chemical properties	Sameness to be confirmed	
Effects	Sameness to be confirmed	Sameness likely
Toxicokinetics and environmental fate and behaviour	Sameness to be confirmed	
PMC membership requirements under REACH	No PMC Member manufacturing/importing nanoAg (outside R&D)	PMC Member will manufacture/import nanoAg soon
Expertise within PMC	None/Limited	Limited/Increased
SIEF requirements under REACH	No SIEF Member coming forward to register nanoAg	
REACH requirements for nanoAg	Nanosilver manufacturers (different legal entities than those registering in 2010) manufacturing lower quantities, hence, later registration deadline	
Other	Time-constraint	Still time-constraint but linked to pressure from Evaluation phase (NL interest)

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Ag: Evaluation - NanoAg

Today:

- Nano TF formed under PMC,
 - Sub-group of Ag WG to integrate attention on nanoAg in preparation for Evaluation by NL
 - Four companies actively involved, four following as “observers”
- Following forms considered in preliminary scope:
 - Uncoated nanoAg,
 - Carbohydrate-Coated nanoAg, and
 - Coated nanoAg in suspension in water
- Following uses considered in preliminary scope:
 - Ink jet printable inks,
 - Aerosol printable inks,
 - Screen printable inks,
 - Water purification filters,
 - Photovoltaic applications,
 - Conductive adhesive applications, and
 - Additive in polymer thick film pastes/applications

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Ag: Evaluation - NanoAg

Today (cont.):

- EBRC and WCA selected as consultants to perform scientific work:
 - Assess basic/framework documentation on nanomaterials at international (OECD), US (EPA) and EU (COM, ECHA, MS) levels
 - Identify recommended methodologies for particle size and surface area characterisation
 - Perform literature search and data gap analysis re REACH endpoints (tonnage band corresponding to highest Ag tonnage band > 1000 t/a)
 - Assess effects of Ag versus nanoAg
 - Assess toxicokinetics and environmental fate of Ag versus nanoAg
 - Propose tests to complete science and REACH data gaps (e.g. bio-elution, T/D, etc.); much literature available already; no (-t many) REACH tests expected
 - Generate CSA/CSR (4 to 5 industrial uses foreseen)
 - Generate IUCLID 5 content
 - Proposed budget around 75000 EUR (excluding any testing and CSA/CSR + ES work)
 - Shared by all Members on basis of existing cost-sharing formula
- PMC Plenary Meeting - Antwerp, 14 June 2012



Ag: Evaluation – NanoAg In our Out?

- **Decision - tiered**
 - Provisional: based on pros and cons document today
 - Updated/refined: based on more complete assessment in Dec 2012 Assembly meeting



So far:

- “Majority” supports a one Dossier approach
- “Minority” undecided and concerned about potential financial consequences
 - Can be resolved with a change in LR and adjustment of cost-sharing formula

- **Timeline – Jan 2013**

- Either:
 - An updated Ag Dossier including nanoAg, or
 - A good case for excluding nanoAg from the Ag Dossier and registering it separately in due course



Ag: Regulatory

(non-REACH)



Regulatory



US TSCA 8(e)

- Background
 - For companies with commercial activities in the US, under jurisdiction of Toxic Substances Control Act (TSCA)
 - Requirement to notify US EPA on **substantial, new** risk information under TSCA 8(e)
 - Tight time limits (need to file within **30 days**) and high penalties (up to USD 32,500/d!)
- PMC Testing Programme
 - Currently conducting extensive testing programme
 - May lead to reportable events (e.g. mutagenicity, sensitisation) in the future
 - PMC secretariat/TAP will assist, but responsibility lies with individual companies
 - PMC member company filed 8(e) submissions based on data from silver dossiers
- **Member companies are invited to evaluate potential reporting requirements under US legislation**



Ag: Regulatory

EU Water Framework Directive (WFD)

- Background
 - Ag not a priority substance and no official 'Environmental Quality Standard' (EQS) developed for Ag
 - Ag listed by UK as Annex VIII "Specific Pollutant" since 2008
 - PMC worked with UK Environment Agency to develop unofficial EQS in parallel with PNEC derivation
- UK public consultation on EQS
 - Silver discarded as Specific Pollutant due to insufficient information
 - Remains on watching brief (b/c nano-silver)
- WFD Pilot Study
 - Ag shortlisted on scope of 'pilot study' for substance to be potentially added to WFD 'watch list'
 - Concerned about potential mis-use of list
 - Working with Eurométaux to share experience on Ag monitoring
 - Established contact with JRC and provided more information



Any question on Ag items?



2.2 Status & Progress of PMC Projects: Au

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Caroline BRAIBANT - EPMF



Au: Scope

Substance	EC n°	CAS n°	Tonnage band	Deadline	LR
Gold	231-165-9	7440-57-5	10-100 t/a	2018	Carl Hafner
Tetrachloroauric acid	240-948-4	16903-35-8	10-100 t/a	2018	Johnson Matthey
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	269-858-3	68365-87-7	1-10 t/a	2018	Johnson Matthey
Non-SCC intermediate	EC n°	CAS n°	Tonnage band	Deadline	LR
Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	273-589-7	68990-27-2	1-10 t/a	2018	Heraeus



Au: Testing Programme

✓ Physico-chemical properties

✓ Ecotoxicity tests

- o Daphnia
- o Algae
- o Activated sludge

• Remaining REACH data gaps (using TCA):

- o Bio-elution: Apr-Jul 2012
- o Genotoxicity: May-Sep 2012
- o OECD 422 Combined repeat dose and reproductive toxicity screening study: Q2-Q3 2012



Au: Next steps

➤ Finalise testing work

➤ Collect information on uses, emissions and exposure

- o Uses required for all substances and intermediates
- o Emissions and exposure data only required for TCA - **perform one for Au metal too?**
- o PGM project data collection starting in Q3 2012 - when to start Au one?

➤ Finalise Registration Dossiers and submit to ECHA

- o Tentatively: end 2013?





Any question on Au items?



2.3 Status & Progress of PMC Projects: PM CN-

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Caroline BRAIBANT - EPMF



PM CN-: Scope

Substance	EC n°	CAS n°	Tonnage band	Deadline	LR
K dicyanoargenta te	208-047-0	506-61-6	10-100 t/a	2018	?
Ag cyanide	208-048-6	506-64-9	1-10 t/a	2018	?
K dicyanoaurate	237-748-4	13967-50-5	10-100 t/a	2018	Umicore

K tetrakis (cyano-C)aurate was removed from scope

LR still lacking!



PM CN-: Testing & Modelling Programme

✓ Physico-chemical properties

❖ Ecotoxicity tests

- o Daphnia – validation of modelling for Ag CN- **successful**
- o Daphnia – validation of modelling for Au CN- **unsuccessful**
 - Oxidation state/complexes of gold after dissolution of Au CN- in aqueous solutions ???
 - Need to conduct direct testing on fish and algae with Au CN-

• Remaining REACH data gaps:

- o Read-across from existing HCN dataset not fully adequate for PM CN-
- o Algae & Fish test for Au CN- compound
- o Assessment of dissolution in physiologically relevant solutions (before launching further bio-elution, tox testing and/or modelling)



PM CN-: Next steps

- Finalise testing and modelling work
- Collect information on uses, emissions and exposure
 - o Uses required for two substances > 10 t/a
 - o When to start?
- Finalise Registration Dossiers and submit to ECHA
 - o Tentatively: early 2014?



