For reference or information only

6th December 2011, 10:30am-3:30pm CET

Precious Metals and Rhenium Consortium Assembly meeting



1. Welcome and introduction

Guy Ethier



Welcome and introduction

- Confidentiality and Competition Law

- Approval of the agenda:
  1. Welcome and introduction
  2. Status and progress of PMC projects
  3. PMC organisation
  4. Expenses, reserves, budget forecasts and invoicing
  5. AOB, next meetings, and closing remarks

- Actions agreed at the last meeting (cf. next slide)

- Approval of the minutes of the last meeting (Cambridge, 17 June 2011) (circulated on 6 Jul 2011)

Actions agreed at the last PMC Assembly meeting

1. Produce list of abbreviations and acronyms for Assembly meetings and make it available in the handouts and/or upon request
2. Submit updated Substance and tonnage band declaration to A. Rondepierre
3. Prepare final PMC inventories on the basis of the Substance and tonnage band declarations received by 30 Jun 2011 and upload them onto EPMF website
4. Submit signed Declaration of commitment
5. Volunteer for (Co-)Chairpersonship of the MC of the PMC
6. Circulate name of nominees for (Co-)Chairpersonship to PMC
7. Put together a business case to justify/describe need for an additional Manager at PMC secretariat - 2012
8. Finalise Internal Rules - 2012
9. Follow-up the discussions and debate on the ECHA Guidance on intermediates and the interpretation of scc and propose an update to the PMC cost-sharing formula if needed - 2012
10. Follow-up reimbursement of sample costs to sample providers
11. Regularly review PMC Reserves and Accounts
12. Revise and provide an up to date figure for the PMC Reserve, to be used when calculating 2012 invoices

Actions agreed at the last PMC Assembly meeting (cont.)

13. Calculate LoA costs to allow (potential) Members to compare the advantages and disadvantages of joining the PMC or purchasing a LoA
14. Submit updated 2012 budget proposal for approval by Assembly
15. Prepare data to complete Appendix 2 and 3 of Dec 2010 ECHA Guidance on Intermediates - 2012
16. Set-up Hydrazine Task Force (HTF) and schedule first conference call/meeting
17. Follow-up discussions on Borax at ECHA, Eurométaux and Borax Consortium level
18. Agree on a strategy to update CLP notifications which were submitted in 2010 and for which new requirements apply or new information has become available
19. Prepare Guidance to update CLP notifications
20. Confirm interest of PMC to participate in the OECD-HPV voluntary programme with the Silver metal dataset to Eurométaux/OECD
21. Create in-house database to store all REACH-relevant information
22. Volunteer for LR for the remaining PM CN-
23. Organise a MC conference call

2. Status and progress of PMC Projects



Generic items

- CLP update
- Nanomaterials
- Testing programmes
- Exposure data collection and assessment

CLP



CLP update

Classifications submitted in 2010 may need to be updated in view of:

- 2nd Adaptation to Technical Progress (ATP) to CLP
  - Adapted on 19 April 2011
  - To be implemented by Dec 2012
  - New/ changed endpoints:
    - Sensitization (skin/ resp.)
    - Environment classification:
      - chronic effects
      - new M factors
    - Pending: “removal from water column” (UWM)
    - (Effects on ozone layer)
- Changes to classification due to new test data

CLP update (cont.)

- Strategy towards classification updates:
- All projects but Refinabes:

	What?	Who?	When?
1.	Send any new information on physico-chemical, tox and ecotox properties to PMC secretariat	All	ASAP / On-going
2.	Forward information to WCA	PMC secretariat	End 2011
3.	Review existing classifications and derive new classifications where relevant	WCA	Jan 2012
4.	Discuss and agree on new classifications proposed	All	End Jan 2012
5.	Update classification via REACH-IT on the basis of PMC Guidance	Lead notifiers + other notifiers	> End Jan 2012
6.	Update labelling, packaging and transport measures according to updated classification	All	< Dec 2012

- For Refinables, cf. item 2.6 below



Nanomaterials

Nanomaterials

- New EU Commission Recommendation for definition on nanomaterials
  - D50 (50% of the **NUMBER** of particles) < 0.1 µm, OR
  - Surface area > 60 m^2/cm^3

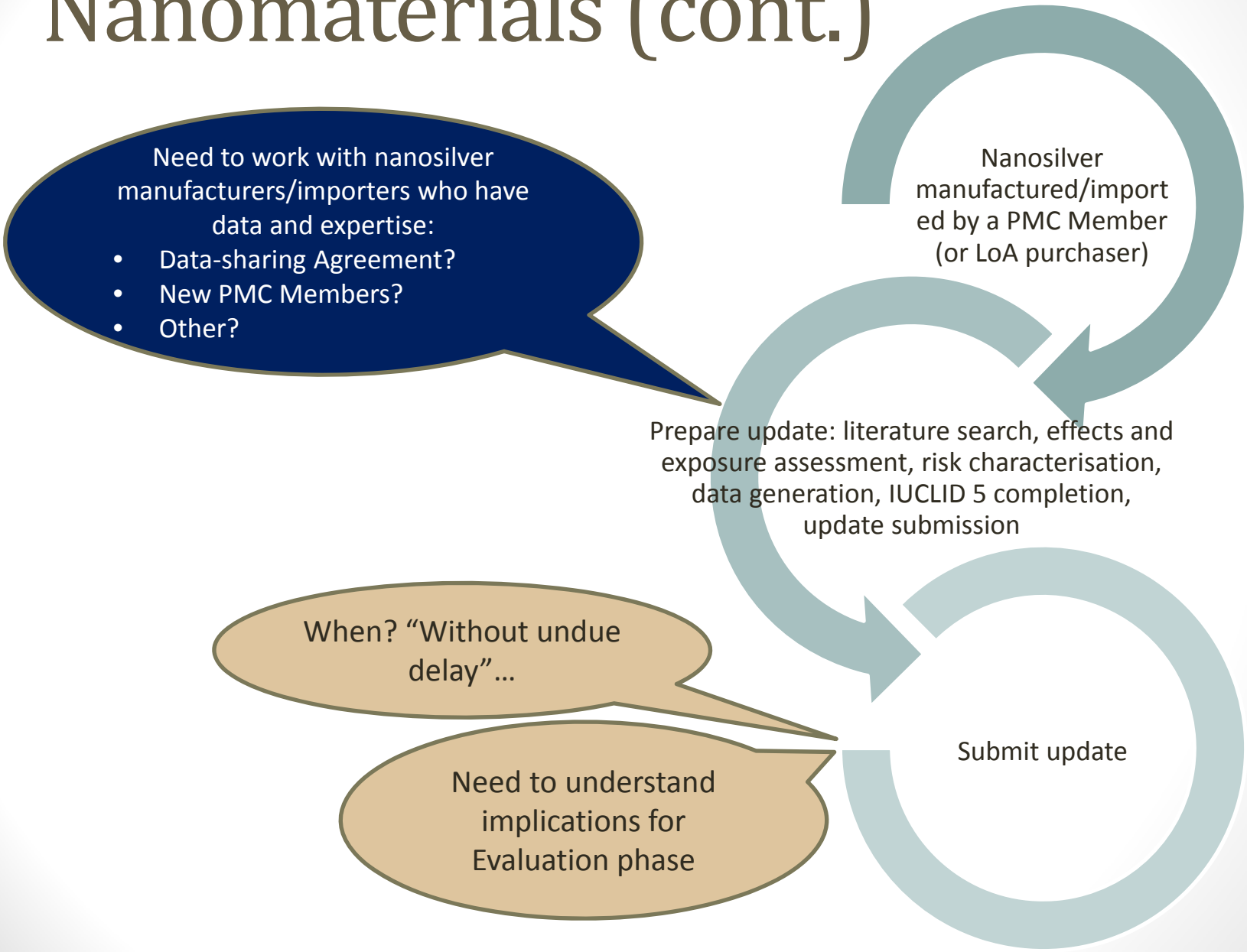
  Not only intentionally manufactured/engineered nanomaterials!

- Next steps:
  - Industry to agree on position: NIA, CEFIC, Eurométaux, Powder manufacturers…
  - Members to check substances and intermediates manufactured and/or imported
    - Request 21 Nov 2011, deadline for response 15 Dec 2011
    - Feed-back received so far indicates:
      - No nanos
      - Maybe nanos – what technique should be used to measure number of particles and surface area?
      - Nanos present… cf. next slide

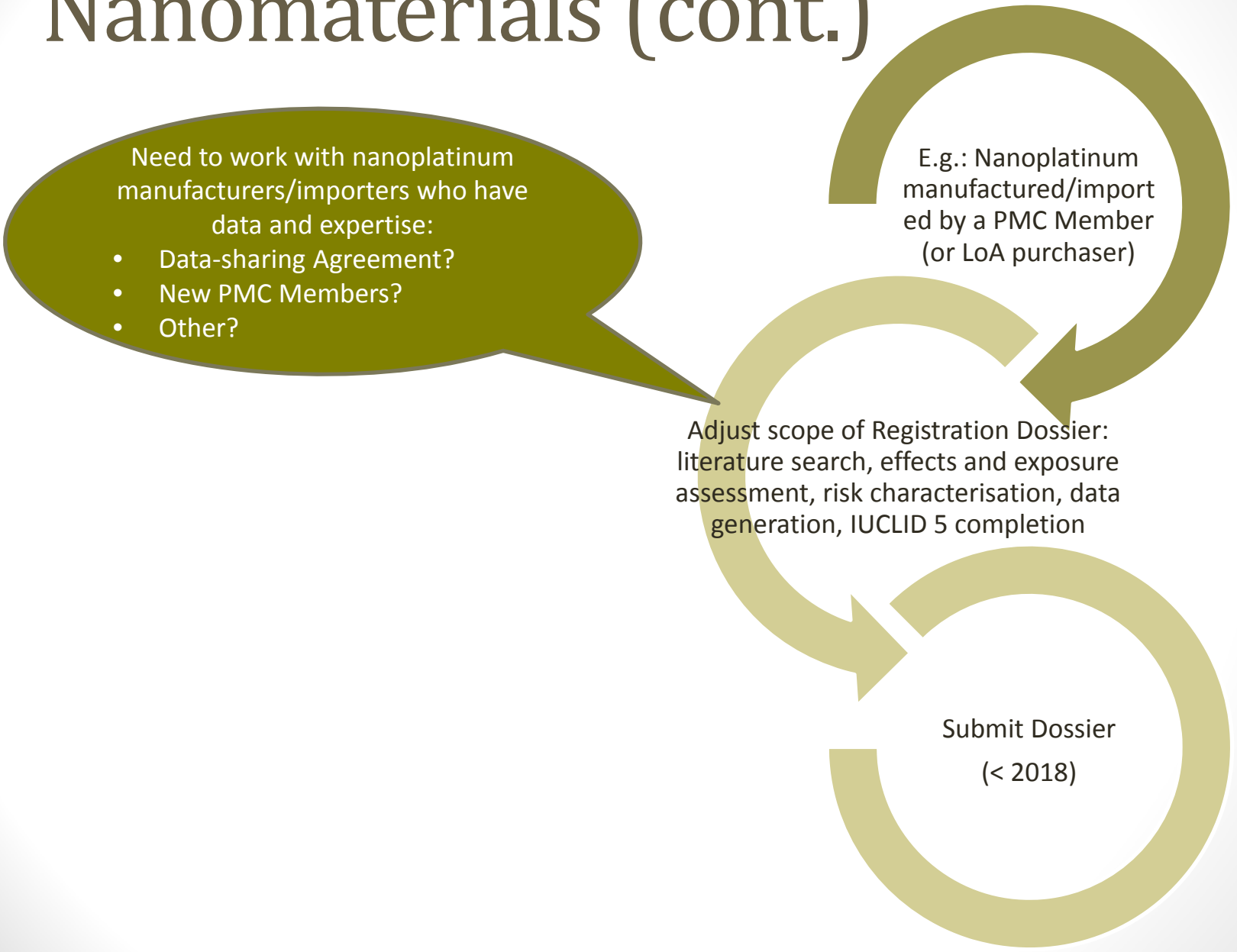
Nanomaterials (cont.)

