



Precious Metals & Rhenium Consortium General Assembly

4 JUNE 2015, MILAN



1. Welcome and introduction

1.1. Competition law and confidentiality



DO	DON'T
<p>Application of competition law Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.</p>	<p>Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.</p>
<p>Consultation in Matters of Competition Law Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.</p>	<p>Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.</p>
<p>Activities in any preliminary phase and at any other stage of operation of the Consortium Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.</p>	<p>Pursuant to Art. 101 and 102 TFEU, activities which have the object of the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including:</p> <ul style="list-style-type: none"> - Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU); - Joint boycotting of other companies; - The unjustified unequal treatment of trade partners; - The abusive exploitation of a dominating market position.
<p>Exchange of Confidential Information Involve a Trustee for the exchange of Confidential Information.</p>	<p>The exchange of Information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to:</p> <ul style="list-style-type: none"> - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
<p>Documentation on Cooperation Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.</p>	

1.2. Quorum



Check of the quorum by the Secretariat



1.3. Approval of the agenda

- Welcome and introduction
- Nanomaterials: the state of play
- PMC Membership news
- PMC Finances
- PMC Business Plan 2016-2019
- Update on PMC Registration Projects
- Authorisation
- A.O.B., next meeting and closing remarks



1.4. Minutes and actions (12/06/14)

	What?	Who?	Status
1	Nominate Mgmt Cttee representatives to take on board (Co-)Chairmanship of PMC for 2016-2018 mandate	Mgmt Cttee	
2	Prepare tentative project plans for Ag, Refinables and Authorisation projects of PMC	R. Nicolay with relevant managers	
3	Include high-level project plan (in .pdf) of each project in bi-monthly updates circulations	A. Rondepierre	On hold
4	Produce ID Cards for all PMC substances and intermediates in the order of registration, using Members' input and expertise	K. Arijs	Ongoing
5	Compare effects datasets and anticipate/collaborate on a response to the possible release of a CLH proposal from KEMI with Ag Biocides TF	K. Rothenbacher + K. Arijs	Ongoing
6	Include place-holder for research work in 2016 budget, as discussed and agreed with the Ag WG and Mgmt Cttee	New S-G	
7	Confirm scope of Au registration dossier: nano in or out? (Consult WGC if needed)	R. Nicolay	Out
8	Document decision-making re genotoxicity testing of TCA	R. Nicolay	
9	Confirm scope of PGM registration dossiers: nanos in or out? (Consult IPA if needed)	K. Rothenbacher/ K. Arijs	Ongoing
10	Update Mgmt Cttee on SID/Sameness discussions around diammonium hexachlororuthenate, progress of Ru testing programme, and overall impact on registration submission window for Ru and Ru compounds	K. Rothenbacher/ K. Arijs	
11	Settle proper Memorandum of Understanding with Reconcile, in order to set legal framework to allow technical cooperation and dossier preparation	K. Rothenbacher/ K. Arijs + A. Palmers	Ongoing
12	Update LoA e-shop with 2014 LoA prices for Refinables	A. Rondepierre	To be discussed under 4.3



1.4. Minutes and actions (03/12/14) (1)

	What?	Who?	Status
1	Share information/experience on literature searches with the PMC Secretariat	PMC Members	Done
2	Review Ag literature search strategy	PMC Secretariat, led by S-G	Done
3	Organise comments from PMC consultants and coordinate comments with the Silver Task Force	PMC Secretariat	Ongoing
4	Check RIVM's position on KEMI's proposal and the possible consequences re additional study requests	K. Rothenbacher/ K. Arijs	Done
5	Analyse the feasibility to end up the registration of Au and Au compounds earlier than currently scheduled (mid-2016) to shift as soon as possible PMC efforts on more complex projects such as PGM registrations	R. Nicolay	Ongoing
6	Analyse the feasibility to end up the registration of PM Cyanides earlier than currently scheduled (about mid-2016) to shift as soon as possible PMC efforts on more complex projects such as PGM registrations	R. Nicolay	Ongoing
7	Send an updated substance and tonnage band declaration to the PMC secretariat	Registrants of Diammonium hexachlororuthenate	Done
8	Send updated substance and tonnage band declaration in case of tonnage band changes	PMC Members	Done



1.4. Minutes and actions (03/12/14) (2)

	What?	Who?	Status
9	Update scope of PGM project following official confirmation of tonnage band changes	PMC Secretariat	Done
10	Follow-up with identified company regarding the higher tonnage band of one PGM substance	K. Rothenbacher/ K. Arijs	Done
11	Finalise MSDS for Re substances	K. Arijs	On hold
12	Costs should be more detailed and Working Groups should be more involved in the budgeting process	PMC Secretariat	Done
13	For future presentation of the budget, compare the budget with the previous 2 years' budgets	New S-G with Office Manager	Done
14	Present a rolling budget for 2016-2018	New S-G with relevant managers	Done
15	Keep the costs for nano-Ag separate in the Ag project	K. Rothenbacher/ K. Arijs + New S-G	Ongoing
16	Prepare and send out 2015 invoices	A_Rondepierre + New S-G	Done
17	Prepare and send out invitations and provisional programme for June Plenary meeting in Milan	A_Rondepierre + New S-G	Done



