Precious Metals & Rhenium Consortium

Assembly Meeting

Brussels, 3rd of December 2009
Copper & Aluminium Rooms
Metals Conference Centre
Rue du Duc 100, B-1150 Brussels



Agenda

1. Welcome and introduction
2. Status and progress of technical programmes
3. Preparation for Registration and classification notification
4. Resources and budget of the Consortium
5. AOB, next meeting and conclusion

1. Welcome and introduction



1. Welcome and introduction

- Safety indications
- Cell phones off please
- Confidentiality & Competition Law
- Quorum & decision-making in PMC
- Welcome to DuPont, our 46th Member!

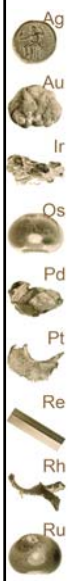


1.1 Membership request

Traxys Europe, based in Luxembourg

- Has submitted Appendix 1, 2 and closing page of Agreement duly completed on 27 November and fulfils conditions for membership
- Represented by:
  - Mr Marc Simon, Authorised Representative
  - Mrs Marie-Laure Ledrich (Luxcontrol - consultant), Environmental Toxicologist
- Interested in:
  - Au, PGM and Re projects

Assembly invited to vote on membership request



1.2 Membership PMC December 2009

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

1. Welcome and introduction (cont.)

- Approval of the Agenda

Assembly invited to comment or approve the Agenda for the day

- Approval of minutes of last meeting
  - No specific pending actions
  - Further progress to be presented today

Assembly invited to comment or approve the Minutes of 19 June 2009 Assembly meeting

2. Status and Progress of Technical Programmes



2.1 Achievements and major challenges



Mark Raffray, Johnson Matthey

Chairman Technical Advisory Panel

2.1.1 Context

- **2009 particularly challenging**
  - CB on maternity leave from Mar-Jun 2009
  - ZH faced very significant responsibilities after few months experience
  - Lost a key technical contributor: JL (Vale Inco) retired
  - Burden on Members' experts increased due to key milestone launch in several registration projects
  - TH and KR joined team in summer 2009: needed to familiarise themselves with PMC + assume increasing workload
- **Official registration deadlines trigger priorities in PMC**
  - Silver and refinables "first"
  - Other projects progress at a steady pace
- **PMC technical approach evolution (moving to new paradigm)**
  - PMC staff increase + acquiring expertise/greater independence
  - Project start-up (members were only experts!) → knowledge transfer
  - Less burden on Members; more on consultants/Sci Manager
  - Finite timeframe → only pragmatic solutions possible



2.1.2 Registration readiness

Ag:

- Tight on timing / technically complex, e.g. Ag environmental risk assessment
- But large volume of technical work progressing!
- Testing program essentially finalised
- Need to repeat a few tests due to inconclusive results…typical path in (eco)toxicology
- Two tests performed when they were actually not needed:
  - EBRC testing recommendation Feb 2009
    - Test for oxidising properties (Ag2O/AgNO3)
    - Test for skin corrosion (AgNO3)
    - No indications for existing C&L reported by EBRC
  - PMC decision to carry out test Apr 2009
    - TAP group review & approval of tests in Feb (mtg) & Mar (telcon) 2009
    - PMC commissioned tests in Apr 2009
  - Bottom Line
    - Consultant (EBRC), PMC staff and Members overlooked existing C&L background
    - Need to avoid any similar errors in future (see slide 2.1.3)
- Key steps will be CSA/CSR (including PNEC refinement) and PMC Members/SIEF consultation



2.1.2 Registration readiness (cont.)

Au & PM CN^-:

- Complexity remains manageable
- Projects have been impacted by some issues with consultants
- Proposal to change consultants & regain momentum
- Au Good Delivery bars issue resolved (joint paper preparation with banks)

PGM:

- Registration deadline not major issue, but complexity drivers – goals remain optimised ITS and cost limitation
- Enabling and first gap filling tests id'd: commence testing in Q1 2010 followed by fuller program



2.1.2 Registration readiness (cont.)

Re:

- Cadence of technical discussion/consultant tasking increased
- ITS extensively debated
- Preliminary tests on their way, full testing programme to scheduled for commencement Q2 2010

Refinables:

- Intermediates registrations: but technically complex
- Some are 2010 deadlines → Tight schedule !
- Doable if members contribute to task completion + we add external technical resource on this specific
- CRO selection for registration imminent (any testing will be defined and actioned)
- Tricky step will be IUCLID 5 compilation (more complex for UVCBs)



2.1.3 Lessons learned/proposed way forward

Better project management discipline	PMC project manager and tools for project management now in place – key issue previously
Transparency without undue delay in decision-making process	Decision-making tree available in handouts
Strengthen PMC staff	Additional (external) resource(s)
Selective peer review of consultant inputs	Some use of cross-checking externals + may reinforce TAP going forward
Depend on consultant as work-horses	Increased understanding of PM technicalities in our group of consultants Simple fact: members are in REACH overload
Try and use member expertise selectively	Concise/clear proposals sent to members – but retain influence/final decision power

Other suggestions / input always welcome!

2.1.4 Co-chairmanship of TAP

Sarah Hottenroth has significantly contributed to the work of the PMC during 2007-2009 as:

- TAP Co-Chairperson
- Au & PM CN- WG Chairperson

THANK YOU Sarah!

We will miss you!



Today, Umicore is required to replace Sarah:

Proposal: Guy Ethier (Umicore)

Assembly invited to vote on proposal



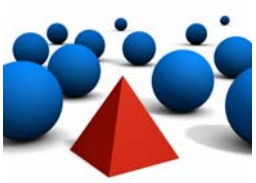
Any question?

