Precious Metals & Rhenium Consortium

ASSEMBLY MEETING

Brussels, 4 December 2013



1. Welcome & Introduction

Guy ETHIER – Umicore



1.1. Reminder on confidentiality and Competition Law

1.2. Tour de table & Apologies

1.3. Approval of the Agenda

1.4. Status of actions agreed at and approval of minutes of the last meeting (Stockholm, 14 June 2013)



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Status of Actions

Table 1. Actions agreed at 14 June 2013 PMC Assembly Meeting

	What?	Who?	When?	Status
1.	Clarify reasons for insufficient evidence of added-value of PMC membership versus LoA purchase	Members	Dec 2013	
2.	Join relevant WG of PMC	BASF	ASAP	
3.	Update Substance and tonnage band declarations following PMC membership mergers Present updated list of PMC Members to Assembly	Glencore+Xstrata SEMPSA+Heimerle Secretariat	ASAP Dec 2013	Today
4.	Nominate representatives for the 2014-2016 PMC Management Committee	Members	Dec 2013	
5.	Present refined 2014 invoices and invite PMC to decide upon use of reserves (including LoA incomes)	Secretariat	Dec 2013	Today
6.	Agree on scope of Au dossier (with or without nanoAu)	Au WG	ASAP	
7.	Identify LR for PM CN-	PM CN-	ASAP	
8.	Progress/Finalise PGM sameness discussions and report to Mgmt Cttee	PGM WG	ASAP	
9.	Consider need for Hydrazine TF-type of initiatives for other PM or non-PM substances added to the SVHC and/or Priority List(s)	PMC	On-going	

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2. PMC Membership news

Caroline BRAIBANT - EPMF



2.1. Presentation of new colleague R. Nicolay, Project Manager



- Some words from our new colleague on his academic background and previous experience…
- Renaud's role in PMC:
  - Authorisation expert
  - Project Manager / Secretariat of Au, PM CN-, and Autorisation projects (Hydrazine and RCF so far)
  - Participation / Representation of PMC in relevant REACH and CLP fora
  - Overall cross-project progress tracking



New Organogramme

Secretary–General (C. Braibant)

- Management and Representation of PMC and EPMF
- PMC's Registration & Evaluation expert (including Secretariat to Ag WG)
- Participation / Representation in REACH & CLP fora

Office Manager (A. Rondepierre)

- Office permanence PMC and EPMF, management and support
- Administration and accountancy
- SIEF communication, and LoA management expert

Project Manager (R. Nicolay)

- Project Manager / Secretariat to Au and PM CN WG, Hydrazine, and RCF projects
- PMC's Registration & Authorisation expert
- Participation / Representation in REACH & CLP for a
- Overall cross-project progress tracking

Scientific Manager (K. Rothenbacher)

- Project Manager / Secretariat to PGM and Ag WG
- PMC's Scientific expert (including hazard and exposure assessment)
- Participation / Representation in scientific and technical fora

Project Facilitator (K. Arijs)

- Project Manager to Refiners, and Re WG
- Shadow secretariat PGM WG
- Data collection templates, ID Cards, Registration Guidance, and other PMC multi-project master exercises / documents
- Facilitation of *ad hoc* tasks across PMC projects



2.2. Nominations for the PMC Management Committee 2014-2017



List of nominees

1.	Francisco Boo	Metalor, Switzerland
2.	Roland Brasch	Heraeus, Germany
3.	Guy Ethier	Umicore, Belgium
4.	Mike Herman	Ames Goldsmith, United States
5.	Jörn Mühlenfeld	Aurubis, Germany
6.	Juha Parkkinen	Norilsk Nickel, Finland
7.	Mark Raffray	Johnson Matthey, United Kingdom
8.	Heinz-Gunter Schenzel	Carl Hafner, Germany

Any objection / other nomination?

Vote by the Assembly



2.3. New Members List



Updated list of Members (following acquisitions)

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



2.4. PMC Cost-sharing formula



Mgmt Cttee response to three PMC Members' questions

Background

- Some Members are involved only in projects for which registration will be submitted before others, and do not anticipate any major REACH challenge after submission (small tonnage, no classification)
  → request to reflect this in PMC cost-sharing formula

- Joining joint registration via LoA seems more advantageous than joining via PMC Membership
  → request clarification on advantages + review of LoA price



Elements of Members' questions and Mgmt Cttee response

- Duration of the PMC:
  - Reference to Articles 9.2 and 2 of Consortium Agreement which state that Consortium will remain in full force until:
    - a) the Consortium has achieved its purposes (joint compliance with pre-registration, registration, classification, evaluation, and autorisation), or
    - b) unanimous decision of Assembly to terminate Agreement
- PMC LoA price:
  - Confirmation that LoA prices will be reviewed in Q1 2014
  - Reminder on how the LoA price is calculated (2007-2020 assuming virtual number of co-registrants including PMC Members and LoA); today may not represent tomorrow
- PMC membership vs LoA purchase:
  - PMC Members pay per company, LoA purchaser per legal entity
  - PMC Members co-own information and can re-use at any time, LoA do not co-own information and cannot use except under separate Licence to Use
  - PMC Members are reimbursed/credited with LoA incomes, LoA purchasers are not entitled to such reimbursements
- PMC cost-sharing formula:
  - Remains fair, transparent, non-discriminatory
  - Use in LoA pricing remains not for profit, and ensures transparent reimbursement of LoA incomes to Members

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2.5. LoA sold in 2013

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LoA intentions by 2018 vs. LoA purchases by 2013

LoA purchase intents collected via SIEF survey in 2009 predicted, by 2018:

- 116 LoA for Ag and Ag compounds
- 24 LoA for Au and Au compounds
- 1 LoA for PM CN-
- 43 LoA for Pt and Pt compounds
- 47 LoA for Pd and Pd compounds
- 20 LoA for Rh and Rh compounds
- 23 LoA for Ru and Ru compounds
- 12 LoA for Ir and Ir compounds
- 30 LoA for Re and Re compounds
- No survey sent to Refinables' SIEF

LoA prices will be reviewed in Q1 2014

Loa overview sold 2010-2013

In euros	2010	2012	2013	TOTAL 2010-2013
Admin fees	385.000,00	77.000,00	346.500,00	808.500,00
Ag	410.125,00	82.000,00	249.000,00	741.125,00
Refinables	31.500,00	0,00	21.000,00	52.500,00
TOTAL	826.625,00	159.000,00	616.500,00	1.602.125,00

In number	2010	2012	2013	TOTAL 2010-2013
Admin fees	10	2	9	21
Ag	9	5	13	27
Refinables	4	0	2	6
TOTAL	13	5	15	33

3. Preparing for Evaluation of Ag

Caroline BRAIBANT - EPMF

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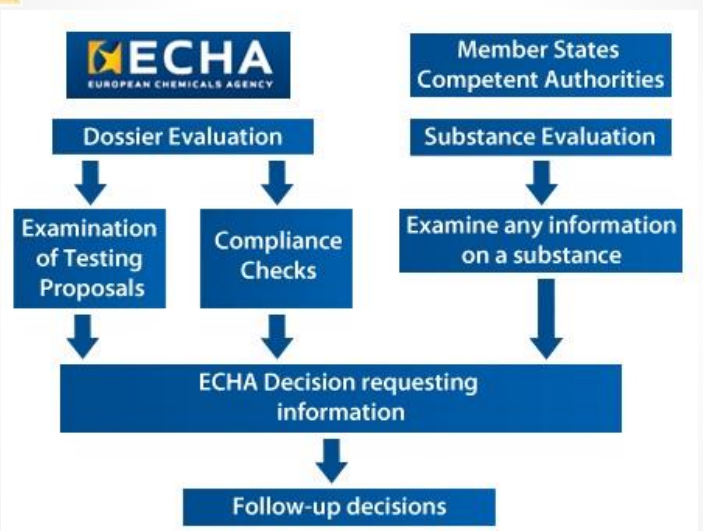
3.1. Evaluation Process

Dossier vs Substance Evaluation



All evaluation processes can take place in parallel/cascade for the same substance!