- If one or more Members find out they do manufacture or import substances which fulfill the recommended definition of nanomaterial…
  - Already submitted files: Ag and Refinables
  - Files in preparation: Au, PM CN-, PGM, and Re

Nanomaterials (cont.)



Nanomaterials (cont.)



Nanomaterials (cont.)

In summary…

- Nanos no longer “none of our business”…
- Metals industry to:
  - Agree and recommend best available techniques to measure number of particles and surface area of powdery materials (for the identification and characterisation) and the need for dustiness /MMAD, bio-elution and transformation/dissolution tests (to prepare risk assessment)
  - Establish contact with nanomaterials’ manufacturers/associations
  - Follow-up on OECD guidelines for the testing of nanomaterials
- Each manufacturer and importer responsible to properly characterise substances and intermediates of its portfolio
- Dossiers to be updated/adjusted as needed



Testing programmes

Learning lessons and key messages

Testing programmes

- Learning lessons of first “full” testing programmes:
  - CLP
  - Re programme
- Administratively burdensome - for each test house/proposal:
  - 2 draft Offer/Proposal + 1 final Offer/Proposal
  - 2 draft Contracts + 1 final Contract

  Reviewed by consultants, LWG Chairperson and PMC secretariat
- Beyond administrative details, for each test:
  - 2 draft protocols + 1 final protocol
  - 1 draft study results
  - 1 draft study report + 1 final study report

  Reviewed by consultants, WG Chairperson and PMC secretariat
- Also (cf. item 3.6 below):
  - Sample requests preparation, tracking and follow-up
  - Sample preparation, shipping and invoicing – very substantial role!

Testing programmes (cont.)

Assuming an average of ~1 h per document:
= ~6 h of work for each test house
= ~6 h of work for each test

Small projects (Au, PM CN- and Re):
Assuming 3 tests per test house:
= ~ 24 h for each testing programme in a different test house
= ~ 3 working days for each testing programme in a different test house
Assuming 3 test houses per project:
= ~ 9 working days per project

Big projects (e.g.: PGM):
Assuming 12 tests per test house:
= ~ 78 h for each testing programme in a different test house
= ~ 10 working days for each testing programme in a different test house
Assuming 6 test houses per project:
= ~ 60 working days per project (i.e. ~ 3 months)

Exposure data collection and assessment

Learning lessons and key messages



Exposure data collection and assessment

- Learning lessons of previous exercises:
  - Ag: full assessment, submitted in 2010 Dossier
  - Refinables: exposure assessment on-going, part of SCC validation and upgrade preparation

- Exposure data needed to:
  - Demonstrate, support or validate SCC assessment of intermediates
  - Demonstrate non-relevance of routes of exposure
  - When hazard identified, for substances and non-SCC intermediates > 10 t/a requiring a full chemical safety assessment

Exposure data collection and assessment (cont.)

- Questionnaires:
  - One per consultant → different working styles, databases, etc.
  - Format → depending on type of assessment (full/local; environment/human health; mono-constituent substance/UVCB; etc.)
  - Content → based on existing information provided by Members (PMC substance and tonnage band declaration; ad hoc questionnaires, ad hoc requests, spontaneous e-mails) and subject to quality screening by consultants
  - Workload → considerable, requires organisation and contribution of several experts within company, exchanges with consultants

- Data:
  - Either none or insufficient
  - Generated via *ad hoc*/targetted exposure monitoring programmes



2.1. Ag

Klaus Rothenbacher

Scope

Silver - 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	*5*	Ames Goldsmith
As from end 2011	*Disilver (1+) sulphate*	*Substance*	*1-10*	*2*	*Johnson Matthey*
	Silver carbonate	*Substance*	*1-10*	*2*	*Johnson Matthey*
	Silver chloride	*Intermediate*	*10-100*	*6*	*Umicore*
	Silver bromide	*Intermediate*	*1-10*	*1*	*Umicore*
	Silver sulphide	*Intermediate*	*10-100*	*1*	*Umicore*

Registration

Remaining Registrations

Silver Carbonate *(CAS 534-16-7)* and Silver Sulphate *(CAS 10294-26-5)*

- Substances, 1-10 tpa band: no ES or CSR necessary
- Dossiers completed and agreed with concerned PMC Members
- Ready for submission

Silver Chloride *(CAS 232-033-3)*

- Intermediate, non-SCC → full intermediate dossier required
- Exposure scenarios: finalised and circulated to concerned PMC Members
- CSR to be finalised once final ES available
- IUCLID 5 completed once CSR available
- Timing: December 2011

Remaining: two intermediates

On-going scientific work

Terrestrial Testing

Background

- Initial tests at Aecom find NOECs << background levels = data not useful
- Decision to initiate more detailed study on ageing, bioavailability correction
- 2-year project, with CSIRO, Australia (Prof. Mike McLaughlin)
- June 2011: contract signed, testing initiated

Status

- On schedule
- 7 soils collected, 1 soil pending
- Range-finding tests started
- Method development for analytics (isotope-dilution method) started

Timing

- Currently discussing with lab if testing can be accelerated to meet Evaluation timeline
- Milestones: see following slide

Terrestrial Testing (cont.)

Time line/ Milestones

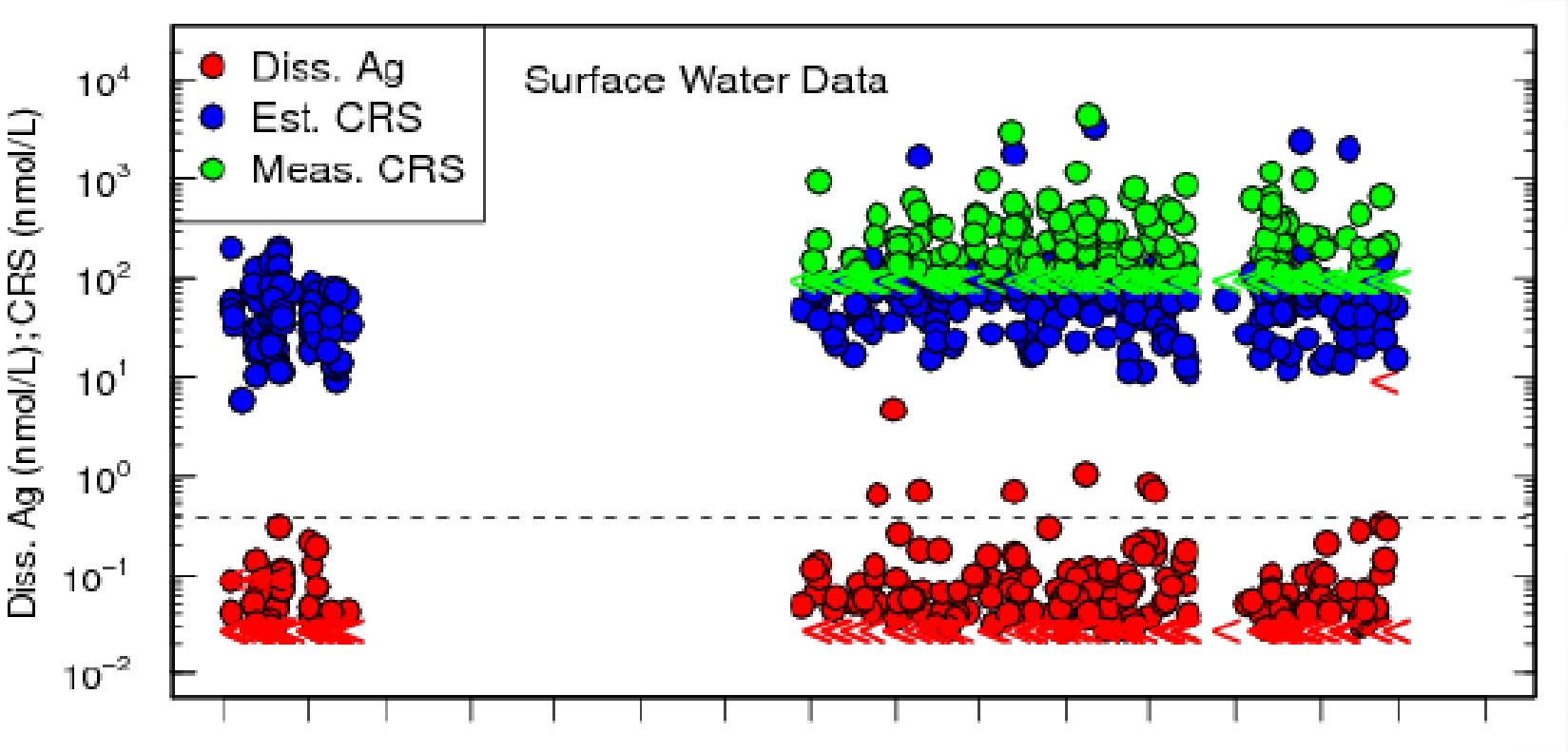
	Year 1	Year 1	Year 1	Year 1	Year 2	Year 2	Year 2	Year 2
Phase	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
1. Soil collection and preparation (Section 2.1)		R						
2. Development of Ag lability methodology (Isotopic dilution)				R				
3. Lability and ageing experiments (Section 2.2)								R
4. Silver ion toxicity to soil microorganisms (Section 2.3)								R
5. Silver ion toxicity to, and bioaccumulation in, plants (Section 2.4)						R		
6. Silver ion toxicity to soil invertebrates (Section 2.5)								R

- Milestone 1 – 6 months – report of soils sampled and physical/chemical characteristics.
- Milestone 2 – 12 months – report of Ag lability method development, preliminary plant toxicity results.
- Milestone 3 – 18 months – report of plant toxicity experiments (barley and tomato)
- Milestone 4 – 24 months – report of invertebrate toxicity experiments, report of microbial toxicity experiments, report of aging lability experiments, report of soil normalisation relationships.

Bioavailability Correction Water

- Background
  - To demonstrate reduced availability (= toxicity) of Ag in the aq. environment due to (insoluble) sulphide formation
  - Monitoring study (chromium reducible sulphides (CRS) and Ag in EU waters) completed
  - Feasibility study with Hydroqual
- Results
  - See graph next slide
  - Working hypothesis: Silver will be toxic where molar concentration of silver exceeds molar concentration of CRS
  - Monitoring data: environmental Silver levels << Sulphide levels
  - Likely significant reduction in Silver availability through sulphide binding
  - Validation with chronic data required if concept to be used in Reach dossier

Bioavailability Correction Water



Comparison of dissolved silver (red) and CRS, either measured (green) or estimated from DOC (blue). Monitoring undertaken in the UK between Jan 2010 and April 2011. CRS concentrations are higher than silver concentrations in all cases.

Classification – T/D testing massive Ag

Background

- Massive Ag not classified, but open questions remain on TD tests
- Agreed to clarify questions in 2011/2. To be used in later dossier update (2012)

Status

- Testing ongoing at ECTX
- Tiered testing approach: pre-tests, followed by TD repeat
- Projected completion: Q2 2012

Testing proposals

ECHA response on testing proposals

PMC testing proposals for Silver, Silver nitrate, Disilver oxide:

- 90d oral study, with a suitable bio-accessible Ag compound + read across to other Ag compounds
- No 2-Gen study proposed, suggest to evaluate results 90d study first
- Soil testing: long-term soil tests (Aecom)

ECHA Response

- 90d study:
  - Did not demonstrate that read across would be appropriate + no specific substance proposed => **request testing all 3 substances**
  - Request **inhalation route for Silver**, not oral
  - New 3rd party studies identified
- No issue with (lacking) 2-Gen study proposal
- Soil: Evaluation of testing proposal terminated since testing already on-going

ECHA response on testing proposals (cont.)

Time line for response

- Soil: “without delay”
- 90d studies
  - 10 working days to request discussion on technical level (done)
  - 30 days for official response (deadline: 19 December)

Proposed response soil

- No need to respond to ECHA (just to address issue)
- PMC addressing the issue already (via ongoing CSIRO work) = “without delay” clause is met
- Update dossier in 2012/13 once all data is ready (Aecom/ CSIRO)
- Propose to seek legal opinion to confirm

ECHA response on testing proposals (cont.)