2.2 Generic topics

Caroline Braibant, EPMF

Secretariat & Trustee

2.2.1 Substance identification and substance sameness



- Substance identification (ID Cards):
  - One per substance, includes:
    - Agreed name, synonyms and "same materials"
    - Basic composition profile
    - Basic physico-chemical properties
    - Overall REACH strategy
  - Prepared by PMC: staff, WG & TAP, consultants
  - Drafts circulated to Assembly for approval; then to pre-SIEF (no response = tacit consent) → pre-SIEF becomes SIEF
  - Aim: define "covered" profile → determines scope of Dossier + covered SIEF registrants

Assembly invited to comment or approve ID Card template (based on Ag example)

2.2.1 Substance identification and substance sameness (cont.)

- Substance sameness:
  - In determining profile, need to cover all forms that can be considered the same under REACH
  - Same = that can be described with the same dataset (starting from physico-chemical properties)
  - A distinction based on concentration/purity can only be considered in sameness approach if impurities impact more than classification & handling of material

2.2.1 Substance identification and substance sameness (cont.)

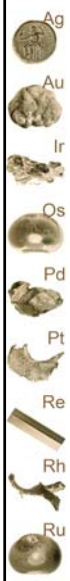
- Substance sameness (cont.):
  - Form:
    - Nanoforms generally present different physico-chemical properties
    - Dataset on nanoforms can show different results
    - Proposed: nanoforms to be considered different → to exclude them from ID Cards/Scope (see Ag ID Card example)

Assembly invited to comment or approve exclusion of nanoforms (based on Ag example)



2.2.1 Substance identification and substance sameness (cont.)

- Substance sameness (cont.):
  - Purity:
    - PMs and Re known as high value/standard materials
    - Commercially associated with highly pure grades
    - Under REACH, need to provide min/max concentration to enable comparison/substance sameness discussion (see Ag ID Card as an example)



2.2.1 Substance identification and substance sameness (cont.)

- Substance sameness (cont.):
  - Purity (cont.): Assembly invited to vote on preferred option (based on next slide and Ag ID Card example)
    - Two options/proposals:
      - A: Min at 80% (as per REACH mono-constituent substance definition)
      - B: Min at:
        - 99,5% for Au and Re (as per LBMA and MMTA standards);
        - 99,9% for Ag (as per LBMA standard); and
        - 99,95 for PGM (as per LPPM standards)



2.2.1 Substance identification and substance sameness (cont.)

- Substance sameness (cont.); Purity (cont.):

A: > 80%	B: > 99,5%, 99,9% and 99,95%
One IUCLID 5 file, one Dossier, one Registration fee, one Registration number	(At least) Two IUCLID 5 files, two dossiers, two Registration fees, two Registration numbers
Different grades, different classifications, different risk management measures, one substance	Different grades, different classifications, different risk management measures, (at least) two substances
Part of existing budget	Would require additional budget for additional dossiers
Advantages	
REACH compliant, simpler, cheaper	Commercial distinction between pure and impure forms
Disadvantages	
No commercial distinction between pure and impure forms through REACH – need other ways	Difficult to justify approach under REACH



2.2.1 Substance identification and substance sameness (cont.)

Next steps:

- Adjust and circulate PMC position/ID cards to Assembly for approval & then to SIEF
- Members shall be prepared to test their materials according to PMC's recommended techniques (tbc):
  - **Elemental analysis** → Provides purity, impurities and empirical formula (micro-analysis)
  - **Spectra – IR for solids; or Raman for liquids/solutions** → Provides substance profile
  - **Additional spectroscopy – XRD [optional]** → only applicable on very crystalline material (not known upfront)
  - **Additional scanning – XRF or ICP** → to confirm IR or Raman profile

2.2.2 Lead Registrants

LR for nomination:

- Silver metal: Aurubis (Germany), represented by Hendrik Roth
- Disilver oxide: Ames Goldsmith (UK), represented by Rob Garrett
- Silver nitrate: Ames Goldsmith (UK), represented by Rob Garrett



Assembly invited to elect Lead Registrants

2.2.2 Lead Registrants (cont.)

Nominated LR (Re project):

- Rhenium metal: KGHM Ecoren (Poland), represented by Ewa Zygnerska
- Perrhenic acid: Heraeus (Germany), represented by Jochen Schlessmann
- Ammonium perrhenate: Heraeus (Germany), represented by Jochen Schlessmann
- Sodium rhenate: Climax Molybdenum (The Netherlands), represented by Aad Van Meerkerk
- Dirhenium heptasulphide: Johnson Matthey (UK), represented by Angela Alderman



2.2.2 Lead Registrants (cont.)

- Nominated Lead Registrants:
  - Sent to SIEF as part of ID Card – two decisions in one go!
  - After approval: Need to be confirmed with ECHA
- Still many "orphans":
  - 5 in silver scope
  - 5 in gold scope
  - 4 in PM CN- scope
  - 56 in PGM scope

Please show Leadership, you will not be left alone!



2.2.2 Lead Registrants (cont.)

F.Y.I.

Article 4.7.2

LR's tasks listed in Consortium Agreement as follows:

- Submit the Registration Dossier to the ECHA
  - As approved by the concerned companies
  - Including confidentiality marks where needed
- Submit a copy of the Dossier to the Trustee, who will then send it to concerned companies
- Forward to Secretariat any communication received from ECHA (after submission)

Only one click, as any other joint registrant

One e-mail (unless IUCLID 5 Hosting System is used)

One forward to braibant@epmf.be

- **Registration dossier will be pre-populated by consultants and PMC staff**
- **Only company-specific information is entered by each registrant**
- **No difference between LR and other registrants**

2.2.2 Lead Registrants (cont.)

- LR's liability described in Consortium Agreement - minimum:
  - Same rights and obligations than other Members
  - Liability attributable to its wilful misconduct, fraud, and gross negligence
  - Liable to the Members with whom it is preparing and submitting a registration



Any question?

2.3 Silver

Klaus Rothenbacher, EPMF

In support of Ag Work Group



2.3.1 Co-chairmanship of Ag WG

Proposal: Hendrik Roth (Aurubis)

Assembly invited to vote on proposal

2.3.2 Scope of Ag project

Substance	Status	Tonnage Band	Registration deadline	CSA required?
Silver	s	> 1000	2010	Yes
Silver nitrate	s	100 - 1000	2010	Yes
Disilver oxide	s	10 - 100	2010	Yes
Silver carbonate	s	1 - 10	2018	No
Disilver sulphate	s	1 - 10	2018	No
Silver chloride	i	100 - 1000	2013	No
Silver bromide	i	10 - 100	2018	No
Disilver sulphide	i	1 - 10	2018	No

2.3.3 Current status of Ag project

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

✓ Completed phase



2.3.4 Progress of testing programme & data-gathering



2.3.4.i Principles of ITS:



- Consider all existing and available data
- Minimize number of tests needed
- If tests are needed, as cost effective as possible
- Read across where possible/appropriate
- Promote use of data in other regulatory assessment, e.g. EU Water Framework Directive, GHS/CLP, Seveso, etc.

