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TAP & PM technical meeting
PM & Re Consortium

16th September 2008
Metals Conference Centre
Brussels, Belgium



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1. Welcome and introduction



1.2. Attendance list

Ag

1. Dave Boyd, Johson Matthey (United Kingdom)
2. Edwin Broekaert, Umicore (Belgium)
3. Helena Byrdziak, KGHM Polska Miedz (Poland)
4. Peter Charlesworth, AngloPlatinum (South Africa)
5. Rob Garrett, Ames Goldsmith (United Kingdom) - - by teleconference
6. Daniel Glowacki, KGHM Polska Miedz (Poland)
7. Peter Grohnert, Heraeus (Germany) - - excused
8. Mike Halhead, AngloPlatinum (South Africa)
9. Sarah Hottenroth, Umicore (Germany)
10. Leila Laine, Norilsk Nickel (Finland)
11. Jeff Levison, Vale Inco (United Kingdom)
12. Aurélie Normand, Metalor (France)
13. Agnieszka Piechota, KGHM Polska Miedz (Poland)
14. Mark Raffray, Johnson Matthey (United Kingdom)
15. Hendrik Roth, Norddeutsche Affinerie (Germany)
16. Werner Selzer, Wieland Dental + Technik (Germany)
17. Mika Toivola, Boliden (Sweden)
18. Susan Visser, Xstrata (Norway)
19. Roland Winde, Umicore (Germany) - - by teleconference
20. Jochen Windhager, Norddeutsche Affinerie (Germany) - - excused

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Secretariat:

Caroline Braibant
Zuzana Hugonin

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1.3. Agenda

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1. Welcome and introduction
2. Update on silver project
3. Update on gold project
4. Update on PGM project
5. Update on PM CN- project
6. PM complex refinables
7. Pre-registration recommendations
8. AOB and conclusions

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1.4. Action points of last meeting

(5 June 2008)

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- Substance categories - to be concluded today (see adjusted inventories in handouts)
- ELINCS substances - phase-in or non phase-in? To be discussed today
- Proposal for PM refinables categorisation - to be discussed today:
 - Phase-in substances with no EINECS number can be pre-registered:
 - Need to declare phase-in status before pre-registering;
 - Phase-in status needs to be documented in house in the event Competent Authorities require evidence of such status.
- No comments received on minutes → Vote





1.5. Objectives of this meeting

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Business Item	Why
Updates on Ag, Au, PGM and PM cyanides registration projects	Progress review and discuss any significant science or project management issues.
Conclude any remaining decision making on sameness and pre-registration path (e.g. on PGM)	PMC members need to proceed with actual pre-registration in a harmonised manner.
Status check of member preparedness/progress on pre-registration activity	PMC pre-registration guidance to members at point of finalisation. Trustee and TAP need to understand support needs.
Conclude plan for handling refinables/complex intermediates	So pre-registration can progress and there is synchronisation with other metals consortia



Last face-to-face meeting before pre-registration window ends ...?



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2. Update on silver project

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2.1. Phase IIa reports

- Recap:
 - In-depth data gap analysis on 11 silver compounds
 - Divided in two parts:
 - Environmental assessment (Env) - conducted by Arcadis (Euras), Belgium
 - Human Health assessment (HH) - conducted by EBRC, Germany
 - Started: January 2008
 - Reports received:
 - ENV: May 2008
 - HH: July 2008
- Phase IIb testing is underway - draft reports due:
 - HH: October 2008
 - ENV: December 2008 (queue at T/D Laboratory)

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2.1. Phase IIa reports

Evaluation of silver chloride studies by EBRC

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- Photographic industry was contacted to determine availability of information on silver and silver compounds
- KODAK USA confirmed having studies on silver chloride (which is an intermediate for PM & Re Consortium)
- Three silver chloride studies were evaluated by EBRC so as to determine whether:
 - They were relevant for the data gap analysis of the silver project
 - They should be purchased from KODAK by the PM & Re Consortium considering:
 - Read-across possibilities
 - Interpretation of "any existing available information" as applicable to intermediates
- EBRC's conclusion: not essential at this stage



