



Precious Metals & Rhenium Consortium Management Committee teleconference

Brussels, 4 & 5 February 2009
Copper/Aluminium Room
Metals Conference Centre



Agenda

1. Welcome and introduction
2. Progress of technical projects →
3. Uses, exposure and emissions information collection
4. Management and budget of the Consortium →
5. Next meetings, AOB and conclusion

MC's approval needed

MC's approval needed



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1. Welcome and introduction



Participants

1. **Angela Alderman**

(Johnson Matthey -
United Kingdom)

2. **Christine Bourda**

(Metalor - France)

3. **Caroline Braibant**

(EPMF - Belgium)

4. **Andrew Griffiths**

(Umicore - Germany)

5. **Mike Halhead** (Anglo
Platinum - South
Africa)

6. **Steve Macy** (Ames
Goldsmith - United
States)

7. **Mark Raffray**
(Johnson Matthey -
United Kingdom)



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2. Progress of technical projects



Standard phases -Metal-specific projects (reminder)



HOW MEMBER ACTIONS & CONTRIBUTIONS FIT IN

I. Literature search

Data share: in-house information (studies, phys-chem, literature references)

II. Data gap analysis and preliminary tests (to enable grouping)

Provide reference samples
Preliminary use & emission data; other info for scoping / directing projects

III. Definition of intelligent testing strategy, Annex VII/VIII testing, test proposals higher Annexes

Provide reference samples

IV. Chemical safety assessment and chemical safety reports

Provide fuller information on uses, exposure & emissions

V. Compilation of Registration Dossiers

Confirm/adjust Signature folio & Substance / tonnage band declaration to Trustee + Id Lead Registrant



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2.1. Silver project



Latest developments: Phase IIb HH of Silver project (1)

- Reports received on 31 Oct (dustiness) and 11 Nov (bio-accessibility) - expected in late Sep
- Results:
 - all silver substances (soluble, insoluble and “nano”) tend to behave similarly!
 - **Dustiness:**
 - Except Ag nitrate, showed comparable (moderate) dustiness
 - Modelling predicts minimal deposition in lower respiratory tract
 - **Bio-accessibility:**
 - Only a small fraction of silver is released regardless of the nature of the test material
 - All test substances with same concentration of dissolved silver ions in all 5 media → need to explain reason (*current working hypothesis: interaction with Cl⁻ in test media*)
- Two options:
 - Easy but dangerous route:** All silver substances in one group and apply read-across from “data-rich” to “data-poor” to fill in data gaps for all endpoints → watch out for default “worst case” gap filling → could be detrimental to “good cases” in silver family!
 - Scientifically sound route:** Find out more about why behaviour is similar in all different media - resolve “strange phenomena”!





Latest developments: Phase IIb HH of Silver project (2)

- Outcomes of meeting with EBRC (20 February 2009, 9 PMC + 2 EBRC attended, chaired by Sarah Hottenroth)
 - PMC to compile list of hypothesis on “strange phenomena” occurring with bio-accessibility tests and share with EBRC by end of Feb
 - PMC to summarise required/recommended tests and derogation/waiving possibilities and send to EBRC by end of Feb for completion
 - EBRC to adjust silver proposal for Phases III, IV and V and revert to PMC by mid March with adjusted contract (one contract for all remaining phases) - including time plan (three silver substance dossiers needed for 2010 - **on track!**).
 - EBRC to develop a uses, exposure and emissions questionnaire for silver (agreed to share “ENV” segment of questionnaire with ENV consultant) to be circulated as from end of March 2009
- Next teleconference scheduled for: 27 March 2009, 15h CET





Latest developments: Phase IIb Env of Silver project (1)

- Report received on 27 Jan 2009 (Transformation/Dissolution) - expected in Dec 2008
- Objective: Evaluate aquatic toxicity of soluble and sparingly soluble silver by comparing:
 - The actual concentration of silver ending up in the solution (following transformation of the compound and/or dissolution of the compound in the solution), with
 - The appropriate standard eco-toxicity data on silver (nitrate).
- Results: Apparently, the risk assessment of Ag and Ag₂O can be based on the effects data for soluble silver salts (e.g.: AgNO₃) → same classification...