2. Nanomaterials: the state of play

CHRISTINE SPIRLET, MANAGER ENVIRONMENT & HEALTH, IZA

PMC - GENERAL ASSEMBLY 04/06/2015

9

Overview

OECD WPNM

- History
- Sponsorship program
- Technical guidelines

Europe

- Commission – REACH revision
- ECHA NMWG

National initiatives

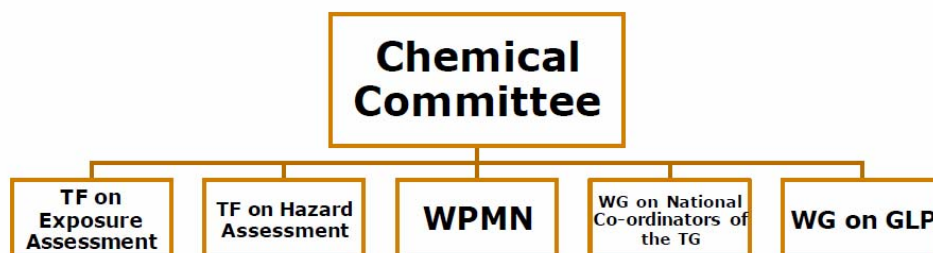


OECD NMWP



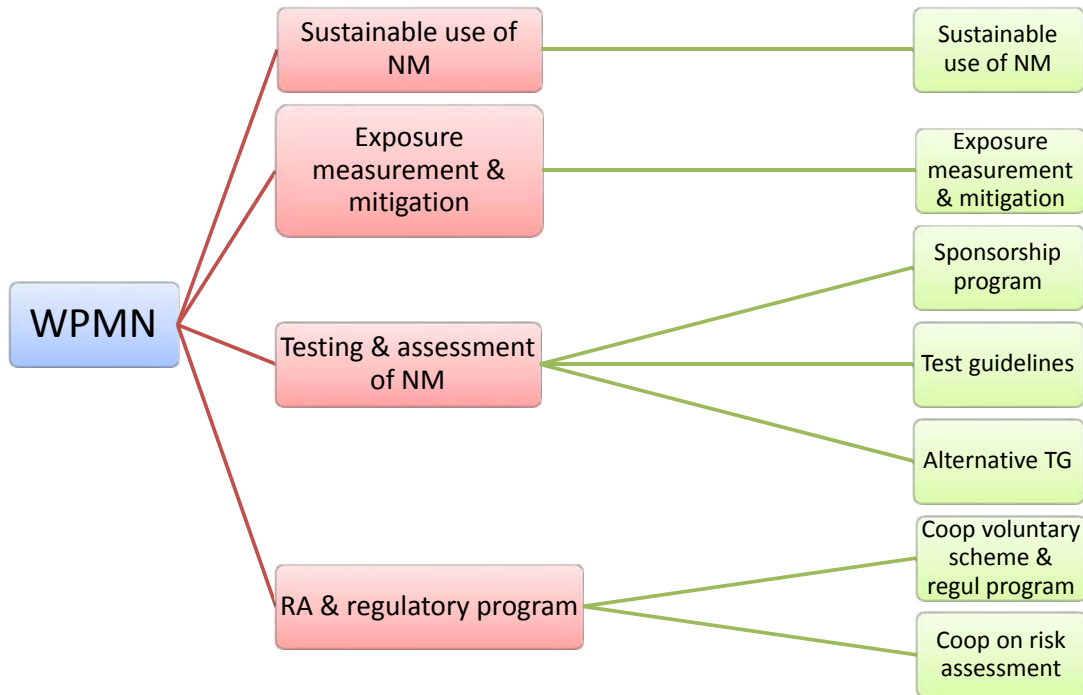
Background

- OECD work on nanomaterials is important because
 - It gives a regulatory awareness at a global level
 - Impact on the implementation of REACH (TG and guidance)
 - Knowledge transfer
- OECD work on nanomaterials – since 2006



Review of WPMN in 2012

- Reduce number of Steering Groups (SG)



SG Testing and Assessment of Manufactured Nanomaterials

5 work-areas

1. Testing guidelines

2. In Vitro methods

3. Communication of the outcome from the Testing Program

4. Assessment of the data from Testing Program

5. Non-testing approaches



Testing guidelines

- **Objective:** Ensure that existing test guidelines are applicable to nanomaterials to support MAD agreement
- 7 SPSFs (standard project submission forms) are under way
 - Amendments to existing TG/GD on inhalation (US)
 - GD on Aquatic and Sediment (CA/US)
 - TG dissolution rate in aquatic media (US)
 - GD dispersion and dissolution in aquatic media (DE)
 - GD accumulation potential (UK)
 - TG on dispersibility and dispersion behaviour in aquatic media (DE)
 - TG removal from waste water (US)
- TG 487, in vitro Genotoxicity, (EU) submitted November to WNT*

*Working Group of the National Coordinators for the Test Guidelines Programme



Testing program

- The data generated from the Sponsorship Program are to be disseminated
- 11 Dossiers have been harmonized in a IUCLID style printed format. They all include a Preamble with the appropriate caveats on the context in which the data was generated.
- 4 assessment reports (SIAR) have been prepared by Lead Sponsors (to be published as separate documents to allow an easier access to them)
- Public Web Site by June 2015 (?)
 - Silver, gold, SiO₂, TiO₂, ZnO, CeO₂
 - Denrimers, CNT, fullerenes, nanoclays



Data assessment from testing program

- To analyse the data generated to explore the possibility to conclude on;
 - the applicability of TGs/GDs used
 - the quality of the data
 - variability within one materials
- Three areas
 - Phys-chem properties (NL lead)
 - human health
 - the environment
- Generate three reports over the next two years



Non-testing approaches

- **Objective:** Develop non-testing approaches to assess potential hazards of nanomaterials
 - Categorisation, grouping and read-across
 - QSARs
 - Cell culture models
 - Etc..



Risk assessment and regulatory program

5 On-going projects:

1. Interspecies Variability in HH RA (final)
2. Dissolution outline (Ag case study) (final)
3. Survey on the use of grouping, equivalence and read across among OECD members (on-going)
4. Analysis of phys-chem properties for RA and read-across purposes (on-going)
5. Uncertainty in a tiered RA (new)



- **Exposure mitigation:**
 - Harmonised Tiered Approach for measuring and assess exposure to airborne nano-objects in the workplace
 - Case Study of Nano-Ag
 - Survey on Consumer and Environmental Exposure
- **Environmentally Sustainable Use of Nanomaterials**
 - Drafting a manual for LCA case-study of MWCNTs



EU Commission



Main subjects

- Revise nano definition
- Revise REACH text with nano definition and characteriser
- Revise REACH annexes with specifics for nanos
- Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market