2.1. Draft report phase IIa HH

Summary of conclusions and recommendations

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- Physico-Chemical:
 - Silver nitrate should be tested for oxidising properties
 - Silver powder could be tested for flammability
- Toxicological:
 - Disilver oxide: inhalation (15 k€) + dermal (4 k€) if read-across from silver not possible (depends on bio-accessibility results)
 - Silver nitrate:
 - oral (cost?) + dermal (4 k€)
 - inhalation lacking but not possible for corrosive
 - Silver nitrate: classified as corrosive but classification might require corroboration, if doubts: *in vitro* corrosivity test
 - Sub-chronic (90-day) oral toxicity in rat (OECD 408) should be conducted on soluble silver compound to derive NOEL, and then read-across to others (watch out for worst case scenario) → 200 k€.
 - Bacterial reverse mutation assay (AMES test) with a soluble silver compound (3 - 5 k€)
 - *in vitro* micronucleus test (20 - 40 k€), and *in vivo* study if result is positive
 - *in vitro* gene mutation assay in mouse lymphoma cells (OECD 476) (20 - 25 k€)

TAP evaluation required!

TOTAL excluding OECD 416 testing proposal:
more than 260 k€ over 1,5 year



2.1. Draft report phase IIa ENV

Conclusions and recommendations

- Eco-toxicological data available only for silver nitrate [see summary table in meeting file (table 25)]
- No aquatic toxicity data, recommended:
 - Activated sludge respiration inhibition test on silver nitrate
 - Growth inhibition to aquatic plants test on silver nitrate and silver carbonate
- Adsorption/desorption and bio-accumulation:
 - (Quality of) Available data requires further investigation
 - Only for > 100 tonnes/year (testing proposal)
- No data on toxicity to terrestrial, sediment and birds:
 - Screening method: Equilibrium partitioning method based on PNEC and Kd
 - Testing proposals only
- Read-across and enabling studies:
 - T/D test on silver and disilver oxide (Phase IIb)
 - Conduct test on short-term toxicity to aquatic invertebrates with silver carbonate (less expensive to perform Annex VII than T/D)

No prediction costs provided by Euras



2.2. Phase IIa ENV: Environmental assessment:

Aquatic PNEC re-evaluation effort (1)

- EURAS Phase IIa assessment indicated very low PNEC (2 ng Ag/L) based on conservative Assessment Factor (AF=50)
- Typical background concentration in non-urban waters (~10 ng Ag/L)
- **PMC objective: Improve dataset to allow re-evaluation of PNEC**
- **A) Near-term actions**
 - Run algal study (OECD 201) to fill trophic level data gap
 - Study start imminent with Norwegian contract research organisation
 - Will permit improved AF (AF=10 instead of 50)
 - As worst case, could end up with lower NOEC but an improved AF. Initial tentative prediction of PNEC of not less than 20 ng Ag/L
 - Other action: Seek more data and comparator PNEC from Biocides registrations of Ag / AgNO₃; expected access of data by Dec 2008

2.2. Phase IIa ENV: Environmental assessment:

Aquatic PNEC re-evaluation effort (2)

- Still not much headroom in the expected PNEC
- Provided enough endpoints and taxonomic groups, AF possibilities could be further improved by Species Sensitivity Distribution model

B) Medium-term actions

- Need at least 10 "long term" NOEC covering fish, 2nd chordate, crustacean, insect, alga, plant, invertebrate plus other phyla
- Our available dataset is almost sufficient for SSD -- could try and make a case now, e.g. using WCA as expert interface to regulators
- More likely some limited gap filling studies may be demanded
- Cost estimates: (i) WCA expert negotiation ~1.7 kEU; (ii) worst case for additional invertebrate studies up to 60 kEU (expected to be significantly less if well negotiated)
- Resulting AF between 5 to 1 with proportionate PNEC improvement

2.2. Phase IIa ENV: Environmental assessment:

Aquatic PNEC re-evaluation effort (3)

- Need a "rescue plan" if outcome is not as favourable as expected from previously described actions

C) Fall back action

- Mitigate risk assessment / low PNEC via bioavailability program
- Evaluate impact of DOC and other factors directly impacting on the *bioavailable* Ag concentrations in the environment
- Last resort -- expensive and time consuming !



2.3. Cooperation with UK authorities

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- EU working on Water Framework Directive (WFD)
 - UK working on Environmental Quality Standards (EQS) for Silver
 - WCA (PGM project consultant) is working with UK authorities on EQS
 - WCA has proposed PM & Re Consortium/EPMF to use REACH results for silver on EQS work
- The MC has agreed to share any data generated, as applicable, with UK authorities (through WCA)
- WCA will at the same time, act as peer reviewer of the silver project (good to avoid/succeed Dossier Evaluation)



Timeline

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Who?	What?	When?
Members	1. Pre-registration by each legal entity	1. Before December 2008
Consultants	2. Silver Phase IIb Draft reports & Algal study results due	2. Before December 2008
TAP, WG's and MC	3. Resolve Issues with Consultants - insurance, performance etc.	3. Before December 2008 Before March 2009
TAP, WG's and MC	4. Agreement on main testing programme	4. Before June 2009
Consultants	5. Phase III - experimental testing	5. and 6. To be started in early 2009 and finalised before September 2010
Members, Consultants	6. Phase IV - production of CSA/CSR - Need Info on uses & emissions	
Consultants	7. Phase V - Production of Registration Dossiers	7. Before October 2010
	Still on-time but Member's quick input essential for on-time registration!	