Any question on PM CN- items?



2.4 Status & Progress of PMC Projects: PGM

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Klaus ROTHENBACHER - EPMF



PGM: Overview

- o Scope
- o Integrated Testing Strategy
- o Testing programme
 - Enabling tests
 - Fast-track testing for DDP
 - Main testing programme
- o CSA/CSR + ES
- o Next steps and timeline
- o Regulatory (non-REACH)
- o Data-sharing with IPA



PGM: Scope



PGM: Scope

Registration by	Family	Status	Highest tonnage Band (t/a)	N° of PMC Members registrations	Lead Registrants
2013	Platinum	11 substances 2 intermediates (2 non SCC, 1 SCC)	Sub: 10-100 Int: 100-1000	53	Vale , JM, Umicore, Heraeus
	Palladium	16 substances 4 intermediates (4 non SCC, 1 SCC)	Sub: 10-100 Int: 100-1000	74	Umicore , Heraeus, JM, C. Hafner
	Rhodium	13 substances 3 intermediates (3 non SCC)	10-100	44	JM , Heraeus, Umicore, Vale
	Iridium	5 substances 2 intermediates (2 non SCC)	1-10	17	JM , Umicore, Heraeus
	Ruthenium	6 substances 4 intermediates (4 non SCC)	10-100	29	Heraeus , Umicore, Vale



PGM: Scope 2013 Registrations

	Highest tonnage	DL	Dossier
Diammonium hexachloropalladate (Intermediate)	• SCC: 100-1000 tpa • Non-SCC: 10-100 tpa	• 2013 • 2018	• Available information • Full dossier
Diammonium hexachloroplatinate (Intermediate)	• SCC: 100-1000 tpa • Non-SCC: 10-100 tpa	• 2013 • 2018	• Available information • Full dossier
Diamine dichloropalladium (Substance)	• 100-1000 tpa	• 2013	• Full dossier

Required by 31 May 2013

- 1 full dossier
- 2 intermediate dossiers (reporting available information)
- Need robust documentation of SCC!
 - Responsibility of the concerned company(ies)
 - WCA and PMC have to assume SCC compliance



PGM: Integrated Testing Strategy (ITS)



PGM: Integrated Testing Strategy (ITS) development

Overall ITS strategy

1. Identify exemptions: Annex III, intermediates - **done**
2. Identify read across options - **done**
3. Initial integrated testing strategy (ITS) - **done**
4. Enabling tests (pH, water solubility, bio-elution, particle size, etc) - **on-going**
5. Updated ITS (full test recommendations) - **on-going**
6. Main testing programme - **to start in Q3 2012**



PGM: Enabling- /phys.- chem. tests



PGM: Oxidising Properties Tests at BAM



Substance	CAS	State	Status
Iridium dioxide	12030-49-8	solid	done
Platinum dioxide	1314-15-4	solid	done
Platinum dinitrate	18496-40-7	solution	done
Dipotassium tetraoxoruthenate	31111-21-4	Solution in aqueous KOH	Not available in pure form test K ₂ O ₄ instead, done
Ruthenium IV oxide	12036-10-1	solid	done
Rhodium trinitrate	10139-58-9	Solid (hydrate)	done
Dihydrogen hexahydroxyplatinate	51850-20-5	Solid	New test - ongoing

- Testing of sentinel substances – read-across to other substances
- Initial tests completed at BAM, Berlin
- Agreed to confirm ox. prop. of dihydrogen hexahydroxyplatinate



PGM: Water Solubility

- **Standard tests**
 - o OECD 105 (shake flask test)
 - o Tests at JMTC completed/ draft report received
 - o 1 result from external lab outstanding
 - Expected in June
- **Non-standard tests**
 - o Based on OECD 105 as well
 - o Tests at JMTC completed
 - o Draft report received
- **T/D testing**
 - o Second round of testing at CANMET completed
 - o Draft report received
 - o Final report in preparation



PGM: Dustiness Lung deposition modelling

- To estimate potential for inhalation exposure
- Status
 - o Testing at DMT completed, reports available
 - o Lung deposition modelling (MPPD) based on dustiness data: completed
 - o Draft results: next slide
- Breathing mode for MPPD calculations
 - o Several modes available (oro-nasal augmenter, oro-nasal mouth, mouth)
 - o PMC 'reasonable worst-case' mode → 'oro-nasal augmenter'
- Selection of substances for bio-elution testing in lung fluids
 - o Only needed if substance actually reaches the lung
 - o Selection based on draft MPPD data and dustiness



Dustiness MPPD modelling - Draft results



Substance name	Oronasal-augmenter				Dustiness
	Head (%)	TB (%)	P (%)	Total (%)	%
Diamminedichloropalladium	52.2	0.29	0.44	52.9	22
Dihydrogen hexahydroxyplatinate	66.4	1.1	2.4	69.9	26.2
Palladium dihydroxide	46.6	0.16	0.19	47.0	13.9
Diammonium sodium hexakis(nitrito-N)rhodate	47.7	0.20	0.32	48.2	23.7
Diammonium hexachloropalladate	48.0	0.11	0.062	48.1	43.5
Dipotassium hexachloropalladate	52.5	0.17	0.15	52.8	55.8
Tetraamminepalladium(2+)dichloride	52.5	0.17	0.15	52.8	1
Diammonium hexachlororuthenate	47.6	0.18	0.26	48.1	34.1
Palladium di(4-oxopent-2-en-2-oate)	40.0	0.14	0.26	40.4	23.2
Ruthenium black*	53.2	0.60	0.81	54.6	40.1
Palladium black*	79.6	0.76	0.79	81.1	X
Platinum black*	72.3	1.8	6.0	80.1	20.5
Rhodium black*	48.7	0.20	0.28	49.2	51.5
Palladium monoxide (anhydrous)*	46.3	0.12	0.085	46.5	56.7
Platinum sponge*	43.9	0.098	0.053	44.1	7.3
Rhodium sponge*	50.4	0.18	0.18	50.8	26.3
Palladium powder*	45.8	0.12	0.08	46.0	28.4
Ruthenium powder*	54.9	0.69	0.89	56.4	4.9



PGM: Bio-elution

- Testing at CIMM, Chile
- Timing: CIMM will close down – need to complete testing by summer
- Final scope based on initial data from dustiness tests/ MPPD modelling (previous slides)
- PdO: no sample provider found

Substance	CASRN	Comment	Gastric/ Dermal	Lung
Platinum	2023600		x	
Platinum black			x	x
Palladium	7440-05-3		x	
Palladium black			x	x
Palladium monoxide (anhydr.)	1314-08-5	Substance not available for testing		
			x	
Palladium dihydroxide	12135-22-7		x	
Palladium (II) di(4-oxopent-2-en-2-oate)	14024-61-4		x	
Rhodium	7440-16-6		x	
Rhodium black			x	x
Diammonium sodium hexakis(nitrito-N)rhodate	64164-17-6		x	
Ruthenium	7440-18-8		x	
Ruthenium black			x	x