Proposed response 90d studies

- Requested technical discussion on:
  1) Selection of a suitable test substance and justification for read-across
  2) Appropriate route of administration
  3) Possible consideration of data identified by third parties

Conference call with ECHA and LR + PMC experts on 13 Dec 2011, 9:30 GMT

- Full response (depending on feedback ECHA call)
  - Propose to evaluate new 3rd party studies on soluble Ag substances. Derive DNEL if possible (probably not)
  - Better explain why read across is appropriate (MERAG/ HERAG)
  - Maintain proposal to test soluble and bioavailable substance and read across
  - Ag inhalation not a relevant route of exposure due to low dustiness, low systemic toxicity, likely technically not feasible

Evaluation

Evaluation

Background

- "Community Rolling Action Plan" (CoRAP) selects substances for REACh Evaluation phase
- Selection of substances based on hazard, and on Member State interest
- Silver shortlisted for evaluation in 2013 (21 October 2011 ECHA draft list)

- Evaluation
  - Is the "E" of REACH; "trust, but verify" approach
  - Likely similar to previous "TC NES" evaluations
    - Rapporteur country conducts evaluation
    - Thorough review of dossier: scientific soundness, are all uses covered, are conclusions logical and well documented, etc.
    - Ag rapporteur not disclosed yet
    - Need for interaction Industry – rapporteur during (and prior to) evaluation phase
  - Possible conclusions of evaluation
    - No need for actions
    - Need for further information: additional studies, documentation, etc
    - Need for action: restrictions, authorization, risk management, etc

Evaluation

- Process/ Timing
  - 21 October 2011: ECHA publishes draft list
  - Dec 2011 or Feb 2012: MSC agrees CoRAP (including rapporteur member states)
  - End Feb 2012: ECHA to officially publish CoRAP
  - Ag scheduled for review in 2013
  - 1 yr for rapporteur to evaluate dossier
  - MSC/ECHA to review draft conclusions/information requests of rapporteur
  - Industry can comment on draft conclusions/information requests

- Informal feedback
  - PMC liaised with other concerned parties: NIA, IRVM, Eurometaux, etc
  - Silver likely selected because of nano issue (and to compare to other dossiers)
  - Note: our Silver dossier does not cover nano materials
  - Silver likely to remain on evaluation list regardless

Evaluation

- Next Steps
  - Ensure Silver dossier is as robust as possible, generate additional data if necessary (see next slides)
  - Update dossier prior to Evaluation phase (end 2012)
  - Establish informal contact with rapporteur in early 2012 to agree on approach/timing

General issues

Issue	Possible actions	Time line/ Budget	Priority/ Consequences
General			
Literature search dated 2008 - **New relevant data may have become available**	Update literature search	2 months Ca 9 000 Euros	Medium
General scientific robustness	Commission external peer review	2 months Ca 5 000 Euros	Medium/ low - PNEC derivation already reviewed externally
"	Develop additional robust narratives in support of positions taken in the CSR	2 months Ca 5 000 Euros	Medium/ low – dossier already contains rationale for conclusions, but more narrative would be useful to support discussion
Prepare for potential nano discussion	• Literature search, initial evaluation of nano vs. bulk Ag properties/ effects • Members to confirm substance form wrt latest EU nano definition	Ca 25 000 Euros Ongoing	• Depends on impact of recommended definition on companies' materials and on future intentions to put nano silver on EU market. • High- need to confirm impact of new situation

Environment part

Issue	Possible actions	Time line/ Budget	Priority/ Consequences
Environment Part			
PNEC aq derivation - **ECHA might disagree with AF, SSD** - **Robustness of database**	Generate additional aquatic tox data to improve robustness of SSD Develop full bioavailability correction model (based on initial feasibility work re. sulphides binding)	6 months Ca 10 - 50 000 Euros 12 months Ca 50 – 100 000 Euros	Medium/ low – PNEC will likely not improve much by simply generating more data; choice of AF and PNEC very conservative Medium – would likely improve PNEC significantly, but expensive
Classification - **ECHA might disagree with not classifying massive Ag**	Currently conducting confirmatory studies to generate robust data.	Ongoing, mid 2012 No additional funds required – already budgeted	High – ECHA might challenge massive Ag classification otherwise
Soil data - **ECHA terminated testing proposal evaluation, official data gap** - **Need to "address the consequences without delay" = no fixed deadline for dossier update**	• Currently addressing this data gap in study programme. • Update dossier once data has been fully generated (2012/13 – to be confirmed with Evaluation rapporteur) • Document rationale how we plan to address the data gap and why we believe we are not putting the soil compartment at risk. • Seek legal advice to substantiate our position	July 2013 No additional funds required – already budgeted Ca 10 000 Euros	High - Alternative would be to report new data from Aecom in dossier update now. But PNEC << background levels = unrealistically low

Issue	Possible actions	Time line/ Budget	Priority/ Consequences
Human Health Part			
Data gap repeated dose (90d study). **Initial ECHA response on testing proposal** - **request to test each registered substance (instead of 1 to read across)** - **need to test inhalation route for Ag 90d study**	Discuss with ECHA 1) selection of a suitable test substance and justification for read-across 2) appropriate route of administration 3) possible consideration of data identified by third parties	Jan 2012 Ca 2000 Euros (consultant time)	High – alternative would be to conduct 3 x 90d studies
	Conduct 90d study	18 months (mid 2013) No additional funds required – already budgeted	High – official data gap
	Seek legal advice in case ECHA insists on 3x 90d studies	Ca 10 000 Euros	Depending on outcome initial ECHA discussions. High priority if ECHA wants 3x 90d studies.
No good basis for read across (bio-elution data not useable)	Measure relative oral bioavailability	Ca 20 – 50 000 Euros	Medium/high - alternative may be requirement for 3 x 90d studies
Dermal absorption: dossier uses default assumptions HERAG	Generate measured data: dermal absorption study	3 months Ca 20 000 Euros	Medium/low – HERAG assumptions sufficient to demonstrate safe use, but ECHA might request testing dermal route in acute or repeated dose testing

Issue	Possible actions	Time line/ Budget	Priority/ Consequences
Human Health Part (cont.)			
Testing proposal did not propose a 2 Gen study, although official data gap. **(Current dossier proposes to first evaluate results 90d study and then decide on need for 2-Gen study.)**	Submit study proposal 2-Gen study	1 week Ca 1 000 Euros (2 Gen study: 500 000 – 1 mio Euros)	Low – Not recommended ECHA did not request 2-Gen study during testing proposal evaluation. Precedent from 20th MSC meeting, 2-4 November 2011
Use of ECETOC assessment factor of 5 for intraspecies variability (extrapolating DNEL workers to DNEL general population) **REACH guidance default AF = 10**	Revise AF	1week Ca 1 000 Euros	Not recommended – Would double risk ratios EBRC response: deviating from ECHA guidance. But justifiable and in line with other metal dossiers

Total estimated costs	
High priority options	ca 97 000 Euros
Medium priority options	ca 125 000 Euros



2.2. Au

Caroline Braibant

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 (in aq. solution)	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

On-going work

- Physico-chemical properties (Balsams): Boiling point, Density, Solubility, Vapour pressure, Partition coefficient

- Ecotoxicity tests (TCA):
  - Daphnia
  - Algae
  - Activated sludge

- Toxicity tests:
  - Bio-elution (Au)
  - Mouse Lymphoma Assay (TCA)
  - Literature search on sodium/potassium/ammonium tetrachloroaurate, gold trichloride, triiodide, tribromide and trinitrate to apply read-across

- Next conference call: 13 Dec 2011, 10 am CET

Project progress/timeline

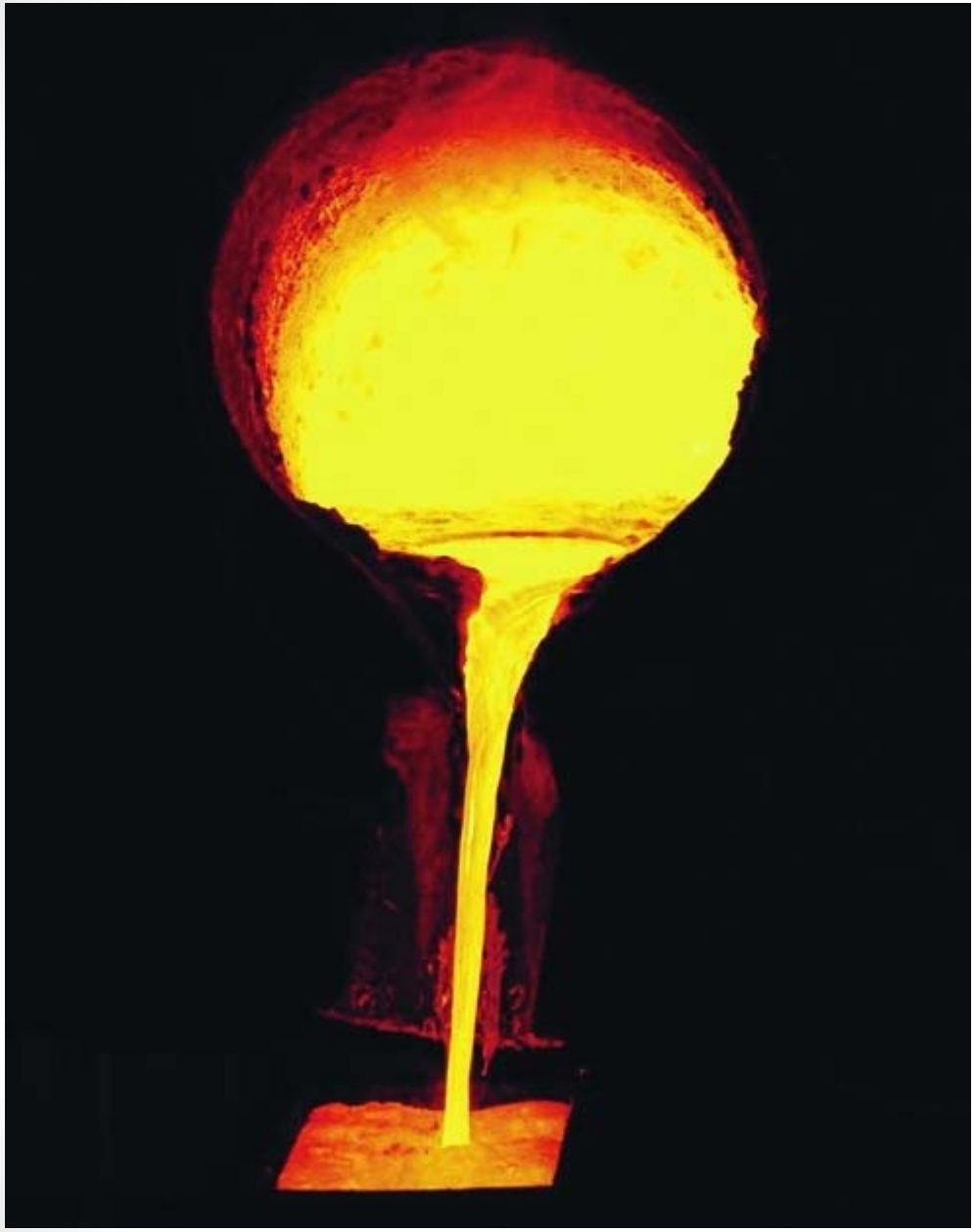
I. Literature search & CLP → done

II. Data gap analysis & ITS → done

III. Testing programme
- Physico-chemical properties → finalised in Q4 2011
- Ecotox → commenced
- Tox → starting in Q1 2012

IV. CSA/CSR
- Exposure data collection → starting in Q1 2012
- Exposure assessment → …
- Effects assessment (including PNEC and DNEL derivation)
- Risk Characterisation

V. IUCLID 5 filling → on-going



2.3. PM CN-: ITS, modelling programme, timeline

Caroline Braibant

Scope

Substance	EC n°	CAS n°	Tonnage band	Deadline	LR
K dicyanoargentate	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	238-145-9	14263-59-3	1-10 t/a	2018	?