Nano definition

- Review of the EC Definition of "nanomaterial" by December 2014
 - JRC offered to provide 3 reports covering related scientific issues in support of the review (3rd one should be out now)
 - COM will consider, consult and reconsider
- ⇒ there are now > 6 months delay on new deadline, CASG nano has been postponed to November/December 2015



Nano definition key issues

- Ambiguity of the vocabulary:
 - "contain": a NM could contain non-particulate matter
 - "unbound state"
 - "constituent particles" used in recitals 4) and 12)
 - "one or more external dimensions". A non-symmetric particle can have many external dimensions
 - "particle" can be interpreted in different ways
- Ambiguity about materials explicitly included in the definition
- Flexible threshold value (between 1 % and 50 %)
- The volume specific surface area (VSSA) \neq 50 %



Issues applying the definition

- How to prove that a material is not a nanomaterial?
- How to identify constituent particles in aggregates and measure their size?
- Comparing the chosen thresholds with measured values



Review of REACH annexes

- Clarify what is being registered:
 - Insert legally binding definition (VI)
 - Introduce terminology to explain 'forms':
 - one substance, but several forms in a single joint registration (VI)
 - Introduce requirements to specifically provide information on the nanoforms registered / justify its relevance (I; III; VI; VII – X; XI and XII)
- Introduce 'characteriser' as binding requirement in case of 'nanoform(s)' in member dossier:
 - Name
 - Particle distribution
 - Surface treatment
 - Shape, morphology etc
 - Surface area
 - Analytical methods



How requirements link with the nanomaterials registered

- Introduce more prescriptive information on how information shall be specific and relevant to the 'forms'
- Specify in Annexes VII – X that characterisation of the nanoform and test conditions shall be submitted
- The above shall apply regardless if it is reporting on a test result or using non-test approaches to document safe use (e.g. read-across)



Possible Legislation to Increase Transparency on Nanomaterials on the Market

- The Commission's Working Document sets out the following policy options:
 - Baseline scenario: Revision of REACH Annexes + MS Initiatives
 - Recommendation for national measure for Member States wishing to establish a national system (soft law approach)
 - Structured approach to collect information ("Nanomaterials Observatory")
 - Regulation creating an EU nanomaterial registry with one annual registration per substance for each manufacturer/importer/downstream user/distributor
 - Regulation creating an EU nanomaterial registry with one annual registration per use (including substances, mixtures and articles where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article)
- As of now, no decision taken



ECHA



Improve REACH dossiers quality

- Continuation of ECHA NMWG, informal discussions with registrants and accredited stakeholders – different sub-groups as phys-chem characterisation, read-across, environment risk assessment
- Working on publication of guidance on registration in 2016 for 2018 deadline
- Dossiers evaluation
 - 2012; Silicon dioxide (synthetic amorphous silica - SAS) – by the Netherlands
 - 2014: Silver - by The Netherlands
 - 2015: Titanium dioxide - by France
 - 2016: ZnO – by Germany



Participate in Int. Activities

- OECD
 - Acting as the Chair for OECD WPMN's Steering Group on Testing and Assessment (SG-TA)
- CEN
 - Following the work of CEN/TC 352 on “Standardisation activities regarding nanotechnologies and nanomaterials” under mandate M/461
- GHS
 - evaluate the applicability of GHS criteria to nanomaterials



Scientific hub

- Strengthening scientific capacity
 - Interaction with FP7 projects (NANOREG, Marina, Nanosolutions)
- Topical Scientific Workshop on Regulatory Challenges NM 22-23 Oct 2014 that covered
 - International Regulations
 - Measurements and Characterisation
 - Metrology and dose metrics
 - Environmental fate
 - Read-across and Categories



National Initiatives



French decree 2012

Purpose	Reporting scheme for quantities and uses of NM and public access
Scope/Definition	As EU COM Recom but only for intentionally manufactured NM; includes mixtures and articles with intended release.
Threshold	100 g
Exemptions	none
Timing	Mandatory from 2013 (May for previous year)



Norwegian law 2013

Purpose	<ol style="list-style-type: none"> 1. Product register 2. Information should be submitted for all dangerous chemicals. The information shall cover the composition of the product, where the product is used, what kind of product etc. 3. The NANO box should be marked if the chemical contains nanomaterials.
Scope/Definition	<p>Scope non nano specific</p> <p>Structures that have a size between 1 and 100 nm.</p> <p>The aim is to reach other properties than the chemical compound usually provide, for example changes in melting point and strength.</p>
Threshold	<p>No specific limits for nanomaterials.</p> <p>The declaration is mandatory for dangerous substances produced/imported/placed on the market in a quantity > 100kg/year</p>
Exemptions	None found