PGM: Irritation/corrosion

- Testing strategy
 - o In-vitro skin irritation (OECD 439) – if positive: OECD 431
 - o In-vitro skin corrosion (OECD 431) – if positive: stop
 - o In-vitro eye irritation (ICE or BCOP) – if positive: stop
 - o In-vivo eye irritation
- Skin corrosion data needed to decide on other tests
 - o Eye irritation
 - o Sensitisation
 - o Acute toxicity
 - o (Genotoxicity)



PGM: Irritation/corrosion



- Testing ongoing
 - o CiToxLAB (EPISKIN/ ICE): in vitro tests completed, in-vivo tests ongoing
 - o Harlan (BCOP): ongoing, substance arrived late

Substance	In vitro skin (EPISKIN) test	In vitro eye (e.g. BCOP or ICE) test	In vivo eye irritation test	Comment
Diammonium hexachlororuthenate (CAS 18746-63-9)	Not irr./corr.	ICE neg	ongoing	Need to confirm initial data with water solubility data (in progress)
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium (CAS 25470-96-6)		-	-	Due to reduction in tonnage, substance now qualifies for Annex III exemption. No testing required any longer.
Diammonium sodium hexakis(nitrito-N)rhodate (CAS 64164-17-6)	Not irr./corr.	ICE neg.	neg.	
Diamminedichloropalladium (CAS 13782-33-7)	Not irr./corr.	ICE neg.	Cat 1	
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)	Not irr./corr.	neg.	Cat 1	
Platinum dichloride (CAS 10025-65-7)				Out of scope now
Tetraammineplatinum dinitrate (CAS 20634-12-2)	Not irr./corr.	BCOP ongoing Substance arrived late	Ongoing Substance arrived late	Supplied as solution, max. conc. 6.6%. Makeup of 20% solution from solid is not possible since solid is not isolated (explosivity); test 6.6% solution in BCOP test.
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (CAS 68478-92-2)	(X)	(X)	(X)	Data sharing under discussion with Silicones sector. Suggest to put testing on hold. (Will decompose in aqueous solution. Consider waiver possibility. Predicted to be a marked irritant.)
Dihydrogen hexahydroxyplatinate (CAS 51850-20-5)	Not irr./corr.			

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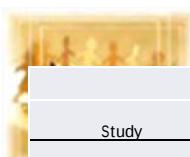
PGM: Fast-track testing - Diamminedichloropalladium



DIAMMINEDICHLOROPALLADIUM: ECOTOXICOLOGY STUDIES



Study	CRO	Protocol	Proposed draft report date	Final Report Issued	Status	Comments
ALGAE (OECD 201)	Fraunhofer	15.02.2012	25.03.2012	18.04.2012	Completed	EC50 (Yield, Growth Rate) derived NOEC Growth Rate & Yield derived
DAPHNIA (OECD 202)	Fraunhofer	15.02.2012	02.04.2012	tba	Reporting	Test required repeat (no extra cost). EC50 and NOEC derived
FISH (OECD 203)	Fraunhofer	15.02.2012	30.05.2012	tba	Reporting	Semi-static conditions EC50 and NOEC derived
ASRIT (OECD 209)	LAUS (sub-contracted by Fraunhofer)	20.02.2012	19.03.2012	22.03.2012	Completed	Preliminary test indicated that a definitive test will be required. EC50 and NOEC derived
Chemical Analysis for Ecotoxicity Tests (inc. Method Development)	Fraunhofer	NA	NA	NA	Reporting	



DIAMMINEDICHLOROPALLADIUM: TOXICOLOGY STUDIES



Study	CRO	Availability of results	Proposed draft report date	Final Report Issued	Status	Comments
Episkin OECD TG431	LAB					Not required as OECD 439 indicates not irritating. Study cancelled 2 Mar 12.
Episkin OECD TG439	LAB	14. Feb 12	24. Feb 12	03. Mai 12	Issued	Non irritant
in vitro eye irritation (ICE)	LAB	w/c 5-Mar	23. Mrz 12	07. Mai 12	Issued	Non irritant
in vivo eye irritation OECD TG405	LAB	16. Apr 12	25. Mai 12		Study complete	Cat 1, 3 animals, 21 days observation
Sensitisation OECD TG429 (LLNA)	HARLAN	3 months from study commencement	Jun 12		Study complete draft report in progress.	Individual method with concurrent positive control. NON-SENSITISER using 25% in 7 : 3 ethanol : distilled water
Ames screen	COVANCE	20. Feb 12	Draft report received 9-Mar-12	19. Apr 12	Issued	Negative
GLP Ames	COVANCE	4 wks from study commencement	w/e 20-Apr-12	02. Mai 12	Issued	Negative
in vitro micronucleus assay in human lymphocytes	COVANCE	6 wks from study commencement	w/e 27-Apr-12	04. Mai 12	Issued	Negative
hrpt assay - mouse lymphoma cells	COVANCE	10 wks from study commencement	w/e 02-Nov-12		Protocol reviewed 24/4. V2 sent for Sponsor review (8/5)	



DIAMMINEDICHLOROPALLADIUM: TOXICOLOGY STUDIES



Study	CRO	Availability of results	Proposed draft report date	Final Report Issued	Status	Comments
Acute oral toxicity - acute toxic class OECD TG423	CHARLES RIVER UK	Apr 12	15. Jun 12		Awaiting draft report	Confirmation of refiner will be required before report finalisation
Preliminary to combined oral repeat dose toxicity with reproduction/development toxicity screening test	CHARLES RIVER UK	07. Mai 12	16. Jul 12		In life phase complete	2 dose levels evaluated and sufficient to meet study objectives
Combined oral repeat dose toxicity with reproduction/development toxicity screening test OECD TG422	CHARLES RIVER UK		Unaudited draft report November 2012		Protocol preparation ongoing	Dose levels agreed: 30/110/370 mg/kg/day
Development of methodologies for the formulation analysis of palladium in oral gavage formulations	CHARLES RIVER UK	Jan 12	No formal report		Completed 10-Feb-12	Acceptable formulation in 0.5% HPMC with good analytical accuracy.
Validation of methodologies for the formulation and analysis of palladium in oral gavage dosing formulations	CHARLES RIVER UK	Feb 12	Apr 12		Draft report received 17-May-12	Completed 01-Mar-12. Formulations prepared at 0.1 mg/mL and 200 mg/mL in 0.5% high viscosity HPMC are stable for at least 9 days at 2-8degC in the dark and at ambient laboratory temperature in the dark.



PGM: Main testing programme



PGM: Main testing programme

- To start in Q3 2012
- Final Scope
 - Depending on outcome of enabling tests
 - Final ITS early Sept. 2012
- Tests
 - Apply learnings from DDP testing
 - Endpoints
 - Ecotoxicity (daphnia, algae, fish, sludge)
 - Sensitisation
 - Genotoxicity (started in Dec. 2011, s. next slide)
 - Acute toxicity (incl. second route of exposure)
 - Repeated dose/ reprotox.