Dossier Evaluation (DE)

Pretty much within the boundaries of the REACH regulation

- Testing Proposals:
  - Information requirements in Annexes IX and X are subject to Testing Proposal; cannot be actioned without ECHA's approval
  - TP are examined in order to investigate whether:
    - Proposed test complies with standard testing requirements, and if not, proper justification is provided and is adequate
    - Proposed studies are appropriate and will increase knowledge of the hazards of the substance (preventing unnecessary animal testing)
- Compliance Checks:
  - General compliance with REACH (proper justifications for waivers, read-across, etc.; presence of CSR; adequacy of RMM; etc.)
  - Targeted compliance with REACH (opt-out situations, misuse of Annex III, substance subject to Substance Evaluation)

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Substance Evaluation (SE)

- Aimed at clarifying concern that a given substance constitutes a risk to human health or the environment
- May result in:
  - No further action
  - Further action needed:
    - Need for further information → may go beyond REACH standard requirements
    - Need for further consideration under REACH or other regulatory frameworks
- Information obtained from SE should be considered for:
  - Identification of SVHC → Authorisation and Restriction
  - Harmonised C&L
  - Community legislation (OEL, EQS, etc.)

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DE vs SE

	DE	SE
Lead by	ECHA	Member States
Secretariat / Coordination	ECHA	ECHA
Timing	• Annually, 5 % of Dossiers + Targeted checks • ECHA provides specific timings to address requests (usually 30 days)	• As per CoRAP List, published in March every year • Draft Decision (DD) on SE sent to ECHA in Dec • DD reviewed by ECHA sent to MSCA in Jan • DD sent to concerned registrants 12 months later at latest (i.e. end Feb) • Registrants have 30 days to comment (sent to MSCA) (Apr) • MSCA issues same or reviewed DD to ECHA and MSC (no specific timing imposed in legal text) • MSC and ECHA have 30 days to propose amendments • MSC has 30 days to approve the (amended) DD • Publication of summary of Final Decision's timing not legally defined (because no specific timing imposed on MSCA to review DD following comments from registrants)
Content	• Compliance (completeness + quality) Checks • Testing Proposals	Evaluation of specific concerns around the registered substance
Associated information requirements	Within REACH (or reasonably in line with REACH legal information requirements)	Can go beyond REACH

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DE vs SE

Continued…	DE	SE
Associated information requirements	Within REACH (or reasonably in line with REACH legal information requirements)	Can go beyond REACH
Practical impact	Dossier update	• Dossier update • Harmonised C&L • OEL • Authorisation • Restriction • Other?
Deliverables	ECHA decision Dossier update	• SE Report* • DD • Proposal for amendments (PfA) • Final decision • Dossier update
Interaction opportunities	• Written notification from ECHA • Informal conference call with ECHA • Through Dossier update	• Written exchanges on form (not on content) with MSCA • Informal conference call(s) or meeting(s) with MSCA • Possibility of involve ECHA if justified • Through Dossier content (to be updated before start of Evaluation) • Through comments on MSCA's DD • Through comments on PfA from MSC

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Dossier Evaluation of Ag

- ECHA:
  - Comment from ECHA on TP and read-across approach in general
  - Informal meeting with ECHA very technical, very useful
- MS:
  - Comments on TP from two MS
  - No possibility to meet, response in writing
- Testing proposal approved



- Registrant-specific compliance check anticipated in preparation of Substance Evaluation phase!

Substance Evaluation of Ag

Ag on CoRAP list:

- Originally up for Evaluation in 2013 by NL (2012)
- 2013 version confirmed Ag Evaluation not before 2014, by NL
- Draft Nov 2013 version confirms Ag Evaluation in 2014, by NL

Initial grounds for concern:

- Nanoparticles/Toxicity of different forms of the substance
- Exposure/Wide dispersive use
- Consumer use
- Aggregated tonnage

Contact with Evaluating MS:

- Various e-mail exchanges
- Informal meeting in Sep 2013

On-going preparation (cf. next slides)



RIVM's timeline

Phase 1: SEv: SEv report, IUCLID, draft DD

	Period 2014										
Action	**feb**	**mar**	**apr**	**may**	**jun**	**jul**	**aug**	**sep**	**oct**	**nov**	**dec**
Review dossier data											
Literature search and evaluation of data											
Assessment											
Draft Report, IUCLID (if applicable), draft decision											
Discussion and review											
Finalisation of all documents											

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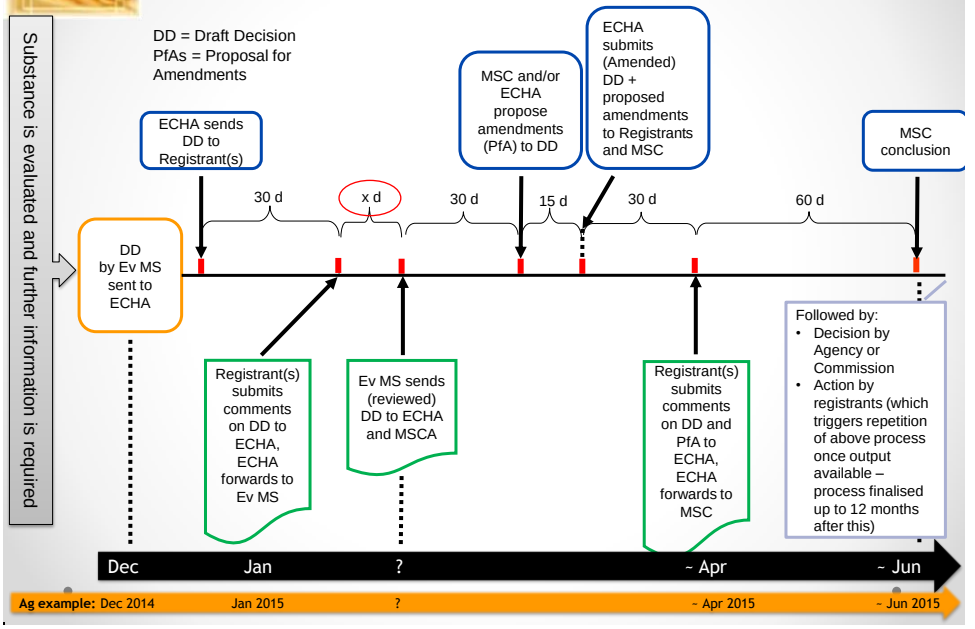
Substance Evaluation: Timing after Evaluation by Ev MS is done





3.2. Joint dossier update



Ag Dossier update preparation

Phys-Chem	Environment	Human Health
• (Aggregated/anonymised) Phys-chem information on nanoAg added	• Relevant literature identified in recent searches summarised in IUCLID 5 • Soil testing programme finalised an used (SSD and eco-regions approach) to derive new PNECsoil (cf. updated PNEC report) • Environmental exposure scenarios updated with most recent PNEC values (using MSafe approach) and to cover nanoAg	• Relevant literature identified in recent searches summarised in IUCLID 5 • DNEL inhalation reviewed on the basis of new (nanoAg) data → DNEL inh nano proposed (cf. DNEL and HEC reports) • Occupational exposure scenarios updated to reflect nanoAg

External review launched + 3 *ad hoc* conference calls to review comments in Dec 2013 + Jan 2014 → Update submission planned in Feb 2014



Work in progress

- In time for inclusion in Dossier update of Feb 2014:
  - ASRIT test to support read-across approach (based on argument that nanoAg is not more toxic than ionic Ag)
  - Oyster embryo testing results to confirm read-across approach
  - Dustiness tests to support robustness of DNEL and occupational exposure assessment
  - PMC findings regarding consumer use of nanoAg (Q to RIVM!)
- Some work may not be ready in time for Mar 2014:
  - SSD Marine to strengthen PNECmarine
  - NanoAg occupational exposure monitoring data to refine occupational exposure assessment for nanoAg relevant ES → PMC Members do not produce nanoAg in sufficient quantity/regularly enough to generate this information in a short timeframe
  - Speciation and BLM work to refine PNECfreshwater → Unilever agreed to sponsor (2 year) work and share with PMC in exchange of soil dataset (to be confirmed in MoU)
  - Further research on the actual fate of (nano)AgS in soil

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Ag Joint Dossier update

- Prepared with input from external reviewers, PMC Members, consultants, PMC Secretariat, and LR
- Using latest version of IUCLID 5 (on an online hosting system), completing only mandatory sections (for efficiency reasons)
- Will be translated into legal entity-specific IUCLID 5 files which will be sent to all co-registrants (Members and LoA purchasers)
- RIVM may go beyond grounds for concern and beyond joint dossier → individual registrations need to be updated too!