Still three LR lacking…

On-going work

- Physico-chemical properties: Density, solubility, dustiness
- Eco-toxicity:
  - Modelling of mixture toxicity: to predict the acute eco-toxicity of Au and Ag cyanide based on acute toxicity of Au, Ag and CN, combined with predictions of the speciation PM CN- in typical ecotoxicity test media using VisualMINTEQ
  - Daphnia and activated sludge tests (K dicyanoAg and Au) to fill gaps and validate mixture toxicity modelling
- Toxicity:
  - Prediction of dissociation species via modelling
  - Predict LD50/classification based on theoretical dissociation predictions
  - Decide whether to read-across from CN- or test
- Next conference call: 13 Dec 2011, 10 am CET

Project progress/timeline

I. Literature search & CLP → done

II. Data gap analysis & ITS → done

III. Testing programme
- Physico-chemical properties → finalised in Q4 2011
- Ecotox testing/modelling → commenced
- Tox testing/modelling → starting in Q1 2012/commenced

IV. CSA/CSR
- Exposure data collection → starting in Q1 2012
- Exposure assessment → …
- Effects assessment (including PNEC and DNEL derivation)
- Risk Characterisation

V. IUCLID 5 filling → on-going



2.4. PGM

Klaus Rothenbacher

Scope

Scope

Registration by	Family	Status	Highest tonnage Band (t/a)	N° of PMC Members registrations	Lead Registrants*
2013 (at least one PGM substance and three PGM intermediates)	Platinum	11 substances 3 intermediates (2 non SCC, 1 SCC)	Sub: 10-100 Int: 100-1000	53	**Vale**, JM, Umicore, Heraeus
	Palladium	16 substances 5 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 (1 non SCC, 3 SCC)	10-100	29	**Heraeus**, Umicore, Vale

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

Diammine dichloropalladium

- "Fast track" testing approach
  - All testing to be completed in 2012
  - Draft testing plan ready
  - Tests that can be started now: already started (irritation, dustiness) or in process of being started (ecotox tests)
  - Other tests to start asap

Diammonium hexachloroPt and Pd

- Prepare 'all available information' dossiers by 2013 and update afterwards
  - Legal compliance ensured
  - Additional registration work for substance status (< 100 t/a) at a later stage via update

Scope – Karstedt Concentrate

- Background
  - Significant data gaps
  - Important product for silicones industry; will also register
- Cooperating with Reconsile consortium
  - General agreement to work together
  - Currently working out details of collaboration
    - Non-disclosure agreement signed on 17 Nov 2011
    - Letter of intent signed on 17 Oct 2011
    - Reconsile preparing Substance Identification Profile for review by PMC
    - WCA and Peter Fisk Associates to discuss science in preparation of dossier
    - Joint registration submission conditions (including Lead Registrant) to be agreed

Integrated Testing Strategy (ITS)

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, bioaccessibility, particle size, etc) - ***ongoing***
5. Updated ITS (full test recommendations) - **ongoing**

ITS

- Scope
  - Ambitious testing scope: 68 Substances x 35 Reach endpoints x n-Studies = many studies, complex discussions
- ITS reports and Enabling Tests
  - Main area of activities in past months
  - Detailed technical discussions
  - External peer reviewers where necessary (TK, genotoxicity, etc)
  - Tests delayed due to late arrival of test materials

Oxidising Properties

For reference or information only

- CRO: BAM, Berlin
- Test 6 sentinel substances
- Draft results received

Water Solubility

- Standard test (OECD 105): 8 substances
- Non- standard test: 10 substances
- TD test: 2 substances
- CRO: JMTC
- Tests delayed due to late arrival of test substances; target: Jan 2012

Bio-elution tests

For reference or information only

- CRO: CIMM, Chile
- Currently working on sample preparation (defined particle sizes needed)
- Contract signed, test to start in Q1 2012

Dustiness tests

For reference or information only

- To estimate potential for inhalation exposure
- Scope
  - Testing of first batch completed at DMT (9 substances) completed, reports available
  - Testing ongoing: 10 substances
  - No testing of chloroplatinates (3 substances)
- Next steps
  - Lung deposition modelling (MPPD) based on dustiness data
- Timing
  - 9 substances: MPPD modelling completed
  - 10 new substances
    - dustiness tests delayed due to late sample arrival
    - MPPD modelling by end Dec 2011

In-vitro irritation/corrosion testing

For reference or information only

- Testing strategy
  - In-vitro skin corrosion(EPISKIN) – if positive: stop
  - In-vitro eye irritation (ICE or BCOP) – if positive: stop
  - In-vivo eye irritation

- Skin corrosion data needed to decide on other tests
  - Eye irritation
  - Sensitisation
  - Acute toxicity
  - (Genotoxicity)

In-vitro irritation testing

For reference or information only

- Testing ongoing
  - CiToxLAB (EPISKIN/ ICE)
  - Harlan (EPISKIN/ BCOP)

Substance	In vitro skin (EPISKIN) test	In vitro eye (ICE) test	In vivo eye irritation test
Diammonium hexachlororuthenate (CAS 18746-63-9)	X	X	X
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium (CAS 25470-96-6)		-	-
Diammonium sodium hexakis(nitrito-N)rhodate (CAS 64164-17-6)	X	X	X
Diamminedichloropalladium (CAS 13782-33-7)	X	X	X
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)	X	-	X
Tetraammineplatinum dinitrate (CAS 20634-12-2)	X	X (BCOP)	X
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (CAS 68478-92-2)	(X)	(X)	(X)
Dihydrogen hexahydroxyplatinate (CAS 51850-20-5)	X		

Ecotox testing

For reference or information only

- Full testing for 6 substances
  - Algae, daphnia, fish, activated sludge
- Confirmatory testing for 2 substances (to confirm read across)

Genotoxicity

- Initial testing recommendations ready
- Expert assessment required on 2 issues
  - Impact of extreme pH on genotox study results
  - (Apparently) conflicting study results on Rh (III) substances
  - Currently consulting with independent genotoxicity expert (David Kirkland)

Sensitisation

For reference or information only

- Initial testing recommendations ready
- Final scope will depend on outcome irritation tests

Irritation

- In-vitro skin irritation tests ongoing
- Scope of other tests will depend on outcome EPISKIN tests

Acute and repeated dose toxicity

- Acute oral
  - Testing recommendations ready
- Acute inhalation/dermal
  - Depending on data from
    - Dustiness (is inhalation relevant at all?)
    - Bio-elution (is dermal/inhal. uptake possible at all?)
    - Irritation (no testing for irritants)
    - Practicalities (can stable testing atmosphere be created?)
- Repeated dose
  - Route of exposure/ dose selection, based on data from acute tests

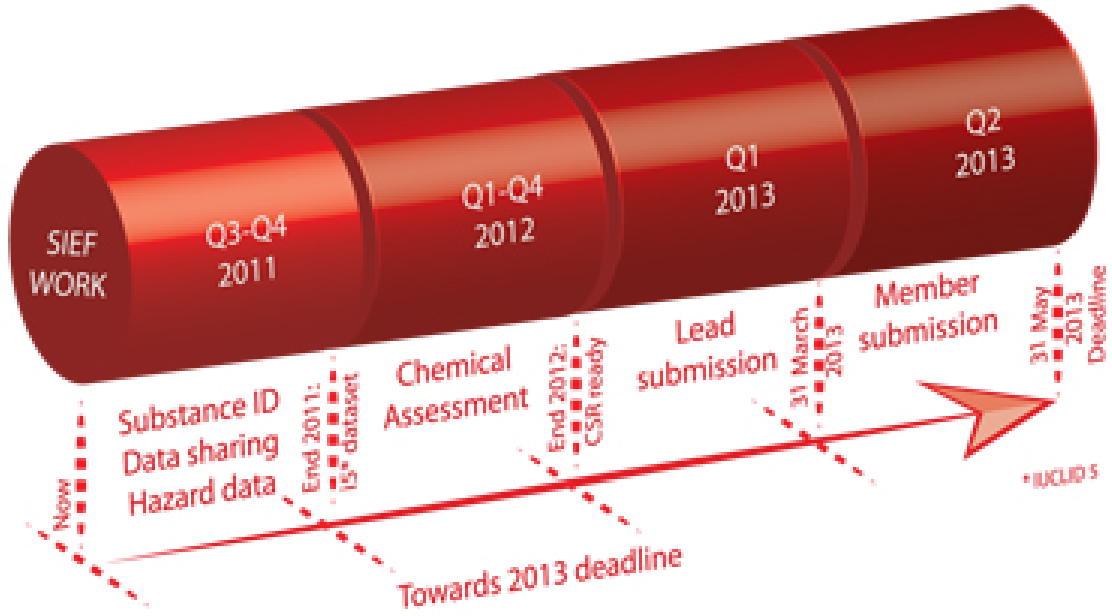
For reference or information only

Timeline

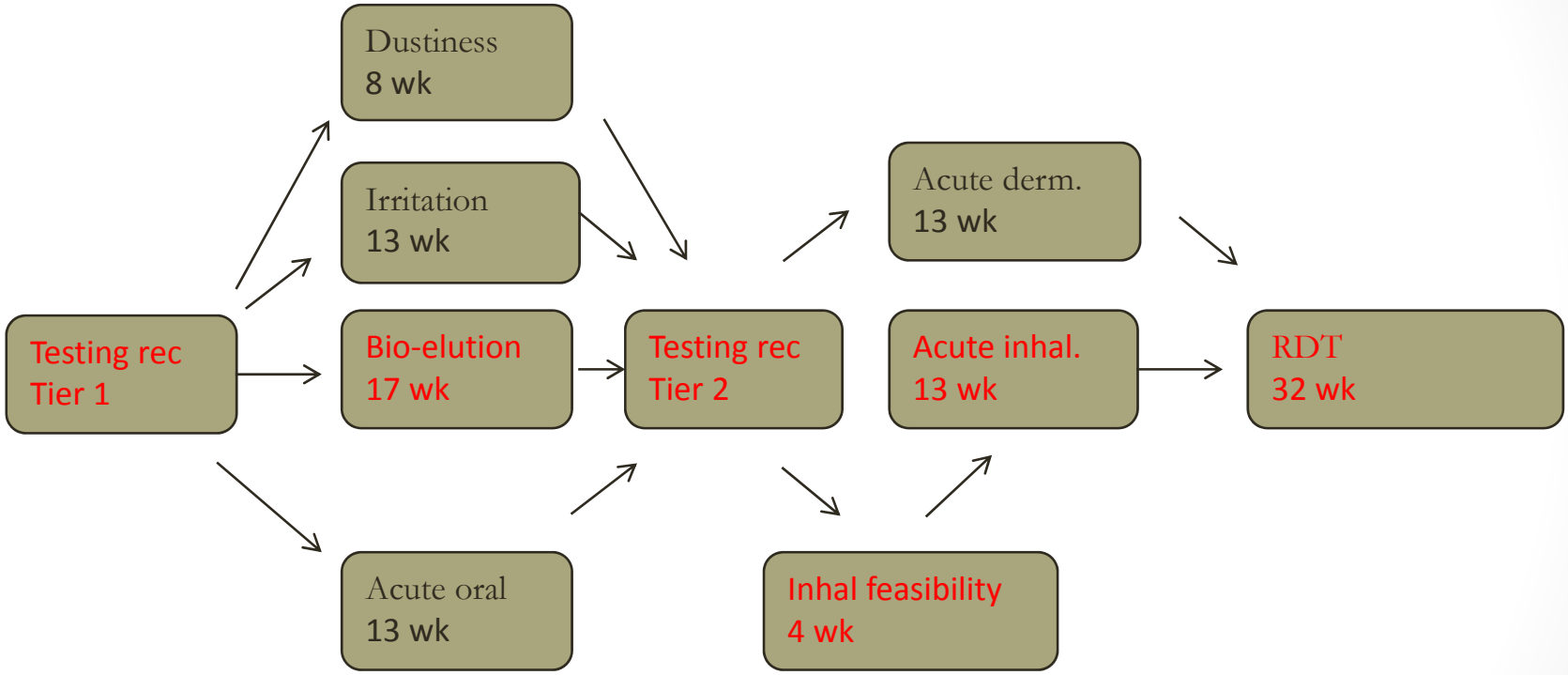
2012 Outlook

- ITS update
  - Update ITS with data from enabling tests
  - Agree on final testing scope
- Testing Programme
  - Complete fast-track testing programme
  - Start majority of testing programmes
- Exposure Scenarios & CSR
  - Time consuming exercise
  - Q1: Collect use/ exposure data
- Update CLP