PGM: Genotoxicity

- Consulted with independent genotoxicity expert (Prof. D. Kirkland) on
 - Impact of extreme pH on PGM genotox study results
 - (Apparently) conflicting study results on Rh (III) substances
- Recommendation
 - Deviate from HERAG
 - Ames assay can produce false negative results for metals
 - But Ames can be used unless evidence to the contrary, in particular if positive results reported/ no cytotoxicity
 - Follow ECHA guidance for genotoxicity testing
- Genotoxicity strategy revised accordingly
 - Testing plan ready, except Rh(III) genotoxicity
- Rh(III) genotoxicity
 - Different views on data interpretation/ read across strategy
 - Set up task force to resolve issue
 - First TF mtg 19th June



PGM: CSA/CSR + ES



PGM: Exposure Scenarios

- Start of ES work in Jul 2012
 - 31st May: Coordination meeting EBRC/WCA/PMC
 - 27th June: Kick-off PGM ES meeting
- Work programme (with EBRC and WCA)
 - Agree on scope/prioritisation: Pd/DDP?
 - Complete use and physical form dataset
 - Complete workplace exposure dataset
 - Complete environmental emissions dataset
 - Produce CSA/CSR + ES

} Three questionnaires
- Logistics
 - We need your support: questionnaires, site-visits (?), meetings, reports
 - K. Arijs will act as coordinator under supervision of K. Rothenbacher

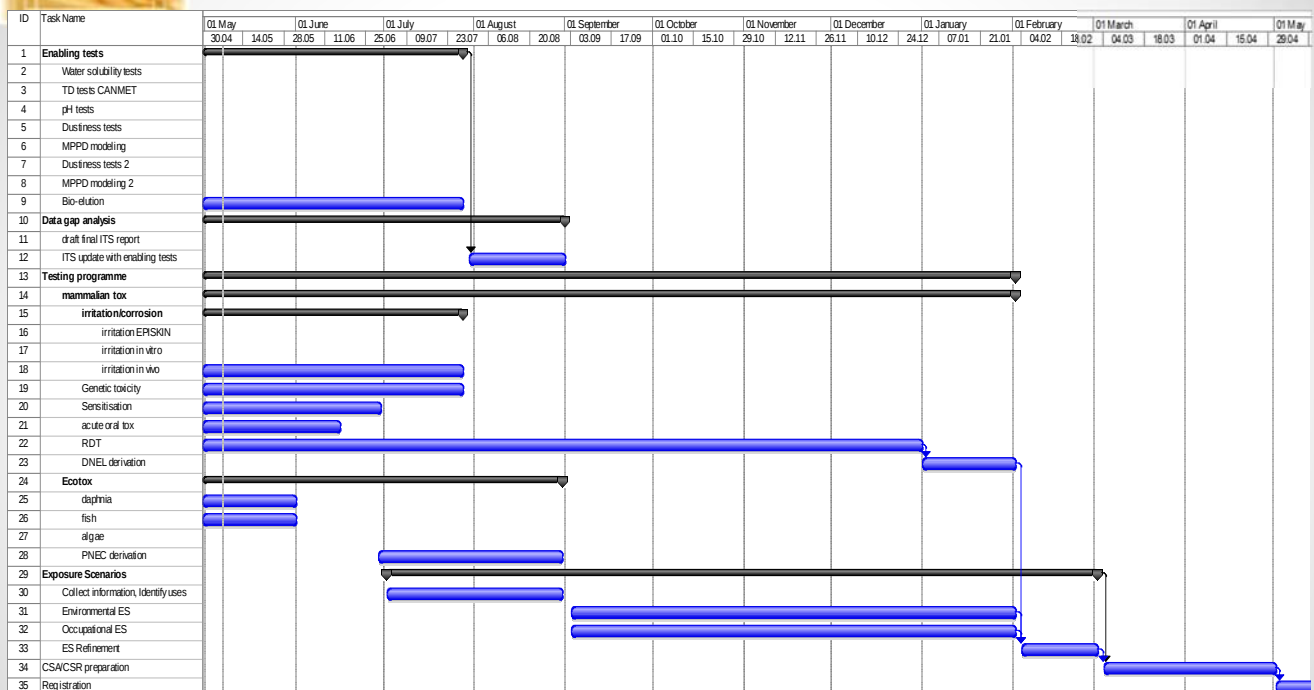




PGM: Next steps & Timeline



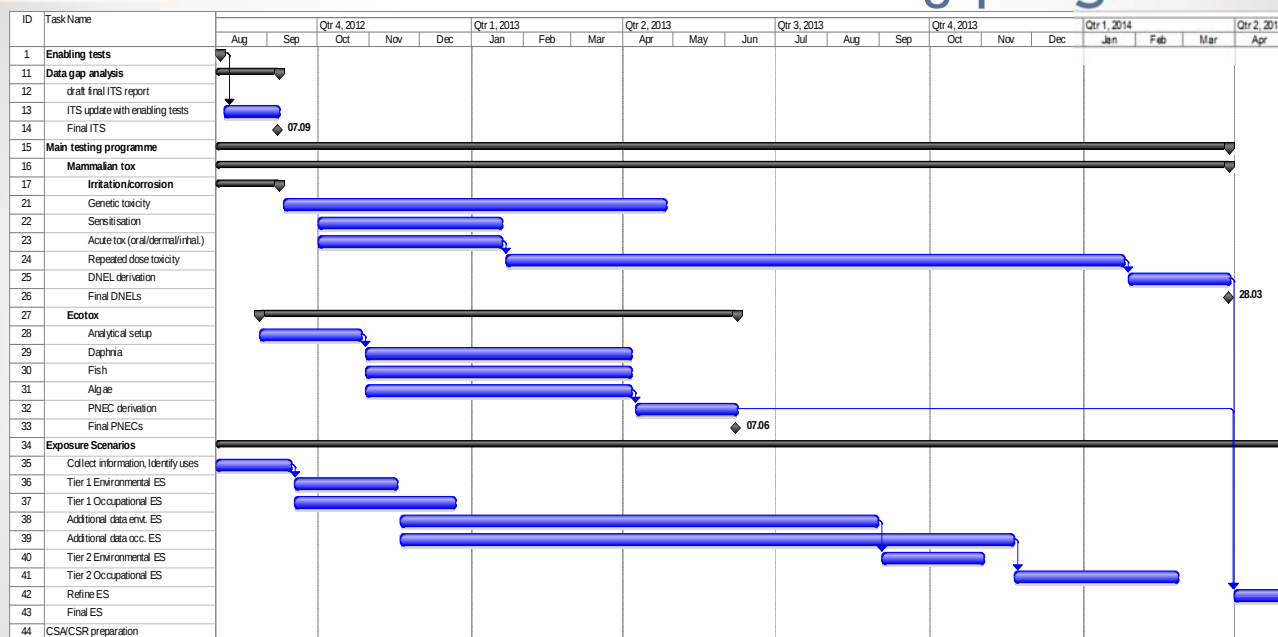
PGM: Timeline for 2013 deadline



- Our first priority
- Tight schedule, but on track for 2013 registration deadline



PGM: Timeline full testing programme



- More detailed plan: see printouts on wall
- Bottleneck: repeated dose toxicity studies
- Registration possible after Q3 2014



PGM: Regulatory

(non-REACH)



PGM: Regulatory



"Measures for the Environmental Management of New Chemical substances (Order No. 7)", of the Ministry of Environmental Protection (MEP) of China (part of "China REACH")

Requirement for non-Chinese companies exporting and producing new chemical substances in China to notify these new chemicals to the Inventory of Existing Chemical Substances in China (IECSC)

PMC member company needs access to following data to notify Platinum dinitrate (CAS 18496-40-7):

- Explosive properties
- Self-ignition temperature
- In vitro gene mutation study in bacteria

In vitro gene mutation study in mammalian cells

- Water solubility
- Oxidizing properties

(All proprietary!)