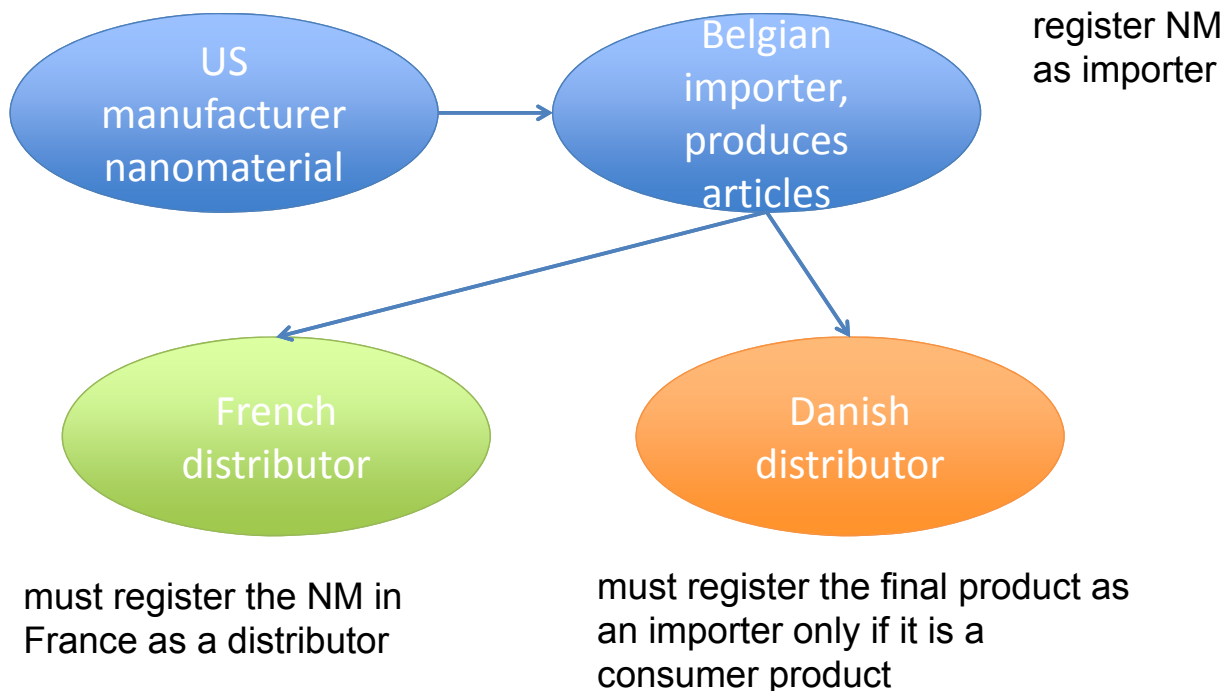
Danish Order 2014

Purpose	Reporting scheme to establish number and type of products containing nanomaterials on the market and their applications
Scope/Definition	<p>"Products containing nanomaterials (EU COM Recom):</p> <ol style="list-style-type: none"> 1. mixtures and articles where nanoparticles are intended to be released 2. intentionally produced in nano-size 3. that possesses specific properties because of its size"
Threshold	100 g/year for each VAT number
Exemptions	<ol style="list-style-type: none"> 1. nanoproducts sold between business 2. products that fall under areas where specific regulations are already in place (e.g. food, feed, pharmaceuticals, medical devices, cosmetics, pesticides and waste) 3. a number of specific products: nanosized products of substances in REACH Annex V, products where the material is not consciously produced in nanosize, products where the nanomaterial is in a fixed matrix.
Timing	Mandatory, first declaration 31st January 2015 to cover from 2014 data. Declaration is foreseen every year.

Belgian royal decree May 2014

Purpose	<ol style="list-style-type: none"> 1. Traceability purpose 2. gain knowledge on characterisation of nanomaterials , risks and exposure 3. Some public access
Scope/Definition	<p>"Registration of substances/mixtures and a notification for articles containing nanoforms (based on COM Rec.) not falling under the foreseen exceptions.</p> <p>To be registered: substances manufactured at the nanoscale, and mixtures containing them</p> <p>To be notified: articles, products, complex objects incorporating substance manufactured at nanoscale if more than 100 g/year are placed on the market and the article emits more than 0.1% of substances manufactured at the nanoscale when in use."</p>
Threshold	100 g of concerned nanos
Exemptions	<p>a) registration : some pigments when included in mixtures or articles. NP already regulated elsewhere</p> <p>b) notification: carbon black, SAS and precipitated, calcium carbonate in articles when used as fillers. Reduced notification for substances in R&D (under some conditions)</p>
Timing	Mandatory before placing on the market; at the latest by 1 January 2016 for substances and 1 January 2017 for mixtures

In practice



Conclusions

- Nanomaterials are covered under REACH
- Challenges still remaining, both on scientific and policy level.
- Despite regulatory challenges, ECHA is addressing nanomaterials throughout legal instruments
- Knowledge exchange is key
- Still a long way to go...



Thank you
Questions?





3. PMC Membership news

FRANCE CAPON



3.1. PMC chairmanship

- Mark Raffray (Johnson Matthey) left his position of Vice-chair of the PMC in June 1 2015.
- ⇒ The Management Committee has elected Heinz-Günter Schenzel (C. Hafner) as Vice-chair of the MC and recommends to the Assembly to elect him as vice-chair of the Assembly.
- Guy Ethier (Umicore) will want to step down as of June 2016 .
- A procedure will start Q1 2016.

For approval by the Assembly: election of Heinz-Günter Schenzel as vice-Chair of the PMC Assembly



3.1. bis New member Management Committee

- Johnson Matthey would like to propose **Dr Nissanka Rajapakse, Group Product Stewardship Manager, Johnson Matthey plc.** as member of the Management Committee, replacing Mark Raffray

For approval by the Assembly: election in the Management Committee of Dr. Nissanka Rajapakse