Latest developments: re-organisation of environmental segment of silver project

- Mgmt performance of Euras not effective enough
 - Although technically good, agreed to identify other ENV consultant to ensure on-time Registration of silver substances
 - Watts & Crane Associates, WCA (UK):
 - Environmental toxicologists
 - Already in charge of PGM & Re projects and providing support to understanding silver project “strange phenomena”
 - Excellent tracking and follow-up attitude
 - Reasonable, practical and open mind-set
 - Link with UK Environment Agency on silver Environmental Quality Standards (EQS)
 - Link with Competent Authorities discussions on nanoparticles
- Best option for next steps on environmental work of silver project:
- EBRC agreed to coordinate silver project efforts with WCA (particularly for CSA/CSR and IUCLID 5 file compilation)
 - Official letters sent to Euras, EBRC and WCA on 7-9 February:
 - Adjusted (draft) proposals received on 11 Feb (EBRC) and 18 Feb (WCA)





Parallel activities: Algal study (1)

- OECD 201 (NIVA report): gap filling in overall Ag dataset for PNEC / improved risk assessment:
 - Technical issue (unexpected by test lab / consultants)
 - Ag recovery from test media low (start & end of study) → complicates definition of actual exposure of algae → opinion from regulators: study still usable if this can be explained
 - VisualMINTEQ model used to predict concentration of silver at equilibrium: Ag concentration should have approximated to nominal test concentration values
 - Several hypothesis considered:
 - Photosensitivity (unlikely)
 - Uptake/adsorption of silver by algal biomass (unlikely to be primary factor - may be investigated to exclude)
 - Interaction with media constituents (Cl⁻ ?) / microprecipitation (possible - requires investigation)



Parallel activities: Algal study (2)

- Torsten Kallqvist (lead investigator / ex. NIVA) in discussion re **follow up work, e.g.:**
 - Assess for micro-precipitation (Millipore filter)
 - Test other exposure media (without chlorides)
 - Explore possible interactions between silver and solutions ingredients
 - Check for Ag sequestration into algal biomass
- Hege Stubberud (XStrata Nickel), in contact with T. Kallqvist - awaiting recommendations
- Others also involved in understanding results:
 - WCA: M. Crane, G. Merrington, and A. Peters
 - UK EA: B. Brown and D. Merckel
 - CEH Lancaster: E. Tipping and S. Lofts



Parallel activities: Overall Ag environmental assessment / risk characterisation

- Probable preliminary very low PNEC (2 ng Ag/L) can be revised upward; but exact new PNEC uncertain (approaching 20 ng/L?)
 - Headroom in relation to environmental levels (PEC) marginal
 - Need better data: emissions & aquatic levels (more on this later !)

1) Species sensitivity distribution modelling

- Dataset borders on what is needed; toxicity to fish is key endpoint
- Assessment Factor debated & estimated already (likely AF 3 to 5)
- Bring us to PNEC of between 12 to 20 ng/L

2) Further ways to mitigate a potentially adverse assessment

- Bioavailability adjustment via Biotic Ligand Model (BLM)
- Low bioavailability means that no adverse effects are occurring
- Simple regression approach (“free sulphide” or DOC) = £25k; 4 mo.
- “Cut-down” multiparameter BLM type = £100k to ~250k; 12 mo.
- Full BLM = £500k to >£1mi; 36+ mo. **Impractical in REACH timescale**
- Informally discussed with UK regulators & consultant (WCA)
- TAP discussion + exchange with WCA/UK EA ongoing**

MC's approval needed



Could be done with Ag reserve (~220 k€)