Timeline for successful submission *(from ECHA website)*



Timeline "normal track" testing - Likely too long for 2013 deadline

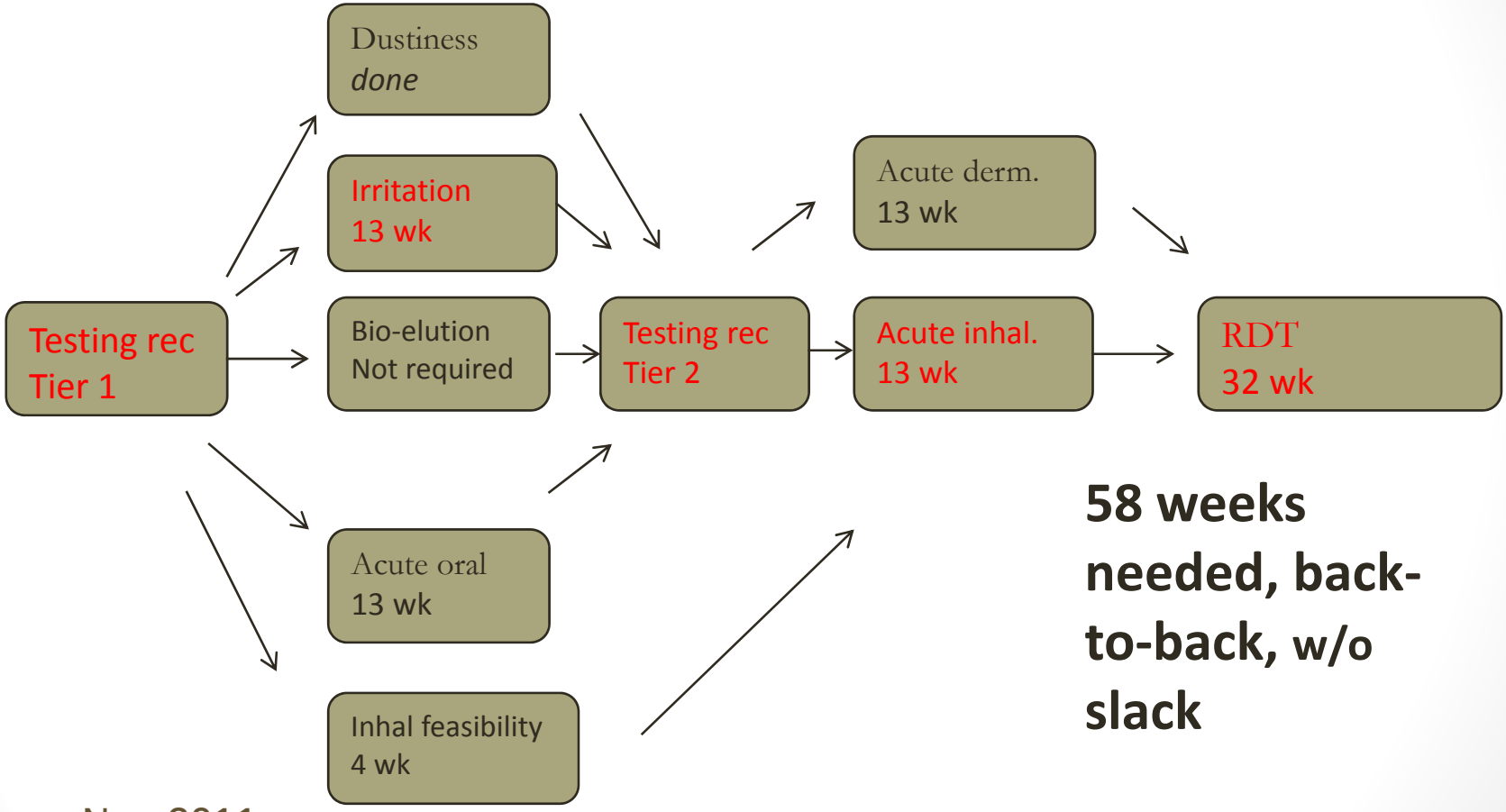


66 weeks needed, back-to-back, w/o slack

Nov 2011 — 2013 — CSR

Timeline fast-track - for 2013 deadline

Bottleneck: test substance availability



58 weeks needed, back-to-back, w/o slack

2.5. Re

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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 (in solution)	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
Non-SCC intermediate	**EC n°**	**CAS n°**	**Tonnage band**	**Deadline**	**LR**
Sodium rhenate (in aq. solution)	236-742-9	13472-33-8	1-10 t/a	2018	Climax Molybdenum
SCC intermediate	**EC n°**	**CAS n°**	**Tonnage band**	**Deadline**	**LR**
Potassium perrhenate	233-953-8	10466-65-6	1-10 t/a	2018	Heraeus
Dirhenium heptasulphide	234-882-5	12038-67-4	1-10 t/a	2018	Johnson Matthey

On-going work

- Physico-chemical properties:
  - Dustiness (K perrhenate)
  - Bio-elution (Rhenium)

- Toxicity:
  - Combined Repeated dose + reprotox study (APR): vehicle for administration subject to discussion, dose-range finding study paused till agreement is reached
  - Acute oral study (may need to be repeated with proper vehicle, depending results of above test)

- Next meeting: 6 Dec 2011, 4 pm CET

Project progress/timeline

I. Literature search & CLP → done

II. Data gap analysis & ITS → done

III. Testing programme
- Physico-chemical properties → finalised in Q4 2011
- Ecotox testing → finalised
- Tox testing → finalised in Q2-3 2012

IV. CSA/CSR
- Need for CSA/CSR to be considered based on results of repeat dose + reprotox study

V. IUCLID 5 filling → on-going



2.6. PM Refinables

Caroline Braibant

Scope

1. Doré
2. Matte, precious metal
3. Slags, precious metals refining
4. Slimes and sludges, precious metals refining
5. Leaching residues
6. Electrolytes
7. Flue dust, precious metals refining
8. Cements and residues, precious metals refining
9. Materials for reclaim
10. Pb bullion, PGM rich

SCC

- Following release of Dec 2010 ECHA Guidance on intermediates, need to re-evaluate whether or not PM Refinables are handled under SCC along their entire life-cycle

- SCC demonstration on the basis of:
  - RiCoG
  - Exposure assessment
  - On-going advocacy of Industry with ECHA

If SCC demonstrated → Dossier update

If SCC not demonstrated → Dossier upgrade

Dossier update

- Update/complete content of 2010 Dossier
  - Opportunity to correct, complete or improve general content where needed (e.g.: classification)
- Generate and upload Appendix 3 of ECHA Guidance to demonstrate SCC
- No additional registration fee

Dossier upgrade

- Can also be made if SCC demonstration is borderline or not accepted by certain local authorities
- Upgrade/adjust 2010 “light” intermediate dossier to a “full” intermediate dossier
  - Annexes VII-X of REACH
  - CSA/CSR (for use as intermediate, i.e. local assessment)
  - Also opportunity to correct, complete or improve general content where needed (e.g.: classification)
- Additional registration fee depending on tonnage band (from SCC to non-SCC intermediate)

On-going work

- Exposure and emission assessment (EBRC and WCA):
  - To support SCC determination
  - In preparation of possible upgrades
- Effects assessment (EBRC, WCA and ARCHE):
  - In preparation of possible upgrades
  - Based on read-across from individual constituents (similar to classification approach, calculated back to individual hazards, inspired from Cu slag file)
    - PM pilot case to be presented to ECHA as example
- Review of classification (ARCHE):
  - New information
  - 2nd ATP to CLP
  - Cluster analysis to obtain groups (and replace individual endpoints)
- Q&A and strategy papers – Project managed by Katrien Arijs, Project Manager (ARCHE)
- Last meeting: 5 Dec 2011

Next steps

1. Finalise RiCoG and Decisive DNEL tools (EBRC)
2. Apply RiCoG to determine RiCo and revert to PMC secretariat with results (PM Refinables WG)
3. Compare exposure and emission data with DNEL and PNEC to qualitatively justify SCC (EBRC and WCA)
4. Determine cases requiring updates from those requiring upgrades and prepare relevant strategy (PMC Secretariat)
5. Determine required budget and agree on cost-sharing formula (PM Refinables WG)
6. Prepare updates and upgrades without delay (All)

2.7. Hydrazine

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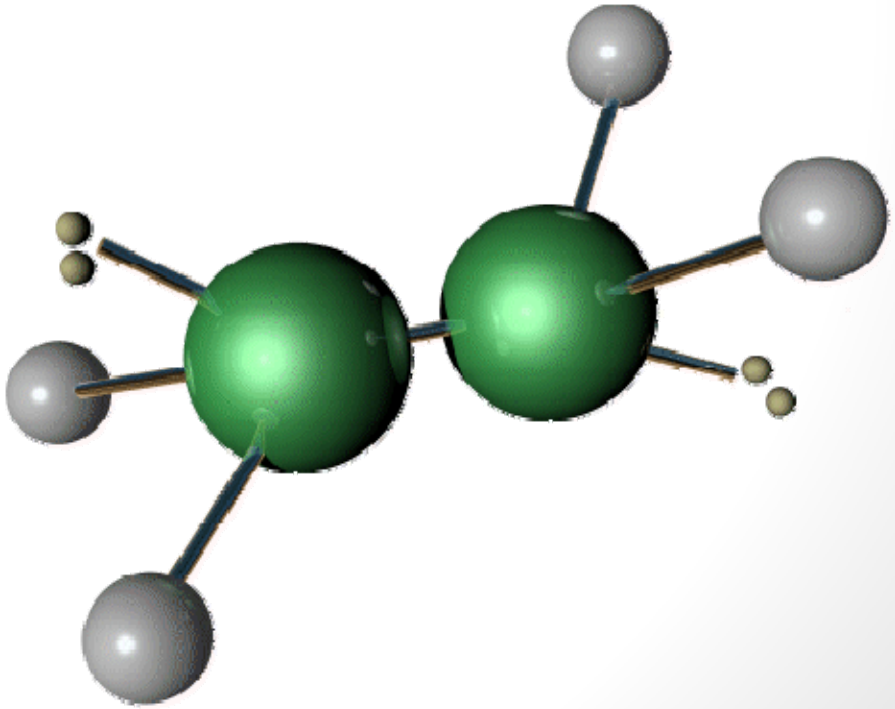

Background

- RPA contacted PMC among other, in order to collect information on the uses of and potential alternatives to Hydrazine and prepare Annex XV dossier
- Hydrazine put on Candidate List in May 2011
- Hydrazine Task Force formed under auspices of PMC following decision of Assembly in Jun 2011
- Hydrazine Task Force has met twice since Jun 2011:
  - Sep 2011: kick-off ftf mtg
  - Oct 2011: follow-up cc
  - Nov 2011: mtg with LR and technico-legal consultants

On-going work

- Uses in PM sector: collected, agreement on absence of alternatives
- Volume used in PM sector: collected, ~ 18-20 t/a
- Likely prioritisation: sufficient scoring for prioritisation
- Intermediate status: Q sent to ECHA Helpdesk, awaiting feed-back
- Lead Registrant's position: Supports use, ready to cooperate with Hydrazine Task Force, not sure whether it will lead authorisation dossier preparation for all uses

On-going work (cont.)

- Advocacy: Legal experts have recommended to advocate against prioritisation of hydrazine; chances of success believed to be very low

- Authorisation requests:
  - Preparation requires technical and REACH legal skills, three consultants interviewed, awaiting formal proposals (12-18 months work excluding any advocacy, ~ 150 000 €).
  - Once consultant selected, Hydrazine TF to decide how to proceed with authorisation request (joint/individual, grouping, etc.)

