

Precious Metals and Rhenium Consortium
Assembly Meeting

Brussels, 3rd of December 2008
Hotel Métropole

- Ag
- Au
- Ir
- Os
- Pd
- Pt
- Re
- Rh
- Ru



Agenda
Chairperson: *Andrew Griffiths, Umicore*

1. Welcome and introduction
2. Membership
3. Clarification on legal terms
4. Status and progress of technical programmes
5. Consortium and SIEFs
6. 2009 Expenses and 2008 budget
7. Next Assembly meeting
8. AOB
9. Conclusion

Precious Metals and Rhenium Consortium

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1. Introduction

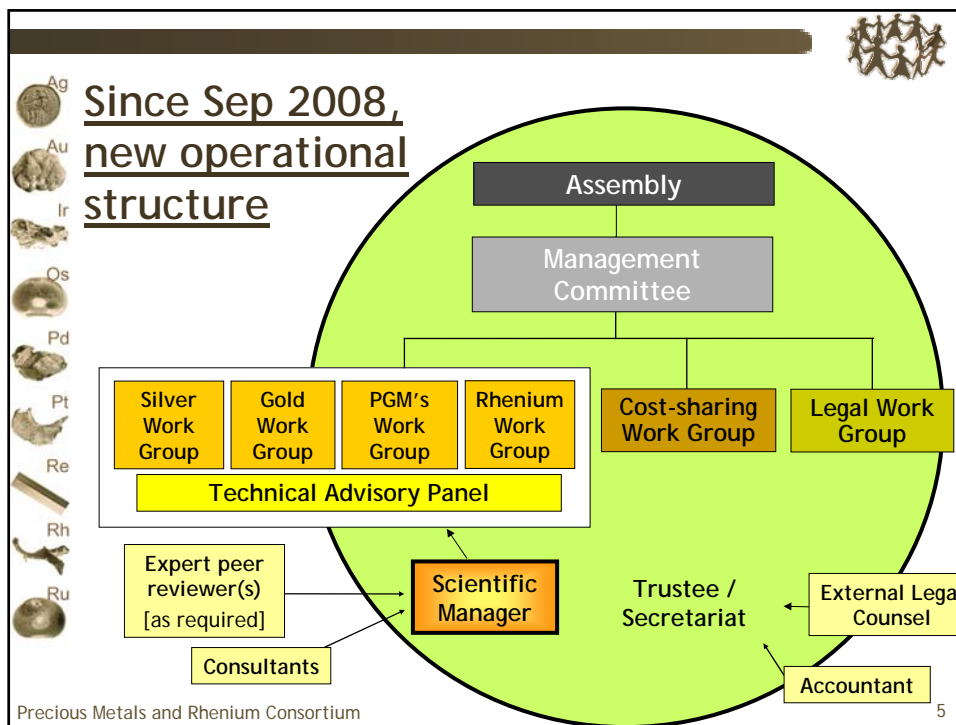
Andrew Griffiths, Umicore
Chairman of the Management
Committee



Objectives of today's meeting



- To update the Assembly of the Precious Metals and Rhenium Consortium on the progress and status of the Consortium.
 - Please fill-in questionnaire provided in handouts and return before lunch.
- To reach a common understanding on how to promote a cooperative exchange between the Consortium and the SIEFs and provide some guidance to the TAP.
- To approve the 2009 budget.



Scientific Manager: background

Zuzana HUGONIN

- Inorganic chemist...
 - *MSc. studies* - P.J. Safarik University, Slovakia
"One-dimensional tetracyanonickellates"
Target: copper-nickel tetracyanides
 - *PhD programme* - Stockholm University, Sweden
"Chemical scissors" - a shortcut to the low-dimensional world"
Target: antimony/antimony-copper oxo-halides
- Recent training:
 - *Post-graduate Certificate in REACH Management* - University of Hull, UK
Module 2 - Testing and Data analysis for Hazard Assessment
Module 3 - Exposure and Environmental Risk Assessment
 - *Applied Toxicology* - University of Surrey, UK
Principles of Experimental Toxicology and Risk Assessment

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Scientific Manager: role

100% dedicated to Consortium:

- **Neutral technical support** on technical discussions
- **Interface between Members and consultants** in charge of Consortium technical programmes

Typical tasks:

- Evaluation of the Silver project reports Phases IIa & IIb
- Evaluation of the Re & PGMs project reports Phase I
- Comparing ECHA's list of pre-registered substances with Consortium's indicative lists

Current/future actions:

- Compilation of **substance profiles** (with specifications provided by Members)
- **Follow-up on Member's data contributions/**feed-back on requests



2. Membership

*Caroline Braibant, EPME
Secretariat & Trustee*



2.1. Presentation of new members



| Company | Country | Representative | Welcomed on |
|----------------|-------------|----------------------|-------------|
| Valcambi | Switzerland | Mr Martin BLESS | 30 Sep 2008 |
| Chimet | Italy | Mr Giovanni PRELAZZI | 28 Nov 2008 |
| SAFT Batteries | France | Mrs Clémence SIRET | 29 Nov 2008 |



2.1.(Cont.) Members of the Precious Metals and Rhenium Consortium (November 2008)



- Agnico-Eagle
- Ames Goldsmith U.K.
- AMI DODUCO
- Anglo Platinum
- Argor-Heraeus
- Boliden
- Britannia Refined Metals
- Carl Hafner
- Cendres & Métaux
- Chimet
- Climax Molybdenum
- Commerzbank International
- Eurotungstene (Eramet)
- Handy Harman
- HCM
- Heimerle & Meule
- Johnson Matthey
- KCM 2000
- KGHM Ecoren
- KGHM Polska Miedz
- Lipmann Walton & Co.
- Lonmin
- Metalor Technologies
- Montanwerke Brixlegg
- Norddeutsche Affinerie
- Norilsk Nickel Finland Oy
- PAMP
- Pemco Euroinks
- PX Holding
- Recylex
- SAFIMET
- SAFT BATTERIES
- SEKOM
- SEMPASA Joyería Platería
- Société des Fonderies de Plomb de Zellidja
- Umicore
- Valcambi
- Vale Inco
- W.C. Heraeus
- Wieland Dental + Technik
- XStrata Nickel



2.2. Membership application

- Tanaka Kikinzoku Kogyo
 - Country: Japan
 - Representative: Mr Hitoshi Kosai
- Joining:
 - Au Sub-Assembly
 - PGM Sub-Assembly
- Membership application:
 - Received on: 19 November 2008 (complete)
 - TTK meets all the requirements for membership, in accordance with Article 3.2.1. of the Consortium Agreement.



Vote of the Assembly



2.2.(Cont.) (Potential) adjusted membership list

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



2.3. Commitment of the Members

Reminder!

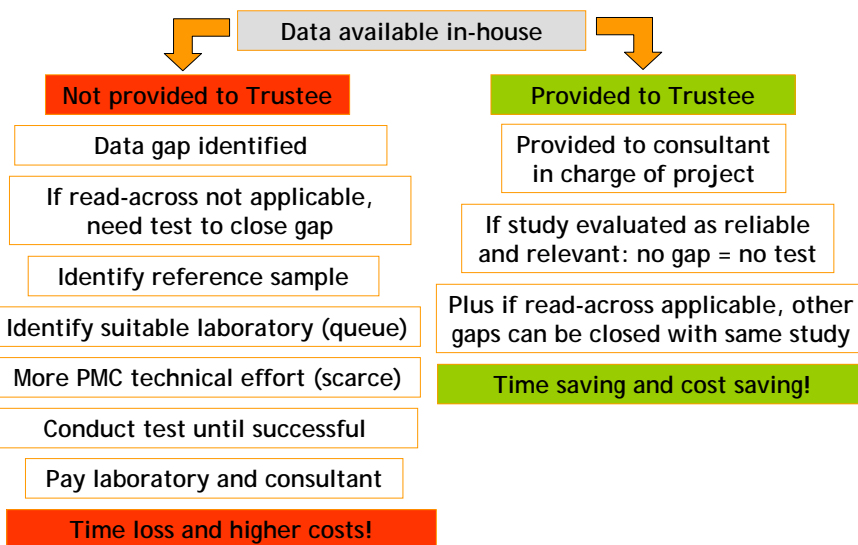
Article 3.2.2 of the Consortium Agreement:

To become a Member, an applicant shall sign the Agreement and shall therefore commit:

- to **respect** any and all terms and conditions set out in the Consortium Agreement;
- to **complete and submit the relevant declarations** (including but not necessarily limited to the Signature folio and the Substance and tonnage band declaration presented in Appendix 1 and Appendix 2, respectively) associated to the Consortium Agreement;
- to **share free of charge any and all Information and/or Study [...] which is(are) available in its domain and not generally available or known to be in the public domain, and relevant for the preparation of the Core Data [...]; and**
- to **pay [...]** its share of the costs as stated in Article 3.2.3.



2.3.1. To share any and all Information





2.3.1.(cont.) share any / all Information

Cost examples: "Simple" phys-chem or *in vitro* studies

- Standard water solubility test (OECD 105): cost 5200 € per substance & around 3 months to run and report study

| Using PGM project as example: | If forced to conduct on 15% of that substance group | If conducted on 50% of group |
|-------------------------------|---|------------------------------|
| | 62 000 € | 195 000 € |

- In reality we'll also rely on some literature values but cannot assume that these will always be fit for purpose
- Mutagenicity studies: even short-term *in vitro* studies beyond Ames level now typically 15-30 k€ per substance



2.3.1.(cont.) share any / all Information

Please DON'T assume that:

- Some of your data is low grade and not of value without first checking with PMC
- Because your data is for a substance not within the Indicative Lists it is therefore not of value **READ-ACROSS !**
- The larger companies must have a good spectrum of data especially for the more common substances [Remember REACH came in because of data gaps across all companies]

Please DO:

- Provide data NOW if not already actioned (see next slide)
- Or if in doubt, clarify with Secretariat / Sci Manager whether it is possibly of relevance
- Remove uncertainty – if you have nothing to contribute provide a 'nil response' i.e. confirm absence of data



2.3.2. Data requests made to date

- **Technical specifications** (physicochemical properties):

- Confirms sameness
- Helps estimate exposure potential:
 - Determine need for Chemical Safety Assessment → **cost and time estimations**
 - Potential for exposure-based waiving → **cost reduction**

Via spreadsheets, *ad hoc* requests, and through MSDS - still some information missing:
Mainly impurities (and IR or Raman spectra), particle size/granulometry (solids)

- **Known primary and secondary literature references:**

- Very useful to corroborate/complete consultant's literature searches:
- Thank you to Ames Goldsmith, Anglo Platinum, Carl Hafner, Cendres & Métaux, Climax Molybdenum, Johnson Matthey, Lipmann Walton, Metalor, PAMP, Umicore, etc.