PGM: Data-sharing with IPA



EPMF PMC – IPA HSRG

Data-sharing agreement

- **Background:**
 - o Same companies/co-owners
 - o Common/overlapping dataset
- **Proposal:** Data-sharing agreement between IPA's HSRG and EPMF's PMC
 - o Strict purpose: STF research & advocacy programme and PMC's REACH compliance
 - o Each party remains owner of supplied information
 - o Free of charge
- Legal experts recommend **listing all information** which will be shared to frame the Agreement
 - o PMC's information corresponds to CLP and REACH endpoints
 - o HSRG's information of broader scope – need to discuss/list information to be shared
- **Any additional comment from PMC?**
 - PMC Plenary Meeting - Antwerp, 14 June 2012



● 75



Any question on PGM items?



2.5 Status & Progress of PMC Projects: Re



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Caroline BRAIBANT - EPMF



Re: Scope

Substance	EC n°	CAS n°	Tonnage band	Deadline	LR
Rhenium	231-124-5	7440-15-5	1-10 t/a	2018	KGHM Ecoren
Perrhenic acid	237-380-4	13768-11-1	1-10 t/a	2018	Heraeus
Ammonium perrhenate	237-075-6	13598-65-7	10-100 t/a	2018	Heraeus
SCC intermediate	EC n°	CAS n°	Tonnage band	Deadline	LR
Sodium rhenate	236-742-9	13472-33-8	1-10 t/a	2018	Climax Molybdenum
Dirhenium heptasulphide	234-882-5	12038-67-4	1-10 t/a	2018	Johnson Matthey
Non-SCC intermediate	EC n°	CAS n°	Tonnage band	Deadline	LR
Potassium perrhenate	233-953-8	10466-65-6	1-10 t/a	2018	Heraeus



Re: Testing Programme

- ✓ Physico-chemical properties
- ✓ Ecotoxicity tests
- ❖ **Toxicity tests** – OECD 422 Combined repeat dose and reproductive toxicity screening study results expected summer 2012



Re: Next steps

- Finalise OECD 422 combined
- Decide whether acute oral toxicity test requires repetition (potential issue with administration vehicle)
- Finalise collection of analytical and use information to finalise ID Cards for SIEF communication
- Depending on outcome of OECD 422 combined, collect emissions and exposure data
 - Would only be required for APR - **perform one for Re metal too?**
 - If needed, data collection starting in Q3 2012
- Finalise Registration Dossiers and submit to ECHA
 - Tentatively: end 2012/early 2013





Any question on Re items?



2.6 Status & Progress of PMC Projects: PM Refinables

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Caroline BRAIBANT - EPMF



Refinables: Scope

	Refinable	Intermediate status	Tonnage band	Lead Registrant
1	Doré	Transported	> 1000 t/a	Aurubis
2	Matte	Transported	> 1000 t/a	Umicore
3	Slags	Transported	> 1000 t/a	Umicore
4	Slimes and sludges	Transported	> 1000 t/a	Aurubis
5	Leaching residues (2)	Transported/On-site	> 1000 t/a	Umicore
6	Electrolytes (2)	On-site	> 1000/100-1000 t/a	KGHM/Aurubis
7	Flue dust	Transported/On-site	> 1000/100-1000 t/a	Johnson Matthey
8	Cements	Transported/On-site	> 1000/100-1000 t/a	Heraeus
9	Materials for reclaim (3)	Transported/On-site	> 1000/10-100 t/a	Johnson Matthey
10	Pb bullion, PGM rich	On-site	10 - 100 t/a	Vale



Refinables: Background

- **2007-2010:**
 - o Composition – Sameness (UVCB!)
 - o Mineralogical characterisation
 - o T/D testing
 - o MeClas to derive classification profiles and pick-lists
 - o Guidance on safe use
 - o Dossier preparation and submission (SCC intermediate)
- **2010-2012:**
 - o Review of new Guidance
 - o Preparation of examples to illustrate NFM-specific SCC for advocacy by EM
 - o Collection of exposure and emission data
 - o Assessment of data and develop approach to risk assess UVCB intermediate
 - o Review of classification to remove pick-lists and include 2nd ATP to CLP



Refinables: Today

- **Project management:**
 - o Katrien Arijs (ARCHE) should be back from maternity on 21 June 2012.
 - o Federica Iaccino (ARCHE) has been replacing Katrien during her maternity leave. Since also part of Eurométaux' REACH Team → very efficient at boosting and coordinating all pending actions which need to be supported by Eurométaux' Members
- **Classification:**
 - o Frederick Verdonck and Hugo Waeterschoot finalising updated classifications
 - o Once overview paper is approved, WCA will update IUCLID 5 files so they can be re-submitted by LR in Summer 2012
- **SCC assessment:**
 - o Examples provided by Eurométaux members to ECHA in order to illustrate NFM-specific SCC → ECHA does not consider do not have clear self-evident examples of SCC
- **Exposure and emission assessment:**
 - o WCA and EBRC have collected most of the information they needed from PMC Members
 - o All models are set to run
 - o Actual assessment will not be conclusive before the latest (Eco-)Toxicity Reference Values (ERV and TRV) become available and models are validated with other consortia



Refinables: Next steps



- **SCC determination:**
 - o PMC Members to use REACH regulation, existing ECHA Guidance on intermediates, view of their national/local authorities, RiCoG, exposure data and expert judgement to decide whether their current registration complies or not with their REACH obligations
 - o Release of RiCoG expected end Jun 2012 → companies to confirm (non-)SCC per intermediate by Sep 2012
- **Risk assessment of complex UVCB:**
 - o ECHA recognises full registration of a complex UVCB can be challenging and may require a different approach (i.e. REACH Annexes VII-X tests)
 - o Short kick-off brainstorming session between technical experts of Eurométaux and ECHA was held on 21 May 2012
 - o Several consortia will produce test cases illustrating possible ways forward
 - o A workshop will be organised in Autumn 2012 to propose solutions to fully risk assessing UVCB under REACH
 - o After non-testing risk assessment approach is discussed and evolved with ECHA, PMC will be in a position of risk assessing its UVCB materials and update or upgrade their Registration Dossiers as applicable

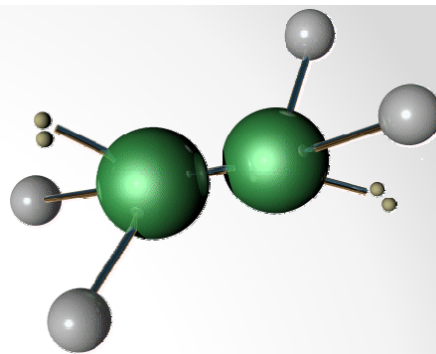


Refinables: Next steps

- **Risk assessment of complex UVCB (cont.):**
 - o **Update versus upgrade:** Several papers are prepared to assist PMC and its Members in reminding/clarifying definitions and possible approaches:
 - A paper on “Intermediates” summarising key concepts from the REACH regulation, ECHA Guidance, Eurométaux factsheets (e.g.: chemical modification), etc.
 - A paper on “UVCB” summarising key concepts from the REACH regulation, ECHA Guidance, Eurométaux factsheets, ECHA discussion and OECD guidance (Draft Revised Document on Grouping Chemicals) (e.g.: grouping of UVCB)
 - A matrix table summarising the advantages and disadvantages of pursuing the update or upgrade route for UVCB intermediates.
- **Next Refiners WG meeting:**
 - o Brussels, 28 June 2012



Any question on Refinables items?