2.3.4.ii Status on data-holders and data-sharing

Company	Type of Data	Status
Pokon & Chrysal B.V.	**Silver thiosulphate** 90-days/subchronic oral toxicity + a 2 generation study	▫ Confidentiality Agreement agreed ▫ Discussing logistics of access & evaluation
Field Fischer Waterhouse (FFW) (secretariat and involved with EU BPD Silver Task)	**Silver thiosulphate** 90-days/subchronic oral toxicity + a 2 generation study	▫ Data existence/availability confirmed ▫ Sharing agreed ▫ In progress
Kodak USA	Mesocosm **Silver thiosulphate** study:- 1) **Silver nitrate** LC50 (EC50 for daphnia) values for minnow, daphnid, snail and flatworm + microfiche (1978) 2) **Silver sulphide** acute aquatic effects on seven species (1989)	▫ Confidentiality Agreement signed, data received by WCA ▫ Awaiting WCA's evaluation (relevance, applicability, possible cost)
PMA (Photographic Manufacturers Association)	Archive dated 18 Feb 2008, containing published & unpublished literature on the Environmental Effects and Fate of Silver.	▫ Data received ▫ Brief overview of the content provided to Chairs of TAP and Ag
ILZRO (International Lead Zinc Research Organisation)	Unknown at this stage	▫ Member of the EU BPD Silver Task Force ▫ Following-up

Testing programme:
2.3.5.iii Environmental endpoints



2.3.5.iii Env: Testing programme

- Majority of data is on AgNO3
- Possible to read-across from AgNO3 to other Ag compounds
- Very few missing data → very few additional data likely to be needed (FELS, soil tox.)
- For Annex IX/X data, only testing proposal required
- Potential issue with aquatic toxicity → need to evolve emissions/exposure knowledge before concluding on testing needs (follows in presentation)



2.3.5.iv Physico-chemical and Human Health endpoints

Recap table circulated in advance of meeting



2.3.5.iv Oxidising properties and corrosivity

New tests indicate potential need to self-classify

Oxidising Properties

- First test: AgNO3 / Ag2O to be classified as "Ox. Solid Cat. **1**"
- But, AgNO3 already classified as "Ox. Solid Cat. **2**"

Skin Corrosion

- First test: AgNO3 to be classified as "Corrosive **1**"
  - Test result does not allow distinction between corrosive 1A/1B/1C
  - No option → Worst case Classification: "Corrosive 1A"
- But, AgNO3 already classified as "Corrosive **1B**"

Next Steps – Agreed at Hannover Meeting Sept. 2009

- Retrieve basis for original C&L of AgNO3
  - Original study not available
  - Umicore volunteered to contact Member State CAs
- Repeat test on oxidising properties
  - Agreed by Ag WG & TAP – if objection, please raise today
  - Currently discussing test protocol with CRO (BAM, Berlin)

Assembly invited to vote on proposal (repetition of oxidising properties test ~ 7000 €)



2.3.5.iv Sensitisation

- Initial test inconclusive:
  - "LLNA" test with AgSO4
  - Results confounded by irritating properties of test substance
  - Remains a data gap today
- Need to repeat test with different test design/substance
  - Currently discussing test design with EBRC
  - No adverse impact on overall timing (short test)
  - Additional cost of ~ 12500 €
  - Not an option, a must → no vote required

2.3.6 Preparation of ES, CSA and CSR

Proposed time frame and plan (awaiting consultants's confirmation):

Step	What?	When
1.	Questionnaire (Q) sent	Spring 2009
2.	Collection of responses to Q	Summer 2009
3.	Exposure Scenario (ES) with default values only	Oct 2009
4.	ES with responses from Q	Dec 2009
5.	Confirmation of covered uses	Dec 2009
6.	Additional data collection for incomplete Q	Dec '09-Jan '10
7.	ES with additional data	Feb 2010
8.	Circulation of final ES for approval	Spring 2010
9.	Upload of final ES in IUCLID 5	Summer 2010

Upcoming/decisive steps!
Please be ready to provide input

2.3.6.i Environment Part: Aquatic Toxicity

Background:

REACH requires to demonstrate safety:

- No-effect levels < exposure
- Predicted No Effect Concentrations < Predicted Environmental Concentrations
- PNEC < PEC

Otherwise: implement risk reduction measures, or cease activities!

Potential risk from Ag to aquatic env.:

Tentative aq. no-effect level Ag (PNECaq): ca 10,8 ng/l

- Nanograms!
- Ag aq. background levels already at ca. 10 ng/l
  - Potential risk already at background levels
  - Risk probably higher near emission point sources

→ Tentative PNECaq unworkable!

Issue Management:

Joint Projects with UK Environment Agency (Details on next slide)



2.3.6.i Env. Part: Joint Projects with UK EA

SITES SELECTED FROM PMC MEMBERSHIP – be ready to cooperate!