- **In-house studies:**

- Contributions received from e.g.: Cendres & Métaux, Johnson Matthey, Heraeus, and Umicore

- **Upcoming requests:**

- Use/application information
- Emission data
- Exposure data



3. Clarification on legal terms

Alain Palmers, Umicore
Chairman Legal Work Group
&

Caroline Braibant, EPMF
Secretariat & Trustee

I'd like the steak with, near or adjacent to french fries, including but not limited to the mixed vegetables, accompanied by, concurrent with and at the same time as a beer.



Content

- One reminder:
Three addenda approved by the Assembly - Toledo, 20 June 2008 Plenary Meeting
- Two clarifications:
 1. Article 3.4 - Change in Representative
 2. Article 3.2.2 - Commitment of "big tonnage" registrants



3.1. Addendum of Consortium Agreement

Three addenda approved by the Assembly
(Toledo, 20 June 2008 Plenary Meeting)

Reminder:

- **Clause 1:** (Co-)Chairperson Management Committee shall be entitled to make **emergency decisions** without requiring the prior approval of the Management Committee or the (Sub-)Assembly;
- **Clause 2:** In the event a Member provides the Consortium with a sample in order to be used in any of the tests, this Member shall be **reimbursed for the cost of the sample**;
- **Clause 3:** In the event a substance and tonnage band declaration is updated by a Member, the past shares of such Member shall be re-calculated according to the cost-sharing formula so the **Member can reimburse** the Consortium accordingly.

Above addenda are "interim" part of the Consortium Agreement



3.2. Application of article 3.4.1.2.

- Members are invited to inform the Secretariat on any change in the information they have originally detailed in the Signature folio (Appendix 1);
- Article 3.4 (“Transfer of Membership”) does not apply to cases where a Member updates its Signature folio so that another company becomes the official representative of this Member (and its Affiliates) at Consortium level
 - **This is not a “transfer of membership” (but a change in Member’s internal organisation) and does not require an Assembly vote.**



3.3. Big tonnages

- REACH knowledge and interpretation is constantly evolving → some companies intend to **pre-register as a precaution, based on estimated tonnage bands.**
- These companies may later decide not to continue with registration (at all or in the estimated tonnage band).
- In the event (i) a company wishes to join the Consortium, or (ii) a Member changes its declaration, for a substance in a higher tonnage band than covered in the Consortium’s indicative list, **this company or Member shall commit to pay for any project work engaged as a consequence of such higher tonnage band.**



3.4. "Full" Consortium Agreement

- "Full" Consortium Agreement is composed of:
 - Consortium Agreement dated 6th May 2008
 - Excel tables (1, 2 and 3) for completion of Appendix 2
 - Addendum
 - Clarification on Article 3.4 (cf. letter dd 1 Sep 2008)
 - Letter to big tonnages (cf. letter dd 23 Oct 2008)



4. Status and progress of technical programmes



4.1. Report of TAP

Mark Raffray, Johnson Matthey
Chairman Technical Advisory Panel



4.1. What technical resource has been committed ?

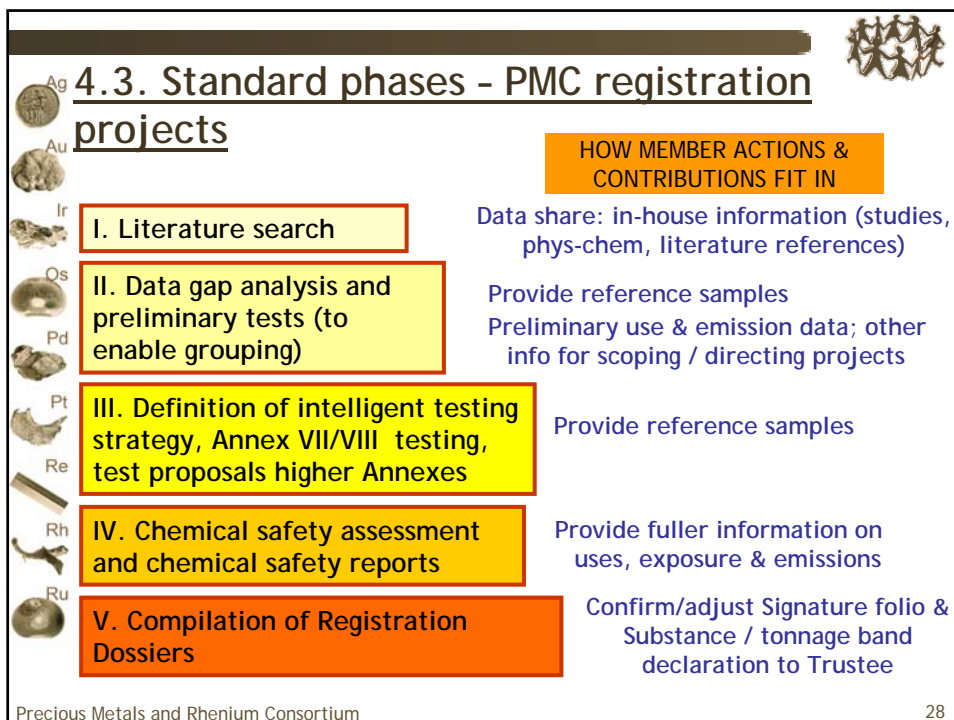
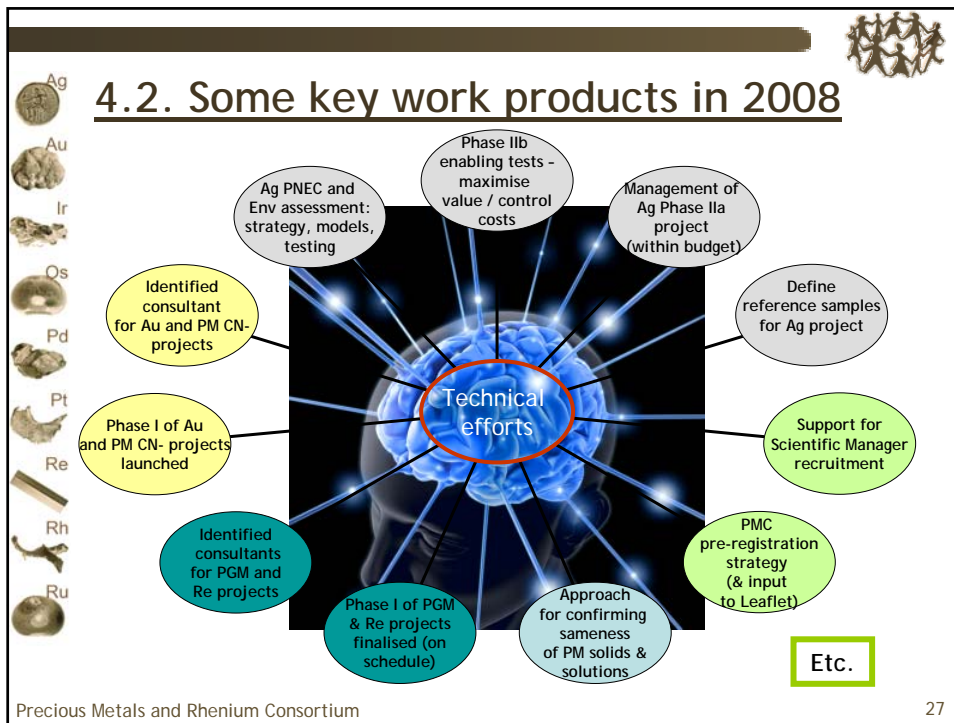
2008: 5 person-months total on main technical efforts alone...

- 13 TAP meetings
 - 6 teleconferences (~ 40 person-hours)
 - 7 face-to-face... Belgium, Germany, Spain and UK (> 175 person-hours, not including travel)
- 4 joint meetings with WG's (Belgium)
 - Always at least 15 participants (> 300 hours)
- Plus 'off-line' assessments, report reviews, consultant dialogue etc.
 - Estimated in excess of 250 hours

Time & commitment of TAP team & Secretariat/Sci Manager - thank you all !!

• Flavour of some 2008 TAP themes & deliverables

1. Identification of suitable consultants, technical project management, review and interpretation of consultant proposals and reports
2. Testing paths: reference sample designation, harmonised methods
3. Preliminary substance sameness evaluations
4. Technical specification work & the 'shape' of PMC existing data
5. Pre-registration preparation and steering ... including on refinables





4.4. Overview of project timelines

| Project/ timeline | 2007 / 2008 | 2009 | | | | 2010 | | | | 2011 onwards | Current status |
|----------------------|----------------|------|-----|-----|----|------|----|----|----------------------|---|---|
| | | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | | |
| Ag | I + II | II | III | | IV | | V | | Higher Annex testing | No reserve time left | |
| Au | I | II | | III | | IV | | V | | Higher Annex testing ⚡ Buffer zone for any project over-runs | On track. (Registration deadline >2010) |
| PM CN- | I | II | | III | | IV | | V | | | On track. (Registration deadline >2010) |
| PGM | I | II | | III | | IV | | V | | | On track. (Registration deadline >2010) |
| Re | I | II | | III | | IV | | V | | | On track. (Registration deadline >2010) |

⚡ If SIEF adjustments become necessary (e.g. tonnages increase > 100 tpa)



4.5. Next priorities and challenges

Ag

- ▶ Complex environmental assessments in the context of growing regulatory scrutiny on Ag environmental effects (including nano Ag)
- ▶ High tonnage substance - need to **finalise** optimal Intelligent Testing Strategy for human health endpoints, whilst avoiding excessive cost

Au

- ▶ The bank gold product issue (more on that later)

PM cyanides

- ▶ Arriving at a definitive technical position: is simple consideration of CN-ion effects key, or an adapted situation ?

PGM

- ▶ 75+ substances: fundamental that grouping & read-across is as optimised and defensible as possible. If not, test costs rapidly escalate !!
- ▶ We picked contractors specifically strong in this regard: 2009 will be key milestone for their project delivery



All projects: Impact of SIEFs → new substances / higher tonnages?