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3.3. Individual dossier updates



Warning: Please prepare information + block time to update Ag individual Registration Dossier in Q1 2014

IUCLID 5 Section	Description	Completed by	Deliverables	Comment
1.1 Identification	Identification of registrant and registered substance	Pre-completed by PMC Completed by Member	In legal entity-specific IUCLID 5 file	Not different from first submission
1.2 Composition	Composition(s) of the substance, to be associated to relevant classification in section 2	Pre-completed by PMC May be adjusted by Member (to retain only relevant compositions)	In legal entity-specific IUCLID 5 file	'Nano' composition will be added
1.3 Identifiers	Reference to (pre-)registration number(s)	Each Member	PMC Guidance	Not different from first submission
1.4 Analytical information	Information demonstrating the identity of the registered substance	Each Member, following PMC recommendations	PMC Characterisation Recommendation	All composition, particle size, surface area, coating, etc. information should be added
1.5 Joint Submission	Name of joint submission object	PMC	In legal entity-specific IUCLID 5 file	Not different from first submission
1.7 Suppliers	Entities represented by Only Representative (OR)	Each OR	PMC Guidance	Not different from first submission

Warning: Please prepare information + block time to update Ag individual Registration Dossier in Q1 2014

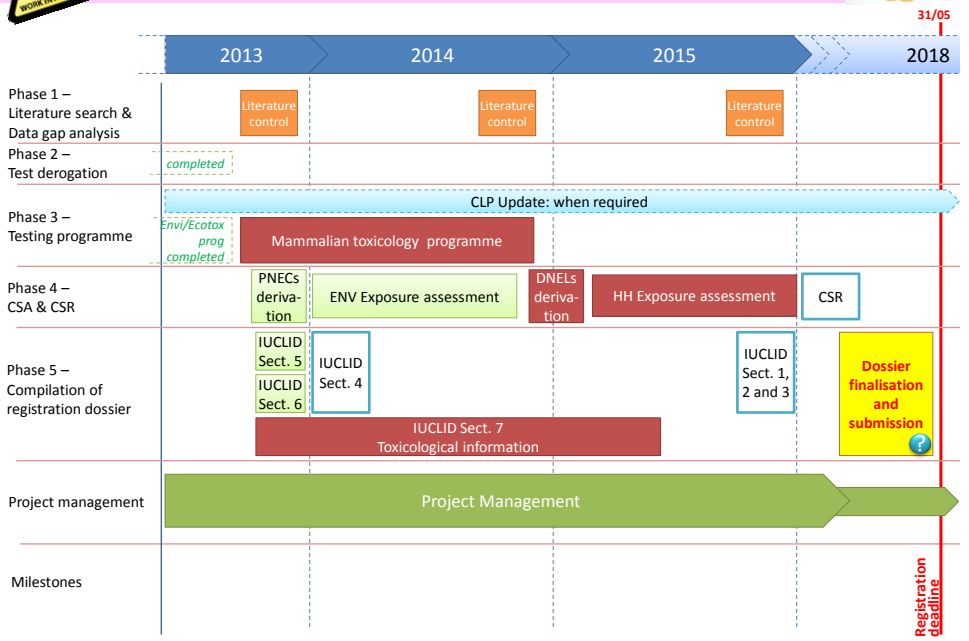
IUCLID 5 Section	Description	Completed by	Deliverables	Comment
3.1 Technological process	Production process of each form of the registered substance	PMC May be adjusted by Member	In legal entity-specific IUCLID 5 file	'Nano' production will be added
3.2 Estimated quantitites	Quantities manufactured/imported of each form of the registered substance	Each Member	PMC Guidance	Use Remarks field to provide form-specific quantity information
3.3 Sites	Sites belonging to the same legal entity where registered substance is manufactured	Each Member	PMC Guidance	May require updating compared to first submission
3.4 Information on mixtures	Report name and composition of mixtures in which registered substance is placed on the market	Each Member	PMC Guidance	Will probably require updating compared to first submission
3.5 Life cycle description	Information on production/use profile of registered substance	Pre-completed by PMC Completed by each Member	In legal entity-specific IUCLID 5 file	Will probably require updating compared to first submission
3.6 Uses advised against	Uses for which registered substance should not be used	PMC	In legal entity-specific IUCLID 5 file	Not different from first submission

4. Update on other PMC Registration Projects: Au, PMCN-, PGM, Re and Refinables

Caroline BRAIBANT – EPMF
Renaud NICOLAY – EPMF
Klaus ROTHENBACHER – EPMF
Katrien ARIJS - ARCHE

Roadmap to Gold & compounds registration







Au project



- Phase III - Test programme:
  - Ecotox testing
    - Finalised
    - PNEC derivation on-going (part of CSA below)
  - Mammalian Tox testing
    - TCA - OECD422 - Phases:
      - DRF Phase 1: Maximum Tolerated Dose
      - DRF Phase 2: Repeated Dose Toxicity 14 days
      - OECD422: Repeated Dose Toxicity 6 weeks + Repro/Development tox.
      - Expected end: Q1 2014
    - TCA - *In vivo* micronucleus assay
      - Feed-back from ECHA
      - Expected end: Q3/Q4 2014?
- Phase IV – CSA/CSR:
  - Overlap with Phase III
  - Format and timing of emission and exposure data collection to be decided with Au WG (not before PNECs are available anyway)
- Phase V
  - In parallel with Phase III
  - Need to confirm scope (nanoAu in or out)
  - Expected end: Q4 2015
- **Dossier ready for submission before 31 May 2018 REACH deadline**

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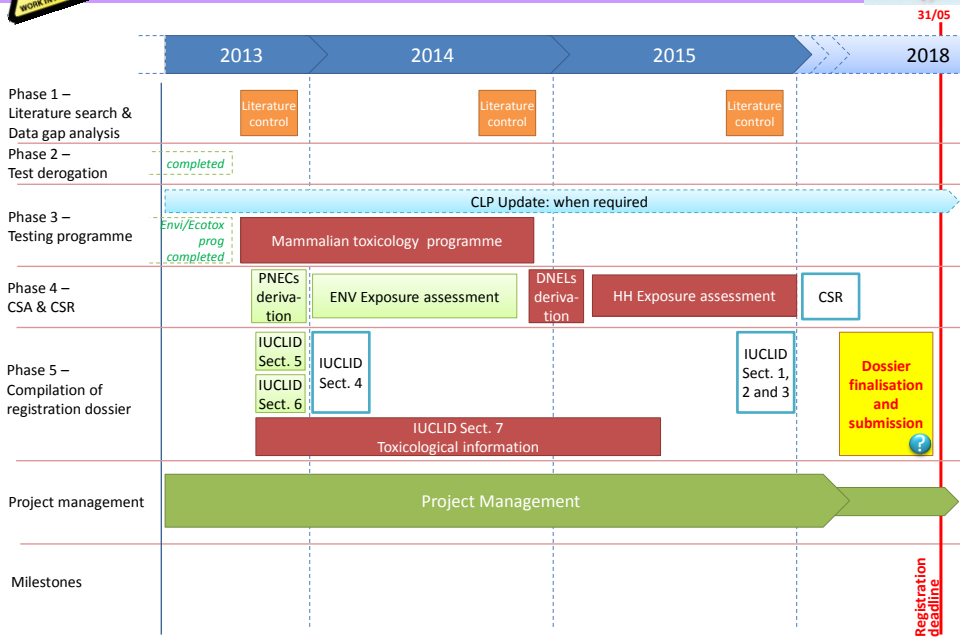
Roadmap to PM CN- compounds registration