Parallel activities: Special case of Nano Ag

- ECHA and COM: As applicable, REACH registrations must be adapted/extended to cover nanoscale forms as well as bulk forms
- Ag consultant work performed to date has factored in this need
- But not a static situation in terms of regulators and researchers !
 - Need to constantly monitor for new science developments on human health & environment
- Human health related projects (e.g.: in current OECD program)
- The working hypothesis to date on environmental side:
 - Ag nanoparticle effects result of 'hot spots' of high ionic Ag caused by localised dissolution from the NPs adjacent to organisms/test systems
 - Some new work disputing this (Bremen University, Swiss groups)
 - Suggesting intracellular uptake/specific toxicities resulting from Ag NP
- PMC also being notified of new programs on Ag NP (e.g. Stockholm Particle Group)



Parallel activities: Nano Ag / Nano PM

TAP + Ag WG (+ consultants) to:

- Monitor ECHA, CA and COM discussions
- Track key research programs (e.g.: Bremen)
- Evaluate worth of participating in voluntary programs, e.g. SPG
- Allow for “fluid situation”: proportionate flexibility on test program and data needs
- Develop nanosilver (nano PMs?) strategy
- Propose to Mgmt Cttee for approval

MC's approval needed



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2.2. & 2.3. Gold & PM CN- projects



Latest developments: Scope of Gold project

- Proposal of additional substance to scope:
 - Following pre-registration “clean-up”, one company has requested one additional substance to be considered for the Au project.

Substance	CAS n°	EC n°	Tonnage band	Status
Gold trihydroxide	1303-52-2	215-120-0	1-10	On-site intermediate

→ TAP supported addition:
➤ Need for Mgmt Cttee’s approval

MC’s approval needed



Latest developments: Phase I report of Gold & PM CN- projects

- Scope needs to be adjusted based on recent addition of new gold substance
- One report for both projects, although two separate ones requested
- One month delayed submission - acceptable
- Objectives “seem” the have been fulfilled, although deliverable does not contain:
 - List of screened data/references and assigned Klimisch ranking
 - Availability of higher tier information sources
- Report lacked of transparency, comments were sent to Dr Knoell Consult on Thursday 19 Feb - **Response received on 23 February - report will be adjusted**



Parallel issues: Gold bars

- **LBMA abandoned intention to “fight” for article status**, although:
 - Solid arguments proving article status
 - Several consultants involved in preparation of “position paper” (half-way to finalisation - just needs final framing and refining)
 - “Simpathy” of some authorities (UK and ECHA Helpdesk)
 - J. Levison has met with LBMA representatives to understand reason behind such abandonment
 - Joint meeting with DEFRA’s waste and REACH specialists on 4th March, in order to discuss the question of good delivery gold bars as articles and the regulatory implications of then using them as substances
 - LBMA have requested a meeting to discuss their joining the Consortium. We have been delaying this meeting pending our meeting with UK Government
- MC’s
approval
needed**
- **Up to Consortium to decide whether or not to continue initiative:**
 - Could limit excessive registration requirements and tighter registration timeline due to higher gold tonnage band
 - Bob Warner has been contacted for quote - he is interested in continuing efforts launched by LBMA



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2.4. PGM project

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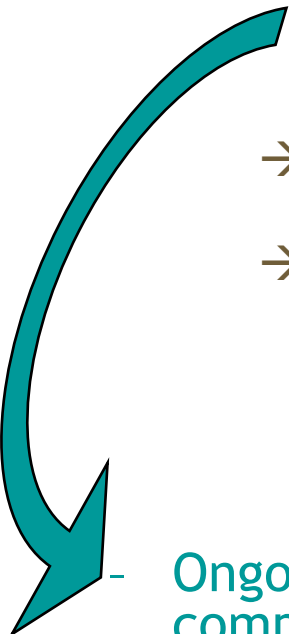




Latest developments: Scope of PGM project (1)

Clarification on ELINCS substances:

- Five ELINCS substances have been pre-registered by some Members of the Consortium
 - "phase-in" status only applicable to the on-site intermediate ELINCS - status/inclusion of substance and transported intermediate ELINCS in Consortium's scope needs further discussion
 - Consortium needs to produce Registration Dossiers for these (along with PGM project timeline - no special priority!)
 - Data-sharing principle can apply in two manners:
 - a) Other substances: information can be used to read-across to other in scope substances
 - b) Same ELINCS substance: information can be "copy-pasted" in specific/correspondent ELINCS substance's Registration Dossier



Ongoing exchanges between Secretariat and concerned companies to confirm which ELINCS substances are of interest + status of these ELINCS substances



Latest developments: Scope of PGM project (2)

- Proposal of additional substances to scope (1):
 - Following pre-registration “clean-up”, the following substances have been proposed to be considered by TAP for the PGM project.