4.6. Introduction to next presentations on PMs/Re & PMC operation

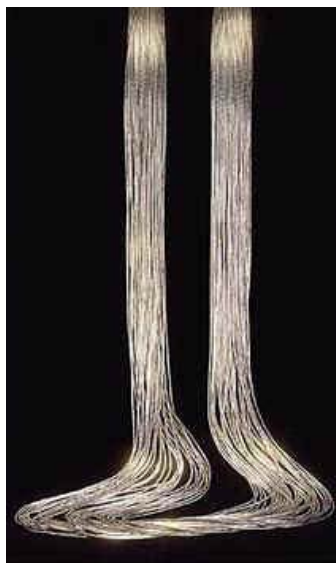


Section 4

- Latest developments and current status of registration projects; expenditures
- Near-term work areas and priorities
- Needs and challenges as we move forward
- Key actions

Section 5

- More on PMC and SIEF interactions - operational implications and some proposals



4.2. Report on Silver Project

Rob Garrett, Ames Goldsmith
Chairman of Silver Work Group
&

Mark Raffray, Johnson Matthey
Chairman Technical Advisory Panel

4.2.1. Achieved to date - Current status



| Phase | Title | Termination and cost | Outcomes |
|-------------------------------------|-----------------------------|--|---|
| | PMC data gathering | End 2007 0 € | Ames Goldsmith, Johnson Matthey and Umicore have contributed information |
| I | Literature search | Feb 2007 50 680 € | Initial identification of key data gaps on silver and its compounds (e.g.: algal study, bio-accumulation, desorption/adsorption). |
| IIa | Data gap analysis | Nov 2008 24 000 € (HH) 24 000 € + 21% VAT (Env) | Broadened: additional literature identified, confirmation of data gaps & preliminary testing recommendations. |
| IIb | Tests to enable read-across | Dec 2008 47 928 € (HH) 43 980 € (Env) | Dustiness & bio-accessibility reported. Transformation/dissolution (almost complete), and initial grouping suggestions / read-across proposals. |
| Extra | Env data gap closure | Nov 2008 Algal study 2200 € Other (later slides) | Algal study closes one data gap. Overall aim: improve stringent PNEC value (still a challenging area even with improvement). |
| TOTAL cost Phases I & II Ag project | | Feb 2007 - Dec 2008 192 788 € | Phase III to be launched in January 2009! |

4.2.2. Project plan and future path




- Latest indicative list (23 Nov 2008):
 - 5 substances & 5 intermediates.
 - Closest registration deadline: 2010.
- Phase IIb: Transformation/dissolution test results still pending

| Timeline | 2007 - 2008 | 2009 | | | | 2010 | | | | 2011 | 2012 | Status |
|------------|-------------|------|-----|----|----|------|----|----|----|------|------|----------------------|
| | | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | | | |
| Ag project | I + II | II | III | | | | | | | | | No reserve time left |
| | | | IV | | V | | | | | | | |

- Phase III: Experimental testing
 - Preceded by defining Intelligent Testing Strategy: **need for all available data** so as to avoid unnecessary tests/costs!
- Phase IV: Chemical Safety Assessment
 - CSA / CSR production: Dangerous silver substances (e.g. silver nitrate)
 - Preceded by collection of **information on uses, exposure and emissions**.

Members' quick input essential!



4.2.3. Identified study needs

Physicochemical properties

- Flammability ~ 1000 €
- Oxidising properties ~ 600 - 3600 €
- Other (contingency) ~ 10 000 €

TOTAL:
2+ tests
~ 15000 €

Toxicological properties

- Acute toxicity - oral 1000 - 2500 €
- Acute toxicity - inhalation 15 000 €
- Sub-chronic toxicity (90 d) 200 000 €

TOTAL:
3 tests
~ 220 000 €

Eco-toxicological properties


- Short-term toxicity on aquatic invertebrate ~ 3000 €
- Growth inhibition study on aquatic plant (e.g.: OECD 401 study on algae) - **in progress** ~ 2500 €
- Activated sludge respiration/inhibition testing ~ 2500 €

TOTAL:
3 tests
~ 8000 €

Total:
~ 245 000 €

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4.2.3. (cont.) Identified study needs

Human Health - evolve preliminary testing proposals:

As might be expected, other data gaps exist therefore additional toxicity tests have been proposed by consultant

1. Some clearly likely to be required (e.g. irritancy, skin sensitisation, certain mutagenicity assays) ▶ about 50 000 to 70 000 EU as package
2. Reprotoxicity 2 generation fertility study (expensive, up to 400 000 EU) proposed, but possibility that test waiver can be obtained
3. Carcinogenicity / 2-yr bioassay (up to 1 000 000 EU) ▶ high probability we can obtain test waiver & therefore escape this cost


- Note re Study placements: test houses under capacity strain & some study cost increases are possible due to these pressures

Some of the above covered by **testing proposals** to ECHA, as part of the Registration Dossier → for budgeting we should assume 1 and 2 above will be done, plus the work covered by previous slide

Together with ecotoxicity package, TOTAL Ag testing program cost will probably reside in range of 1 000 000 - 1 500 000 EU

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4.2.4. Ag environmental assessment: Aquatic no effect level re-evaluation

- EURAS assessment indicated very low PNEC (2 *nanogram* Ag/L) derived by applying conservative uncertainty factor (AF=50)
- Typical background concentration non-urban waters (~10 ng Ag/L)
- **Objective: Improve dataset = ↑ PNEC (above environmental levels)**

1) First pass approach



- Fill data gaps (e.g. algal study, obtain data from Ag Biocides registrants) ▶ try to reduce uncertainty factor that way
- Alternate path: with aid of consultant, apply a specialised effect model (Species Sensitivity Distribution) using weight-of-evidence
- Reasonable confidence PNEC could be improved to circa 20 ng/L

2) Fall back plan (last resort)

- Mitigate risk assessment & low PNEC via bioavailability modelling
- Different model (BLM): factors in impact of DOC, pH etc. on *bioavailable* Ag concentrations in the environment
- Used for other metals (Mn,Cu) / expensive (>>100 000 EU)

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4.2.5. Ag Phase IIb latest

Enabling tests to aid read-across and test waiving

- Now completed for **Dustiness** assessment and **Bioaccessibility**

Dustiness

- Basically good news
- Except Ag nitrate, samples showed comparable (moderate) dustiness
- Modelling predicts minimal deposition in lower respiratory tract
- Will help limit need for expensive inhalation work

Bioaccessibility (in surrogate physiological fluids)

- Results not typical of other metals tested in this system !
- Insoluble and soluble forms ▶ similar bioaccessibility !
- Needs more follow up
- *Good News*: Simpler grouping for Ag & fewer tests needed
- *Bad News*: Less basis for differentiation of hazard based on insoluble (e.g. Ag oxide) versus soluble forms (e.g. Ag nitrate)

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4.2.6. Needs, challenges and issues ahead

1. SIEF level discussions:
 - a. Confirm substance sameness ▶ should be quite straightforward
 - b. Assess impact of new entrants to PMC especially new substances in scope or increased tonnages **CRUCIALLY IMPORTANT** (more later)
 - c. Identify lead registrants
 - d. PMC / SIEF members: get data on **emissions** and **uses / exposure**

Supports Ag PNEC (priority)

For CSA/CSR and to apply for exposure-based waiving
Test reduction = COST REDUCTION!

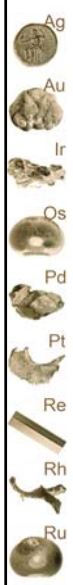
2. Ag Environmental: progress Ag PNEC improvement effort
3. Finalise substance categories and identify "Source substance" (i.e. reference Ag substance) in each category for read-across
4. Robust enough to counter current regulator scrutiny on Ag dispersion / environment effects + their focus on nano Ag



4.3. Report on Gold Project

Sarah Hottenroth, Umicore
Chairwoman Gold \





4.3.1. Achieved to date - Current status

| Phase | Title | Termination and cost | Outcomes |
|----------------------------|------------------------------|---------------------------|--|
| | Identification of consultant | Spring 2008 0 € | Two meetings with Dr Knoell Consult, agreement on scope of work, objectives and deliverables of each phase, and costing estimates. |
| | Data gathering | Summer 2008 0 € | Cendres & Métaux, Johnson Matthey and Umicore have contributed with gold information. |
| I | Literature search | Jan 2008 9000 € | Identification of key data gaps on gold and gold compounds. |
| TOTAL Gold project in 2008 | | June - Dec 2008 9000 € | Phase II to be launched at beginning 2009! |

This project was slightly delayed due to insurance issues - to be solved soon.



4.3.2. Project plan and future path

- Latest indicative list (23 Nov 2008):
 - 4 substances
 - Closest registration deadline: 2018 (may become 2013 or 2010 depending on SIEF discussions and final situation for gold bullion ingots/bars).

- Phase I: Report still pending (to be released in Jan 2009)

| Timeline | (2007 -) 2008 | 2009 | | | | 2010 | | | | 2011 | 2012 | Status |
|------------|---------------|------|----|----|-----|------|----|----|----|------|-----------------------------------|--------|
| | | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | | | |
| Au project | I | | II | | III | | IV | | V | | Some reserve time left - On track | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |

- Phase IV: Chemical Safety Assessment
 - 1 CSR: gold.
 - Preceded by collection of information on uses, exposure and emissions.

Members' input essential!



4.3.3. Future work areas

- Establishing substance categories might be difficult (four substances in scope are quite different)
- No powder forms - should limit need for "inhalation" tests
- Impossible to confirm test requirements at this stage
 - See you at next Assembly meeting with updated strategy!



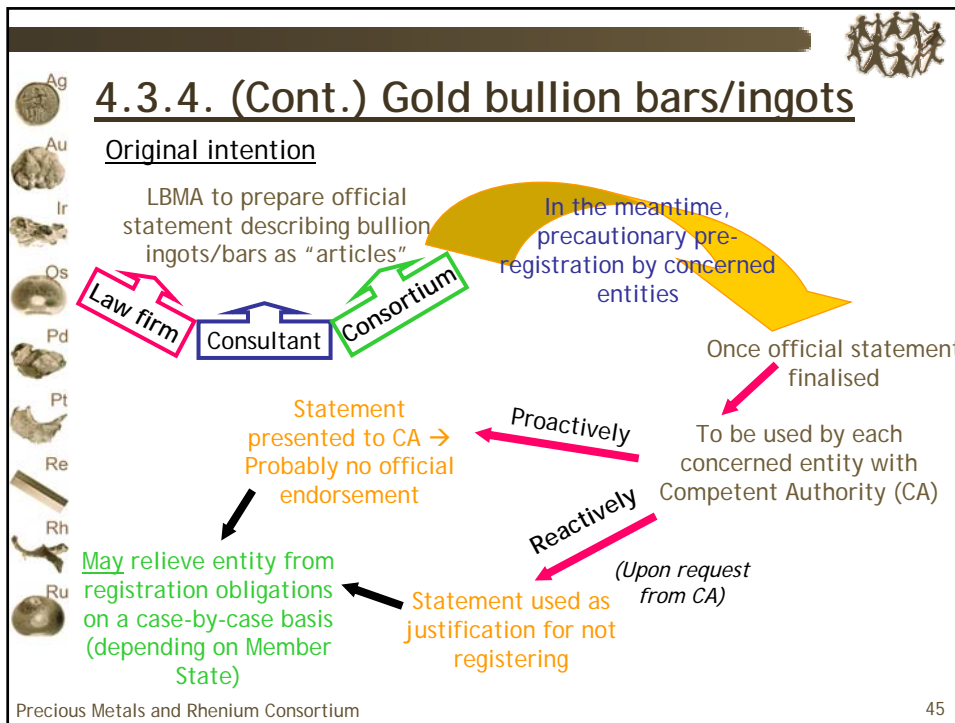
4.3.4. Gold bullion bars/ingots

Context - Bullion ingots/bars fulfil REACH "article" definition:

- Standard specifications imposed on shape, size, weight and marks/purity of LBMA Good Delivery Bars - allows to differentiate "investment" bars from other (feedstock) bars
- Form is more important to function (storage) than chemical composition (not to be confused with value)
- Comparable to coins, which are clearly articles - bars are preferred to coins because of easier handling and lower manufacturing premium/cost

Small "but":

Although they can have an extremely long shelf-life, ultimate control on whether bar is used as investment product or as raw material/feedstock for re-processing is not always possible.