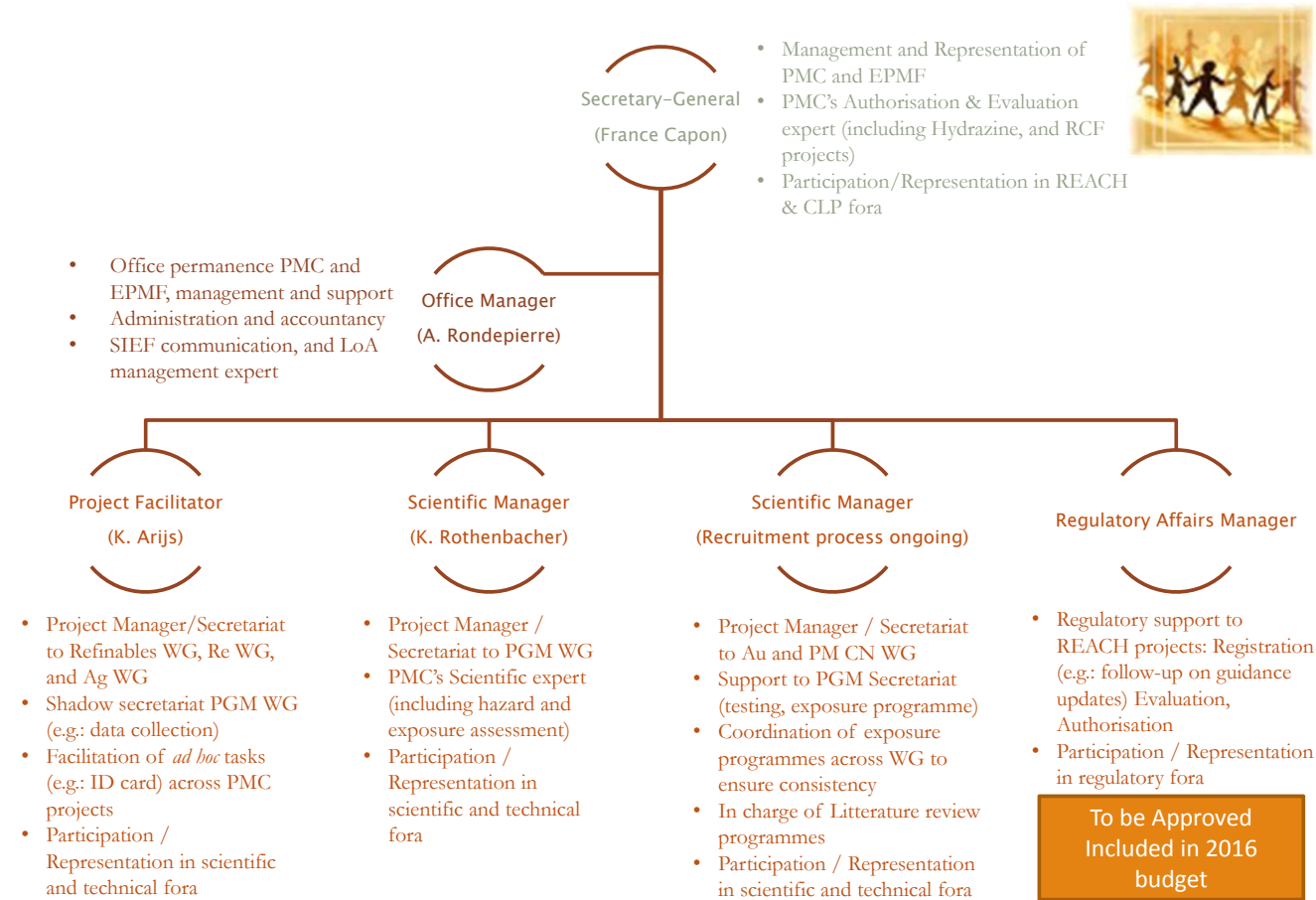
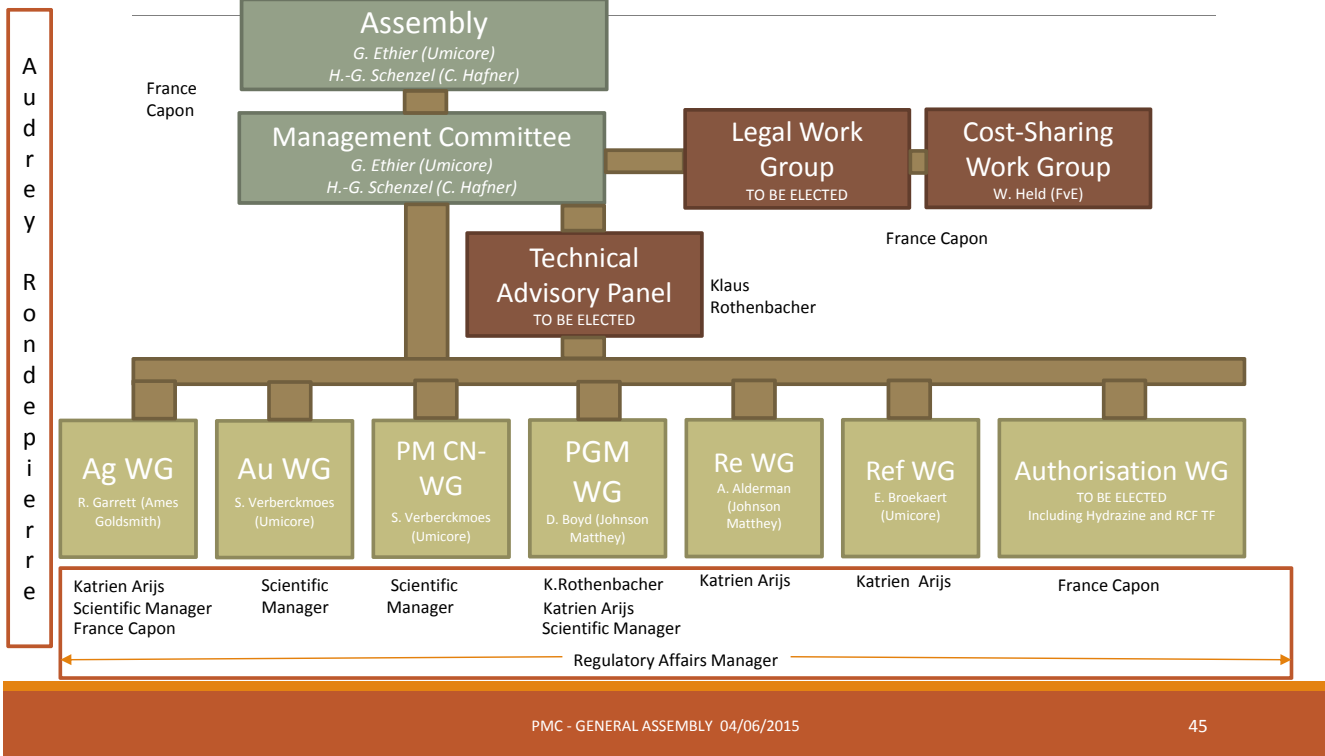


3.2. Legal working group chairmanship

- Alain Palmers (Umicore) left his position of PMC Legal Counsel and of Chair of the Legal Work group on 1st June 2015
- ⇒ The position of Chair of the Legal Work group is open and discussions are ongoing with potential candidates
- ⇒ A budget is included in 2016 draft budget to outsource the function of PMC Legal Counsel