Priority	Option	Principle	Status
1	Refine exposure levels	- Measure actual env. levels (background, near point sources) - In absence of data, worst case models have to be used - Individual sites selected based on questionnaires	- Developed monitoring programme with UK EA - Start Jan 2010 - Interim report March 2010 - Results July 2010
2	Refine no-effect level	Reassess PNEC, SSD, focussing on key data sets	- Ongoing - Results in Dec 2009
3	BLM approach	Demonstrate Ag bioavailability is reduced by environmental factors (DOC, pH, hardness, $SO4^{2-}$, S^{2-}, Ca^{2+}, Mg^{2+}, Na^{+}, etc.)	- Pilot study completed - Data inconclusive - Requested peer review by independent experts (~ 5000 €)
4	Added risk approach	Background levels (from historic contamination) vs. "new" emissions	Depending on outcome of above options

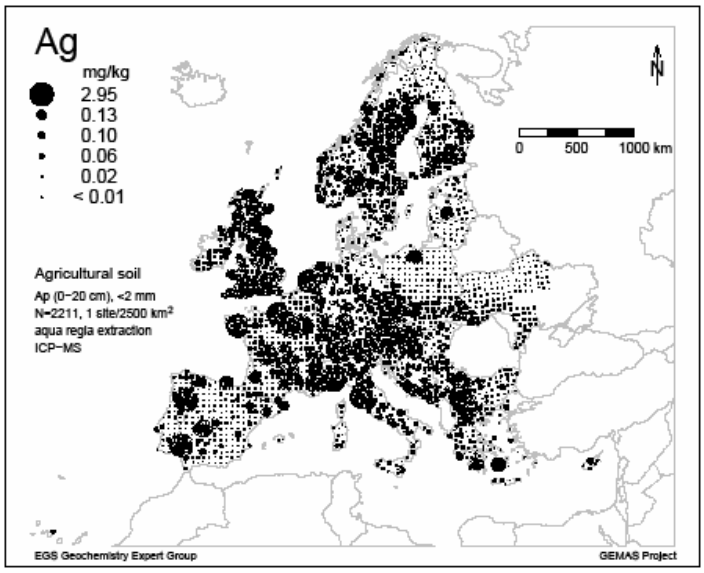


2.3.6.ii Update on GEMAS

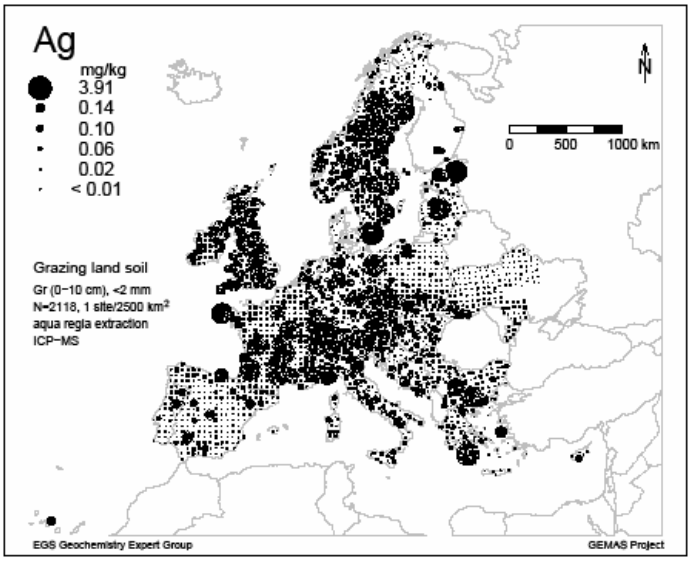
- Objective
  - Generation of harmonised EU soil database
  - Ca. 4500 samples
  - Harmonised sampling and analytical protocols
  - Support REACH soil evaluation of metals (and other reg. processes)

- Scope/Status
  - Ag levels in agr. soil and grassland
    - Done, 2 months ahead of schedule
    - Results circulated to TAP, Ag WG, available from PMC on request
  - PSD, CEC, TOC, pH
    - end 2009
  - Total C, total S, Kd
    - 2010
  - Publications
  - Kd might also useful for aquatic toxicity assessment

2.3.6.ii Update on GEMAS (cont.)



2.3.6.ii Update on GEMAS (cont.)



2.3.7 IUCLID 5 preparation

IUCLID 5 sections	Completed by
Section 1 General Information	PMC
Section 2 Classification Notification	EBRC
Section 3 Manufacture, Use & Exposure	PMC
Section 3.5 Identified Uses	EBRC + WCA
Section 4 Physical & Chemical Properties	EBRC
Section 5 Environmental Fate & Pathways	WCA
Section 6 Ecotoxicological Information	WCA
Section 7 Toxicological Information	EBRC
Section 8 Analytical Methods	EBRC + PMC
Generate final CSR	EBRC + WCA

PMC = PMC staff, LR and/or other Members with support of WG and TAP

2.3.8 Overall Silver project plan

Project plan available in handouts

Steady progress but no reserve time left!



Thank you!

Any question?



2.4 Gold and Precious Metal Cyanides



Tim Hird, EPMF

In support of Au and PM CN- Work Groups

2.4.1 Chairmanship of Au & PM CN- WG

THANK YOU (again) Sarah!
We will miss you!

Proposal: Guy Ethier (Umicore)

Assembly invited to vote on proposal

2.4.2.i Scope of Au Project

Substance	Status	Tonnage Band	Registration deadline	CSA required?
Gold	s	10-100	2018	Yes
Tetrachloroauric acid	s	10-100	2018	Yes
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	s	1-10	2018	No
Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	s	1-10	2018	No
Gold trihydroxide	i	1-10	2018	No

2.4.2.i Scope of Au Project (cont.)



Good Delivery gold bars

- PMC & LBMA industry sector position: GD Au bars are articles
  - should not be registered under REACH
  - tonnage should not be considered in Au registration
- Background/status:
  - Meeting with UK authorities to present case
  - Draft position paper produced by LBMA
  - Circulated for comments and adjusted by PMC
  - New draft available today

Thanks for submitting your comments!

- Next steps:
  - Last round of comments from LBMA & PMC (before mid Dec)
  - Finalisation by consultants & legal firm (end year)
  - To be used in a reactive manner upon request from authorities (as from 2010)

2.4.2.ii Scope of PM CN- Project



Substance	Status	Tonnage Band	Registration deadline	CSA required?
Potassium dicyanoargentate	s	10-100	2018	Yes
Silver cyanide	s	10-100	2018	Yes
Potassium dicyanoaurate	s	10-100	2018	Yes
Potassium tetrakis (cyano-C) aurate	s	1-10	2018	No

2.4.3 Change of consultancy

Context:

- Dr Knoell Consult (DKC) was selected as consultant for Au and PM CN- projects in 2008
- Outcomes of Phase I showed the need to frame cooperation according to Consortium's phases I – V and content
- DKC not supportive of changing its modus operandi
- Proposed: to find another consultant (supported by WG, TAP and Mgmt Cttee)



2.4.3 Change of consultancy (cont.)

Changing consultancy would mean:

- Placing the project in the hands of a consultant who is familiar / comfortable with PMC's working approach (e.g.: WCA – confirmed interest)
- Facilitating PMC staff coordination work and minimising Members' input to reasonably necessary
- Identifying other pragmatic options (knowing that most of quality consultants are busy with 2010 registration projects) and obtaining competitive quote from other consultants (cf. WCA proposal)
- Delay in Au project (~ 2 months, re-start in Jan 2010)
- Financial impact: contractual engagements with DKC (~ 20 000 € (?) + revision of DKC work by new consultant (?)