4.3.4. (Cont.) Gold bullion bars/ingots

Latest info: LBMA's initiative abandoned (26 Nov e-mail):

- Banks in SIEF (not only in Pre-SIEF)
- Banks with interest in (joint) registration
- Banks with larger tonnage bands (up to 1000 t/a or more of Au)
- Banks with larger (and more expensive) information requirements
- Banks with earlier registration deadline

If banks join Consortium:

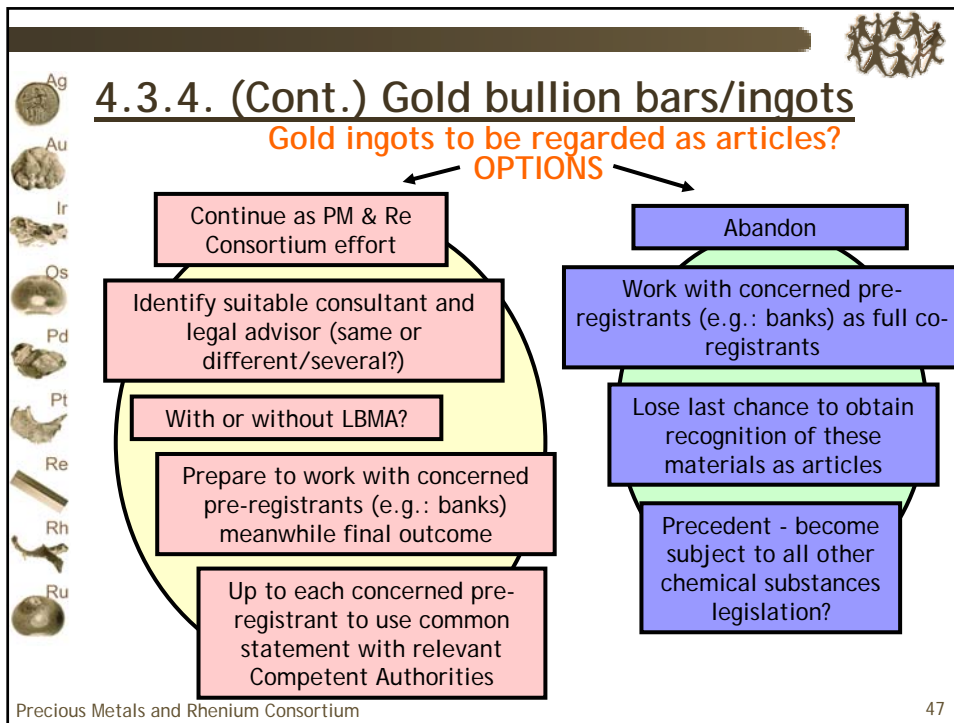
- Membership enlarged:
 - Share of generic costs per Member decreased
 - Increased workload on Secretariat & Trustee
- Gold project "squeezed":
 - More information required - gold-specific costs
 - In less time (2010 or 2013)
 - Increased workload on Scientific Manager, TAP and Au Work Group

If banks do not join Consortium:

- Membership remains "operational"
- Gold project remains "manageable"
- Need to find other way of complying with joint registration obligations:
 - Nominating Lead Registrant (bank or manufacturer?)
 - Agreeing on required information in Registration Dossier and subsequent cost-sharing
 - Agree on data-sharing between Consortium and banks: Letter of access, license to use, etc. - to be defined by Management Committee

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4.3.5. Needs, challenges and issues ahead

- Meet SIEF colleagues and:
 - Confirm substance sameness
 - Confirm registration deadlines
 - Address best way to consider "investment gold" under REACH
 - Will depend on which tonnage band banks will need to register
 - Identify lead registrants
 - Continue gathering:
 - available information on gold and gold substances
 - data on uses, exposure and emissions
- Agree on substance categories (probably potential for cross-SIEF approach) and identify source substance per category to maximise read-across potential
- Agree on classification and labelling (notification to ECHA by 2010!)


To produce CSR and to apply for exposure-based waiving
 test reduction →
COST REDUCTION!

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Ag
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Coffee/Tea break



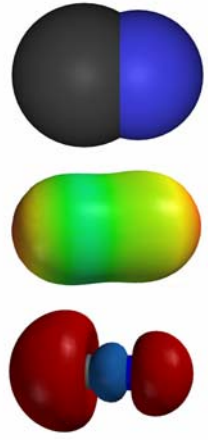
pausing
for breath



Ag
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4.3.1. Report on Precious Metal Cyanides Project

Sarah Hottenroth, Umicore
Chairwoman Gold Work Group

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4.3.1.1. Achieved to date - Current status

| Phase | Title | Termination and cost | Outcomes |
|------------------------------|------------------------------|---------------------------|--|
| | Identification of consultant | Spring 2008 0 € | Two meetings with Dr Knoell Consult, agreement on scope of work, objectives and deliverables of each phase, and costing estimates. |
| | Data gathering | Summer 2008 0 € | Ami Doduco, Metalor, Umicore have contributed with PM CN-information |
| I | Literature search | Jan 2008 9000 € | Identification of key data gaps on precious metal cyanides. |
| TOTAL PM CN- project in 2008 | | June - Dec 2008 9000 € | Phase II to be launched at beginning of 2009! |

This project was slightly delayed due to insurance issues - to be solved soon.

4.3.1.2. Project plan and future path

- Latest indicative list (23 Nov 2008):
 - 4 substances
 - Closest registration deadline: 2018 (may become 2010 depending on SIEF discussions).

- Phase I: Report still pending (to be released in Jan 2009)

| Timeline | (2007 -) 2008 | 2009 | | | | 2010 | | | | 2011 | 2012 | Status |
|---------------|---------------|------|----|----|----|------|----|----|----|------|------|-----------------------------------|
| | | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | | | |
| PM CN-project | I | | | | | | | | | | | Some reserve time left - On track |
| | II | | | | | | | | | | | |
| | III | | | | | | | | | | | |
| | IV | | | | | | | | | | | |
| | V | | | | | | | | | | | |

- Phase IV: Chemical Safety Assessment
 - 3 CSR: Silver cyanide, potassium dicyanoargentate and dicyanoaurate.
 - Preceded by collection of information on uses, exposure and emissions.

Members' input essential!



4.3.1.2. (Cont.) Project plan and future



path



- Originally → PM CN- considered as satellite project of Au project
- Now → preferred as separate project run by Au WG and TAP (and same consultant as Au project):
 - Separate indicative list
 - Separate REACH requirements
 - Separate quotation
 - Separate reports
 - Separate budget? - Would mean:
 - Additional metal-specific cost block (in addition to Ag, Au, PGM and Re)
 - Separate accountancy
 - More transparent follow-up

Proposed approach agreed by the Assembly?



4.3.1.3. Future work areas



- Establishing substance categories will probably be straightforward: effect of CN- is key:
 - Effect of Ag and Au on dissociation and solubility (in specific pH conditions) should not be neglected in assessment though
- Impossible to confirm test requirements at this stage, but unlikely to be many as much information exists on CN- already.



4.3.1.4. Needs, challenges and issues ahead

- Meet SIEF colleagues and:
 - Confirm substance sameness (should be quite straightforward)
 - Confirm registration deadlines
 - Identify lead registrants
 - Continue gathering:
 - available information on PM CN-
 - Data on uses, exposure and emissions
- Agree on substance category(ies) and identify source substance per category to maximise read-across potential
- Agree on classification and labelling (notification to ECHA by 2010!)

To produce CSR and avoid unnecessary testing



4.4. Report on PGM Project

Dave Boyd, Johnson Matthey
Chairman PGM Work Group





4.4.1. Achieved to date - Current status

| Phase | Title | Termination and cost | Outcomes |
|---------------------------|------------------------------|-------------------------------|---|
| | Identification of consultant | Winter - Spring 2008 0 € | Two meetings with WCA/BIBRA, agreement on scope of work, objectives and deliverables of each phase, and costing estimates. |
| | Data gathering | Summer 2008 0 € | Anglo Platinum, Carl Hafner, Johnson Matthey, PAMP and Umicore have contributed with PGM information. |
| I | Literature search | Nov 2008 ~ 34 000 € | Identification of key data gaps on PGM and PGM compounds, preliminary category approach, and preliminary REACH Annex III exemption estimates. |
| TOTAL PGM project in 2008 | | June - Nov 2008 ~ 34 000 € | Phase II to be launched in December 2008! |



4.4.2. Project plan and future path


- Latest indicative list (23 Nov 2008):
 - Pt: 12 substances and 4 (simple) intermediates
 - Pd: 17 substances and 5 (simple) intermediates
 - Ir: 5 substances and 1 (simple) intermediate
 - Os: 1 (simple) intermediate
 - Rh: 13 substances and 4 (simple) intermediates
 - Ru: 6 substances and 3 (simple) intermediates
 - TOTAL: 53 substances and 16 (simple) intermediates
 - Closest registration deadline: 2018 (may become 2013 or 2010 depending on SIEF discussions).
- Phase I: Report received in Oct 2008 - meeting with WCA/BIBRA to clarify outcomes - updated report expected in early Dec 2008.

| Timeline | (2007 -) 2008 | 2009 | | | | 2010 | | | | 2011 | 2012 | Status |
|-------------|---------------|------|----|----|----|------|----|----|----|------|------|------------------------------|
| | | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | | | |
| PGM project | I | | | | | | | | | | | Reserve time left - On track |
| | II | | | | | | | | | | | |
| | III | | | | | | | | | | | |
| | IV | | | | | | | | | | | |
| | V | | | | | | | | | | | |

- Phase IV: Chemical Safety Assessment
 - 4 CSR Pt, 5 CSR Pd, 2 CSR Ru - TOTAL: 11 CSR out of 53 substances.
 - Preceded by collection of information on uses, exposure and emissions.