PM CN- project: Mammalian Testing Programme

Silver Cyanide

- Skin corrosion: negative
- Skin irritation: positive
- Skin sensitisation (LLNA): negative

Potassium Dicyanoaurate

- Skin corrosion: negative
- Skin irritation: positive
- Skin sensitisation (LLNA): Positive (draft result subject to review)

Next steps: Phase III Testing Programme

- *In vitro* Micro Nucleus Assay:
  - Potential issue: production of HCN > 10 ppm during testing phases? → handling hazard? Sufficient containment standard?
  - May delay test start for few days

Phase IV: In parallel with Au project
Phase V: In parallel with Phase III
Dossier ready for submission by 31 May 2018 REACH deadline

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PGM project (1/6)



- Sameness
  - Substance ID cards being refined
  - Discussions on Diamminedichloropalladium (DDP) and Diammineplatinum (II) nitrite completed
  - Aug. 2013: expert meeting on sameness of PGM nitrates
    - Initial delay due to issues with data generation (reported at last meeting)
    - Open issues now resolved; discussions completed
    - Sameness between Pt- and Rh-nitrate solutions vs. solids concluded
  - For approval: facilitate sameness discussions by circulating prop. spectra to members of sameness expert group via email
- Scope
  - New LR for Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol", CAS 68133-90-4: BASF
  - Any objections?

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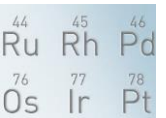
PGM project (2/6)



- Main testing programme progressing (1/3)
  - Jan. 2013: agreed on final testing scope at expert meeting
  - Currently conducting human health tests
    - 81 tox. studies, on genotoxicity, sensitisation, irritancy/corrosivity, acute and repeated dose tox. (RDT), incl. analytical method dev., stability confirmation, etc.
  - Monthly updates on testing programme
  - Tests resulted in 3 new TSCA 8(e) notifications so far
  - Nov. 2013: PGM WG/ tox. expert meeting to review initial test results and feedback from sameness expert group
    - Refined testing programme in view of new data
    - Need to better understand Rh(III) genotoxicity: further research proposed (speciation, confirmatory genotoxicity tests, etc.)
    - Testing proposals (= *in vivo* testing) for genotoxicity of Pt-nitrate/ Hexachloroplatinic acid/ Dihydrogen hexahydroxyplatinate required (need to submit together only with final dossiers)

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PGM project (3/6)

44 Ru 45 Rh 46 Pd
76 Os 77 Ir 78 Pt

- Main testing programme ongoing (2/3)
  - DDP repeated dose testing at CiToxLAB
    - PGM Project's highest priority
    - Extensive method development: palatability study completed, final method development on-going
    - Main study to start in Q1 2014
  - General issue: extensive method development required for most studies
    - Due to complex chemistry/ oxidation states of PGMs
    - To validate appropriate solvents/ vehicles
    - To confirm substance stability
  - Corrositex work completed: allows to refine transport class. most PGMs from UN Packing Group (PG) I to PG II

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PGM project (4/6)

44 Ru 45 Rh 46 Pd
76 Os 77 Ir 78 Pt

- Main testing programme ongoing (3/3)
  - Repeated dose work for other PGMs has started
    - Most time/ cost intensive part of testing programme
    - To be completed by 2015
  - Ecotoxicity work to start in Q1 2014
    - Not a bottleneck
    - 5 substances/ 10 tests + potential follow-up tests
    - To be completed in 2014
- PNEC/ DNEL derivation
  - When final data from testing programme are available
  - Ecotox tests completed by end 2014 = PNEC in Q1 2015
  - Mamm. tox. tests completed by end 2015: DNEL by Q1 2016

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PGM project (5/6)

- Exposure Scenarios
  - Initial ES for Pd: completed as far as possible
  - Site-specific monitoring necessary to demonstrate safe use
  - Other PGMs: collaborating with International PGM Association (IPA) to make best use of available (occ.) monitoring data on Pt
  - Developing standard phrases together with Eurometaux to facilitate ES/ eSDS generation
  - Definitive ES will be developed once robust PNECs/ DNELs are available (2015/16)
  - Will do all preparatory work (collect available data, monitoring, etc.) in the meantime
- Registration approach/timing:
  - Phased registrations (Pd first)
  - In window 2016-2017
    - Well in time for 2018 if momentum kept
    - Time contingency for 'unexpected' events (study repeats, additional monitoring, etc.) considered
  - Overview on next slide

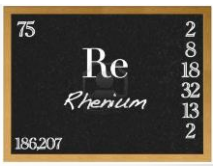
PGM project (6/6)



Item	2014	2015	2016	2017	2018
Testing prog env.					
Testing prog mamm.					
Hazard assessment					
Use and exposure data collection					
Exposure data generation: environmental monitoring					
Exposure data generation: occupational monitoring					
Exposure assessment: environment					
Exposure assessment: human health					
Dossier finalisation					
CSR + ES finalisation					
Review of Dossier before submission					
Registration					



Re project (1/2)



- 4/6 dossiers (Ammonium Perrhenate, Perrhenic acid, Potassium perrhenate and Rhenium) completed and submitted by LR + sent to co-registrants for joint registration
- 2 other dossiers (Dirhenium heptasulphide and Sodium rhenate) on hold while relevant companies sort out registration need/strategy
- PMC Registration project completed well before 2018 registration deadline
- **Next**: calculate LoA price for approval by PMC + public announcement in 2014

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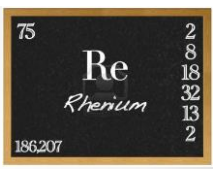
Re project (2/2)



	2008	2009	2010	2011	2012	2013
Phase 0 - Identification of CRO + contract						
Phase I - Literature search and data gap analysis						
Phase II - Read-across / grouping approach and testing strategy			Phys-chem/Env ITS; MamTox ITS			
Phase III - Testing programme			Phys-chem/Env testing	MamTox, PSD & bio-elution testing		
Phase IV - Chemical Safety Assessment/Report						
Phase V - IUCLID 5 file preparation			IUCLID filling		ID cards; Revie w; Submissi on	

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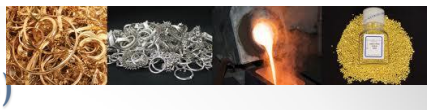

Refinables project (1/6)

- Non-waste UVCB substances used as intermediates in the PM sector
- 14 Refinables registered as intermediates under strictly controlled conditions (SCC) in 2010
  - Dec 2010 ECHA Guidance on intermediates: majority of PMC Members had to reconsider the SCC status of their intermediates
  - UVCB / intermediate / waste / by-product status also checked / reconsidered following and supporting metals' industry initiatives
  - 1 is now considered REACH exempt (waste/by-product route)
  - 1 remains an SCC intermediate under the Dec 2010 guidance (i.e. only requiring 'update' confirming SCC status)
  - 12 are considered non-SCC intermediates
- For these 12 non-SCC intermediates, dossier 'upgrades' from REACH Article 17 or 18 to Article 10 dossiers are under preparation

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Refinables project (2/6)