Substance	CAS n°	EC n°	Tonnage band	Status
Disodium hexahydroxoplatinate	12325-31-4	235-590-0	1-10	On-site intermediate
Rhodium tris(2-ethylhexanoate)	20845-92-5	244-079-1	1-10	Substance
Ruthenium tetrachloride	13465-52-6	236-697-5	1-10	Substance



Latest developments: Scope of PGM project (3)

- Proposal of additional substances to scope (2):

Substance	CAS n°	EC n°	Tonnage band	Status
Iridium tetrachloride	10025-97-5	233-048-8	1-10	Substance
Dipotassium hexachloroiridate	16920-56-2	240-976-7	1-10	On-site intermediate
Triammonium hexachloroiridate	15752-05-3	239-842-0	1-10	On-site intermediate
Tripotassium hexachloroiridate	14024-41-0	237-854-0	1-10	On-site intermediate

→ TAP + PGM WG (+ WCA) to:

- Assess possible impact on PGM project (technical assessment based on Appendix 4 of Consortium Agreement)
- Mgmt Cttee will be invited to approve TAP recommendation after assessment





Latest developments: Pilot Phase II PGM project (1)

- Adjusted confirmation letter sent to WCA - new “scope” and deadline (13 March 2009):
 - PGM registration project highly dependant on defining an optimal grouping strategy (**maximise read-across / minimise cost**)
 - To ensure grouping methodology is robust, **Hexachloroplatinic acid (CPA) and Palladium (Pd) selected as start-point representatives** of preliminary valency-based categories Pt4 and Pd0 (Phase I report)
 - Datasets based on “substance profiles” provided by PMC to WCA BIBRA
 - Expected outcomes:
 - Use this pilot project as stepping stone into Phase II project (no repetition, or waste of effort since this evaluation is needed anyway)
 - Refine (1) categorisation methodology (with TAP/WG oversight and agreement) and (2) cost predictions to PMC



Latest developments: Pilot Phase II PGM project (2)

- In stepwise manner, WCA BIBRA will:
 1. Identify, obtain, and Klimisch score all relevant studies
 2. Extract key endpoint information for registration requirements, or necessary for purposes such as read-across, into spreadsheet (as data assembly tool)
 3. Initially use physico-chemical parameters (e.g. water solubility, particle size, dissociation state etc.) to evolve Phase I preliminary categories (which were based only on valency/chemical entity ‘equivalence’)
 4. Then further refine category modelling process using data from mammalian toxicology and eco-toxicology endpoints
 5. Above approach will be verified as acceptable by TAP and PGM / Re WG
 6. Compile and retain the information and evaluations (quality-assessment of information, extend Phase I gap analysis, define enabling tests etc.)
 7. Work outwards in a logical manner to extend above efforts into the full Phase II projects for PGMS and Re



Platinum reports: DECOS + IRIS report

(Issue(s) addressed under umbrella of EPMF's EHS Committee)

- First level response to DECOS report drafted, approved and circulated/posted in January
- Now US EPA released draft Toxicological Review on Pt → IPMI has already prepared draft response and set a meeting date (Pennsylvania, 18 March 2009)
- Both reports need careful attention by Consortium as it may constitute source of information for PGM + require input from Consortium "findings".