4.4.3. Future work areas

- Gather technical specifications on all PGM substances in order to: 
- Establish substance categories, taking into account:
 - Metal oxidation state
 - Presence of typical chemical group (e.g.: ammine forms, halogenated forms, etc)
 - Other
- Confirm Annex III exemption predictions
- Impossible to confirm test requirements at this stage - need to await for Phase II outcomes! **See you at next Assembly meeting with updated strategy!**



4.4.4. Needs, challenges and issues ahead

- Meet SIEF colleagues and:
 - Confirm substance sameness:
 - Raman spectra required for solutions
 - UVCB composition to be reduced down to minimum possible
 - Confirm registration deadlines
 - Identify lead registrants
 - Continue gathering:
 - available information on PGM and PGM substances
 - data on uses, exposure and emissions
- Agree on substance categories and:
 - identify source substance per category to maximise read-across potential
 - ensure secure shipment of samples to research laboratories
- Agree on classification and labelling (notification to ECHA by 2010!)

To produce CSR and to apply for exposure-based waiving

test reduction →

COST REDUCTION!



4.5. Report on complex refinables initiatives

Jeff Levison, Vale Inco
Co-Chairman Management Committee



4.5.1. Context

- Conventional PGM refineries have numerous on site isolated intermediates >1 tonne p.a.
 - Some are "simple", i.e. mono- or multi-constituents substances or simple preparations
 - Others are complex, i.e. UVCBs
- Even greater diversity with PM refinery feeds and by-products, whether primary or secondary
 - REACH would only apply to the latter if non-wastes
 - These materials often straddle the waste/REACH interface
 - Uncharted territory for regulators
- Sufficient compositional data for complex materials for practical purposes, i.e. commercial, operational
 - Lots of constituents, often considered in groups rather than individually
 - Insufficient for theoretical ideal REACH identification



4.5.2. Initial Phase

- Faced with seemingly intractable problem
 - Consensus amongst interested parties that best way forward would be to agree common industry approach for UVCBs
 - Need to be pragmatic and credible, not provide a lazy refuge
 - Must assume all are intermediates under strict control
- Interesting but not inexhaustible supply of promising EINECS Nos for substance identification
 - One can in principle adjust EINECS descriptors
 - Planned to fill gaps by pre-registering without EINECS Nos
- Two initial lists
 - One with EINECS Nos, one without, but both unstructured
 - Secretariat sought to assign EINECS Nos to members' UVCBs



4.5.2. Examples

| Name | CAS number | EC number | Description | Covering for Pre-registration |
|---|------------|-----------|--|--|
| Doré | 69029-47-6 | 273-793-6 | Gold and silver bullion. | E.g.: Doré metal (raw silver) smelting in the anodal furnace, raw or impure gold/silver, etc. |
| Slimes and sludges, precious metal refining | 98072-61-8 | 308-516-0 | Not available in EC database - Indicative definition proposed by the Consortium: " <i>Sludges and Slimes (are sometimes used synonymously), are reaction products from precious metals hydrometallurgy refining operations, either as separated out or as solids after drying.</i> " | E.g.: Gold anode slime, PGM slime, PGM Liquors, hydroxide sludges, "concentrates" (rich, poor, primary, secondary), leach insolubles and blacks, and PM sweeps, etc. |
| Balsams, copaiba, sulfurised, mixed with turpentine, gold salts | 68990-27-2 | 273-589-7 | Not available in EC database | Balsams, copaiba, sulfurised, mixed with turpentine, gold salts |



4.5.3. Second Phase

- However substances “placed on the market” without EINECS No. are not phase in, as defined by REACH
 - Also, pre-registration entries in REACH IT and IUCLID 5 plug in module require declaration that substances are phase in
- Developed “angst flowchart” explaining REACH realities
- Developed a crude classification system for substances (e.g. residues, metallics, furnace by-products), recommended potential EINECS Nos for each type and provided expanded list of other possible EINECS Nos.
- Secretariat provided pre-registration guidance to Consortium members along these lines



4.5.3. Second Phase

- Must wait and see how members have actually identified their complex materials and pre-registered them
 - Also see what other SIEF members have done
- Diversity of approach is not fatal
 - The important thing is that a genuine attempt has been made to pre-register in line with ECHA guidance
- Equally important that the Secretariat knows what members have done
 - Where the “same substances” have been placed in different SIEFs, they can initiate inter-SIEF dialogue



4.5.4. Next Phase

- Confirm sameness within and across SIEFs:
 - Develop defensible criteria but based on what information?
Chemical or mineralogical composition?
 - Review names and descriptors seeking to meet industry's aspirations within the framework of REACH Guidance on identification & naming
- Combine or split SIEFs?
 - Interesting and challenging SIEF management issues
 - Level of dialogue with ECHA?
- Need for reliable data
 - Composition, tonnage band
 - Confirm intermediate status and strictly controlled conditions
 - On site or transported? Need for test samples?



4.5.4. Next Phase

- Expand consultant's work to complex refinables
 - GHS classification challenges with diverse compositions





4.6. Report on Rhenium Project

Angela Alderman, Johnson Matthey
Chairwoman Rhenium Work Group



4.6.1. Achieved to date - Current status

| Phase | Title | Termination and cost | Outcomes |
|---------------------------|------------------------------|-----------------------------|---|
| | Identification of consultant | Winter - Spring 2008 0 € | Two meetings with WCA/BIBRA, agreement on scope of work, objectives and deliverables of each phase, and costing estimates. |
| | Data gathering | Summer 2008 0 € | Climax Molybdenum, Johnson Matthey and Lipmann Walton have contributed with Re information. |
| I | Literature search | Nov 2008 ~ 1500 € | Identification of key data gaps on Re and Re compounds, preliminary category approach, and preliminary REACH Annex III exemption estimates. |
| TOTAL PGM project in 2008 | | June - Nov 2008 ~ 1500 € | Phase II to be launched in December 2008! |



4.6.2. Project plan and future path

- Latest indicative list (23 Nov 2008):
 - 4 substances and 3 (simple) intermediates
 - Closest registration deadline: 2018.
- Phase I: Report received in Oct 2008 - meeting with WCA/BIBRA to clarify outcomes - updated report expected in early Dec 2008.

| Timeline | (2007 -) | 2009 | | | | 2010 | | | | 2011 | 2012 | Status |
|------------|----------|------|----|----|-----|------|----|----|----|------|------|------------------------------|
| | 2008 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | | | |
| Re project | I | | | II | | | | | | | | Reserve time left - On track |
| | | | | | III | | | | | | | |
| | | | | | IV | | | | | | | |
| | | | | | | V | | | | | | |
| | | | | | | | | | | | | |

- Phase IV: Chemical Safety Assessment
 - 1 CSR for Ammonium Perrhenate.
 - Preceded by collection of information on uses, exposure and emissions.



4.6.3. Ni alloy scrap

- Rhenium can be imported on as part of nickel alloy scrap:
 - Heterogeneous form (before melting), or
 - Homogeneous form (after re-melting)
- Composition is somehow variable:
 - Aluminium (Al)
 - Cobalt (Co)
 - Chromium (Cr)
 - Hafnium (Hf)
 - Iron (Fe)
 - Molybdenum (Mo)
 - Nickel (Ni)
 - Tantalum (Ta)
 - Titanium (Ti)
 - Tungsten (W)
 - Rhenium (Re)





4.6.3. (Cont.) Ni alloy scrap: a complex material

- Does not have an EINECS number:
 1. Could be regarded as a UVCB: variable composition
 2. Could be regarded as a multi-constituent substance: several constituents with “usual” composition ranges
 3. Could be regarded as a (special) preparation: as it is an alloy.
- All three routes have been considered during pre-registration in order to maximising potential for REACH compliance!



4.6.4. Future work areas

- Establishing substance categories, taking into account:
 - Metal oxidation state
 - Presence of typical chemical group
 - Other
- Confirm Annex III exemption predictions
- As Re is a data-poor substance in low tonnage band, there are many data gaps but impossible to confirm test requirements/costs at this stage:
 - unlikely to be many
 - need to await for Phase II outcomes

See you at next Assembly meeting
with updated strategy!



4.6.5. Needs, challenges and issues ahead

- Meet SIEF colleagues - Depending on pre-registration route, this can mean:
 - One SIEF per "simple" substance + **one** for Ni alloy scrap, or
 - One SIEF per "simple" substance + **several** for Ni alloy scrap...
- Confirm substance sameness
- Confirm registration deadlines
- Agree on substance categories and:
 - identify source substance per category to maximise read-across potential
 - ensure secure shipment of samples to research laboratories
- Identify lead registrants
- Gather data on uses, exposure and emissions
- Agree on classification and labelling (notification to ECHA by 2010!)

Test reduction →
COST REDUCTION!



4.7. Key action points

Mark Raffray, Johnson Matthey
Chairman Technical Advisory Panel





4.7. Other key action points to consider

SIEF impacts on our registration projects:

- EU-COM originally anticipated 200 000 pre-registrations
- At the time of compilation of these slides, total pre-registrations recorded by ECHA numbered 1 987 096 !!
- **All** consortia now face increased complexity in terms of sorting out SIEF interactions
- What are some of the impacts ?
 - More complex communications between PMC and SIEFs
 - More non-genuine pre-registrants to gate out
 - More sameness evaluations to undertake
 - Secretariat burden likely to be significantly increased (especially 1st half of next year)
 - Importantly, registration projects may be more affected than originally anticipated → new joiners to PMC with new substances or requests to cover higher tonnages for existing substances → **Consequential impact on our current plans**
- **Later today** ▶ initial analysis on PM & Re pre-registrations



4.7. (Cont.) Other key action points

SIEF impacts on our registration projects:

- Per the expectations of the regulators:
 - Still need to participate in the pre-SIEF aspects of substance sameness
 - Go on to interact with formed SIEFs to agree data sharing, registration timing, designation of lead registrant etc.
- Some within industry consortia now consider that established consortia must drive decision making in their favour rather than taking a passive role & more pain later
- Secretariat, TAP and WG will need to be ready to respond to these challenges (more later today)
- Remember: No regulatory system has ever attempted anything similar before
- You may find some of us rather pre-occupied at the start of next year !!!



4.7. (Cont.) Other key action points

Gathering information on uses, exposure and emissions:

- Example from earlier is relevance to Ag environmental risk assessment
 - Need emissions data to check environmental concentration assumptions and then relate to PNEC
- First select priority substances and the main data elements required
- Choose format (e.g. EM multi-metallic questionnaire, consultants' format, or combination?)
- Agree on timescale for completion by Members
- Provide data back to consultants
- Options to achieve this currently under TAP consideration ▶ will revert to members with proposals early next year



This is complex and dynamic !!