Assembly invited to vote on proposal







Any question?





2.5 Platinum Group Metals

Tim Hird, EPMF

In support of PGM Work Group





2.5.1 Scope of PGM project

Indicative list:

- **Pt:** 12 substances and 3 intermediates
- **Pd:** 16 substances and 4 intermediates
- **Ir:** 6 substances and 1 intermediate
- **Rh:** 14 substances and 4 intermediates
- **Ru:** 6 substances and 3 intermediates
- **TOTAL:** 54 substances (from which 20 > 10 t/a) and 15 intermediates

→Registration by 2013 (2 intermediates > 100 t/a) and 2018

Osmium is now out of scope



2.5.2 Status of PGM project

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

✓ Completed phase



2.5.3 Testing programme

Recap table circulated in advance of meeting

- **Tier 1 (agreed):** water solubility and transformation/dissolution tests
- **Tier 2 (on hold):** Other physico-chemical tests and ecotox tests (agreed in principle but awaiting results of tier 1)
- **Tier 3 (tbd):** Tox tests (in preparation, not shown in recap table)



2.5.4 Overall PGM project plan

Project plan available in handouts

Any question?





Caroline Braibant, EPMF

In support of Re Work Group



2.6.1 Scope Re project

Substance	Status	Tonnage Band	Registration deadline	CSA required?
Rhenium	s	1-10	2018	No
Perrhenic acid	s	1-10	2018	No
Ammonium perrhenate	s	10-100	2018	Yes
Sodium rhenate	i	1-10	2018	No
Dirhenium heptasulphide	i	1-10	2018	No



2.6.2 Status of Re project

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

✓ Completed phase



2.6.3 Testing programme

Recap table circulated in advance of meeting

- **Tier 1 (agreed):** UV visibles, water solubility and transformation/dissolution tests, and ecotox
- **Tier 2 (tbd):** Tox tests (in preparation)



2.6.4 Overall Re project plan

Project plan available in handouts



Thank You

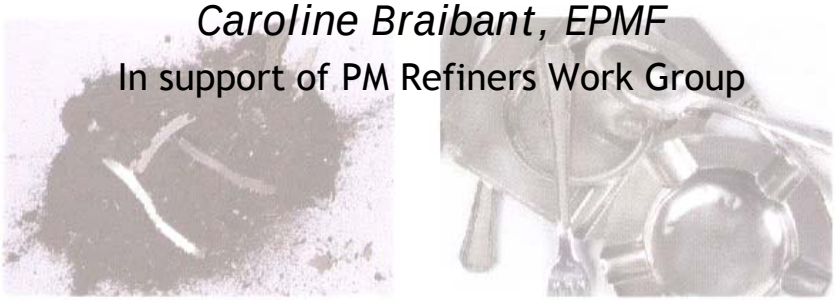
Any question?





2.7 Precious Metals Refinables

Caroline Braibant, EPMF
In support of PM Refiners Work Group





2.7.1 Scope Refinables Project

1. Doré
2. Matte, Precious metal refining
3. Slags, Precious metal refining
4. Slimes and sludges, Precious metal refining
5. Leaching residues:
    - *5.1. Residues, copper-iron-lead-nickel matte, sulfuric acid-insol.*
    - *5.2 Residues, copper speiss acid leaching*



2.7.1 Scope Refinables Project (cont.)

6. Spent electrolytes:
    - *6.1 Silver electrolyte*
    - *6.2 Gold electrolyte*
7. Flue dust, Precious metal refining
8. Residues, precious metal refining cementation and reduction
9. Reclaimed materials:
    - *9.1 Reclaimed materials, PMs with or without supports*
    - *9.2 Reclaimed materials, PMs in bricks, crucibles, trays, etc.*
    - *9.3 Reclaimed materials, PM production by-products*



2.7.2 Consultancy

- So far, work done in-house with support of Jeff Levison & Christian Canoo
- Status today:
  - 13 Confirmed groups – see handouts
  - One ID Card per group – circulated for approval
  - SIEF strategy defined for each group
  - Possible information and testing needs defined for each group
- Next steps to be supported by external consultant (quotations requested already)



2.7.3 Testing programme

- Difficulty in testing arises because of:
  - ? minimum/maximum number of samples
  - Selection of sample provider(s) (ideally at least Lead Registrant)
  - Sample preparation
  - Sample representativity: UVCB!
- Then: Interpreting results? Where to place them in IUCLID 5? (see next slide)
- Recommendation: keep testing programme and overall dataset pragmatic



2.7.4 Preparation of IUCLID 5 files



Background:

- **OSOR principle: One Substance, One Registration Dossier**
- **Refinables are UVCB**
  - UVCB = unknown or varying composition
  - Only typical composition ranges possible
- **UVCB are difficult to classify – lead by typical composition**
  - by addition of classification of individual constituents
  - What if not sure about constituents?
  - What if no classification available, e.g.: “minerals” and “alloys”?
- **UVCB are difficult to test**
  - How to select and prepare sample?
  - How to interprete/how to use the test results?