Extra: Overview of current pre-registration status

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• Pre-SIEF:

- Silver - approx 70 members
- Silver nitrate - 23 members
- Silver Oxide - 15 members
- Silver Chloride - 9 members

NB:

- Some companies are pre-registering every available chemical
- Consultants and traders are pre-registering several chemicals as commercial strategy - not all SIEF members are potential registrants

To be discussed:

- Should we be contacting these companies to get them to join the consortium?
- Should we be ensuring the SIEF Formation Facilitator is a Consortium Member?



3. Update on gold project

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3.1. Adjusted gold indicative list

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- Four substances, one in 10-100 tonnes/year band and three in 1-10 tonnes/year band.
- Only one CSR required.
- Legal deadline: 2018.
- Expected deadline: 2010-2013 max.

Name	CAS	EC	Maximum tonnage band
Gold	7440-57-5	231-165-9	10-100
Tetrachloroauric acid	16903-35-8	240-948-4	1-10
Ammonium gold (1+) sulphite	71662-32-3	275-798-9	1-10
Aurio(1+)2,6,6-trimethylbicyclo[3,1,1]heptanethiolate; gold pinanyl mercaptide	68365-87-7	269-858-3	1-10



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3.2. Confirmed quotation from Dr Knoell Consult

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- Meeting with Dr Knoell Consult on 5th March and 8th June 2008 to present Consortium and REACH projects
- Quotation requested and clarified; last revised version:
 - Timeline: September 2008 - 2010 (up to Consortium to define strategic timeline)
 - Cost (excluding testing): 71 800 €

3.3. Phase I initiation: data, studies and information received from Members



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- Several oral and written requests for data/information on gold have been circulated
- Feed-back is rather disappointing
- Thank you to companies who have replied but had no data, e.g.:
 - Ames Goldsmith, Boliden, Metalor, PAMP, Vale Inco, etc.
- Thank you to those having contributed with references and studies:
 - Carl Hafner, Germany
 - Cendres & Métaux, Switzerland
 - Johnson Matthey, United Kingdom
 - Umicore, Germany

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3.4. Update on LBMA activities related to Gold bank products



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- Gold ingots/bars - not purely involving Consortium interpretation - also LBMA and banks involved
- LBMA's intention to produce position document to be presented to several Competent Authorities for "endorsement":
 - LBMA's membership trying to consider ingots/bars as articles (no registration requirements)
 - Not sure whether intention is for gold ingots or all PM ingots to be covered by discussion
 - Working with Bob Warner (ChemWise) and Mayer Brown (legal support)
- Should LBMA's attempt fail:
 - Tonnage might increase from 10-100 to 100-1000 (or more?) and registration deadline might be earlier.
 - Consortium intends to tackle this issue separately from project with consultant:
 - Data-gap analysis can commence - further phases of Gold project can be adjusted based on LBMA's attempt results, if necessary.

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Extra: Pre-registration experiences

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- Any generic comment from the participants?

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4. Update on PGM project



4.1. Adjusted PGM indicative list

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- Available in handouts
- 68 - 73 substances and intermediates in scope (depending on ELINCS discussion)
- Definition of "sponge" and assessment method for such form(s) provided by AngloPlatinum
- Pre-registration recommendations have been put forward during several meetings - compiled into Pre-registration suggestions leaflet



4.2. Update on Phase I

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- Phase I has commenced in late July 2008, following meeting with WCA on 4th June
- Available studies from Members following several oral and written requests:
 - Feed-back is rather disappointing
 - Thank you to companies who have replied but had no data, e.g.:
 - Ames Goldsmith, Cendres & Métaux, Metalor, Vale Inco, etc.
 - Thank you to those having contributed with references and studies:
 - Anglo Platinum, South Africa
 - Boliden, Sweden
 - Carl Hafner, Germany
 - Johnson Matthey, United Kingdom
 - PAMP, Switzerland
 - Umicore, Germany
 - Sent to WCA on 4th September
 - Report due for November 2008