Flexible thinking is needed by all involved;
Efforts may occasionally not be perfect - but TAP & the Secretariat will be trying hard to avoid any significant failures





4.8. Next TAP meeting

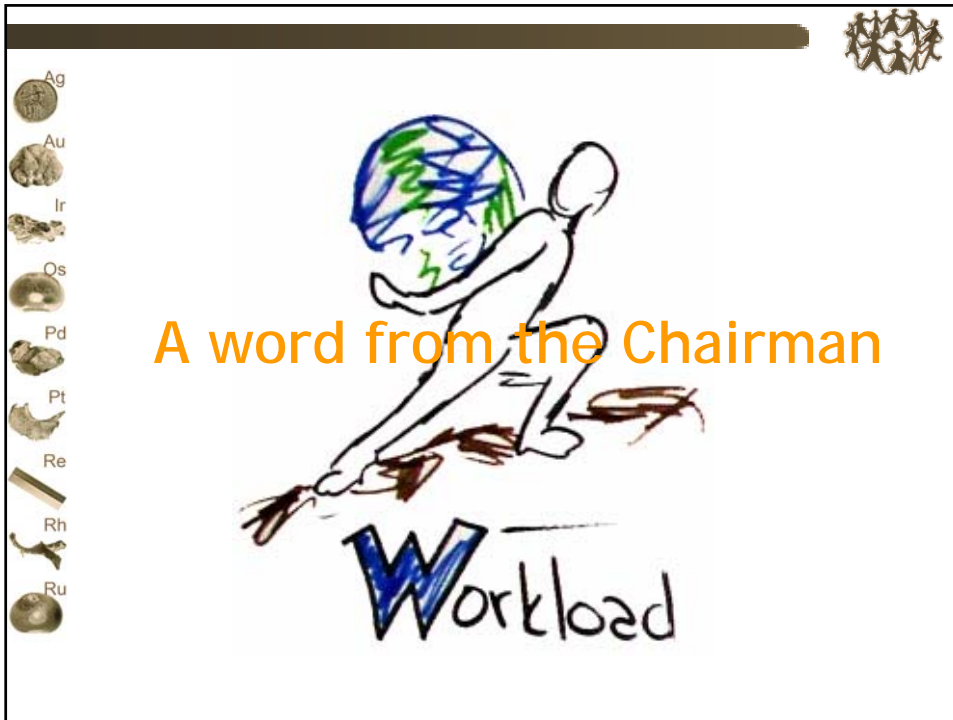
- Agenda items:
 - Live Pre-SIEF access (for some non-confidential examples)
 - Pre-SIEF analysis:
 - Key SIEF players
 - Key substances
 - Exposure data collection
 - "Master (technical) specifications" to launch substance sameness discussions
 - License to use vs. Letter of access (conditions - then cost predictions with Cost-sharing WG + Legal WG)
 - Evaluation of Phase I of Au and PM CN- projects
 - Evaluation of Phase II of PGM and Re projects - pilot projects
- Venue:
 - Brussels or Hanau (tbc)
- Proposed dates:
 - 4 Feb or 5 Feb 2009 - please block these if on TAP



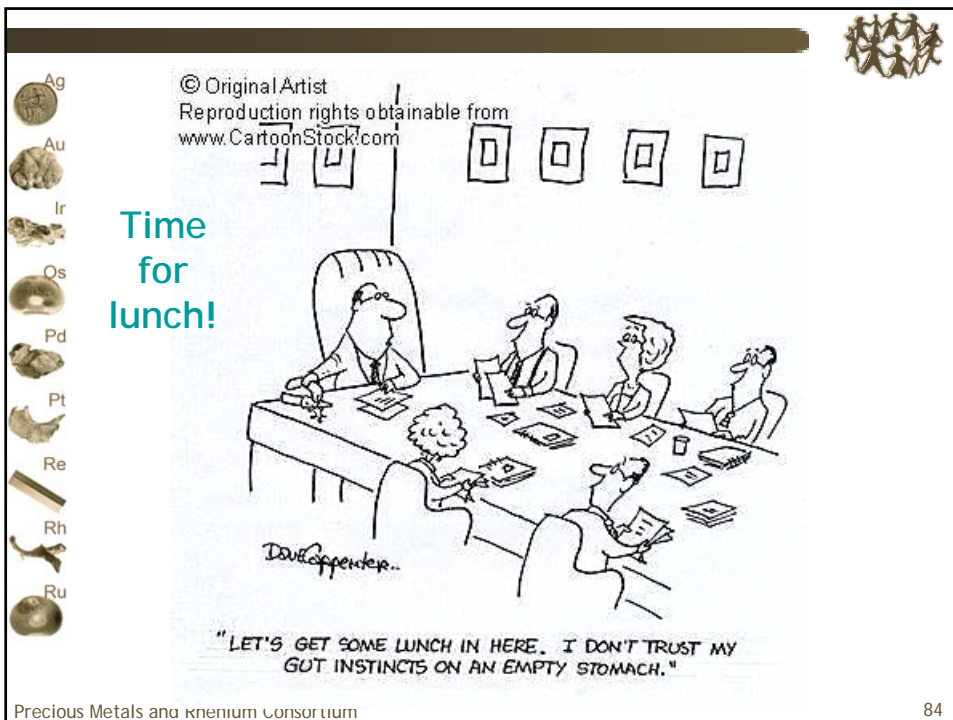
Questions



Any round up questions for the technical presenters



A word from the Chairman





5. Consortium and SIEFs

Caroline Braibant, EPMF

Secretariat & Trustee

&

Mark Raffray, Johnson Matthey

Chairman Technical Advisory Panel



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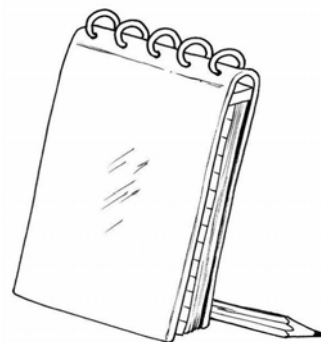
"I NEVER KNOW WHEN TO
EXPECT THE POSTMAN
THESE DAYS...."



5.1. Pre-registration leaflet

Caroline Braibant, EPMF

Secretariat & Trustee





5.1.1. Pre-registration leaflet



What:

- One "body" - four chapters (covering generic, metal-specific and IT questions)
- Nine annexes:
 - Latest indicative lists
 - Inventory of complex intermediates
 - REACH & Waste document
 - SME user guide
 - Letter to SIEF



Why:

- To ensure global understanding of REACH
- To ensure harmonised pre-registration approach
- To ensure structured SIEF formation
- To help/assist/clarify/complete Members' pre-registration initiatives and actions



When?

- Circulated on 28 October (interim version) and 3 November 2008 (complete version)



5.1.2. Comments on leaflet



• Immediate feed-back

- Considered as very useful because it contained recent all information in one place, clarifications, experiences, and suggestions on pre-registration, and key recommendations on metal-specific issues (in particular: complex intermediates).
- Though circulated a bit late...



• Today's feed-back

- through questionnaires
- "live" comments





5.1.3. Lessons learned

- Pre-registration leaflet is **first "major" deliverable** prepared by Consortium
 - Difficult to "compare" with other consortia who usually have: Risk Assessment experience, more staff, less substances, less Members' intervention...
- **Efficiency** of Consortium's operation and service to Members **will continue to improve** thanks to:
 - Members' ideas, comments, suggestions shared with staff
 - Members' input and contributions to staff, consultants, TAP, and WG (data) requests
 - Exchanges with other consortia (Eurométaux' platform - REACH Forum, chaired by G. Ethier (Umicore), meeting every three months)
 - Experience - REACH is a new business for everyone!
- Overview of comments on Consortium's organisation/deliverables from questionnaire



5.2. List of pre-registered substances

Zuzana Hugonin, EPMF
Scientific Manager





5.2.1. List(s) of Pre-registered substances

- Two “interim” lists of pre-registered substances have been published:
 - First one: 7 Oct
 - Second one: 7 Nov
- Next one: January 2009 - hopefully official one, last one!
- List contains:
 - Name, EC number, CAS number, estimated registration deadline, related substances



5.2.2. Funny pre-registrants!

- Examples of funny registration deadlines:
 - Pt: 2010
 - Pd: 2010
 - Ir: 2010
 - Rh: 2010
 - Re: 2010
- For Ag substances (our initial priority) ▶ 94 pre-registrations with 15 (simple Ag substances) entered as 2010 deadline (only 5 M/I currently in scope of our project with only 2 at mandatory deadline of 2010)
- One of the first issues to investigate quickly

Impossible for these deadlines to be tonnage band-related - unless somebody is retaining a huge secret on Re and PGM sources...

This and numerous other anomalies needs to be “resolved” as soon as we meet our SIEF colleagues!!



5.2.3. Pre-registered PM and Re



| Substance family | Related pre-registrations | In-scope of Consortium's projects | Difference |
|------------------|---------------------------|-----------------------------------|------------|
| Ag | 94 | 10 | 84 |
| Au | 83 | 4 | 79 |
| CN- | 403 | 4 | 399 |
| Pt | 60 | 16 | 44 |
| Pd | 52 | 22 | 30 |
| Rh | 39 | 17 | 22 |
| Ru | 28 | 9 | 19 |
| Ir | 15 | 6 | 9 |
| Os | 6 | 1 | 5 |
| Re | 32 | 7 | 25 |



5.2.3. (Cont.) Potential impact on Consortium



- We need to:
 1. See who is "behind" each additional substance
 2. Check if information on additional substances could be useful for Consortium's data gap analysis/read-across/test minimisation
 3. Check if 1 tonne/year is exceeded already/likely to be exceeded so that registration will occur (versus pure precautionary pre-registration initiatives)
 4. Check if additional substance is compatible with Consortium's categories for read-across
 5. Seek for cooperation where applicable and agree on mode of cooperation with concerned company(ies)
 - See next Agenda item
 6. Adjust projects' scopes, budget and timeline as required
 - Impossible to predict at this stage






5.3. SIEF & PM & Re Consortium: how to work together?

Caroline Braibant, EPMF Secretariat & Trustee



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5.3.1. What are the possible scenarios?

All SIEF colleagues interested in joining

All key SIEF colleagues interested in joining

Key SIEF colleague being pre-registrants with data, expertise and confirmed registration interests

Consortium members are a quantitative and/or qualitative majority in SIEF
 ↓
 Consortium members are a quantitative and/or qualitative minority in SIEF

None of key SIEF colleagues interested in joining

None of SIEF colleagues interested in joining

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5.3.2. Possible impact - some reminders

All potential registrants are bound to:

- **One Substance, One Registration (OSOR principle)**, meaning:
 - One Dossier per Substance, no matter: tonnage band, substance/intermediate status
 - Consortium and non-Consortium colleagues need to work together
 - Highest tonnage band in SIEF will trigger deadline to finalise registration dossier compilation
- **Notifying agreed classification and labelling in 2010**, meaning:
 - Most of work will need to be done by 2010 anyway!