2.7 Status & Progress of PMC Projects: Hydrazine

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Caroline BRAIBANT – EPMF
&
Mark RAFFRAY – Johnson Matthey



Hydrazine: Background

May 2011: Hydrazine added to Candidate List of substances potentially subject to Authorisation under REACH

Jun 2011: PMC Members form a Hydrazine Task Force (HTF) to prepare for the possible prioritisation of hydrazine for Authorisation

Dec 2011: Several experts indicate chance for Hydrazine to be prioritised is high. Eurométaux following-up discussions on prioritisation in ECHA Committees and updating PMC within limitations of confidentiality terms

Feb 2012: Use of hydrazine in PM sector cannot be considered as an intermediate under REACH and can hence not be exempted from Authorisation obligations (ECHA helpdesk)

Mar 2012: HTF+RPA+Hydrazine Consortium meeting → ok to launch scoping phase of preparation for the Authorisation application



Hydrazine: Latest news

MSC meeting April 2012 → Hydrazine not put forward
for preliminary 4th Priority List

→ *More pragmatic ECHA and MS thinking on
actual risk associated with most of hydrazine's
industrial applications...?*

MSC meeting June 2012 → decision
ratification, two scenarios possible:

- A) Hydrazine on 4th Priority List
- B) Hydrazine not on 4th Priority List (but
remains on Candidate List and can be
prioritised any time in future)



Hydrazine: next steps

Possible scenarios discussed at 12 Jun 2012 HTF cc:

- **Scenario 1** – Hydrazine is included in 4th Priority List

Commence work as per May 2012 RPA's contract proposal
(Sep 2012 – Q1 2014; for a total cost of ~ 116.900 €)

- **Scenario 2** – Hydrazine is not included in 4th Priority List, but can
be prioritised in future

Adjust the original RPA plan to focus on a revised scoping
phase which considers analysis of alternatives and factors
relevant to exposure/emission risk mitigation arguments
(Oct 2012 – Mar 2013; for a total cost of ~ 35.000 €)

- **Scenario 3** – Hydrazine is not included in 4th Priority List, and is
unlikely to be prioritised in future (sector surmise/decision)

Approach: Do nothing at this stage



Hydrazine: selected scenario and cost-sharing formula

Preferred scenario: 2

- Pro 1: early preparation = safe preparation
- Pro 2: early preparation = in time for input at relevant MSC meeting (Mar-Apr 2013)
- Pro 3: RPA available now, maybe not later/in future
- Con 1: additional expenditure to general REACH expenses (cf. cost-sharing below)
- Con 2: companies need to make hydrazine/process experts available for two days in 2012 (and possibly for 0,5-1 day in 2013) for RPA to launch analysis of alternatives and exposure/emission profile of hydrazine's use in PM sector

Cost-sharing: equal

Assuming 6 companies for total budget of 35.000 € + 10%:

- ~ 3000 €/company in 2012
- ~ 4000 €/company in 2013

● PMC Plenary Meeting - Antwerp, 14 June 2012



Any question on Hydrazine items?



Lunch time!



3.1 PMC Organisation: PMC Membership

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Caroline BRAIBANT - EPMF



PMC Membership: reminder



- | | |
|-------------------------------|--|
| 1. Agnico-Eagle | 24. KGHM Polska Miedz |
| 2. Ames Goldsmith U.K. | 25. Lipmann Walton & Co. |
| 3. DODUCO | 26. Krastsvetmet |
| 4. Anglo Platinum | 27. Lonmin |
| 5. Argor-Hereaus | 28. Metalor Technologies |
| 6. Aurubis | 29. Montanwerke Brixlegg |
| 7. Boliden | 30. Norilsk Nickel Finland Oy |
| 8. Carl Hafner | 31. PAMP |
| 9. Cendres + Métaux | 32. Pemco Euroinks |
| 10. Chimet | 33. PX Holding |
| 11. Climax Molybdenum | 34. Recylex |
| 12. Commerzbank International | 35. SAFIMET |
| 13. DuPont | 36. SAFT Batteries |
| 14. Dragtsvetmet | 37. SEMPISA Joyería y Platería |
| 15. Eurotungstene (Eramet) | 38. Société des Fonderies de Plomb de Zellidja |
| 16. Ferro | 39. Tanaka Kikinzoku Kogyo |
| 17. Glencore | 40. Traxys Europe |
| 18. Handy Harman | 41. Umicore |
| 19. HCM | 42. Uralinteh |
| 20. Heimerle & Meule | 43. Valcambi |
| 21. Johnson Matthey | 44. Vale Europe |
| 22. KCM 2000 | 45. Heraeus |
| 23. KGHM Ecoren | 46. Wieland Edelmetalle + Technologie |
| | 47. XStrata |



3.2 PMC Organisation: Mgmt Ctte & (Co-)Chairmanship

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Caroline BRAIBANT - EPMF



PMC Management Committee: reminder

Dec 2011 - Dec 2013

1. Ron Davies (Ames Goldsmith, US) + Rob Garrett (UK)
2. Guy Ethier (Umicore, Belgium); **Chairman**
3. Marcus Hannakam (Heraeus, Germany)
4. Neville Plint (Anglo, South Africa)
5. Mark Raffray (Johnson Matthey, UK); **Co-Chairman**
6. Jacques Schaffnit (Metalor, France)
7. Heinz-Gunter Schenzel (Carl Hafner, Germany)

Mohamed Moukassi (SFPZ, Morocco) has left the Mgmt Cttee; Mgmt Cttee remains quorated



3.3 PMC Organisation: Sample Management Protocol

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Caroline BRAIBANT
EPMF



Sample management protocol



	What?	Who?	When?
Sample request	For each test/test house	PMC Secretariat	ASAP
Sample provision	For each test/test house	Sample provider	ASAP
Sampling tracking	To ensure provision of correct sample, with required information, by applicable deadline	PMC Secretariat + consultant + test house	On-going
Sample payment	To sample providers	PMC Secretariat	As soon as sample received by test house and invoice received by PMC secretariat
Sample identification	To ensure required information accompanies each sample	Sample provider	With sample provision
Sample storage	To ensure proper storage in and centralised dispatch from one or more test houses	Test house	During testing programme
Sample use	To ensure minimisation of amounts used/lost	Test house	During testing programme
Sample recovery and return	To minimise loss of precious metals from testing programme	Test house to Carl Hafner	Every 6 mo or at the end of testing programme in each test house



3.4 PMC Organisation: Revised LoA costs

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Caroline BRAIBANT
EPMF



LoA: Background

- REACH requires joint registration: One Substance, One Registration → all common data in one single Dossier submitted by a Lead Registrant
- Legitimate joint registrant is a registrant which contributes to the preparation of the Dossier → data- and cost-sharing by:
 - o Joining PMC
 - o Purchasing a LoA
- In fairness, transparency, non-discrimination, and non-profit PMC membership and LoA costs should be calculated on equivalent/comparable conditions
 - o cf. *ad hoc* paper and excel sheet