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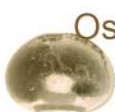
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2.5. Rhenium project



Latest developments: last and next meetings

• Last meeting held on 4 Dec 2008:

- Agreed to proceed with identification of volunteer Lead Registrants
- Much interest in testing predictions/minimisation:
 - Category/Read-across approach
 - Application of Annex III criteria on rhenium indicative list
- Nickel alloy scrap: need to agree on registration strategy
- Requests:
 - List of Re references in Phase I of Rhenium project
 - Confirm estimated registration date (2010, 2011?)
 - Outcomes of Phase II pilot project

• Next meetings:

- Teleconference 2 March
- Face-to-face meeting 17 April 2009 (Brussels)
- Face-to-face meeting 15 June 2009 (London)



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2.6. Complex refinables



Context (1)

- Amongst primary and non-waste secondary feeds, many complex substances of unknown and/or variable composition, i.e. UVCBs
 - Lack of full compositional data, let alone speciation
 - All assumed handled under strictly controlled conditions
 - Many are transported (Annex VII tests apply if >1000 tonnes)
- With data requirements generally restricted to classification and “existing available information”, limited set of possible outcomes, hence generic approach
 - Main short term challenge to come up with acceptable naming and identification



Context (2)

- Consortium pre-registration advice:
 - Pre-register as mono- or multi-constituents or preparations, if feasible
 - If not, use suggested EINECS numbers
- Now must sort out what Consortium members have done with these complex materials before tackling other SIEF members
 - Individual UVCB SIEFS may contain substances which cannot be called the same
 - The same substance may be distributed through different UVCB SIEFs and beyond
 - Looking for data for a raft of metals other than PMs
 - Some low PM materials may be better fit with other consortia



Agreed on 4 & 5 Feb meeting

- Cross-check how pre-registration has been performed
- Request firm declaration of complex refinables (using Appendix 2 of Consortium Agreement)
- Launch substance sameness discussions
- Create one ID card per refinable/refinable group
- F-t-f meeting organised on 26 Feb:
 - “Official task force” formed, chaired by J. Levison (Vale Inco)
 - Continue to strongly encourage uniformity over diversity



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3. Use, exposure/emissions information collection



What are we aiming for?

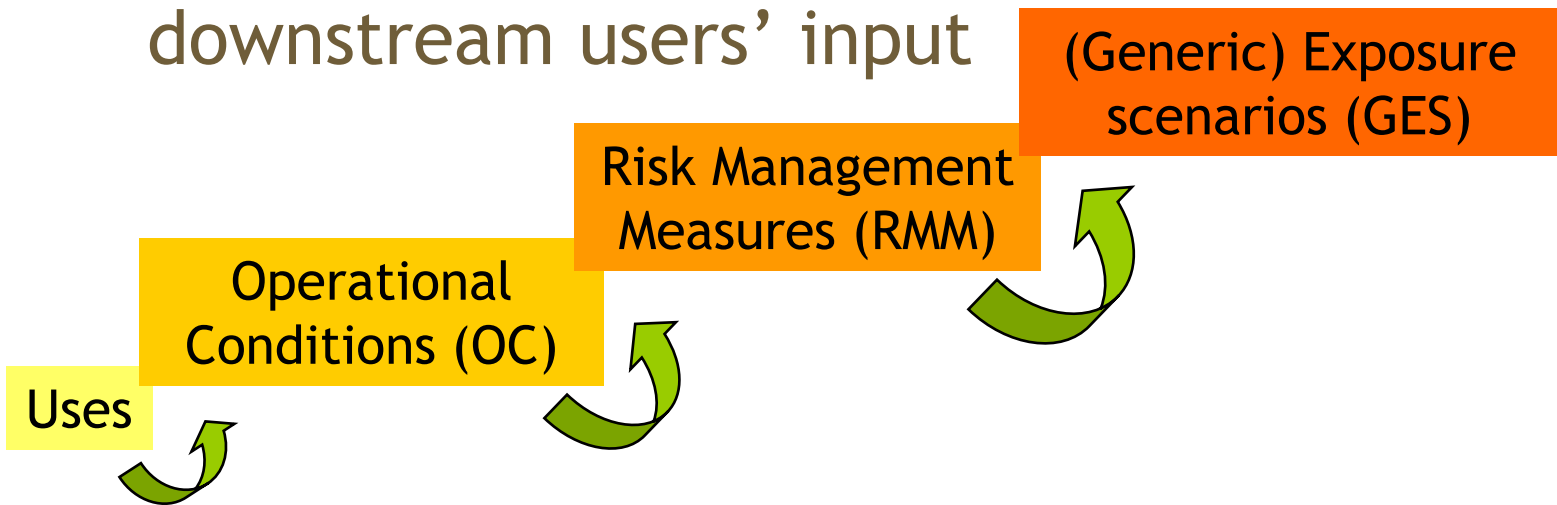
- Set up the limits of a data collection tool so that it is proportionate to data-needs associated to:
 - Basic REACH requirements:
 - information on manufacture and use of the substance
 - > 10 tonnes/year situations:
 - CSA/CSR required
 - Dangerous/PBT or vPvB situations:
 - CSA/CSR + Exposure assessment + risk characterisation
 - Exposure-based waiving needs:
 - No exposure data → no waiving possibilities
- Starting with Ag as priority / first experience