Work in progress:

Consortia working together to identify best way of reporting:

- varying composition, and
- associated (also varying) classification
- testing endpoints

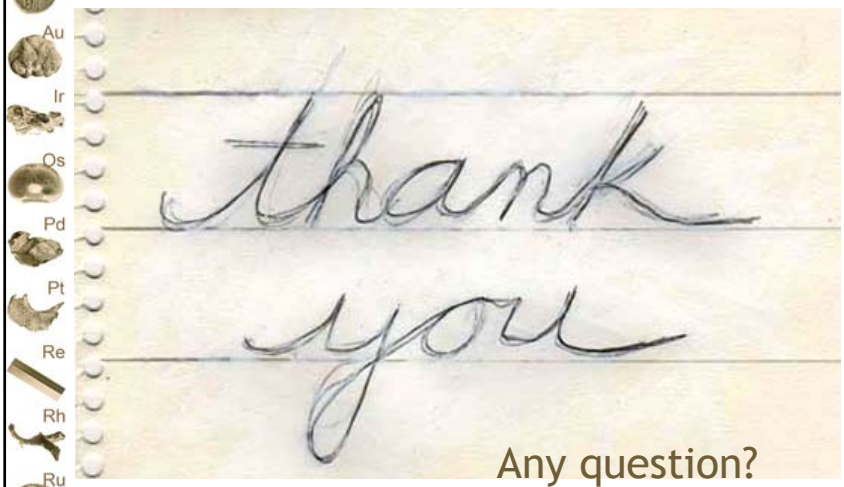
in IUCLID 5





2.7.5 Overall Refinables project plan

Project description available in handouts – to be refined once consultant is identified



Any question?



3. Preparation for Registration and classification notification

3.1 Communication with pre-SIEFs

- Communication through REACHsuite (RS):
  - Minimises e-mails back
  - Allows using surveys (populating feed-back)
  - Provides web-based page for each pre-SIEF
  - Maximises time & cost efficiency



- Communication in stepwise manner:
  1. Presentation Done
  2. Scope, substance sameness
  3. Lead Registrant
  4. Joint submission, Letter of access, etc.

See next slide

3.1 Communication with pre-SIEFs (cont.)

FYI.

I. ID Cards will be prepared (stepwise) by PMC and reviewed by WG & TAP:
   1. Refinables, Ag and Re
   2. PGM
   3. Au & PM CN-

II. Final ID Cards will be circulated to Assembly for approval

III. Approved ID Cards will be circulated to respective pre-SIEF (using RS survey forms) for SIEF formation:
   - Sameness confirmation
   - Appointment of Lead Registrant
   - Notification to ECHA

IV. SIEF formation will allow to launch joint submission preparation:
   - Identify confirmed potential registrants/deadlines (RS surveys)
   - Develop letter of access/licence to use (LoA/LtU)
   - Circulate LoA/LtU for signature/payment (RS tool)
   - Training & guidance for joint submissioners



3.2 Classification proposals

- Classification notification as per GHS/CLP Directive shall be submitted by December 2010
- Two situations arise:
  - Substances being registered in 2010: dataset produced for registration shall be used when producing classification
  - Substances subject to later registration: existing dataset with no additional testing shall be used to produce classification



3.2 Classification proposals (cont.)

- Preparation of classification is part of consultants' work:
  - Consultants to propose classification (earlier or later depending on existing dataset)
  - WG, TAP and Assembly to approve classification
  - Formal classification notification to be prepared by consultants
  - Classification notification to be sent to Members before deadline
- Submission of notification (IUCLID 5 section 2) and implementation at site level is PMC Members' responsibility:
  - Start preparing for changes in MSDS, etc.

3.3 Overall Consortium Plan

Available in handouts

3.4 Guidance and training



- As done for pre-registration, PMC aims at preparing guidance for Registration:
  - IUCLID 5 completion
  - REACH Dossier submission (for LR & non-LR)
  - Any other? (e.g.: GHS/CLP implementation)
- Guidance will be prepared for and in follow-up of training sessions:
  - In Brussels
  - Back-to-back with other technical meetings
  - Outsourced where needed
- Experience from other consortia is naturally welcomed! Please provide recommended contacts to PMC staff

3.5 LoA & LtU: underlying principles

- Consortium doors remain open but need to keep manageable number of Members → promote Letter of Access (LoA) & Licence to Use (LtU)
- LoA = right to have "name on joint dossier"
- LtU = right to use dossier data for other purposes
- LoA and LtU involve:
  - Conditions of access/use – legal terms
  - Cost – shall be transparent, fair and non-discriminatory
- Legal terms to be prepared with existing examples (CEFIC SIEF Agreement, Eurométaux, other consortia, etc.)
- Basic principles and hypothesis considered when defining cost (see next slide)

3.5 LoA & LtU: underlying principles (cont.)

Principles

- Letter of Access preferred (LtU on a case-by-case basis)
- PMC Members shall be reimbursed for their investment since 2007
- "Excess" shall be used to finance the permanence of PMC after all registrations have been submitted
- Cost charged per legal entity, per substance/intermediate and per tonnage band
- No co-ownership rights

Hypothesis/Options

- Cost of LoA should correspond to: 25, 50, 75 or 100% of PMC Members' contribution since 2007 (tbd)
- Cost of LoA should be calculated assuming 20% of pre-registrants will register (tbc)

Work in progress - CWG, LWG and Mgmt Cttee to meet and agree final LoA model & cost

PMC Assembly invited to share other experiences + comment proposed principles



3.6 Voluntary OECD-HPV Programme

Scope:

- Information resulting from hazard assessments (e.g.: REACH) of chemicals organics & inorganics

Main Benefits:

- Approved data sets are summarised in a SIAR (SIDS Initial Assessment Report)
- Worldwide reference for all OECD countries (ca. 30) and others which have signed the Mutual Acceptance of Data agreement
  - Data sets cannot be disputed but only complemented with new evidence
- Excellent platform for national/regional chemicals management initiatives
- Effect data source for standard setting and others
- Promotes adoption of some of the MERAG/HERAG effects and risk characterisation principles (e.g. T/D also used by PMC) at OECD level

Possible downside (to be clarified by PMC):

- Risk of PMC owned-data leakage
- Other? Understood to be work in progress, PMC to follow-up and report back



3.6 Voluntary OECD-HPV Programme (cont.)

Programme looking to establish:

- Harmonised standards for Mutual Acceptance of Data (TGs, GLP, compliance monitoring procedures)
- Tools and guidance for assessment
- Streamlined chemical management practices
- Co-operative , internationally agreed hazard assessments
- Dissemination of products and increased use beyond member countries

Supported/promoted by: Nickel Institute, Eurométaux and ICMM

EM inviting metals consortia to consider this proposal

Need for PMC Assembly approval for TAP to take this forward



Any question?