Refinable	Nr of companies	Nr of updates	Nr of upgrades	Highest status	Highest tonnage band
1. Doré	8	4	4	Non-SCC intermediate	≥ 1000
2. Matte, PM Refining	4	0	4	Non-SCC intermediate	≥ 1000
3. Slags, PM Refining	7	2	5	Non-SCC intermediate	≥ 1000
4. Slimes & sludges, PM Refining	9	3	6	Non-SCC intermediate	≥ 1000
5.1. Matte leaching residues	3	0	3	Non-SCC intermediate	≥ 1000
5.2. Speiss leaching residues	0	-	-	REACH exempt	-
6.1. Ag electrolyte	3	2	1	Non-SCC intermediate	≥ 1000
6.2. Au electrolyte	1	1	0	SCC intermediate	10-100
7. Flue dust, PM Refining	5	1	5	Non-SCC intermediate	100-1000
8. Residues, PM cementation and reduction	8	2	6	Non-SCC intermediate	100-1000
9.1. Materials for reclaim - PM w/ or w/o support	5	0	5	Non-SCC intermediate	100-1000
9.2. Materials for reclaim - PM in bricks, crucibles, trays, etc.	5	0	5	Non-SCC intermediate	100-1000
9.3. Materials for reclaim - PM production by-products	3	0	3	Non-SCC intermediate	100-1000
10. Pb bullion PM Rich	1	0	1	Non-SCC intermediate	10-100
		24%	76%		

Split?

7-12 dossier upgrades

Refinables project (3/6)

- Refinables slags, slimes & sludges and flue dust over-grouped? -> Task force (TF) to explore possible criteria and approaches to split these entries
- Aim of splitting exercise: check if splitting is necessary and if not, have sufficient arguments to demonstrate how and why grouping was done
- PM Ref WG agreed on registration of 2 sub-groups for slags based on source/process/composition differences
- 5 sub-groups for slimes & sludges proposed by the TF -> exercise on-going to determine composition/classification boundaries of sub-groups, then decide on registration strategy
- 1/no sub-groups for flue dust



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Refinables project (4/6)

- **Phys-chem** data gaps for some Refinables; testing recommendation provided -> currently checking which tests
  1) can be performed (or are already available) at LR level
  2) can be waived
  3) should be done at Harlan (rather than by LR)
- **Environmental** assessment of the Refinables: WCA is in the process of refining/finalising the generic/site-specific exposure assessment (by end 2013)
- **Human health** assessment of the Refinables: EBRC is producing 1st draft company-specific ES to distribute to relevant companies for comment (by end 2013) -> will be refined/finalised following company review + outcome EM/ECHA workshop (cf. next slide)

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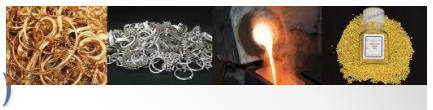
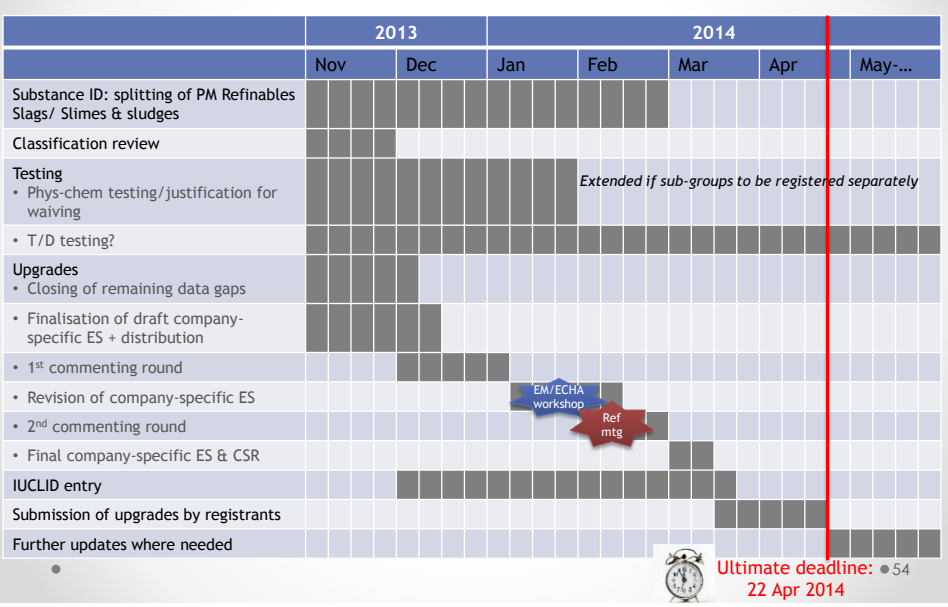


Refinables project (5/6)

- Art 10 registration of a very complex UVCB cannot be performed robustly via testing (large variability) but can be done by using the information available on the **constituents** of the UVCB instead:
  - Approach being developed for all inorganic UVCB, by several consortia under the EM umbrella and with regular updates presented to ECHA (next update on full risk assessment is planned 22 Jan 2014) -> common approach(es) properly justified and documented in an internal EM Guidance + IUCLID template
  - Data-sharing agreements currently being signed between PMC and relevant consortia
  - ECHA expects dossier upgrades following read-across approach to take place by 22 Apr 2014
- **Equal cost-sharing**: all PMC Members going for updates/upgrades contribute to the costs of the dossier upgrade preparation, with the exception of KGHM:
  - Received confirmation on Refinables' SCC status from the enforcing authorities -> unlikely they will need upgrades in the near future
  - Despite not contributing to upgrade costs, happy to contribute data (to advance the assessment + to be ready for upgrades if needed in future, in which case they will pay the corresponding amount)
  - KGHM will pay 1500 €/Refinable to allow legitimate access to other work under PM Refinables project instead of full amount
  - Voting



Refinables project (6/6)





5. PMC & Authorisation

Renaud NICOLAY - EPMF



5.1. Authorisation Process



The two faces of REACH…



Registration	Authorisation
One Substance, One Registration Dossier per Substance	One Substance, one or more Authorisation Applications per use or group of uses
Joint submission or justified opt-out	Joint or individual submission(s)
Manufacturers, Importers and OR	Manufacturers, Importers, OR and Users
Specific deadlines	Evolving target/deadlines (LAD, SD)
Preparation since pre-registration (2007)	Preparation since 1st Priority List (2009)
First registration submissions 2010	First application submissions 2013

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REACH Authorisation (1/5)
What is it?

Authorisation is the REACH toolset for substituting the most hazardous chemicals ('SVHC') manufactured or imported in EU.

REACH Authorisation?



- A procedure aiming at …
- Assuring proper **control** of **risks** from **SVHC**
- Assuring progressive **substitution** of SVHC by **suitable** alternative substances or technologies, economically and technically viable
- While ensuring good **functioning of** EU **market**

⇨ M/I/DU applying for Authorisation(s) shall:

- ⇨ Analyse the availability of alternatives, consider their risks, and the technical and economic feasibility of substitution
- ⇨ Demonstrate their (involvement in) research activities to identify and develop alternatives

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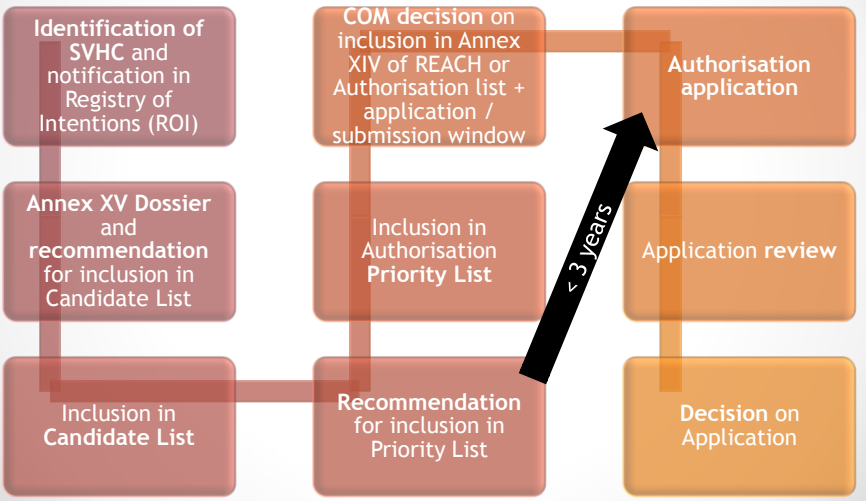
REACH Authorisation (2/5)

From the Candidate List to the Authorisation List…



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REACH Authorisation (3/5)

Who is impacted?