4.3. Impact of DECOS report (1)

Chloroplatinates - new external OEL evaluation

- Dutch Expert Committee on Occupational Standards (DECOS) & Nordic Expert Group (NEG)
- Recent exposure limit assessment (June 2008) - key health effect is respiratory sensitisation potential (human data)
- Workplace chloroplatinate OEL (long-term exposure limit) established at 5 nanogram/m³ (as Pt)
- Known for some time that established OEL of 2 microgram/m³ adopted by numerous regulators is not fully health protective for chloroplatinates
- However DECOS OEL is very conservative: represents a 400-fold reduction
- DECOS declined to set OELs for other soluble Pt compounds (perceived data gaps). Some commentary that reduction of soluble Pt OEL is appropriate



4.3. Impact of DECOS report (2)

Science considerations

- Science approach precautionary (partly due to uncertainties in demonstrating precise thresholds for sensitisation)
- Heavily influenced by single epidemiology study* in a German autocatalyst production plant (Degussa; 1989-1995) - note:
 - Variability of airborne levels in high-exposure group
 - Exposure stratum 50-500 ng m⁻³: response data inadequate
 - Even study authors acknowledge cannot discriminate effect threshold for sensitising exposures
 - DECOS OEL derived from de minimis basis that no sensitisation occurred after negligible exposures (~ 10 ng m⁻³)
- DECOS OEL doesn't account for important peak exposures
- Some errors in DECOS report - not well peer reviewed ?
- OEL is actually lower than that which can be derived from a recent DECOS review (2005) of Cisplatin (genotoxic)

*Merget et al. (2000) J Allergy Clin Immunol 105: 364-370



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4.3. Impact of DECOS report (3)

Implications & impact assessment

- Challenging to accurately quantitate ng/m³ levels in workplace
- Overall impact assessment:
 - 1. Territorial applicability of this OEL guidance not itself a major issue for sector
 - 2. However could precipitate re-evaluation of OELs for chloroplatinates (and other soluble Pt species) by other limit setting bodies
 - 3. Increases chances of prioritisation for regulatory control (e.g. under REACH)
 - 4. Potential aggravation of autocatalyst issues (misconceptions remain commonplace re assumed content of chloroplatinates in autocatalysts, emissions, conversion of emitted Pt in the environment)
- **CONCLUSION:** Sector review and counteractive statement is recommended (via EPMF, IPA, AECC etc.)



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4.3. Impact of DECOS report (4)

- Task Force launched at EPMF level:
 - Umicore (2x), Anglo Platinum (2x), Johnson Matthey, Vale Inco and Heraeus have proposed candidates
 - Xstrata?
 - Good start but smaller companies representation might be recommended!

4.4. Status of PGM substances and process intermediates



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- Conclude discussion on:
 - Substance category (especially UVCB)
 - Distinction of oxides, hydroxides and hydrated oxides
 - ELINCS:
 - Phase-in or non phase-in?
 - In scope or out of scope of activity?
 - In scope of free data-sharing or not?
- Wait and see how substance sameness discussions are tackled at SIEF level (if non-Consortium participants)

Extra: Pre-registration experiences



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- Any generic comment from the participants?



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5. Update on PM CN- project

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5.1. Proposed quotation from Dr Knoell Consult

- Meeting with Dr Knoell Consult on 5th March and 8th June 2008 to present Consortium and REACH projects
- Quotation requested and clarified; last revised version:
 - Timeline: September 2008 - 2010 (up to Consortium to define strategic timeline)
 - Cost (excluding testing): 118 400 €
- Studies and references received so far from Metalor and Umicore

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Extra: Pre-registration experiences

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- Any generic comment from the participants?

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6. Update on PM refinables (complex intermediates)

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Precious metal refinables/complex intermediates

Actions supporting: Inventory, Pre-registration action, Registration path

Ag	Overall REACH <i>strategy</i> to handle Refinables and Complex Intermediates	Refer to document packs
Au	Refinables and intermediates - <i>generic substance inventory</i> (indicative list) for PM sector	Refer to document packs
Ir	Preferred <i>analytical method</i> for characterisation	
Os	PMC <i>Pre-registration guidance</i> : will include some advice on refinables situations	Currently being compiled
Pd	<i>Inter-consortia linkages</i> (mainly EM platform)	Report later in this segment
Pt	1. Map assignment of entities to various Consortia	
Rh	2. Life cycle/production route rationale for these assignments	
Ru		

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Objectives of today's review - finalisation