4. Resources and budget of the Consortium





4.1 2007-2009 Expenses of PMC

4.1 Expenses for 2009

Background:

- Consortium budget predictions based on:
  - Consultant predictions + “best guesstimates” + contingency
  - Idea to progress with all projects in parallel
  - Need to have monies available to avoid project delay due to invoicing time
- Different projects run with different scopes, different consultants, different costs → different budget predictions and different budget progresses

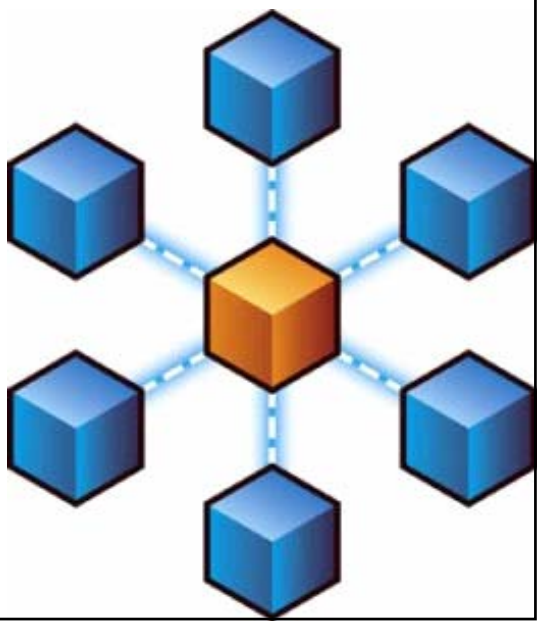
4.1 Expenses for 2009 (cont.)

Costs	Invoiced in 2007-2009 (€)	Spent over 2007-2009 (€)*	Reserve left (€)**
Generic	831.516,67	683.588,49	147.928,18
Ag-specific	729.244,00	288.735,07	440.508,93
Au-specific	192.810,00	10.982,82	181.827,18
PM CN- -specific	129.820,00	10.090,00	119.730,00
PGM-specific	843.900,00	208.175,56	635.724,44
Re-specific	238.000,00	24.054,15	213.945,85
TOTAL (€)	**2.965.290,67**	**1.225.626,09**	**1.739.664,58**

* Up until 13 October 2009

** Excluding 13 Oct – 31 Dec 2009 expenses

4.2 IUCLID 5 Hosting System



4.2 IUCLID 5 Hosting System

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

- Each substance requires its own technical dossier and therefore its own IUCLID 5 file
- Hosting system allows to give Lead Registrants (read-only) access to their IUCLID 5 files so they can follow the build of the file 'live' - *confidentiality*
- Other Consortia Members would have access via PMC
- Main advantage is that all data is held in one place/centralised (put in by the contractors)

- Allows consultants to work together more easily
- PMC can follow up and supervise the work done by the consultants
- Reduces the possibility of errors due to more efficient handling of files
- More secure than e-mailing IUCLID5 export files around (still some) - *time- and cost-efficient*
- Finalised copies can be stored in RS giving ease of access/traceability

4.2 IUCLID 5 Hosting System (cont.)

- PMC looked at offers by Penman Consulting and WCA
- Penman offer seems less competitive/flexible
- WCA is a bolt-on to their consultancy work
- One single/separate hosting instance (licence) per project
- 6 projects (Ag, PGMs, Re, Au, PMCNs & Refinables) = 6 instances
- Set-up cost (once) of 250 £
- Hosting cost (monthly) of 200 £

~ 3000 € per project or instance per year

Assembly invited to vote on proposed system

4.3 Resources of the Consortium



4.3 Resources of the Consortium

- Since Jul/Aug 2009 PMC workload shared across three full time officers:
  - Secretariat & Trustee
  - Scientific Manager
  - REACH Project Manager
- Job descriptions provide idea of tasks and responsibilities
- Three officers form team and as such, share workload according to experience and competence

4.3 Resources of the Consortium (cont.)

It is believed that:

- Members' experts on TAP and WG need to be relieved of "purely technical" level discussions and invited to contribute to strategical discussions only + regular general updates
- Progress should be driven by consultants and PMC staff with support from TAP, WG and MC when needed (testing strategy, additional needs, budget, etc.)

Therefore:

- Additional support needed (probably on a mission or *ad hoc* basis)

However:

- Cannot afford "learning" time: need for existing/known REACH metal experts (legal + (eco-)tox + practical/pragmatism)

Proposal:

- Work with *ad hoc* experts for isolated or specific missions or *ad hoc* needs (e.g.: Refinables, Exposure Scenario, etc.) + use CROs to an extent more than currently done

Assembly invited to comment and/or vote on proposal



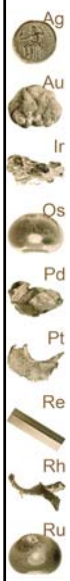
4.4 2010 Budget



4.4 Presentation and Approval of 2010 Budget

(2010 Budget predictions available in handouts)

- 2010 Generic costs:
  - Increased staff time
  - Decreased travel and meeting costs (pragmatic approaches instead: SIEF services through RS only, telcon, webinars, etc.)
  - Decreased RS cost as per contract with Baytouch
- 2010 Ag costs:
  - Additional testing/monitoring/peer review budget
  - Minimise "nanosilver" related activities
  - IUCLID 5 Hosting system
- 2010 Au and PM CN- costs:
  - Budget for Phase I completeness check by future consultant
  - Overall progress of Phases II-V
  - Cost of legal review of GD bars paper (for Au project only)
  - IUCLID 5 Hosting system



4.4 Presentation and Approval of 2010 Budget (cont.)

(2010 Budget predictions available in handouts)

- 2010 PGM costs:
  - Project phases III to V-related costs
  - IUCLID 5 Hosting system
- 2010 Re costs:
  - Project phases III to V-related costs
  - IUCLID 5 Hosting system
- 2010 Refinables costs:
  - No budget defined for this project yet
  - Agreed to charge cost of preparing IUCLID 5 files for each group of refinable to each (group of) potential registrants following cost-sharing:
    - Transported > 1000 t/a = weight of 5
    - Not transported > 1000 t/a = weight of 1 (equal share no matter tonnage band)
  - Once Consultancy has been selected, costs have been determined, and overall budget has been approved → *ad hoc* invoice sent in 2010



4.4 Presentation and Approval of 2010 Budget (cont).

What to do with the reserve monies?