Any EU company with *SVHC* in its substance portfolio is concerned: each of its *use* will either have to be authorised or to be dropped.



SVHC? Substance of **V**ery **H**igh **C**oncern ➔ Annex XV = 'Candidate List'

- CMR 1A, 1B
- PBT & vPvB
- Substance of equivalent concern

Uses?

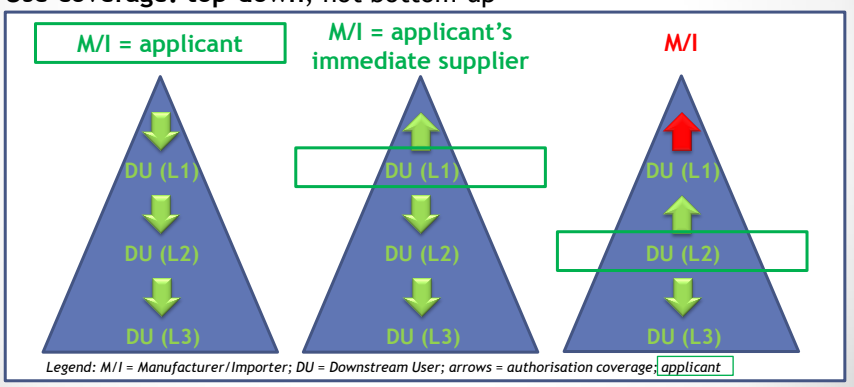
- Temporary **Authorisation per use** of the substance
- **Not** Authorisation per **substance.**
- No Authorisation = use definitely forbidden



REACH Authorisation (4/5)
Who should apply?

A supplier has no obligation to submit an Authorisation Application → Its immediate customer should then apply or see its supply chain interrupted.

- **M/I: No obligation** to apply for Authorisation
- **Use coverage: top-down**, not bottom-up



⇨ **Potential supply-chain disruption**

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REACH Authorisation (5/5)
Tips to prepare for Authorisation

Successful tackling of the Authorisation challenge will require knowledge, resources mobilisation and peer collaboration.

- Knowledge
  - Know/track your portfolio
  - Have a knowledgeable staff and/or outsource
  - Clear identification of business impact if substance cannot be used
  - Awareness raised along the supply chain (especially from immediate suppliers and users)
  - Educate your management: awareness raised up the company organogram



- Resources
  - Plan your budget (years) ahead
  - Mobilize sufficient staff
  - (IT) System to track portfolio vs SVHC or Candidate List is a must



- Association
  - Associate as far as competition to reduce costs: Authorisation Application fee is significant and repetitive
  - ⚠ Various possible scenarios: all users substitute, some substitute, no one substitutes → consider impact on competitiveness + supply/availability + image
  - Need to conciliate different interests





5.2. Hydrazine



Background

- Hydrazine on Candidate List, not yet prioritised
  - Carcinogen
  - No tight timing/pressure
  - PMC's first Authorisation experience
- PMC one of smallest user of hydrazine, used as reducing agent:
  - In small quantities
  - Controlled conditions
  - Full decomposition during use
  - No emissions or exposure
  - No alternatives identified so far for all PM uses…
- If Hydrazine is prioritised, need to quickly prepare Authorisation Application
  - Manufacturers' unlikely to move ahead with Authorisation preparation before prioritisation (and then, only 3 years to prepare + submit Authorisation Application for relevant uses!)
  - Manufacturers may have commercially more important customer uses to consider/cover than PM…
  - PMC has engaged into learning + data collection exercise in anticipation of the above
- Also, data collected by PM sector may be used in advocacy

Recent activities from PMC (and others) and next steps

PMC Analysis of Alternatives (with RPA)

- Outcome: PRELIMINARY AoA report
  - Presentation: PMC Workshop 20/11/2013
  - 'Preliminary': insufficient information collected to conclude on feasibility of all alternatives and complete the analysis → mainly due to confidentiality
  - Lots of Confidential Business Information (appropriately handled by RPA)
  - **From non-CBI data collected, it currently appears that no publicly-known alternative is feasible**
- Next steps
  - RPA to evolve report into **advocacy paper** in Q1 2014
  - PMC to launch collection of exposure data to strengthen advocacy arguments around controlled conditions and no exposure
  - Hydrazine TF to decide on next steps and m.o. regarding SEA needs

Cross-industry fertilisation: the Aerospace exemption case

- Used as fuels in closed system
- End-use in article
- Used for Research & Development

→ Evaluation of exemption request by Commission/MSCA in the next weeks

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5.3. RCF

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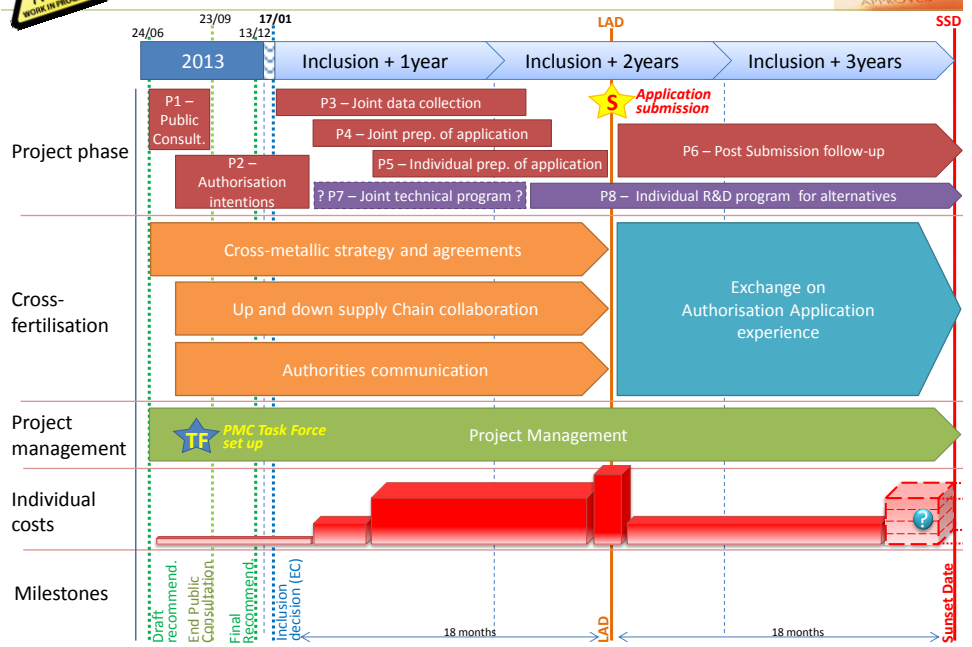
Roadmap to Zr/Al-RCF Authorisation



Recent activities

The PM sector sets up a monitoring RCF Task Force

MC, Oct. 2013

- Set up **monitoring** platform, the 'RCF Task Force'
  - Status aligned with roles of PM sector in the RCF supply chain
  - No chairing required
  - Monitoring coordination: PMC Secretariat
- RCF status **review early 2014?**
  - When Authorities' final decision is known
  - Either evolve to steering TF,
  - Or continue a monitoring approach

24/06/2013: Public Consultation start

24/06/2013: ECHA - 5th draft priority list published

19/09/2013: EM - joint-metallic response to Public Consultation

23/09/2013: PMC response & Public Consultation end

29/10/2013: PMC meets with Automotive associations

30/10/2013: PMC – MC approves TF and attributes a monitoring status

18/11/2013: PMC – RCF TF kick-off

today

Importance of RCF for the Precious Metals sector

Some very high temperature applications, above 900°C and up to 1.600°C, do not have known /ready to be implemented alternatives.