5.3.2. (Cont.) Possible impact

PRECIOUS METALS AND RHENIUM CONSORTIUM
ASSEMBLY MEETING
3 December 2008

Possible impacts of SIEF on Consortium

| Item of discussion | CONSORTIUM AS MAJORITY (General impact) | CONSORTIUM AS MINORITY - worst case predictions | | | |
|---|--|---|---|---|---|
| | | General impact | Impact/workload on Secretariat and Management Committee | Impact/workload on Scientific Manager and technical groups | Overall impact on Dossier preparation and quality |
| Substance sameness | Consortium's methodology likely to be basis for discussions - few SIEF colleagues corroborating sameness with agreed substance profile in Consortium | Consortium needs to obtain recognition for previous technical assessments and conclusions from rest of SIEF | Need to resolve "confidentiality" issues to allow data-sharing on substance information | Need to re-activate assessment of received substance info and overall substance profile | <ul style="list-style-type: none"> • Sameness confirmation delayed • Testing period squeezed • Possible impact on Dossier's quality |
| Source substances and reference samples | Consortium's approach and identified reference samples (and samples suppliers) unlikely to be challenged because already representative | Need to check recognition on Consortium's approach and representativity of identified samples with rest of SIEF | Need to resolve "organisational" issues to allow technical experts to meet | Need to re-open discussions on "technical" assessment of alternative approaches | <ul style="list-style-type: none"> • Category approach confirmation delayed • Intelligent Testing Strategy delayed • Testing period squeezed • Possible "excessive" testing if no agreement was reached • Higher testing costs • Struggles in cost-sharing agreements • Possible impact on Dossier's quality |



5.3.3. To join or not to join?

- Impossible to determine **firmly** who in SIEF is:

- **Active** potential registrant
- **Passive** potential registrant
- **Precautionary** pre-registrant (covering DU, and exemptions such as recovery or re-import)
- **"Observer"**

Acknowledgement/support

Membership to Consortium not essential

Cooperation/contribution

Ideal: Member

- Unlikely that precautionary pre-registrants and observers will want to join (and hence, share the costs)...



5.3.3. (Cont.) To join or not to join?

Active SIEF colleagues:

- Should be invited to join the Consortium, and
- Become co-owners of the data generated by the Consortium

Enlarges membership

Decreases individual costs

Increases Consortium internal operational workload

Decreases Consortium operational workload with SIEF

Maximises chances of successful registration

N.B.: The more co-owners an information has, to more complicated "using" or "selling" this information can become

Passive SIEF colleagues can be:


- Invited to join the Consortium, or
- Given the possibility to obtain a legitimate right to refer or use the information by granting them:

- A letter of access to refer to the applicable part of the Registration Dossier (only right to refer - for < 10 tonnes/year registrations)
- A license to use all or a specific part of the Registration Dossier (right to use - for > 10 tonnes/year who require to "use" CSR information in their SDS).

Need to agree on cost and conditions of such rights

Task for cost-sharing WG + TAP





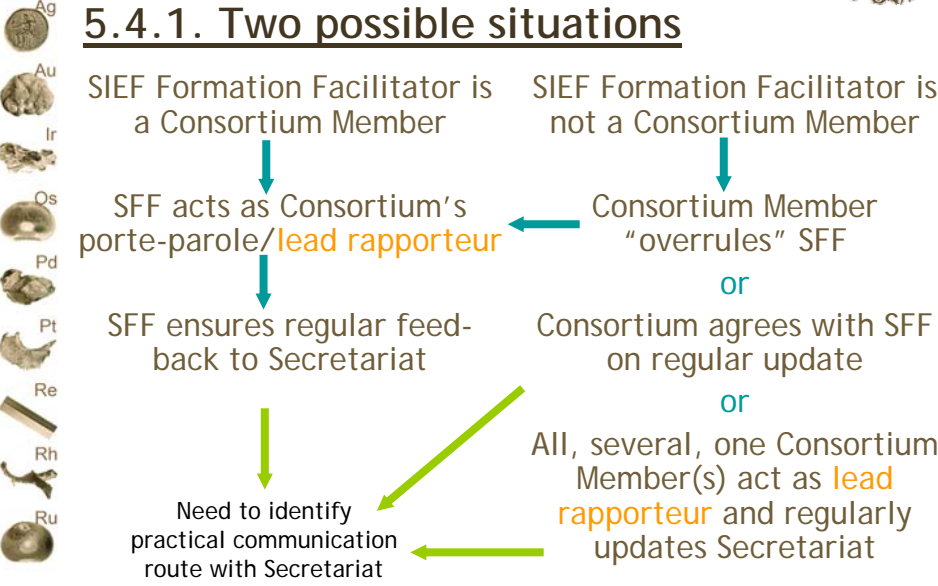
Ag
 Au
 Ir
 Os
 Pd
 Pt
 Re
 Rh
 Ru

5.4. Operational link between Consortium and SIEF

Caroline Braibant, EPMF
Secretariat & Trustee

Precious Metals and Rhenium Consortium

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Ag
 Au
 Ir
 Os
 Pd
 Pt
 Re
 Rh
 Ru

5.4.1. Two possible situations

| | |
|---|--|
| <p>SIEF Formation Facilitator is a Consortium Member</p> <p>↓</p> <p>SFF acts as Consortium's porte-parole/lead rapporteur</p> <p>↓</p> <p>SFF ensures regular feedback to Secretariat</p> <p>↓</p> <p>Need to identify practical communication route with Secretariat</p> | <p>SIEF Formation Facilitator is not a Consortium Member</p> <p>↓</p> <p>Consortium Member "overrules" SFF</p> <p>or</p> <p>Consortium agrees with SFF on regular update</p> <p>or</p> <p>All, several, one Consortium Member(s) act as lead rapporteur and regularly updates Secretariat</p> |
|---|--|

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5.4.2. Possible solutions

1. Provide Secretariat with “read-only access” to Pre-registrant account:
 - Allows Secretariat to access all Pre-SIEF directly
 - **All Pre-SIEF** → even non-PM/Re Pre-SIEF → confidentiality issue...
2. Identify suitable communication tool to ensure link while ensuring confidentiality
 - Several tools existing, all at raw stage of development/in development
 - Cost outweighs practicality and time-efficiency of tool
 - See section 5.5.



Coffee/tea
break



5.5. Ideas for Consortium and SIEF operation

Mark Raffray, Johnson Matthey
Chairman Technical Advisory Panel



5.5.1. Communication tools available

| | EPMF Website | REACHsief | REACHsuite |
|----------------------|---|---|--|
| Managed by | PM & Re Consortium Secretariat | REACHlink (CEFIC spin-off) | Baytouch (Consortium Manager company) |
| Stage of development | Requires further update/development | Fully developed - may be adjusted to consortia needs upon request | In constant development - can be tailored to PM & Re Consortium needs |
| Accessible to | All | Only pre-registrants having purchased it | Selected users authorised by owner (e.g.: Consortium, consultants, etc.) |
| Works as | Unilateral portal (only one user posts comments/docs) | Bilateral (all users can post comments/documents) | |
| Cost | Part of website cost (+ cost of improvement) | 300 € per legal entity, per substance, per user | 300 € per substance |

Other ideas welcomed!

Can be used to post "public" notes

Recognised by ECHA

Already used by known consortium and consultants



5.5.2. Voting rules

• Voting approach:

- Proposals posted on informative portal?
- Proposals sent by e-mail?
- Proposals presented orally at meetings?

Probably a combination

• Voting rights:

- One pre-registrant, one vote?
- One corporate pre-registrant, one vote?
- Vote of precautionary pre-registrants and observers?
- Who is entitled to vote - how to identify/list/follow-up on duly authorised representatives?

May depend/impact on cost-sharing

• Voting quorum:

- 50% + 1 of all pre-registrants?
- 50% + 1 of corporate representatives?
- 50% + 1 of active and passive pre-registrants only?

Needs to be practical, considering timing



5.5.2. (Cont.) Voting rules

• Voting majority

- Simple majority?
- Qualified majority (2/3? 3/4? Other?)?
- Unanimity?

Recommended

Impossible

• Voting timing

- One day?
- Three days?
- One week?
- Two weeks?
- One month?

Most probably, depending on urgency/complexity of issue to be voted on

Unpractical



5.5.3. Confirming substance sameness

- **Why?** Pre-SIEF becomes SIEF once substance sameness had been assessed and confirmed
 - Subsequent phases “paralysed” until then (lead registrant, testing, etc.)
 - Triggers confirmed registration deadline
- **Who?** Active + passive pre-registrants - those with immediate/confirmed interest in registration
- **How?** With information on the substance:
 - Technical specifications (physicochemical properties), and
 - Composition profile (main constituents + impurities)
- **When?** ASAP! - e.g. for complex intermediates, it can take time to obtain, compare and agree on “typical” composition profile



5.5.4. Lead Registrant

- In practice difficult to fully separate from SFF:
 - Ideally: same entity
- **“Common” responsibilities:**
 - ✓ Establish cooperation in SIEF
 - ✓ Organising exchange/acquisition/generation of technical data
 - ✓ Cross-SIEF communication (for read-across)
 - ✓ Facilitate agreement on classification and labelling
 - ✓ Responsible for submitting joint Registration Dossier
 - ✓ Primary contact with ECHA in regard to Registration Dossier



5.5.4. (Cont.) Lead Registrant

Weight of above tasks and commitments can only be minimised if Lead Registrant works with:

- Agreed rules: Consortium Agreement
- Permanent "neutral" and dedicated support: Consortium staff

Proposed way forward:

Consortium to nominate Lead Registrant amongst membership and submit it for remarks/comments to SIEF



5.5.5. In summary...

- Very early days for everyone...
- Still, limited time ahead!
- Need to identify:
 - Priority substances: e.g.: silver, complex intermediates
 - Areas of priority: e.g.: sameness, lead registrant
 - Priority SIEF colleagues: e.g.: highest tonnage bands, major manufacturers, major data-holders

Key Agenda items for Q1 2009 technical meetings!