3.3. Staff reorganisation





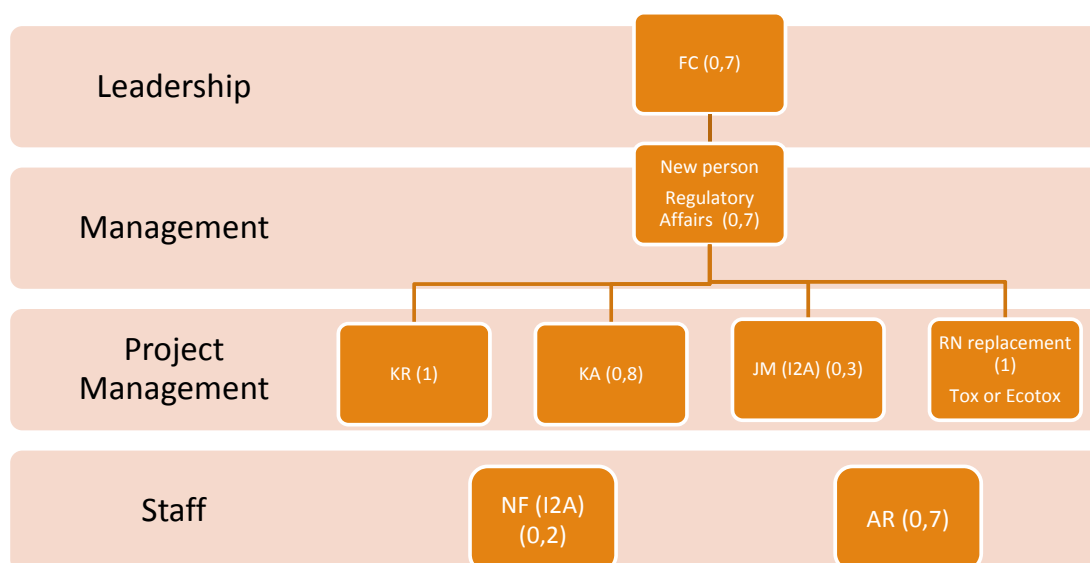
3.3. Staff reorganisation

- I2A is looking for a part time (0,4 FTE) Sec Gen since January 2015 to cover:
 - Strategic issues
 - Administrative issues
 - Advocacy issues
- PMC (C/O EPMF) is looking for
 - 0,2 FTE to cover administrative issues
 - 0,3 FTE to support scientific manager
 - 0,7 FTE to cover (mainly REACH) Regulatory affairs

Key question: can some HR be mutualized between I2A and PMC?



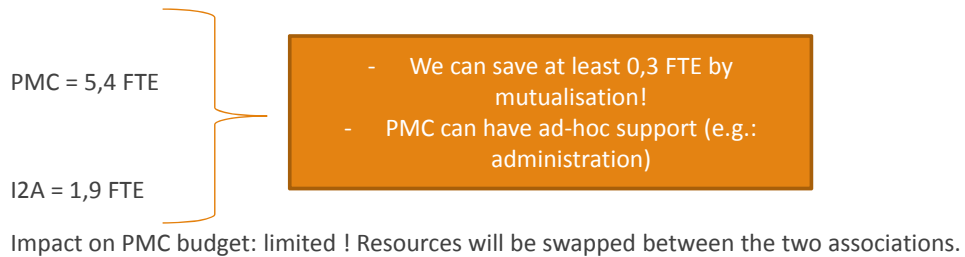
3.3. Staff reorganisation: PMC



FC (France Capon); KR (Klaus Rothenbacher); KA (Katrien Arijis); JM (Jelle Mertens), NF (Nathalie Francis), AR (Audrey Rondepierre).



3.3. Staff reorganisation



3.3. Staff reorganisation

FOR APPROVAL by the Assembly: develop synergies between I2A and PMC (EPMF)



3.4.1. PMC scope: freezing

- Background:
 - Request for predictability in HR and financial resources
 - Next Registration deadline (2018) approaching
 - Remaining uncertainties in the scope of the PMC:
 - Substances
 - Tonnage bands
 - Nano forms
- Proposal: freezing of the substances inventory in 2015 and until next registration deadline (May 2018).
- If new tonnage, substance, nanos...: the information can be declared to the Secretariat to be included in the PMC Rolling plan for the maintenance of the dossiers in 2018 and beyond.



3.4.1. PMC scope: freezing

Silver

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band to be registered	Nano form
	CAS	EC				
Silver (Powder <0.0001.mm)***	7440-22-4	231-131-3	Mono-constituent	Substance	> 1000 t/a	Yes
Silver (Powder <1mm)						
Silver (Massive > 1mm)						
Silver nitrate (Solid <250µm)	7761-88-8	231-853-9	Mono-constituent	Substance	100-1000 t/a	No
Silver nitrate (Solid > 250 µm)						
Silver nitrate (> = 5% AgNO3 solution)						
Silver nitrate (3-5% AgNO3 solution)						
Silver nitrate (< 3% AgNO3 solution)						
Disilver oxide	20667-12-3	243-957-1	Mono-constituent	Substance	100-1000 t/a	No
Silver carbonate	534-16-7	208-590-3	Mono-constituent	Substance	1-10 t/a	No
Disilver(1+) sulphate	10294-26-5	233-653-7	Mono-constituent	Substance	1-10 t/a	No
Silver chloride	7783-90-6	232-033-3	Mono-constituent	Substance	100-1000 t/a	No
Silver bromide	7785-23-1	232-076-8	Mono-constituent	Substance	100-1000 t/a	No
Silver iodide	7783-96-2	232-038-0	Mono-constituent	Substance	1-10 t/a	No



3.4.1. PMC scope: freezing

Gold

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band	Nano form
	CAS	EC				
Gold	7440-57-5	231-165-9	Mono-constituent	Substance	10-100 t/a	No
Tetrachloroauric acid	16903-35-8	240-948-4	Mono-constituent	Substance	10-100 t/a	No
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	68365-87-7	269-858-3	Mono-constituent	Substance	1-10 t/a	No
Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	68990-27-2	273-589-7	UVCB	Non-SCC Intermediate	1-10 t/a	No