Alternatives for uses with operating temperature < 900°C

- RCF have feasible alternatives: appliance for authorisation has few chances of success
- These alternatives are most often implemented or it is advised to do so as soon as possible

Less alternatives for uses with operating temperature > 900°C

- Most uses have no known alternatives: **no substitution possible**
- Alternatives implementation may require **planning years ahead**
  - Cost: need to forecast important budget
  - Equipment operating-life counted in decades for furnaces
- Alternatives should offer **similar or better technical specs, withstand energy saving** policies and be **safe(r)**

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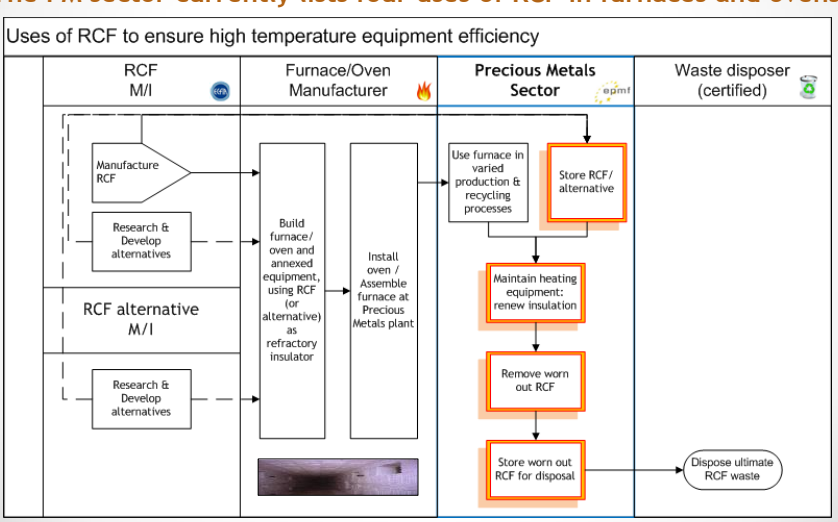
Roles and uses of RCF in the supply chain (1/2)

The PM sector currently lists four uses of RCF in furnaces and ovens …



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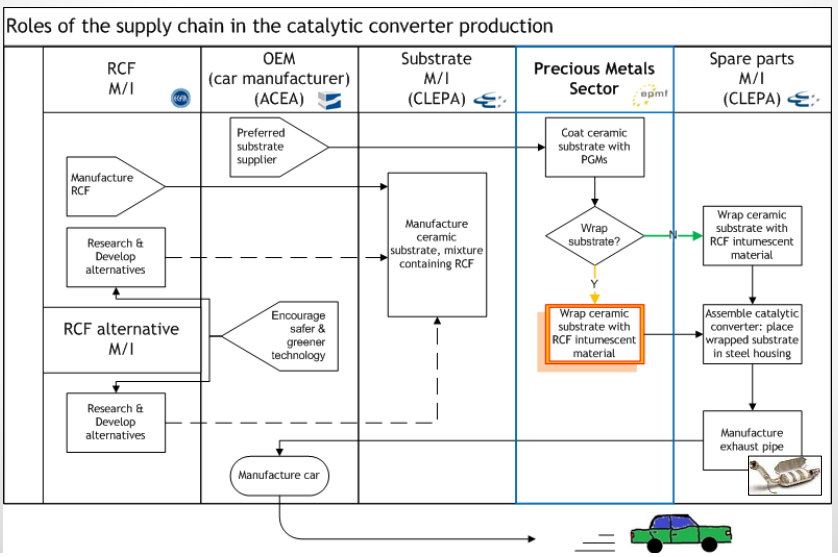
Roles and uses of RCF in the supply chain (2/2)

… and one potential use of RCF in the catalytic converter supply chain.



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Next steps

PMC will continue collecting internal data to frame PM sector roles in the RCF supply chain; PM interests may differ from other associations

- Collect internal and collective data from PMC members
  - In order to frame the role/weight of the PM sector in a possible RCF application for authorisation
  - Secretariat will prepare and distribute a tailored questionnaire
- The PMC Secretariat will continue its monitoring activities, also with third-party associations:
  - RCF manufacturers (ECFIA) via Eurométaux
  - Automotive associations (CLEPA, ACEA & AECC), participating in meetings to share common understanding and intentions
  - RCF Lead Registrant, via Eurométaux
- Secretariat will explore technical consultants' availability in case Authorisation Application needs to be prepared

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5.4. Other?



PM sector is clearly subject to **Registration** obligations for many precious metals and their compounds…



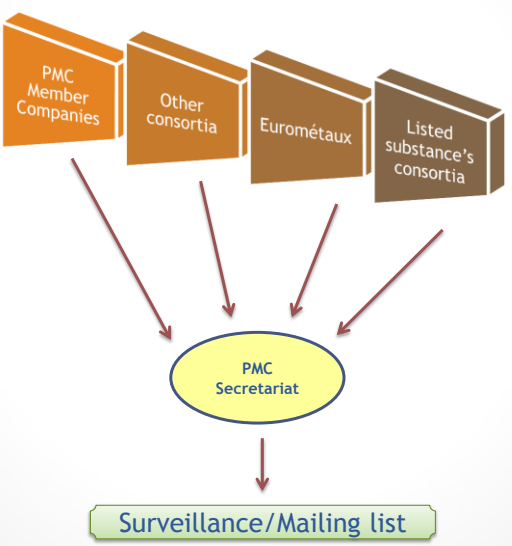
But the sector is before all a user of many substances which may or not be SVHC, potentially subject to specific **Authorisation** or **Restriction** processes for their uses to continue!

Please watch the ECHA SVHC List and report substances of interest!!!!

http://echa.europa.eu/web/guest/candidate-list-table



Monitoring and channelling of new information





Recommendations

- Authorisation applies per use, and hence, to users!
- Some manufacturers/importers (M/I) may get involved in Authorisation, some may not – Even when they do:
  - M/I may not cover a use which is deemed 'minor', and
  - M/I will need information from their users to produce a robust Authorisation Application!
- Users have an obligation of:
  - Monitoring and communication
    - To the authorities (e.g. public consultations, Annex XV dossiers authors)
    - To their customers (notify presence of SVHC and status of Authorisation)
    - To their company colleagues (track, inform relevance for company, consult R&D, prepare possible black-listing effect response, mobilise resources, etc.)
    - To their suppliers (find out what ingredients are present in mixtures, who is registrant and what are registrant's intentions)
  - Organisation – follow-up Authorisation preparation in a structured manner
  - Authorisation preparation – provide info, pay contribution?
  - Authorisation submission, review, and re-submission

- Monitor ECHA SVHC List + Priority List
- Liaise with other users of same substance via centralised network

Even if M/I in charge, users' information and input will be required to produce a robust application!