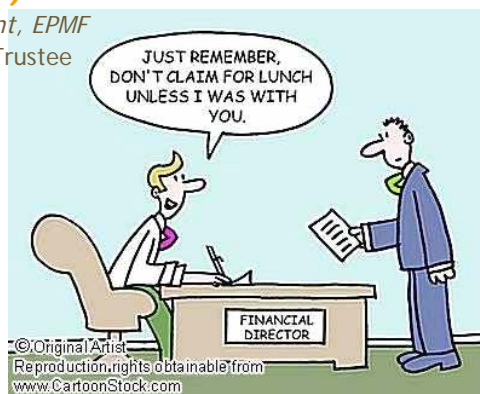
6. 2008 Expenses and 2009 budget

Caroline Braibant, EPMF
Secretariat & Trustee



6.1. 2008 Expenses, 2009 budget and 2009(1) cost-shares

Caroline Braibant, EPMF
Secretariat & Trustee





6.1.1. Invoices 2008(2)

- Invoices sent on 1st Sept 2008
- Deadline: 5 Nov 2008
- Past generic costs erroneously invoiced to Re members (~ 38 656,75 €)
 - New invoices prepared for Re Members only, and
 - Share of past generic costs not paid by Re members (Re not in original scope of Consortium)
- Several Members have not updated Signature folio with correct invoicing address/contact:
 - (Several) Corrections needed
 - Delayed payments as a consequence



6.1.2. Predicted 2008 budget vs. projected 2008 expenses

| Cost item | Predicted | Spent | Difference |
|-------------------|------------------|------------------|------------------|
| Generic | 250 419 € | 199 391 € | 51 027 € |
| Ag-specific | 324 000 € | 100 844 € | 223 156 € |
| Au-specific | 80 000 € | 0 € | 80 000 € |
| PM CN- - specific | 0 € | 0 € | 0 € |
| PGM-specific | 300 000 € | 35 400 € | 264 600 € |
| Re-specific | 36 550 € | 2 400 € | 34 150 € |
| TOTAL | 990 969 € | 338 035 € | 653 000 € |

Note 1: Scientific Manager was hired later than expected

Note 2: 51 027 € - 38 656,75 € = 12 370 € is actual difference for Generic costs

Note 3: Projects were started later than expected



6.1.3. Options for "differences"

Up until now, differences were subtracted from next invoices... (e.g.: 2009(1))


With arrival of SIEF activities: three options

1. Keep as "reserves" →
 - Allows to confirm 2009 Members' shares immediately, and
 - Provides financial resources to be used for SIEF-related events (unpredictable at this stage)
2. Subtract 100% from proposed 2009(1) budget
 - 2a. Subtract 50% from proposed 2009(1) budget
 - In both cases: decreases 2009(1) Members' shares



6.1.4. Proposed 2009 budget and 2009(1) Members' shares


- Detailed budget and Members' shares available in handouts - three "versions":
 - (1) Keeping 100% of reserves for "unpredicted (SIEF) events"
 - (2) Subtracting 100% of reserves from 2009(1) budget
 - (2a) Subtracting 50% of reserves from 2009(1) and keeping 50% of reserves for "unpredicted (SIEF) events"
- In all cases, all four "new Members" have been included in calculations



6.1.5. Proposed 2009 budget - option 1

| Cost block | 2007 budget | 2008 projected expenses | 2009 proposed budget | Share of 2009 budget to be invoiced in Feb 2009 (keeping reserves) |
|-------------------|------------------|-------------------------|----------------------|--|
| Generic | 131 831 € | 198 211 € | 357 637 € | 219 438 € (~ 61% of total) |
| Ag-specific | 0 € | 100 844 € | 385 244 € | 321 344 € (~ 81% of total) |
| Au-specific | 0 € | 0 € | 112 810 € | 80 310 € (~ 72% of total) |
| PM CN- - specific | 0 € | 0 € | 129 820 € | 97 320 € (~ 75% of total) |
| PGM-specific | 0 € | 35 400 € | 543 900 € | 480 000 € (~ 88% of total) |
| Re-specific | 0 € | 2 400 € | 83 950 € | 51 450 € (~ 61% of total) |
| TOTAL | 131 831 € | 336 855 € | 1 613 361 € | 1 249 862 € (~ 77% of total) |


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6.1.5. (Cont.) Proposed 2009 budget - option 2

| Cost block | 2007 budget | 2008 projected expenses | 2009 proposed budget | Share of 2009 budget to be invoiced in Feb 2009 (subtracting reserves) |
|-------------------|------------------|-------------------------|----------------------|--|
| Generic | 131 831 € | 198 211 € | 357 637 € | 219 438 - 11 300 = 208 138 € |
| Ag-specific | 0 € | 100 844 € | 385 244 € | 312 344 - 223 156 = 89 188 € |
| Au-specific | 0 € | 0 € | 112 810 € | 80 310 - 80 000 = 310 € |
| PM CN- - specific | 0 € | 0 € | 129 820 € | No reserve 97 320 € |
| PGM-specific | 0 € | 35 400 € | 543 900 € | 480 000 € - 264 600 € = 215 400 € |
| Re-specific | 0 € | 2 400 € | 83 950 € | 51 450 € - 34 150 € = 17 300 € |
| TOTAL | 131 831 € | 336 855 € | 1 613 361 € | Option 1: 1 249 862 € Option 2: 623 656 € |

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6.1.5. (Cont.) Proposed 2009 budget - option 2a

| Cost block | 2007 budget | 2008 projected expenses | 2009 proposed budget | Share of 2009 budget to be invoiced in Feb 2009 (subtracting 50% of reserves) |
|-------------------|------------------|-------------------------|----------------------|---|
| Generic | 131 831 € | 198 211 € | 357 637 € | 219 438 - (11 300/2) = 213 788 € |
| Ag-specific | 0 € | 100 844 € | 385 244 € | 312 344 - (223 156/2) = 200 766 € |
| Au-specific | 0 € | 0 € | 112 810 € | 80 310 - 80 000/2 = 40 310 € |
| PM CN- - specific | 0 € | 0 € | 129 820 € | No reserve 97 320 € |
| PGM-specific | 0 € | 35 400 € | 543 900 € | 480 000 - (264 600/2) = 347 700 € |
| Re-specific | 0 € | 2 400 € | 83 950 € | 51 450 - (34 150/2) = 34 375 € |
| TOTAL | 131 831 € | 336 855 € | 1 613 361 € | Option 1: 1 249 862 € Option 2: 623 656 € Option 2a: 934 259 € |

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6.1.5. (Cont.) Preferred option?

- More details on impact of each Members' cost-share in handouts
- Attendees are invited to indicate preferred option

Simple majority vote

Precious Metals and Rhenium Consortium



6.2. REACH projects

Caroline Braibant, EPMF
Secretariat & Trustee



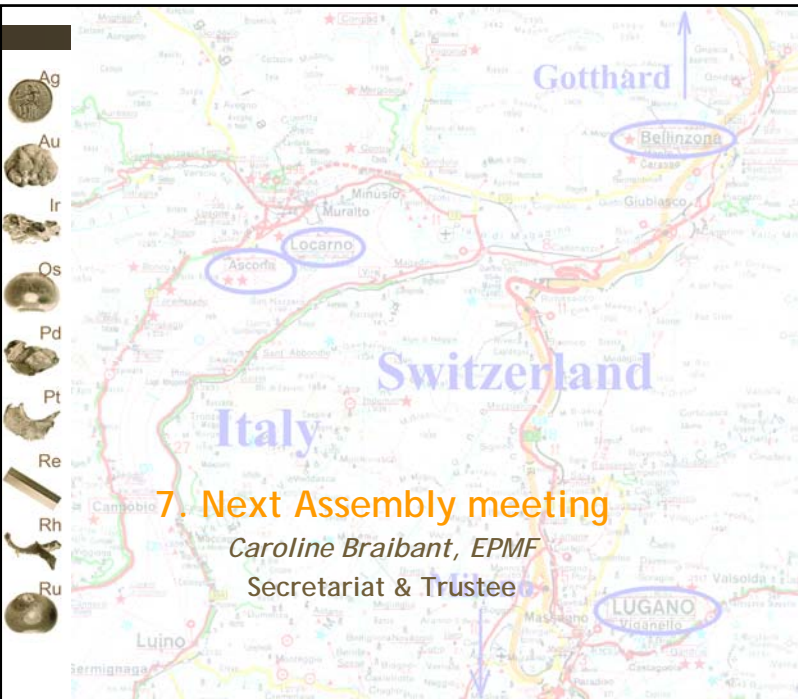
6.2.1. Detail of REACH projects

1. Metal-specific guidance on Socio-Economic Analysis
2. Downstream consequences of C&L
3. REACH interpretation, implementation and communication
4. Translation of RA concepts into EU REACH implementation
5. GHS joint project
6. HERAG/MERAG guidance for alloys
7. Development of data-gathering and exposure assessment tools
8. Update of current HERAG/MERAG
9. Unit World Model (alternative approach to PBT criteria)
10. Assessment and management of risks associated with inorganic particles (e.g.: nanos)



6.2.2. Evaluation of projects

- Proposed as a package: take it or leave it!
 - Package covers all priority issues for REACH implementation
 - Some projects provide direct benefits to PM & Re, other provide indirect benefits
- Consortium would need additional person just for these projects - EM "offers" to provide this as a service to its Members in metal consortia
- In general: improves overall dataset on metal-specific arguments under REACH
- Contribution to all 10 projects results in ~15 000 € in 2009, ~ 10 000 € in 2010




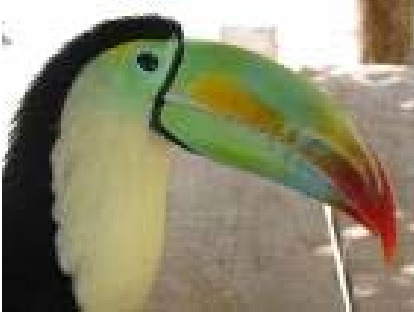



7.1. Next Assembly Meeting

- As agreed at last Plenary Meeting (Toledo 2008), the next Plenary Meeting will:
 - Be held in: [Lugano, Switzerland](#) (Grand Hotel Eden Lugano: www.edenlugano.ch)
 - Take place on: [19 June 2009](#) (full day)
 - Preceded or followed by a social event on 18 or 19 June 2009 evening (to be confirmed) and a city-tour on 20 June 2008 morning
 - Be hosted by the Association Suisse des Fabricants et Commerçants de Métaux Précieux (represented by Cédric Léger, PX Holding)
 - The proposed programme will be circulated in due course






Some pictures of
Lugano...
We look forward to
see you there!

8. Any other business?

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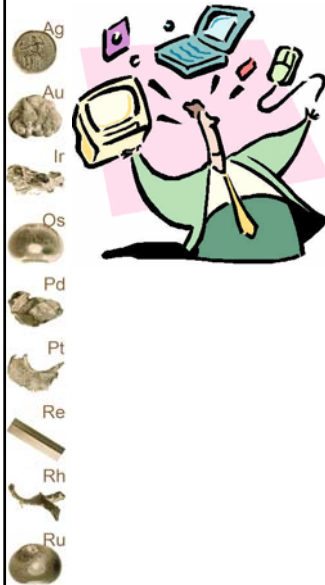




9. Conclusion

Andrew Griffiths, Umicore
Chair Management Committee
&
Jeff Levison, Vale Inco
Co-Chair Management Committee

Precious Metals and Rhenium Consortium

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Thank you very much to All for your presence and participation!

Welcome to our new Members!

And a particularly big **THANK YOU** to our chairpersons/speakers.

Have a safe journey back home, enjoy your end-of-year holidays and...
See you soon in the Pre-SIEFs!