Precious Metals cyanides

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band	Nano form
	CAS	EC				
Potassium dicyanoargentate	506-61-6	208-047-0	Mono-constituent	Substance	10-100 t/a	No
Silver cyanide	506-64-9	208-048-6	Mono-constituent	Substance	10-100 t/a	No
Potassium dicyanoaurate	13967-50-5	237-748-4	Mono-constituent	Substance	10-100 t/a	No



3.4.1. PMC scope: freezing

Palladium

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band to be registered	Nano form
	CAS	EC				
Palladium (solid only)	7440-05-3	231-115-6	Mono-constituent	Substance	10-100 t/a	Yes
Palladium dichloride	7647-10-1	231-596-2	Mono-constituent	Substance	10-100 t/a	No
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	Mono-constituent	Substance	10-100 t/a	No
Diamminedichloropalladium	14323-43-4	238-269-3	Mono-constituent	Substance	10-100 t/a	No
Dichlorobis(triphenylphosphine)palladium (solid only)	13965-03-2	237-744-2	Mono-constituent	Substance	1-10 t/a	No
Palladium (II) di(4-oxopent-2-en-2-oate) (solid only)	14024-61-4	237-859-8	Mono-constituent	Substance	10-100 t/a	No
Palladium(II) acetate	3375-31-3	222-164-4	Mono-constituent	Substance	1-10 t/a	No
Palladium monoxide (solid only)	1314-08-5	215-218-3	Mono-constituent	Substance	1-10 t/a	No
Tetraamminepalladium (II) nitrate	13601-08-6	237-078-2	Mono-constituent	Substance	1-10 t/a	No
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	Mono-constituent	Substance	10-100 t/a	No
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	Mono-constituent	Substance	1-10 t/a	No
Tetrakis(triphenylphosphine)palladium (solid only)	14221-01-3	238-086-9	Mono-constituent	Substance	1-10 t/a	No
Palladium sulphate (in solution)	13566-03-5	236-957-8	Mono-constituent	Substance	1-10 t/a	No
Tetraamminepalladium(2+) diacetate (in solution)	61495-96-3	262-819-1	Mono-constituent	Substance	10-100 t/a	No
Disodium tetrachloropalladate	13820-53-6	237-502-6	Mono-constituent	Substance	10-100 t/a	No
Palladium dinitrate (in solution)	10102-05-3	233-265-8	UVCB	Substance	10-100 t/a	No
Palladium dihydroxide (solid only)	12135-22-7	235-219-2	Mono-constituent	Non-SCC intermediate	10-100 t/a	No
Diammonium hexachloropalladate (solid only)	19168-23-1	242-854-9	Mono-constituent	Non-SCC intermediate	10-100 t/a	No
Dipotassium hexachloropalladate (solid only)	16919-73-6	240-974-6	Mono-constituent	Non-SCC intermediate	10-100 t/a	No

Latest changes in the PMC scope



3.4.1. PMC scope: freezing

Platinum

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band to be registered	Nano form
	CAS	EC				
Platinum (solid only)	7440-06-4	231-116-1	Mono-constituent	Substance	10-100 t/a	Yes
Hexachloroplatinic acid	16941-12-1	241-010-7	Mono-constituent	Substance	10-100 t/a	No
Tetraammineplatinum dichloride	13933-32-9	237-706-5	Mono-constituent	Substance	1-10 t/a	No
Tetraammineplatinum dinitrate (in solution)	20634-12-2	243-929-9	Mono-constituent	Substance	10-100 t/a	No
Diammineplatinum (II) nitrite	14286-02-3	238-203-3	Mono-constituent	Substance	1-10 t/a	No
Dipotassium tetrachloroplatinate (solid only)	10025-99-7	233-050-9	Mono-constituent	Substance	1-10 t/a	No
Platinum dioxide (anhydrous)	1314-15-4	215-223-0	Mono-constituent	Substance	1-10 t/a	No
Platinum dioxide (hydrate)						
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (in solution)	68133-90-4	268-717-3	Mono-constituent	Substance	10-100 t/a	No
Dipotassium hexachloroplatinate (solid only)	16921-30-5	240-979-3	Mono-constituent	Substance	10-100 t/a	No
Platinum dinitrate	18496-40-7	242-383-9	UVCB	Substance	10-100 t/a	No
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (in solution)	68478-92-2	270-844-4	UVCB	Substance	10-100 t/a	No
Diammonium hexachloroplatinate	16919-58-7	240-973-0	Mono-constituent	Non-SCC intermediate	10-100 t/a	No
Dihydrogen hexahydroxyplatinate (solid only)	51850-20-5	257-471-2	Mono-constituent	Non-SCC intermediate	10-100 t/a	No

Latest change in the PMC scope



3.4.1. PMC scope: freezing

Rhodium

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band to be registered	Nano form
	CAS	EC				
Rhodium (solid only)	7440-16-6	231-125-0	Mono-constituent	Substance	10-100 t/a	Yes
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium (solid only)	25470-96-6	247-015-0	Mono-constituent	Substance	1-10 t/a	No
Carbonylhydrotris(triphenylphosphine)rhodium (solid only)	17185-29-4	241-230-3	Mono-constituent	Substance	1-10 t/a	No
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium (solid only)	14874-82-9	238-947-9	Mono-constituent	Substance	1-10 t/a	No
Rhodium tris(2-ethylhexanoate) (in solution)	20845-92-5	244-079-1	Mono-constituent	Substance	1-10 t/a	No
Rhodium trichloride (anhydrous)	10049-07-7	233-165-4	Mono-constituent	Substance	1-10 t/a	No
Rhodium trichloride (hydrate)						
Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I) (solid only)	12092-47-6	235-157-6	Mono-constituent	Substance	1-10 t/a	No
Tris(triphenylphosphine) rhodium (I) chloride (solid only)	14694-95-2	238-744-5	Mono-constituent	Substance	1-10 t/a	No
Rhodium triiodide (solid only)	15492-38-3	239-521-5	Mono-constituent	Substance	1-10 t/a	No
Dirhodium trisulphate	10489-46-0	234-014-5	Mono-constituent	Substance	1-10 t/a	No
Dirhodium trioxide (solid only)	12036-35-0	234-846-9	Mono-constituent	Substance	1-10 t/a	No
Rhodium (III) acetate	42204-14-8	255-707-9	UVCB	Substance	1-10 t/a	No
Rhodium trinitrate (in solution)	10139-58-9	233-397-6	UVCB	Substance	1-10 t/a	No
Rhodium trihydroxide (solid only)	21656-02-0	244-508-2	Mono-constituent	Non-SCC intermediate	1-10 t/a	No
Triammonium hexachlororhodate (solid only)	15336-18-2	239-364-2	Mono-constituent	Non-SCC intermediate	1-10 t/a	No
Diammonium sodium hexakis(nitrito-N)rhodate (solid only)	64164-17-6	264-713-0	Mono-constituent	Non-SCC intermediate	10-100 t/a	No