How to achieve this?

- First: map uses

- Done on 4 & 5 Feb meeting
- Provided to EBRC to compose questionnaire
- May need to be completed by downstream users' input





How can Mgmt Cttee representatives contribute?

- Make sure:

- Questionnaire is distributed to “right hands”
- Enough resources are assigned to completion of questionnaire:
 - By company and key downstream users of company - need a total of 3 full questionnaires by use
 - Uses, exposure and emissions information will be requested
- Questionnaire is completed and forwarded to Scientific Manager by indicated deadline:
 - Otherwise, risk of delaying silver project 😞
 - Although no reserve time left!



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4. Management and budget of Consortium



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4.1. REACHsuite



Data management and communication tools: what is available?



	REACHSief	REACHSuite	MoCon
Owner	REACHlink (CEFIC spin-off)	Baytouch (managing LOA Consortium)	Molybdenum Consortium
Primary goal	Organise SIEF communication and data management	Organise Consortium organisation and data management	Communicate with SIEF participants
Extensions	Envisaged: adapt to Consortium organisation needs	SIEF Management module, including C-forms to communicate with SIEF participants	None envisaged, fulfils very specific objective
Applicability to PM & Re Consortium	Poor, as mainly oriented to support SIEF having no consortia	Very high: Experience of Consortium manager Many substances and/or large membership Large database capacity Room for tailor-made improvements and adaptations	Significant: Experience of Consortium manager Quick and easy-to-use communication tool to deliver urgent messages to SIEF participants
Associated cost	From 5000 to 40 000 € (excluding any future add-ons)	For PM & Re Consortium: ~ 65 000 € for first year, ~ 55 000 € for the following year(s)	~ 5000 € for ten substances



Data management and communication tools: What do they do?



	REACHSief	REACHSuite	MoCon
Link to website/info portal	?	Yes	Yes
Data storage	Yes	Yes	No
Confidentiality levels (and security)	?	Yes	Not applicable
Super-SIEF set-up	Yes	Yes	No
Mass e-mailing system	Yes	Yes	Yes
Surveys (e.g.: sameness, lead registrant, etc.)		Yes	Yes
Automatic follow-up of surveys	?	Yes	Yes
Actions tracking and deadlines monitoring	?	Yes	No



Example of data management segment applications

- Substance/project, linked to:
 - Each (concerned) Member in Consortium
 - Other substances (Categories)
 - Available dataset
 - Required information (as per highest tonnage band - kind of precursor to IUCLID 5 filling)
 - Project planning and tracking



Example of SIEF management segment applications

- SIEF people:
 - Regularly updated, informed on progress:
 - Identified/Supported uses C&L
 - Letter of access availability
 - Given opportunity to comment:
 - E-mail out (forms for targeted responses)
 - Collection of responses



Standard contractual terms and conditions, and cost

MC's
approval
needed

- Pricing model revised:
 - From 80 000 to 67 450 € for year 1
 - From 66 000 to 50 000 € for year 2
 - Test system implemented for 2000 € + VAT (included in full contract)
 - First two hours of training free of charge (2 March, 10h00 - 12h00)
 - Valid until 28 Feb 2009
 - Payable within 30 days of signature of Agreement
- Confidentiality and security:
 - Confidentiality Agreement signed on 24 Jan 2009
 - Security ensured by single server + SSL certificate
 - IT specialists have evaluated Agreement and provided comments that have been shared with Baytouch
- All legal/IT comments and questions sent to Baytouch for consideration