6. Financial items

Caroline Braibant - EPMF

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6.1. 2013 expenses by 31 Oct



Situation up to 31 Oct 2013:
Draft P&L 2013

1.INCOMES	PMC		
	Budget	Real	Delta
1.2PMC membership fees	1.888.198 €	1.888.198 €	0 €
1.3Letters of Access and new Members	0 €	925.513 €	925.513 €
1.4Bank interests	15.000	10.852	-4.149
1.5Released from reserves	1.990.303,85	1.990.303,85	0,00
TOTAL	3.893.502 €	4.814.866 €	921.365 €

2.EXPENSES	PMC		
	Budget	Real	Delta
2.1Generic costs	601.278 €	281.943 €	319.335 €
2.2Ag-specific costs	444.641 €	350.544 €	94.097 €
2.3Au-specific costs	148.950 €	31.283 €	117.667 €
2.4PM CN- -specific costs	361.105 €	81.602 €	279.503 €
2.5PGM-specific costs	1.636.208 €	504.903 €	1.131.305 €
2.6Re-specific costs	50.950 €	34.635 €	16.315 €
2.7Refinables-specific costs	612.150 €	93.599 €	518.551 €
2.8Hydrazine-specific costs (as per 11 Oct 2012 HTF mtg)	38.220 €	14.725 €	23.495 €
TOTAL	3.893.502 €	1.393.233 €	2.500.269 €

3.INCOMES vs EXPENSES	PMC		
	Budget		
3.Incomes minus expenses	0,00	3.421.633,06	-1.578.904,06



6.2. 2014 Budget and invoices



2014 Budget content per project

Project	Budget 2014	Key content	Comment
Generic	745.140 €	Staff, office, meeting, and external costs	
Ag	210.285 €	Marine comparative testing, SSD marine work, and preparation for Evaluation	Co-sponsoring of additional freshwater and soil research possible (tbd)
Au	117.300 €	Continuation of mamm tox testing and CSA/CSR + IUCLID 5	
PM CN	165.300 €	Continuation of mamm tox testing and CSA/CSR + IUCLID 5	
PGM	817.650 €	Continuation of mamm tox testing, ecotox testing, monitoring programme, CSA/CSR + IUCLID 5	
Re	9.450 €	Dossier maintenance	
Refinables	8.400 €	Permanent budget items only	Finalise dossier updates commenced in 2011 using existing monies
Hydrazine	60.000 €	Exposure assessment + advocacy	SEA work currently paused
RCF	0 €	Monitoring	Exact role / need for PMC support currently pending further exploration + outcome on decision on ECHA's 5th Priority List



Available reserves

+ Unspent monies from previous years (when place-holders were used rather than exact budget predictions)
+ LoA incomes (not every year)
+ Reimbursement on past costs from new Members (not every year)
= "RESERVES"

Reserves are used on a case-by-case basis to either:

- Ligthen invoices
  → depending on the profile of the project, as approved by PMC Assembly!
- Cover contingency/unpredicted cost items
  → after approval from relevant WG and Mgmt Cttee!

Reserves are kept per project!

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Available reserves per project and their proposed use in 2014

Project	Profile	Estimated reserves by end 2013	Use of 2013 reserves in 2014?
Generic	N/A	213.227,50 €	Yes → reduced 2014 invoices
Ag	High	208.192,20 €	Yes → payment holiday
Au	Low	179.819,77 €	Yes → reduced 2014 invoices
PM CN	Low	92.542,73 €	Yes → reduced 2014 invoices
PGM	High	903.735,08 €	Yes → reduced 2014 invoices
Re	Low	127.423,34 €	Yes → payment holiday
Refinables	Medium	758.637,58 €	Yes → payment holiday
Hydrazine	Medium	0,00 €	N/A

Criteria for project profile:
Low profile: Small scope, no/low classification, late registration deadline
Medium profile: Small scope, REACH work difficult to predict
High profile: Big scope and/or classification which could trigger additional REACH requirements (e.g. Evaluation, Authorisation, etc.)

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Resulting 2014 invoices (1/2)

ID Code	2014 Generic cost-share per Member	2014 Au-specific cost-share per Member	2014 PM CN- -specific cost-share per Member	2014 PGM-specific cost-share per Member	2014 Hz-specific cost-share per Member	Amount to be invoiced in 2014
1	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
2	4.900,01 €	620,86 €	0,00 €	5.586,38 €	7.500,00 €	18.607,26 €
3	4.900,01 €	1.199,52 €	0,00 €	1.200,76 €	0,00 €	7.300,30 €
5	4.900,01 €	1.199,52 €	0,00 €	0,00 €	0,00 €	6.099,54 €
6	4.900,01 €	0,00 €	22.787,72 €	3.001,90 €	0,00 €	30.689,63 €
7	4.900,01 €	620,86 €	18.324,14 €	0,00 €	0,00 €	23.845,02 €
8	4.900,01 €	1.199,52 €	4.620,19 €	0,00 €	0,00 €	10.719,73 €
9	4.900,01 €	2.399,05 €	0,00 €	4.803,04 €	7.500,00 €	19.602,10 €
10	4.900,01 €	620,86 €	9.240,38 €	1.200,76 €	0,00 €	15.962,01 €
11	4.900,01 €	1.820,38 €	22.787,72 €	38.510,05 €	7.500,00 €	75.518,17 €
12	4.900,01 €	1.199,52 €	0,00 €	1.200,76 €	0,00 €	7.300,30 €
13	4.900,01 €	620,86 €	0,00 €	0,00 €	0,00 €	5.520,87 €
14	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
15	4.900,01 €	2.441,24 €	13.860,57 €	37.263,55 €	7.500,00 €	65.965,38 €
16	4.900,01 €	620,86 €	0,00 €	11.590,18 €	0,00 €	17.111,06 €
17	4.900,01 €	1.199,52 €	18.324,14 €	1.801,14 €	7.500,00 €	33.724,82 €
18	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
19	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
20	4.900,01 €	1.199,52 €	0,00 €	600,38 €	0,00 €	6.699,92 €
21	4.900,01 €	1.199,52 €	0,00 €	1.200,76 €	0,00 €	7.300,30 €
23	4.900,01 €	620,86 €	0,00 €	0,00 €	0,00 €	5.520,87 €
24	4.900,01 €	620,86 €	0,00 €	1.200,76 €	7.500,00 €	14.221,63 €



Resulting 2014 invoices (2/2)

ID Code	2014 Generic cost-share per Member	2014 Au-specific cost-share per Member	2014 PM CN- -specific cost-share per Member	2014 PGM-specific cost-share per Member	2014 Hz-specific cost-share per Member	Amount to be invoiced in 2014
25	4.900,01 €	1.862,58 €	0,00 €	17.356,87 €	7.500,00 €	31.619,46 €
27	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
28	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
29	4.900,01 €	620,86 €	0,00 €	0,00 €	0,00 €	5.520,87 €
30	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
31	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
32	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
33	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
34	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
35	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
36	4.900,01 €	620,86 €	0,00 €	1.200,76 €	0,00 €	6.721,63 €
39	4.900,01 €	1.199,52 €	0,00 €	1.200,76 €	0,00 €	7.300,30 €
40	4.900,01 €	1.199,52 €	9.083,76 €	3.736,84 €	0,00 €	18.920,14 €
41	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
42	4.900,01 €	620,86 €	0,00 €	600,38 €	0,00 €	6.121,25 €
43	4.900,01 €	620,86 €	0,00 €	1.846,88 €	0,00 €	7.367,75 €
44	4.900,01 €	0,00 €	0,00 €	4.202,66 €	0,00 €	9.102,67 €
45	4.900,01 €	620,86 €	0,00 €	7.896,42 €	0,00 €	13.417,29 €
46	4.900,01 €	0,00 €	0,00 €	0,00 €	0,00 €	4.900,01 €
47	4.900,01 €	620,86 €	0,00 €	3.001,90 €	0,00 €	8.522,77 €
48	4.900,01 €	0,00 €	0,00 €	1.200,76 €	7.500,00 €	13.600,77 €
49	4.900,01 €	0,00 €	0,00 €	4.202,66 €	0,00 €	9.102,67 €
50	4.900,01 €	0,00 €	0,00 €	6.095,28 €	0,00 €	10.995,30 €
TPR 1	TPR 1					
TOTAL	220.500,62 €	27.390,12 €	119.028,63 €	161.702,60 €	60.000,00 €	588.621,97 €



8. AOB, Next Meetings & Closing Remarks

Guy ETHIER - Umicore



- Any other business?
- Next Assembly meetings:
  - Plenary meeting: Bern, 12 Jun 2014 (hosted by Swiss association)
  - Assembly meeting: Brussels, 3 Dec 2014





Thank you!


If Winter comes, can
Spring be far behind?
- Percy Bysshe Shelley