- Next conference call: Q1 2012

Project plan

- Phases
  1. Intermediate use/Exemption
  2. Companies/uses/scope of authorisation request(s)
  3. Prioritisation follow-up
  4. AoA and SEA
  5. Authorisation request submission and follow-up

- Human resources
  - HTF
  - LR/Suppliers
  - Technico-legal expert
  - Eurométaux

Timeline

- 2012 Prioritisation proposal + Consultation period
- 2013 Annex XIV inclusion
- 2015 Authorisation submissions
- 2017 Sunset Date (phase-out date)



3. PMC organisation

Caroline Braibant



3.1. PMC Management Committee and (Co-) Chairmanship

Nominations for chairmanship

- Difficult process
- Neville Plint (Anglo)
- MC decision for consideration by Assembly:
  - Chairman: Guy Ethier, Umicore
  - Co-Chairman: Mark Raffray, Johnson Matthey
  - Period: Dec 2011 – Dec 2013

Alternatives, Objections, Comments and Vote by the Assembly

N.B. Next PMC Mgmt Cttee nominations by Nov 2013

PMC Management Committee

Dec 2010 – Dec 2011

- Ron Davies (Ames Goldsmith, US) + Rob Garrett (UK)
- Guy Ethier (Umicore, Belgium)
- Gerhard Gutekunst (Wieland, Germany)*
- Marcus Hannakam (Heraeus, Germany)
- Mohamed Moukassi (SFPZ, Morocco)
- Neville Plint (Anglo, South Africa)
- Mark Raffray (Johnson Matthey, UK)
- Jacques Schaffnit (Metalor, France)

* G. Gutekunst retiring – thanks for all and enjoy!

PMC Management Committee

Dec 2011 – Dec 2013

- Ron Davies (Ames Goldsmith, US) + Rob Garrett (UK)
- Guy Ethier (Umicore, Belgium)
- Marcus Hannakam (Heraeus, Germany)
- Mohamed Moukassi (SFPZ, Morocco)
- Neville Plint (Anglo, South Africa)
- Mark Raffray (Johnson Matthey, UK)
- Jacques Schaffnit (Metalor, France)
- Heinz-Gunter Schenzel (Carl Hafner, Germany)*

* H.-G. Schenzel's addition approved by MC, subject to Assembly's vote – welcome!

3.2. WG chairpersons in place and opportunity to volunteer



Chairpersons in place

Group	Chairman	Co-Chairman
Ag	Rob Garrett (Ames Goldsmith, UK)	Hendrik Roth (Aurubis, Germany)
Au + PM CN-	Steven Verberckmoes (Umicore, Belgium)	-
PGM	Dave Boyd (Johnson Matthey, UK)	-
Refinables	Edwin Broekaert (Umicore, Belgium)	Daniela Cholakova (Aurubis, Belgium)
Re	Angela Alderman (Johson Matthey, UK)	Ken Kloska (Climax Molybdenum, US)
Hydrazine	Mark Raffray (Johnson Matthey, UK)	-
TAP	Mark Raffray (Johnson Matthey, UK)	-
LWG	Alain Palmers (Umicore, Belgium)	-
CWG	-	Wilfried Held (Fachvereinigung Edelmetalle, Germany)

3.3. Reminder on budget format and content, especially content of Generic costs



Generic costs include…

- ***Salaries and salary-related costs:*** Salaries, lunch vouchers, company car costs, social insurances, social charges, social secretariat costs, penalties for changes in personnel, etc.
- ***Office, travel and training costs:*** Office rental costs, shared charges, cleaning, furniture, printing, internet, fax and phone costs, postal and DHL costs, IT, travel and accommodation, external administrative/logistics support, withholding taxes, etc. – 90% PMC and 10% EPMF
- ***Committees, Work Groups and Assembly meeting costs:*** Meeting room rental costs, lunch, conference calls, etc. – 90% PMC and 10% EPMF
- ***External costs:***
  - Eurométaux membership fee: EPMF's membership fee to Eurométaux (non-REACH) – EPMF only
  - Eurométaux REACH package and other tools: PMC's share of Eurométaux' REACH metal-specific work package – PMC only
  - REACHsuite: PMC's access to REACHsuite (Baytouch) which is used for massive communication with SIEF as well as a database accessible to Consultants, PMC officers and Members – PMC only
  - Website and other communication costs – 50% EPMF and 50% PMC
  - Liability Insurance: Special insurance covering all PMC officers in the event of any loss of confidential information (except in the case of gross negligence or wilful misconduct) – 90% PMC and 10% EPMF
  - Legal support: *Ad hoc* costs to register the EPMF under Belgian Law and comply with legal requirements, to support PMC's secretariat before releasing position papers or publications, or in the event of legal challenges (e.g.: exclusion of a Member) – ad hoc
  - Accountancy and audits: Software, budget reviews, annual accounts, VAT declarations, audit support – 90% PMC and 10% EPMF
  - Financial costs: All bank costs resulting from currency changes, etc. – 90% PMC and 10% EPMF

Metal-specific costs include…

- IUCLID 5 Hosting System costs which allows IUCLID 5 files for each substance to be hosted in a centralised server accessible to all consultants, officers and registrants required to complete these
- Consultants' (evolving) budget predictions for each phase (including participation in various meetings)
- Peer reviewers' and additional consultants' time (utilised as needed on an *ad hoc* basis)
- Testing programme's potential costs
- Sample costs
- Cost to purchase data from external data-holders (to minimise testing duplication and build more solid weight of evidence approaches)
- 0-20% contingency to cover uncertainties/unexpected costs occurring on agreed projects

PMC

- Represents and defends the interests of 47 companies representing close to 200 Affiliates
- Covers more than 100 substances and intermediates distributed across 5 Registration projects and three registration deadlines (+ intermediary REACH processes: testing proposals, Evaluation, Authorisation, etc.)
- Works daily with at least six CRO (EBRC, WCA, ARCHE, BIBRA, CSIRO, Hydroqual, CIMM, ECTX, etc.) + two *ad hoc* experts (H. Waeterschoot, D. Kirkland)
  - Robustness, harmonisation, consistency, read-across and cross-project fertilisation maximised
- Does not limit its work to preparing Registration files:
  - Addresses *ad hoc* Members' needs and expectations: Au bars, registration workshops, CLP coordination, cost-sharing, sample provision, Hydrazine, etc.
  - Participates and builds into NFM REACH networking, knowledge-building and advocacy via Eurométaux
  - Participates and follows-up isolated developments which may influence REACH: Water EQS, Nanomaterials, etc.
  - Supports and channels SIEF communication



3.4. Illustration of impact of changes in Members' declarations in inventories and invoicing

Caroline Braibant

Consortium Agreement

For reference or information only

Members declare their registration intentions in Substance and tonnage band declaration:

- Substances
- Intermediates
- Tonnage band

Secretariat uses declaration to prepare inventories and invoices

Inventories

Base for:

- Consultant's work and budget predictions
- ITS building
- CSA/CSR needs prediction
- IUCLID 5 files filling

Invoicing

Proportionate allocation of predicted budget based on:

- Substances in each tonnage band
- Number of substances

Inventories

Example 1

Change in tonnage

- Decrease: if substance was reference substance for testing and read-across, this may change if the tonnage is lowered:
  - Need to check if it can remain reference substance
  - If not, need to identify another reference substance, review and update the ITS
- Increase:
  - May change registration deadline and need to fast-track testing programme et al.
  - May replace existing reference substance (cf. above)

Review of ITS require from 3 to 25 h consultancy work = ~ 450 – 3750 €/change
(+ relevant WG and PMC secretariat's time!)

Example 2

For reference or information only

Change in status

- From substance to non-SCC intermediate or vice-versa: ok (same information requirements)
- From substance to SCC intermediate: cf. Example 1
- From SCC intermediate to substance: cf. Example 1
- From SCC intermediate to non-SCC intermediate: increases information requirements, a non-SCC intermediate may become candidate for reference substance (cf. Example 1)
- From non-SCC intermediate to SCC intermediate: decreases information requirements, a SCC intermediate should ideally not be used as reference substance (cf. Example 1)

Inventories (cont.)

For reference or information only

Example 3

Addition of substance

- Substance or non-SCC intermediate:
  - Need to re-do literature search, data gap analysis, ITS
  - New substance may be suitable reference substance (cf. Example 1)
- SCC intermediate:
  - Need to re-do literature search and prepare additional IUCLID 5 file
  - 1 to 3 h consultancy work = 150 – 450 €/addition (+ relevant WG and PMC secretariat's time!)

Example 4

Removal of substance

- Substance or non-SCC intermediate:
  - Data gap analysis, ITS and IUCLID 5 work done for nothing
  - If reference substance cf. Example 1
- SCC intermediate:
  - Literature search and IUCLID 5 work done for nothing
  - 1 to 3 h consultancy work (150 – 450 €/removal) lost

Invoicing

For reference or information only

- Beyond impact on overall budget, the addition or removal of a substance/intermediate and an adjustment of its tonnage band also complicates invoicing

- Following examples assume total budget of 100 000 € and three Members, where one Member makes changes to its declaration – base case:

Member	S/I in 100-1000 t/a	S/I in 10-100 t/a	S/I in 1-10 t/a	Share (€)
1	2	1	1	65 909
2	0	2	0	19 772
3	0	0	2	14 318

Invoicing (cont.)

For reference or information only

Example 1

- Addition of a substance

Member	S/I in 100-1000 t/a	S/I in 10-100 t/a	S/I in 1-10 t/a	Share (€)	Difference (€)
1	2	1	1	62 400	- 3 508
2	0	2	0	18 253	- 1 518
3	0	0	3	19 345	+ 5 027

Example 2

- Removal of a substance

Member	S/I in 100-1000 t/a	S/I in 10-100 t/a	S/I in 1-10 t/a	Share (€)	Difference (€)
1	2	1	1	72 689	+ 6 779
2	0	1	0	11 064	- 8 708
3	0	0	2	16 246	+ 1 928

Invoicing (cont.)

For reference or information only

Example 3

- Increase in tonnage band

Member	S/I in 100-1000 t/a	S/I in 10-100 t/a	S/I in 1-10 t/a	Share (€)	Difference (€)
1	2	1	1	63 793	- 2 115
2	0	2	0	19 396	- 376
3	0	1	1	16 810	+ 2 492

Example 4

- Decrease in tonnage band

Member	S/I in 100-1000 t/a	S/I in 10-100 t/a	S/I in 1-10 t/a	Share (€)	Difference (€)
1	2	0	2	65 384	- 524
2	0	2	0	20 192	+ 419
3	0	0	2	14 423	+ 105



3.5. Simplified invoicing approched

Background

For reference or information only

- PMC Founding Members requested a fair, transparent and non-discriminatory cost-sharing formula
- Need to recognise balance between data and expertise provided by "big" Members and sharing of costs by "medium" and "smaller" Members
  - The more the merrier!
- Agreed to charge:
  - Per company (not per legal entity)
  - Secretariat/Generic costs equally to all Members
  - Technical project/Metal-specific costs:
    - 50% based on substances in each tonnage band (each tonnage band has its own weight)
    - 50% based on number of substances declared
- Intermediates assumed to require only existing available information → not considered in original cost-sharing formula

Change in 2008

For reference or information only

- Intermediates all assumed to be SCC
- However, there is more than expected in "*Any existing available information*" → data gathering and evaluation, classification, read-across, IUCLID 5 filling, etc.
- Intermediates added to calculation of metal-specific costs in a symbolic/light manner:
  - Weight of 1 in first half of calculation
  - No contribution to second half of calculation

Change in 2011

For reference or information only

- Intermediates no longer all SCC
- Need to distinguish “light” intermediate dossier requirements from “full” intermediate dossier requirements
- Agreed to weight non-SCC intermediates as substances :
  - Weight according to tonnage band in first half of metal-specific costs
  - Considered when calculating second half of metal-specific costs
- Above applied for simple intermediates only, not for Refinables (agreement on update vs. upgrade needs not yet final)

Can we expect other changes?

- Once update/upgrade clarified → probably need to adjust PMC cost-sharing formula to reflect change to Refinables project (in 2012?)

- Hence… let's take the opportunity to improve overall cost-sharing
  - From complex to simple
  - From transparent to more transparent

- You may wonder "*What is wrong with PMC's cost-sharing formula…?*"

For reference or information only

What is wrong with PMC's formula…?