1. Check overall strategy is robust and still supported by members
2. Finalise inputs for Pre-registration guidance to members. PMC needs members to check and agree:
 - a. All their refinables / complex intermediates covered by the 2 lists (Table 1 and 2)
 - b. Is content of Table 1 [EC nr. indexed entries] fully acceptable ?
 - c. Is Table 2 [Non-EC nr. entries] acceptable; e.g. are substance descriptors ok (flexible enough without being too vague) ?
 - d. All affected companies can foresee how to consistently map each of their substances to a listed entry (for pre-registration/sameness)
3. Trustee can recap on key inter-consortia agreements and actions
4. Members have an opportunity to raise any high level and tactical questions or issues for resolution

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Envisaged pre-registration actions & timing



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Guidance from PMC

- Harmonised pre-registration guidance covering refinables and complex intermediates finalised by end September

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PMC member action

- Conduct related pre-registrations (October timeframe)

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6.1. Adjusted Precious Metals refinables indicative list



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1. Included a review of existing ESIS entries applicable to PM
2. Members have contributed descriptions of related substances
3. Mapped to the entries in Table 1 and 2; new entries established as necessary
4. Table 1 (EC nr listed) believed to be as complete as possible
5. Little new input recently received on Table 2, still opportunity to adjust to member needs:
 - Any refinables/complex streams missing ?
 - Are substance descriptors ok (flexible without being too vague) ?
 - Do any of the entries need to be split or further stratified, e.g. concentrates ?
 - Integration of low and high grade refinable intermediates

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6.2. PM Refinables - categories proposal



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PGM Classification Schedule		
%Precious Metal	Sub Class	Class (Option 1)
0,001 to 0,01	I	"A"
0,01 to 0,1	T I	
0,1 to 1	T I	"B"
1 to 10	T I	
10 to 100	T	

I	Individual element
T	Total of elements present

A	Low grade refinable intermediates, precious metals refining
B	High grade refinable intermediates, precious metals refining

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6.3. Other consortia (EM platform) activity



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EM has set up an Intermediates group for Consortia managers to meet on a regular basis so as to determine:

- Overlaps between complex intermediates inventory in each Consortium
- Extent of species characterisation of complex intermediates from one Consortium to another
- Way to maximise cost-efficiency for consortia members by promoting data-sharing exercises between consortia
- Consistency of pre-registration, registration approaches, etc. (naming, grouping, categorisation, sampling, characterisation, testing of complex intermediates)

Most recent meeting: as we speak!

NB: Adjusted REACH & Waste meeting released recently (in handouts)

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6.4. Roundtable feedback of members on pre-registration actions & support requests



- In concept, pre-registration should be no different to M/I substance situations...but...
- PMC pre-registration leaflet coverage of all situations where questions could arise is difficult → consider contact to Secretariat where uncertainty exists
- Based on member returns, worst case is maximum 5 companies pre-registering an equivalent refinables/complex intermediate
- RIP 3.10 categorisation (Mono, MCS, UVCB) → member approaches could differ
- Given the variable nature of such streams, and typically indicative analyses, UVCB is a logical default
- **Chance to raise anything else on pre-registration support !?**

7. Pre-registration recommendations





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7.1. Report on Pre-registration seminars

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- LBMA (3rd September) and Eurométaux (10th September) have organised Pre-registration seminars to present the routes for pre-registration

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- Well attended seminars, with different audiences

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- Most participants have not yet pre-registered

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- Most participants having “played around” with available IT solutions intend to use IUCLID 5 Plug-in so as to avoid duplication of work by the time of Registration

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7.2. Proposed Pre-registration suggestions

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- To be discussed

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7.3. Roundtable feedback of Members on pre-registration actions



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- Please feel free to share your comments through “confidential form” circulated at the beginning of the meeting
- We are definitively interested in learning from your experience so far to finalise the leaflet and make sure Pre-registration is as structured as it can be

7.4. Way forward



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- Key point to be considered right after closure of Pre-registration period:
 - How to work within SIEF?
 - How to distinguish potential registrants from data holders and “curious joiners”?
 - Agreements with non-Consortium members...



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8. AOB and conclusion

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Reminders:

- Template Agreement for Only Representative appointment is available to PM & Re Consortium members on request to Secretariat
- EM is seeking clarification on the role of Importer and the need or not to own the material you import/register
- Legal entity definition according to UK REACH enforcing authorities is available on request to Secretariat (Courtesy of LBMA)

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Next meeting?

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Thank you and have a safe journey back home!

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