2010 & 2011 PMC LoA prices

Project / Dossier	Band	Max
Generic	N/A	38.500 €
Ag	Intermediate	125 €
	1-10	6.500 €
	10-100	8.500 €
	100-1000	18.000 €
	> 1000	124.500 €
Au	Intermediate	1.500 €
	1-10	23.000 €
	10-100	45.000 €
PM CN-	Intermediate	1.500 €
	1-10	20.000 €
	10-100	41.000 €
PGM	Intermediate	2.500 €
	1-10	30.000 €
	10-100	60.000 €
Re	Intermediate	2.000 €
	1-10	20.000 €
	10-100	41.000 €
Refinables	Intermediate	10.500 €



2012 PMC LoA prices



Project / Dossier	Band	Max
Generic	N/A	38.500 €
Ag	Intermediate	145 €
	1-10	8.000 €
	10-100	10.500 €
	100-1000	22.000 €
	> 1000	152.000 €
Au	Intermediate	2.500 €
	1-10	35.500 €
	10-100	69.000 €
PM CN-	Intermediate	2.000 €
	1-10	28.500 €
	10-100	59.000 €
PGM	Intermediate	2.500 €
	1-10	34.000 €
	10-100	71.500 €
Re	Intermediate	2.000 €
	1-10	22.000 €
	10-100	49.500 €
Refinables	Intermediate	12.000 €

May 2012 review indicates cost predictions made for 2011-2013 are reasonable for all projects except for the Silver and the Refinables projects

Underestimated costs triggered by:

- Dossier Evaluation and updates (e.g. testing proposals, updated classification, SCC reporting, etc.);
- On-going scientific research and Substance Evaluation; and
- Changes in the scope of the project → additional and changes to proportion of costs

Proposal: review the cost of the LoA of all PMC projects. Only LoA for the Generic costs, Ag 100-1000 t/a, PGM 1-10 t/a, and Re 1-10 t/a remain unchanged



Any question on PMC organisation items?



4.1 Expenses, Reserves, Budget Forecasts & Invoicing: 2011



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Caroline BRAIBANT - EPMF



2011: Incomes, expenses and reserves

	Project-Incomes (€)	Project-Expenses (€)	Cumulative Reserves per project* (€)
Generic costs	441.645	396.571	53.777
Ag-specific costs	651.510	169.458	623.537
Au-specific costs	106.439	109.224	400.761
PM CN- -specific costs	109.166	91.889	191.071
PGM-specific costs	811.220	493.203	2.241.255
Re-specific costs	291.297	101.798	375.121
Refinables-specific costs	792.480	269.061	581.122
Hydrazine	0	482	-482
TOTAL (€)	3.309.015 €	1.631.686	4.466.161

*50% of cumulated reserves are regularly credited from invoices to PMC Members, 50% of 2011 reserves provided above have been credited from 2012 invoices.



2011: Summary

YEAR	2011
Budgeted incomes	
PMC	2.485.390
Budgeted expenses	
PMC	3.309.015
Real incomes	
PMC	2.356.519
Real expenses	
PMC	1.631.686
Delta	
PMC	724.833
Produits à reporter	
PMC	4.466.161
Cash at bank	
PMC	n/a
Cash to receive from members	
PMC	12.992
Cash to receive VAT	
EPMF/PMC	
Cash to pay	
EPMF/PMC	352.944
Costs to postpone	
EPMF/PMC	2.098
Fixed Assets	
EPMF/PMC	50



2011: See also...

- 2011 P&L statement
- 2011 Bilan interne
- 2011 Summary
- 2010 + 2011 Audit reports

Thanks to Metalor for raising questions → Accountant clarified reconciliation of numbers across files

Any comment or question?





4.2 Expenses, Reserves, Budget Forecasts & Invoicing: 2012

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Caroline BRAIBANT - EPMF



2012: Deviations to 2012 Budget



Item	Description	Original 2012 budget	Reviewed 2012 budget	Delta	Available reserves by 30 May 2012	2 nd 2012 invoice needed?
Generic costs	- Removal of Ref consultant - Addition of Generic consultant (K. Arijs) to support use, exposure and emission data collection exercise - Removal of 10% of C. Braibant's time A. Rondepierre in maternity leave - Temporary replacement for A. Rondepierre - Eurométaux REACH package - REACH communication - Adjustment of meeting, travel and office costs + re-balance with EPMF (20% scenario)	539.968 €	512.006 €	27.962 €	26.888,70 €	No
Ag	On-going work: - On-going soil work - Aq classification review: Additional requirements: - Updated ES (exposure via food, waste) Preparation for Evaluation: - Updated literature search - Nano Dossier preparation: - Update of existing Dossiers - Remaining Dossiers (I&P)	117.980 €	611.287 €	- 493.307 €	311.768 €	No
Hydrazine	Scenario 2: Launch data collection and analysis of alternatives only	0 €	15.000 €	- 15.000 €	- 482 €	Yes (~ 3000 € / company)



2012: (Reviewed) Budget and expenses by Apr 2012

	Reviewed 2012 budget (€)	Expenses by Apr 2012 (€)
Generic costs	508.712	125.023
Ag-specific costs	611.571	31.525
Au-specific costs	226.111	819
PM CN- -specific costs	159.290	845
PGM-specific costs	1.874.135	63.087
Re-specific costs	60.942	36.866
Refinables-specific costs	255.230	13.379
Hydrazine*	16.982	0
TOTAL (€)	3.712.491	271.544

* Cf. hydrazine budget proposed by HTF at 12 Jun 2012 cc



4.3 Expenses, Reserves, Budget Forecasts & Invoicing: 2013



...

Caroline BRAIBANT - EPMF

A LOOK
at the
BUDGET



2013 forecast - background

- Due to likely changes to resources and continuous adjustment of work programmes, draft 2013 budget has been prepared for information/reference only!
- Formal proposal will be prepared by Mgmt Cttee in Sep/Oct 2012 for presentation to and approval by PMC in Dec 2012
- Prediction presented below (calculated on 2012 budget + ball-park figures) does not include:
 - Potential LoA incomes
 - Deduction of 50% of reserves
 - Updated proposals from consultants



2013 forecast - draft

Item	2013 Budget
Generic costs	556.484 €
Ag-specific costs	282.696 €
Au-specific costs	202.316 €
PM CN- -specific costs	135.495 €
PGM-specific costs	1.229.371 €
Re-specific costs	22.980 €
Refinables-specific costs	555.230 €
Hydrazine-specific costs (Scenario 2)	22.000 €
TOTAL	3.006.572 €