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4.2. Technical resources of the Consortium and fall-back plan during C. Braibant's maternity leave



MC's
approval
needed

Proposed re-organisation

- Maternity leave from 8 March till 8 June
- Basic re-organisation foresees:
 - S. Delhove to respond to “administrative” requests with “typical response letters” (e.g.: membership requests, Assembly meeting in Lugano)
 - Z. Hugonin to manage “technical” exchanges / meetings / activities
 - Less priority issues to be “frozen” during absence of Secretariat & Trustee
 - Chairpersons of Consortium’s working structure to support Z. Hugonin and feed-back to Secretariat & Trustee
- See Annex





Technical resources

- Departure of Z. Hugonin in Summer 2009 due to personal reasons (after return of C. Braibant)
 - Interview with Tim Hird (25 Feb): promising profile, needs 3 months-notice to quit current position and move to Belgium, need to see salary expectations...
 - Above demonstrates “fragility” of Consortium’s staff platform...
 - Other consortia have:
 - existing risk assessment experience/data
 - a minimum of 3 full-time members personnel
 - for 10 times less substances, and
 - with at least 2 times bigger testing budgets...
- Need to ensure success of Registration for all PM & Re projects
- Ideally: contract additional (technical) resource for Consortium:
 - Foresee place holder in 2009 budget
 - Post new job advertisement - [see Annex](#)



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4.3. Approval of expenditures and use of Consortium's reserves - see Annex



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4.4. Final 2009 budget, and 2010 & 2011 budget predictions - see Annex



Revised 2009 budget

- 2009 budget presented at Assembly meeting did not include REACHsuite cost and possible additional technical resource to replace/complement Z. Hugonin
- 2009 cost-shares have been adjusted following companies' pre-registration check-up and Substance and tonnage band declaration updates
- MC invited to approve revised budget before circulation to Assembly for final approval (and invoices release)

**MC's
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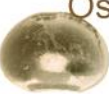
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4.5. Communication with Pre-SIEF - see Annex



Presence of PMC in Pre-SIEFs

Tiered approach to communicate with Pre-SIEF:

1. Respond to (self-claimed) SIEF Formation Facilitators (under umbrella of Eurométaux to ensure harmonised response)
2. Prepare presentation letter of PMC:
 1. Who we are, membership conditions and alternatives (letter of access/licence to use)
 2. What we do/intend to achieve
 3. What we do not do
3. Present PMC's initiatives to Pre-SIEF:
 1. ID cards (substance sameness discussions)
 2. Lead Registrant (volunteers, duties and liability, and risks of opting out from joint submission).
4. Further develop conditions to access and use PMC's information

Drafts to be prepared by PMC and sent to Mgmt Cttee for approval/signature by Chairperson



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4.6. Registration deadlines



Registration deadlines per project

Project	As per Pre-SIEF	As per Consortium Members' declarations	As per Consortium's proposed time plan*
Ag	2010	2010	2010 - 2011
Au	2010	2018	2010 - 2011
PM CN-	2010	2018	2010 - 2011
PGM	2010	2018	2010 - 2011
Re	2010	2018	2010 - 2011
Complex refinables	2010	2010	2010 - 2013

In all cases, registration deadlines envisaged by pre-registrants are earlier than actual tonnage-band triggered deadlines

*Some substances in each project apply for earlier registration deadlines than others



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4.7. Initiatives and experiences of other consortia



Any idea to be considered by PMC?

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5. Next meetings, AOB and conclusion



Next meetings

- Technical meetings:

- Refinables TF: f-t-f 26 Feb, teleconference tbd
- Re WG: teleconference 2 March, f-t-f 17 Apr
- TAP & PM WG: tbd

- Management Committee meeting:

- Proposed: 10 June 2009

- Assembly meeting:

- Lugano (Switzerland), 19 June 2009