For reference or information only

- Nothing in essence… In practice however, very complex!

  a) PMC only charges according to agreed budget
     - Budget changes every year, is shared among Members via two invoices per year, each invoice is different, each year's share is different…

  b) PMC calculates invoices on the basis of each Members' substance and tonnage band declaration
     - Members sometimes adjust their substance and tonnage band declarations (REACH remains unpredictable)
     - Changes in one Members' declaration triggers changes in Members' invoice as well as in all other invoices (proportion changes = invoice changes!)

- Altogether:
  - Difficult to predict invoices and company's budget for PMC
  - Complicated calculation corrections by PMC secretariat

What should be done?

For reference or information only

Forbid changes to the Members' declarations
(theoretically great but impossible in practice)

OR

Simplify application of cost-sharing formula

Proposed approach

1. Based on 2007-2011 invoices, calculate a typical cost per substance or SCC intermediate per:
   - Tonnage band
   - Project
   - Year

   (Similar to exercise done for LoA calculation)

2. Charge these to Members at the beginning of the year

3. At Jun PMC Plenary meeting check sufficiency of resources

4. At Dec PMC Assembly meeting check sufficiency of resources, reserves and use outcome to calculate cost per substance or intermediate per tonnage band and per project for following year

Approximate amounts

For reference or information only

2007 + 2008 (1)

	2007 Budget	s 1-10	s 10-100	s 100-1000
Ag	50.680,80 €	3.421,91 €	3.801,32 €	5.824,83 €
Au		1.993,71 €	2.447,55 €	
PM CN-				
PGM		618,26 €	1.306,27 €	
Re				
Refinables				
Generic costs	134.100,00 €			

Approximate amounts

For reference or information only

2008 (2)

	2008 Budget	s 1-10	s 10-100	s 100-1000	s > 1000
Ag	324.000,00 €	1.875,95 €	2.103,80 €	3.318,99 €	16.989,87 €
Au	80.000,00 €	1.126,37 €	2.197,80 €		
PM CN-					
PGM	300.000,00 €	1.264,28 €	2.720,45 €		
Re	36.550,00 €	2.547,96 €	5.253,14 €		
Refinables					
Generic costs	250.419,00 €				

Approximate amounts

For reference or information only

2009

	2009 Budget	s 1-10	s 10-100	s 100-1000	s > 1000
Ag	405.244,00 €	4.719,88 €	5.371,40 €	8.846,16 €	47.937,22 €
Au	112.810,00 €	2.984,39 €	5.670,34 €		
PM CN-	129.820,00 €	4.755,31 €	9.748,39 €		
PGM	543.900,00 €	2.303,44 €	4.952,39 €		
Re	201.450,00 €	11.596,63 €	24.608,95 €		
Refinables					
Generic	449.265,99 €				

Approximate amounts

For reference or information only

2010

	2010 Budget	s 1-10	s 10-100	s 100-1000	s > 1000	SCC i any tonnage
Ag	570.135,52 €	4.102,81 €	4.681,36 €	7.766,93 €	42.487,35 €	39,36 €
Au	343.601,74 €	6.102,86 €	11.777,00 €			384,02 €
PM CN-	135.733,03 €	2.779,06 €	5.697,08 €			
PGM	1.981.479,21 €	7.786,06 €	16.511,46 €			579,90 €
Re	179.994,59 €	4.989,41 €	10.084,91 €			449,79 €
Refinables	638.884,50 €					2.387,00 €
Generic	479.355,30 €					

Approximate amounts

For reference or information only

2011

	2011 Budget	s 1-10	s 10-100	s 100-1000	s > 1000	SCC i any tonnage
Ag	661.524,00 €	2.438,16 €	2.759,32 €	4.472,22 €	23.742,25 €	21,79 €
Au	111.188,00 €	2.694,50 €	5.159,48 €			170,11 €
PM CN-	109.166,00 €	4.288,67 €	8.967,22 €			0,00 €
PGM	766.980,00 €	3.160,65 €	6.679,85 €	2.228,00 €		232,81 €
Re	300.955,00 €	16.658,71 €	45.144,37 €			1.497,62 €
Refinables	792.480,00 €					9.123,87 €
Generic	457.833,00 €					

Average amounts

For reference or information only

Average 2007-2011

	Average Budget/y	s 1-10	s 10-100	s 100-1000	s > 1000	SCC i any tonnage
Ag	402.316,86 €	3.311,74 €	3.743,44 €	6.045,83 €	32.789,17 €	30,58 €
Au	161.899,93 €	2.980,37 €	5.450,43 €			277,07 €
PM CN-	124.906,34 €	3.941,01 €	8.137,56 €			
PGM	898.089,80 €	3.026,54 €	6.434,08 €	2.228,00 €		406,36 €
Re	179.737,40 €	8.948,18 €	21.272,84 €			973,71 €
Refinables	715.682,25 €					5.755,44 €
Generic	354.194,66 €					

Average amounts (cont.)

For reference or information only

Round figures 2007-2011
(proposed as base to invoice as from 2013;
test case to be presented at June Plenary meeting)

	Average Budget/y	s 1-10	s 10-100	s 100-1000	s > 1000	SCC i any tonnage
Ag	402.316,86 €	3400 €	3800 €	6100 €	33 000 €	50 €
Au	161.899,93 €	3000 €	5500 €			300 €
PM CN-	124.906,34 €	4000 €	8200 €			
PGM	898.089,80 €	3100 €	6500 €	2300 €		400 €
Re	179.737,40 €	9000 €	21500 €			1000 €
Refinables	715.682,25 €					6000 €
Generic	354.194,66 €					

How will it be applied?

- Rule of three using slide 23's figures:

$$\frac{\text{2007-2011 Average invoiced amount for a given tonnage band} * \text{Year X Budget}}{\text{2007-2011 Average Budget}}$$

- Example PGM compound in 10-100 t/a (using 2012 budget; slide 41):

$$\frac{6500\ € * 1.874.135,14\ €}{898.089,80\ €} = 13\ 564,21\ €$$

- Example Au compound in 1-10 t/a (using 2012 budget; slide 41):

$$\frac{3000\ € * 226.111,09\ €}{161.899,93\ €} = 4189,83\ €$$

- When budgets are presented for approval, the typical cost per substance in each tonnage band and project will be announced

Comments, questions and vote by the Assembly

- Simplified approach to be implemented as of 2013
- Follow-up of Reserves
- Difference between foreseen budget and incomes
- Other…?

3.6. Simplified approach for sample reimbursement



Current approach - complex

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1. Individual samples sent from sample providers to several Labs

2. Invoice for each sample for freight and insurance sent to PMC, PMC:
    1. Pays invoice, and
    2. Owes sample cost to sample provider

3. Each Lab:
    1. Uses (part of) sample for test, which can be either:
        1. Used and recovered – can be sent to a refinery for PM content recovery
        2. Spent and lost – charged by sample provider but impossible to recover part of the cost via PM content recovery
    2. Keeps part of sample archived for GLP
    3. Keeps remainder of sample for future test/for return to sample provider

4. Upon finalisation of test, samples can be:
    1. Fresh or unused – if not needed for future tests they can be sent back by each Lab to sample providers who charge PMC for the lost part
    2. Used and recovered – this portion is sent by each Lab to a refinery for PM content recovery, which is paid by the refinery to PMC which uses this money to reimburse sample providers for the lost part

Proposed solution - simpler

For reference or information only

1. Total sample sent from sample provider to one Lab

2. Invoice for freight, insurance, and sample cost sent to PMC, PMC pays full invoice

3. Lab:
    1. Responsible for storing and dispatching samples to other labs
    2. Uses (part of) sample for test, which can be either:
        1. Used and recovered – and sent to a refinery for PM content recovery
        2. Spent and lost – charged by sample provider but impossible to recover part of the cost via PM content recovery
    3. Keeps part of sample archived for GLP
    4. Keeps remainder of sample for future test/for return to sample provider

4. Upon finalisation of test, samples can be fresh/unused or used/recovered which will all be sent altogether by the Lab to refinery for PM content recovery, which is paid by the refinery to PMC which uses this money to reimburse sample providers for the total sample cost

Original versus new

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	Original approach	New solution
Number of sample requests	Sometimes up to 5 requests for the same sample	1 or 2 maximum
PMC Members invoices	In two parts: - Freight and insurance paid upon receipt of invoice - Lost sample after tests are finalised, samples have been collected and returned, Member has checked amount returned and issues an invoice to PMC	Once: freight, insurance and total sample reimbursed upon receipt of invoice
Mgmt of samples at Lab	Need to store and ship separately: - Fresh/unused - Used/recovered from test - GLP amount	Need to store GLP amount. Remainder can be kept together and sent to PM Refinery
Recovery of PM content	From used/recovered samples only, by selected refinery Amounts paid to PMC would used to pay “lost sample” invoices	From total samples, by selected refinery Amounts paid to PMC used to pay full sample invoices
Pros	Fresh and used samples not mixed and sent for recovery together	Simple, more transparent and straightforward
Cons	Complicated, not transparent and burdensome	Fresh and used samples could be mixed

To be considered…

Accountant viewpoint: supports simplified approach which would improve the Accountancy around sample reimbursement overall

Opinion of sample providers:

- OK to proceed with simplified approach
- Need to maximise efficiency of sample requests
  - Good prediction of required amounts
  - One request for all samples
  - Matrix record to facilitate tracking

Cost of sample versus income from refining of samples:

- When samples (whether fresh+used or used only) are sent to PM Refinery:
  - PM content/value is recovered (not PM compound/value)
  - PM content/value is paid to PMC (not PM compound/value)
  - Value of PM content recovered from refiner may not be equal to value of sample as originally manufactured and/or invoiced by sample provider
- In PMC metal-specific budgets (especially PGM), need to add contingency (paid by all PMC Members) for:
  - Difference between compound and PM value (cost difference)
  - Difference between actual sample cost and amount received following PM recovery (cost fluctuation)

Meanwhile contract with refiner is established, sample providers have been request to send their invoices for samples provided in 2010 and 2011



3.7. Internal LoA costs for reference

LoA

For reference or information only

- Allows legal entities not financing the registration preparation via their PMC membership to be part of the joint submission
- Agreement in place since 2010
- LoA costs based on:
  - 2007-2009 confirmed expenses
  - 2010-2020 expense predictions
  - 3% annual inflation rate
  - 20% contingency to cover for uncertainties
- PMC Members use LoA prices to benchmark PMC membership cost-benefit – PMC Members:
  - Can review REACH files before submission
  - Co-own data generated for REACH files
  - Can use REACH data for other purposes than REACH free of charge
  - Are reimbursed with LoA 'incomes'

2010 LoA prices

For reference or information only

Project / Dossier	Band	Exact amount	+ 20% contingency	Min	Max
Generic	N/A	31.743,77 €	38.092,53 €	32.000,00 €	38.500 €
Ag	Intermediate	98,52 €	118,23 €	100,00 €	125 €
	1-10	5.394,41 €	6.473,30 €	5.500,00 €	6.500 €
	10-100	6.872,28 €	8.246,73 €	7.000,00 €	8.500 €
	100-1000	14.754,22 €	17.705,06 €	15.000,00 €	18.000 €
	> 1000	103.426,03 €	124.111,24 €	103.500,00 €	124.500 €
Au	Intermediate	1.217,67 €	1.461,20 €	1.500,00 €	1.500 €
	1-10	18.944,33 €	22.733,20 €	19.000,00 €	23.000 €
	10-100	37.209,38 €	44.651,26 €	37.500,00 €	45.000 €
PM CN-	Intermediate	1.161,96 €	1.394,35 €	1.500,00 €	1.500 €
	1-10	16.425,86 €	19.711,03 €	16.500,00 €	20.000 €
	10-100	33.855,23 €	40.626,27 €	34.000,00 €	41.000 €
PGM	Intermediate	1.709,45 €	2.051,34 €	2.000,00 €	2.500 €
	1-10	22.929,52 €	27.515,42 €	23.000,00 €	30.000 €
	10-100	48.571,31 €	58.285,58 €	46.000,00 €	60.000 €
Re	Intermediate	1.264,29 €	1.517,15 €	1.500,00 €	2.000 €
	1-10	15.197,18 €	18.236,61 €	15.500,00 €	20.000 €
	10-100	34.161,56 €	40.993,87 €	34.500,00 €	41.000 €
Refinables	Intermediate	8.514,91 €	10.217,89 €	9.000,00 €	10.500 €