Cf. details in handouts



2013 invoices - draft

ID Code	2012 Generic cost-share per Member	2012 Ag-specific cost-share per Member	2012 Au-specific cost-share per Member	2012 PM CN-specific cost-share per Member	2012 PGM-specific cost-share per Member	2012 RE-specific cost-share per Member	2012 Ref-specific cost-share per Member	2012 Hz-specific cost-share per Member	Amount to be invoiced in 2012
1	11.840,08 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	11.840,08 €
2	11.840,08 €	0,00 €	4.585,95 €	0,00 €	44.129,38 €	0,00 €	7.028,23 €	0,00 €	67.583,63 €
3	11.840,08 €	3.046,36 €	8.860,23 €	0,00 €	9.487,69 €	0,00 €	0,00 €	0,00 €	33.234,36 €
4	11.840,08 €	4.951,97 €	8.860,23 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	25.652,27 €
5	11.840,08 €	26.413,80 €	8.860,23 €	0,00 €	0,00 €	0,00 €	49.197,59 €	0,00 €	96.311,70 €
6	11.840,08 €	8.424,49 €	0,00 €	25.940,20 €	23.719,22 €	0,00 €	7.028,23 €	0,00 €	76.952,21 €
7	11.840,08 €	4.975,79 €	4.585,95 €	20.859,13 €	0,00 €	0,00 €	0,00 €	0,00 €	42.260,94 €
8	11.840,08 €	0,00 €	0,00 €	5.259,35 €	0,00 €	0,00 €	0,00 €	0,00 €	17.099,43 €
9	11.840,08 €	8.424,49 €	17.720,46 €	0,00 €	37.950,76 €	0,00 €	0,00 €	3.142,86 €	89.842,93 €
10	11.840,08 €	2.689,06 €	4.585,95 €	10.518,70 €	9.487,69 €	0,00 €	0,00 €	0,00 €	39.121,48 €
11	11.840,08 €	34.388,31 €	13.446,18 €	25.940,20 €	304.242,62 €	0,00 €	63.254,05 €	3.142,86 €	467.018,58 €
12	11.840,08 €	4.951,97 €	8.860,23 €	0,00 €	9.487,69 €	0,00 €	0,00 €	0,00 €	35.139,96 €
13	11.840,08 €	26.413,80 €	4.585,95 €	0,00 €	0,00 €	0,00 €	42.169,37 €	0,00 €	85.009,20 €
14	11.840,08 €	11.044,69 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	22.884,77 €
15	11.840,08 €	7.998,33 €	18.032,13 €	15.778,06 €	294.396,24 €	6.646,18 €	35.141,14 €	3.142,86 €	403.739,28 €
16	11.840,08 €	2.712,88 €	4.585,95 €	0,00 €	91.567,82 €	0,00 €	56.225,82 €	0,00 €	166.932,55 €
17	11.840,08 €	13.376,46 €	8.860,23 €	20.859,13 €	14.231,53 €	0,00 €	56.225,82 €	3.142,86 €	139.300,39 €
18	11.840,08 €	3.046,36 €	0,00 €	0,00 €	0,00 €	0,00 €	7.028,23 €	0,00 €	21.914,67 €
19	11.840,08 €	3.046,36 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	14.886,44 €
20	11.840,08 €	4.951,97 €	8.860,23 €	0,00 €	4.743,84 €	0,00 €	21.084,68 €	3.142,86 €	65.387,94 €
21	11.840,08 €	4.951,97 €	8.860,23 €	0,00 €	9.487,69 €	0,00 €	0,00 €	0,00 €	35.139,96 €
23	11.840,08 €	2.689,06 €	4.585,95 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	19.115,09 €

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2013 invoices – draft (cont.)

24	11.840,08 €	2.689,06 €	4.585,95 €	0,00 €	9.487,69 €	0,00 €	0,00 €	0,00 €	28.602,78 €
25	11.840,08 €	16.422,82 €	13.757,84 €	0,00 €	137.113,45 €	3.717,35 €	63.254,05 €	3.142,86 €	260.012,74 €
26	11.840,08 €	7.998,33 €	4.585,95 €	0,00 €	14.590,23 €	0,00 €	28.112,91 €	0,00 €	67.127,49 €
27	11.840,08 €	3.046,36 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	14.886,44 €
28	11.840,08 €	0,00 €	0,00 €	0,00 €	0,00 €	2.478,24 €	0,00 €	0,00 €	14.318,31 €
29	11.840,08 €	0,00 €	4.585,95 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.426,02 €
30	11.840,08 €	0,00 €	0,00 €	0,00 €	0,00 €	2.478,24 €	0,00 €	0,00 €	14.318,31 €
31	11.840,08 €	0,00 €	0,00 €	0,00 €	0,00 €	112,65 €	0,00 €	0,00 €	11.952,72 €
32	11.840,08 €	3.046,36 €	0,00 €	0,00 €	0,00 €	0,00 €	7.028,23 €	0,00 €	21.914,67 €
33	11.840,08 €	3.046,36 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	14.886,44 €
34	11.840,08 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	7.028,23 €	0,00 €	18.868,30 €
35	11.840,08 €	0,00 €	0,00 €	0,00 €	0,00 €	2.478,24 €	0,00 €	0,00 €	14.318,31 €
36	11.840,08 €	3.046,36 €	4.585,95 €	0,00 €	9.487,69 €	0,00 €	0,00 €	0,00 €	28.960,08 €
37	11.840,08 €	3.046,36 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	14.886,44 €
39	11.840,08 €	3.046,36 €	8.860,23 €	0,00 €	9.487,69 €	0,00 €	35.141,14 €	0,00 €	68.375,50 €
40	11.840,08 €	10.687,39 €	8.860,23 €	10.340,42 €	29.520,62 €	0,00 €	70.282,28 €	0,00 €	141.531,02 €
41	11.840,08 €	3.046,36 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	14.886,44 €
42	11.840,08 €	0,00 €	4.585,95 €	0,00 €	4.743,84 €	0,00 €	0,00 €	0,00 €	21.169,87 €
43	11.840,08 €	26.389,98 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	38.230,06 €
44	11.840,08 €	0,00 €	0,00 €	0,00 €	33.206,91 €	0,00 €	0,00 €	0,00 €	45.046,99 €
45	11.840,08 €	3.046,36 €	4.585,95 €	0,00 €	62.387,37 €	0,00 €	0,00 €	0,00 €	81.859,76 €
46	11.840,08 €	4.951,97 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	16.792,04 €
47	11.840,08 €	3.046,36 €	4.585,95 €	0,00 €	23.719,22 €	2.478,24 €	0,00 €	0,00 €	45.669,85 €
48	11.840,08 €	7.641,03 €	0,00 €	0,00 €	9.487,69 €	0,00 €	0,00 €	0,00 €	42.875,94 €
49	11.840,08 €	0,00 €	0,00 €	0,00 €	33.206,91 €	0,00 €	0,00 €	0,00 €	45.046,99 €
TPR 1	TPR 1					2.590,88 €			2.590,88 €
TOTAL	556.483,57 €	282.696,00 €	202.316,01 €	135.495,18 €	1.229.371,50 €	22.980,00 €	555.230,00 €	22.000 €	3.006.572 €

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Any question on Budget items?



5. Presentation from Cu Consortium: *REACH is here to stay*

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Katrien DELBEKE, ECI



Cu experience:

Once upon a time a risk assessment initiative...



• REACH is not one-stop regulatory requirement, REACH is here to stay!

• For most substances, REACH only starts with Registration Dossier submission!

• Dossier maintenance and update necessary for all Dossiers

• Evaluation...

• Authorisation...

• National implementation (MS)...

• International reference (USA, China, Korea, Switzerland, OECD, etc.)...

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Cf. separate slide set

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6. AOB, Next Meetings & Closing Remarks

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Guy ETHIER - Umicore



6.1 AOB?



6.2 Next Assembly Meetings

- PMC Assembly Meeting: Brussels, 5 December 2012
- PMC Plenary Meeting: Stockholm, 13 June 2013

6.2 Other PMC Meetings

- Nano TF Conference Call: 25 June 2012
- PGM ES Meeting: Brussels, 27 June 2012
- Refinables Meeting: Brussels, 28 June 2012



Thank you!