- In 2007, reserve monies were not kept but reduced from Members' invoices for 2008
- In 2008, Members voted in favour of carrying over reserves available to PMC to 2009 in light of upcoming uncertain times (SIEF world) and economic situation
- Proposal for 2009 reserve presented in next slides – General idea:
  - Ligthen 2010 invoices
  - Allow for additional PMC staff resource



4.4 Presentation and Approval of 2010 Budget (cont.)

PMC proposal for 2007-2009 reserve monies

Costs	Reserve left (€)*	Proposed by PMC
Generic	147.928,18	Not increase 2010 generic costs and use reserve for additional PMC staff resource (missions/*ad hoc*)
Ag-specific	440.508,93	Need reserve to purchase data (partially sufficient): • Mesocosm study • 90 day study • 2 Generation study Cannot afford to lighten 2010 Ag budget
Au-specific	181.827,18	Lighten 2010 Au costs + use reserve for: • Cost impact of consultancy change • Cost for legal review of GD bars paper • Au-specific IUCLID 5 hosting system
PM CN- -specific	119.730,00	Lighten 2010 PM CN- costs + use reserve for: • Cost impact of consultancy change • PM CN- -specific IUCLID 5 hosting system

4.4 Presentation and Approval of 2010 Budget (cont.)

PMC proposal for 2007-2009 reserve monies (cont.)

Costs	Reserve left (€)*	Proposed by PMC
PGM-specific	635.724,44	Lighten 2010 PGM costs + use reserve for: • Upcoming testing programme • PGM-specific IUCLID 5 hosting system • Refinables project (until further defined, then reimbursed by concerned Members)
Re-specific	213.945,85	Lighten 2010 Re costs + use reserve for: • Upcoming testing programme • Re-specific IUCLID 5 hosting system
TOTAL (€)	1.739.664,58	Total to be invoiced in 2010 brought from 1.993.840,35 € to 1.093. 202,95 €

Assembly invited to propose alternatives and/or vote on the proposed budget

4.5 2010 Invoicing





4.5 Invoicing in 2010

- As per Consortium Agreement, two invoices sent per year (one in Winter and one in Summer)
- For practicality, PMC proposes to send one invoice per year, in Winter
- 2010 invoices would be finalised after closure of 2009 fiscal year by Accountant (end of Feb 2010)
- If needed, additional budget/invoices for 2010 can be presented, discussed and agreed at Plenary Meeting and *ad hoc* invoices can be sent in Summer accordingly

Assembly invited to vote on the proposed schedule



4.5 Invoicing in 2010 (cont.)

- 2010 invoices:
  - Estimated cost-shares available in handouts (company number available on request to PMC)
  - Estimates may slightly change based on confirmed reserve monies + corrections in Members' tonnages and n° of substances
- Reminder: "Simple" intermediates not considered in 2007-2010 invoices:
  - Cost will be calculated towards the end based on actual cost of preparing Dossier
  - Cost will be charged to interested companies only
  - Exact cost-sharing developed in tandem with LoA and LtU (same principle)



4.6 2011 (Budget) Predictions

4.6 (Budget) Predictions for 2011

To be presented at June Plenary Meeting:

- 2011 budget predictions
- LoA and LtU forms/method/success (RS)
- Remaining projects and predicted status of each
- Consortium Membership after 2010:
  - Rights and obligations
  - Permanence for ECHA & SIEF life
  - General cost-sharing

4.6.i Termination of the Consortium

Article 9.2. of PMC Agreement: Duration

"This Agreement […] shall remain in full force and effect until terminated by decision of the Assembly."

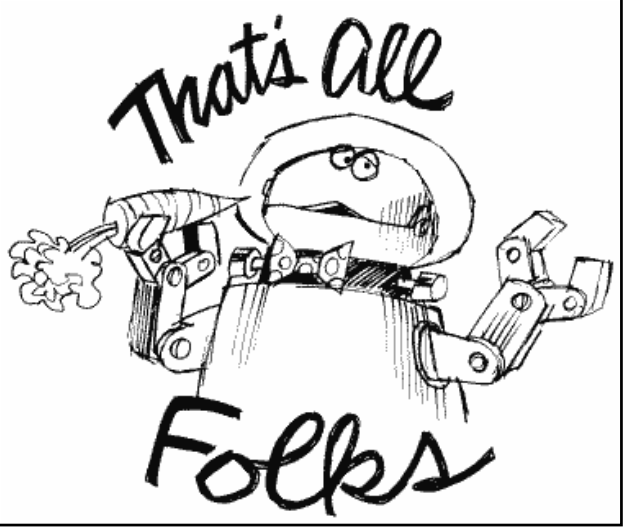
Article 4.1.2. of PMC Agreement: Role of the (Sub-)Assembly

"The (Sub-)Assembly shall take the necessary decisions related to the Consortium, its objectives and activities and shall in this regard, particularly, but not exclusively, come to a decision on: […] (m) proposal to end the Consortium and terminate this Consortium Agreement."

Article 4.1.6.1. of PMC Agreement: Adoption of decisions during Assembly meetings (Oral decisions)

"Any decision shall be taken by a majority of 50% (fifty percent) plus 1 (one) Member of the (Sub-)Assembly present or represented at the meeting, except for: (a) Decisions related to point […] (m) of Article 4.1.2 which shall be taken by a qualified majority of 2/3 (two-thirds) of the Members of present or represented at the meeting."

Any question?



5. AOB, Next Meetings and closing remarks

Any Other Business?



5.1 Next Meetings

Hamburg, 18 June 2010: Plenary Meeting

Brussels, 2 December 2010: Assembly Meeting

5.2 Closing remarks



Ag

Au

Ir

Os

Pd

Pt

Re

Rh

Ru

Enjoy your stay and see you next year!

Thank you!