Delta predicted expenses May 2010 vs. confirmed expenses/refined predictions Oct 2011

For reference or information only

DETAIL OF BUDGET ITEMS	Delta 2010	Delta 2011	Delta 2012	Delta 2013	TOTAL deltas 2010-2013	Total deltas 2010-2013/project
1. REACH Generic costs	-92.854,70 €	135.838,72 €	117.469,82 €	-71.087,39 €	89.366,44 €	89.366,44 €
2. Ag	-49.626,48 €	-40.783,60 €	-117.980,00 €	171.359,52 €	-37.030,56 €	242.308,96 €
2.3. Ag Future costs				279.339,52 €	279.339,52 €	
3. Au	309.103,74 €	311.120,80 €	158.994,55 €	-38.216,60 €	741.002,48 €	741.002,48 €
3.2. Au Future costs						
4. PM CN-	111.790,03 €	93.881,93 €	-35.178,60 €	-44.016,60 €	126.476,77 €	126.476,77 €
4.2. PM CN- Future costs						
5. PGM	1.601.122,21 €	1.936.197,35 €	383.597,00 €	-235.574,52 €	3.685.342,03 €	3.685.342,03 €
5.2. PGM Future costs						
6. Re	103.632,59 €	122.392,80 €	45.241,40 €	-21.522,84 €	249.743,94 €	249.743,94 €
6.2. Re Future costs						
7. Refinables	372.509,50 €	-278.273,00 €	-1.002.980,00 €	62.706,45 €	-846.037,05 €	-780.350,60 €
7.2. Refinables Future costs			0,00 €	65.686,45 €	65.686,45 €	

Way forward

- All predictions made by May 2010 were sufficiently conservative/precautionary

- Another review must take place once further expenses are confirmed and the cost of the Ag Evaluation can be predicted (~ 280 000 € had been foreseen for future costs in original prediction)

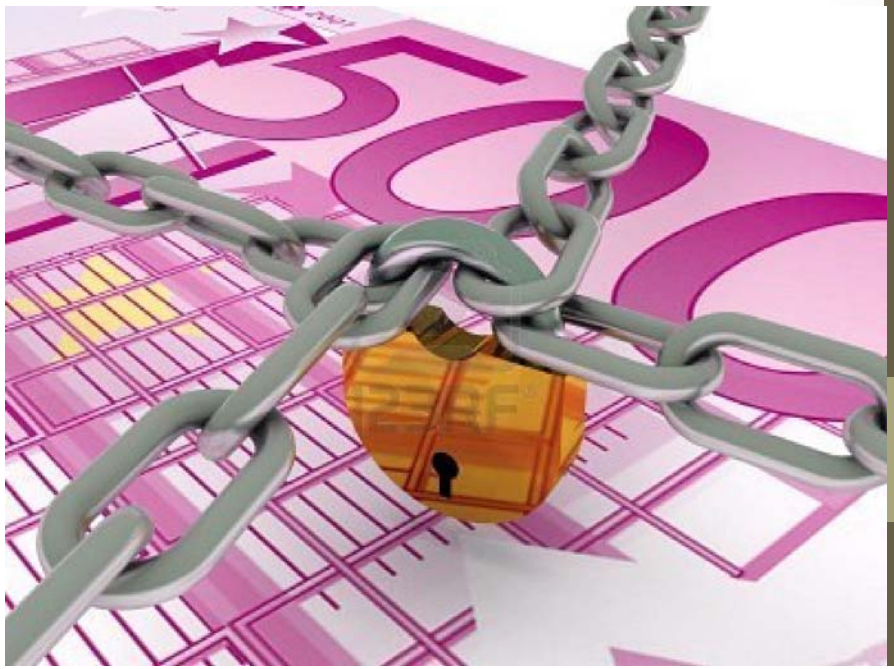
- Refinables is a special case, where it is difficult to predict LoA costs

→**Recommended by Management Committee:**

- Leave LoA May 2010 prices unchanged and review in Q3 2012
- Inform SIEF that:
  - Prices have been reviewed and seem correct except for Ag and Refinables which may be adjusted upwards
  - LoA will be sold as closely as possible before the applicable registration deadline

4. Expenses, reserves budget forecasts and invoicing

Caroline Braibant &
Audrey Rondepierre





4.1. Status of 2011 expenses

2011 Expenses

	Confirmed expenses by 26 Oct 2011 (10 months)	Best estimate of expenses for 2011 (extrapolated to 12-14* months)
Generic costs*	304.007,37 €	472.900,35 €
Ag-specific costs	138.373,57 €	215.247,78 €
Au-specific costs	42.269,40 €	65.752,40 €
PM CN- -specific costs	33.340,97 €	51.863,73 €
PGM-specific costs	194.946,42 €	303.249,99 €
Re-specific costs	49.374,88 €	76.805,37 €
Refinables-specific costs	190.448,79 €	296.253,67 €
Hydrazine	0,00 €	0,00 €

(*Based on 14 months Belgian regime)

4.2. Status of 2011 reserves



2011 Reserves

	Predicted expenses - confirmed expenses	Reported reserve by 26 Oct 2011	Probable reserve by Dec 2011 *(to be confirmed in Mar 2012)*
Generic costs	168.892,98 €	184.522,05 €	15.629,07 €
Ag-specific costs	76.874,21 €	662.158,23 €	585.284,02 €
Au-specific costs	23.483,00 €	472.009,38 €	448.526,38 €
PM CN- -specific costs	18.522,76 €	249.151,56 €	230.628,80 €
PGM-specific costs	108.303,57 €	2.483.628,05 €	2.375.324,48 €
Re-specific costs	27.430,49 €	449.028,96 €	421.598,47 €
Refinables-specific costs	105.804,88 €	656.342,79 €	550.537,91 €
Hydrazine	0,00 €	0,00 €	0,00 €

(Assuming all Members pay their 2011 membership)

4.3. 2012 Budget and 2012 invoices



2012 predicted budget

	2012 Budget
Generic costs	539.968,13 €
Ag-specific costs	117.980,00 €
Au-specific costs	226.111,09 €
PM CN- -specific costs	159.290,26 €
PGM-specific costs	1.874.135,14 €
Re-specific costs	60.942,13 €
Refinables-specific costs	1.002.980,00 €
Hydrazine	

Same as announced in Jun 2011 except for:
Ag: 10 000 € added for Dossier update costs
Re: 11 800 € added for additional testing monitoring costs

Payment holiday feasibility
Assuming 100% reserve

For reference or information only

	To be invoiced in 2012 *(assuming 100% reserve is deducted)*	**Likely payment holiday in 2012** *(100% reserve scenario)*	**Comment/Question** *(100% reserve scenario)*
Generic costs*	532.153,59 €	No	50% of the reserve kept in any case One or two invoices (~ 1x 11 000 € or 2x ~ 5500 €)?
Ag-specific costs	-467.304,02 €	Yes	(to be reviewed in Jun 2012)
Au-specific costs	-222.415,29 €	Yes	(to be reviewed in Jun 2012)
PM CN- -specific costs	-71.338,54 €	Yes	(to be reviewed in Jun 2012)
PGM-specific costs	-501.189,34 €	Yes	(to be reviewed in Jun 2012)
Re-specific costs	-360.656,34 €	Yes	(to be reviewed in Jun 2012)
Refinables-specific costs	452.442,09 €	?	(to be reviewed in Jun 2012)
Hydrazine		?	(to be reviewed in Jun 2012)

*For Generic costs 50% of the reserve is kept as a minimum

Payment holiday feasibility
Assuming 75% reserve

For reference or information only

	To be invoiced in 2012 *(75% reserve deducted)*	Likely payment holiday in 2012 *(75% reserve scenario)*	Comment/Question *(75% reserve scenario)*
Generic costs*	532.153,59 €	No	50% of the reserve kept in any case One or two invoices (~ 1x 11 000 € or 2x ~ 5500 €)?
Ag-specific costs	-320.983,02 €	Yes	(to be reviewed in Jun 2012)
Au-specific costs	-110.283,70 €	No	(to be reviewed in Jun 2012)
PM CN- -specific costs	-13.681,34 €	No	(to be reviewed in Jun 2012)
PGM-specific costs	92.641,78 €	No	(to be reviewed in Jun 2012)
Re-specific costs	-255.256,72 €	Yes	(to be reviewed in Jun 2012)
Refinables-specific costs	590.076,57 €	?	(to be reviewed in Jun 2012)
Hydrazine	0,00 €	?	(to be reviewed in Jun 2012)

*For Generic costs 50% of the reserve is kept as a minimum

Payment holiday feasibility
Assuming 50% reserve

	To be invoiced in 2012 *(50% reserve deducted)*	**Likely payment holiday in 2012** *(50% reserve scenario)*	**Comment/Question** *(50% reserve scenario)*
Generic costs	532.153,59 €	No	50% of the reserve kept in any case One or two invoices (~ 1x 11 000 € or 2x ~ 5500 €)?
Ag-specific costs	-174.662,01 €	Yes	(to be reviewed in Jun 2012)
Au-specific costs	1.847,90 €	No	(to be reviewed in Jun 2012)
PM CN- -specific costs	43.975,86 €	No	(to be reviewed in Jun 2012)
PGM-specific costs	686.472,90 €	No	(to be reviewed in Jun 2012)
Re-specific costs	-149.857,11 €	Yes	(to be reviewed in Jun 2012)
Refinables-specific costs	727.711,05 €	?	(to be reviewed in Jun 2012)
Hydrazine	0,00 €	?	(to be reviewed in Jun 2012)

Payment holiday feasibility
Assuming 25% reserve

For reference or information only

	To be invoiced in 2012 *(25% reserve deducted)*	**Likely payment holiday in 2012** *(25% reserve scenario)*	**Comment/Question** *(25% reserve scenario)*
Generic costs	532.153,59 €	No	50% of the reserve kept in any case One or two invoices (~ 1x 11 000 € or 2x ~ 5500 €)?
Ag-specific costs	-28.341,01 €	Yes	(to be reviewed in Jun 2012)
Au-specific costs	113.979,50 €	No	(to be reviewed in Jun 2012)
PM CN- -specific costs	101.633,06 €	No	(to be reviewed in Jun 2012)
PGM-specific costs	1.280.304,02 €	No	(to be reviewed in Jun 2012)
Re-specific costs	-44.457,49 €	Yes	(to be reviewed in Jun 2012)
Refinables-specific costs	865.345,52 €	?	(to be reviewed in Jun 2012)
Hydrazine	0,00 €	?	(to be reviewed in Jun 2012)

MC's recommendation

- Apply a 50% deduction scheme on the 2012 budget
- Invoice the total resulting amount in one invoice in spring 2012
- Review PMC's expenses and available reserves in mid-Q2 2012
- Explore whether or not a second 2012 invoice is required in Jun 2012 (Assembly meeting)
  - Especially Ag and PGM!

Result:

- Full payment holiday in 2012 for the Ag and Re projects
- Very small invoices for the Au and PM CN- projects
- 2012 invoice mainly composed of a typical share of Generic costs plus a reasonable share of PGM costs
- Refinables project? *Ad hoc* invoicing proposed

5. AOB, next meetings and closing remarks

Guy Ethier

Any other business?

Next meetings



- Next PMC Plenary Meeting: Antwerp, 14 June 2012
  - Hosted by Umicore
  - Key items already identified:
    - Ag Evaluation?
    - Hydrazine Authorisation?
    - Refinables: upgrades, budget and cost-sharing
- Next PMC Assembly Meeting: Brussels, 5 December 2012
  - Key items already identified:
    - Preparation of 2013 registration files

Thank you again Dr Gutekunst!

Welcome on board Dr Schenzel!

Thank you All!

Enjoy your winter holidays!

See you in Antwerp!