3.4.1. PMC scope: freezing

Ruthenium

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band to be registered*	Nano form
	CAS	EC				
Ruthenium (solid only)	7440-18-8	231-127-1	Mono-constituent	Substance	10-100 t/a	Yes
Ruthenium trichloride (anhydrous)	10049-08-8	233-167-5	Mono-constituent	Substance	10-100 t/a	No
Ruthenium trichloride (hydrate)						
Ruthenium (IV) oxide (solid only)	12036-10-1	234-840-6	Mono-constituent	Substance	1-10 t/a	No
Tris(nitrate-O)nitrosylruthenium	34513-98-9	252-068-8	Mono-constituent	Substance	1-10 t/a	No
Hexakis[μ-(acetato-O:O)]-μ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	55466-76-7	259-653-7	Mono-constituent	Substance	1-10 t/a	No
Tetraammonium decachloro-μ-oxodiruthenate(4-) (solid only)	85392-65-0	286-924-7	Mono-constituent	Non-SCC intermediate	10-100 t/a	No
Potassium tetraoxoruthenate (in solution)	31111-21-4	250-473-4	Mono-constituent	Non-SCC intermediate	1-10 t/a	No
Ruthenium trihydroxide (solid only)	12135-42-1	235-221-3	Mono-constituent	Non-SCC intermediate	1-10 t/a	No

Last changes in the PMC scope

Iridium

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band	Nano form
	CAS	EC				
Iridium (solid only)	7439-88-5	231-095-9	Mono-constituent	Substance	1-10 t/a	Yes
Iridium trichloride	10025-83-9	233-044-6	Mono-constituent	Substance	1-10 t/a	No
Reaction mass of Iridium tetrachloride and Iridium trichloride	tba	tba	Multi-constituent	Substance	1-10 t/a	No
Hexachloroiridic acid, Hydrogen hexachloroiridate (IV)	16941-92-7	241-012-8	UVCB	Substance	1-10 t/a	No
Diammonium hexachloroiridate (solid only)	16940-92-4	241-007-0	Mono-constituent	Non-SCC Intermediate	1-10 t/a	No



3.4.1. PMC scope: freezing

Rhenium

Name of the substance	Identification numbers		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band	Nano form
	CAS	EC				
Rhenium	7440-15-5	231-124-5	Mono-constituent	Substance	1-10 t/a	No
Perrhenic acid (in solution)	13768-11-1	237-380-4	Mono-constituent	Substance	1-10 t/a	No
Ammonium perrhenate	13598-65-7	237-075-6	Mono-constituent	Substance	10-100 t/a	No
Sodium rhenate (in aq. solution)	13472-33-8	236-742-9	Mono-constituent	SCC Intermediate	1-10 t/a	No
Potassium perrhenate	10466-65-6	233-953-8	Mono-constituent	Non-SCC Intermediate	1-10 t/a	No
Dirhenium heptasulphide	12038-67-4	234-882-5	Mono-constituent	SCC Intermediate	1-10 t/a	No



3.4.1. PMC scope: freezing

Refinables

Group	Name	EC and CAS numbers	Covering	EC and CAS numbers	Type of registration dossier prepared by PMC	Highest tonnage band
1	Doré	273-793-6; 69029-47-6	Residues, silver refining Black metal, copper electrolytic slime smelting	308-309-5; 97926-88-0 266-974-6; 67711-97-1	Non-SCC intermediate	> 1000
2	Matte, PM	308-506-6; 98072-52-7	N/A	N/A	Non-SCC intermediate	100-1000
3	Slags, PM refining	308-515-5; 98072-60-7	Slags, silver-smelting Slags, dore furnace Slags, precious metal recovery lead refining	308-315-8; 97926-95-9 266-975-1; 67711-98-2 273-826-4; 69029-85-2	Non-SCC intermediate	> 1000
4	Slimes and sludges, PM refining	308-516-0; 98072-61-8	Residues, silver sludge-electrolysis zinc-pptd., precious metal-contg. Slimes and Sludges, copper pickling wastewater treatment Leach residues, precious metal smelting scrap	309-641-3; 100656-52-8 293-678-4; 91081-71-9 309-770-5; 100995-79-7	Non-SCC intermediate	> 1000
5.1	Matte leaching residue	310-050-8; 102110-49-6	N/A	N/A	Non-SCC intermediate	> 1000
5.2	Speiss leaching residue	309-643-4; 100656-54-0	N/A	N/A	REACH exempt	-
6.1	Ag electrolyte	911-538-9; none	N/A	N/A	SCC intermediate	> 1000
6.2	Au electrolyte	913-584-5; none	N/A	N/A	SCC intermediate	10-100
7	Flue dust, PM refining	308-496-3; 98072-44-7	Flue dust, silver-refining	308-276-7; 97926-57-3	Non-SCC intermediate	100-1000
8	Residues cementation and reduction, PM refining	310-051-3; 102110-50-9	N/A	N/A	Non-SCC intermediate	100-1000
9.1	Materials for reclaim, PM with or without support	308-526-5; 98072-70-9	N/A	N/A	Non-SCC intermediate	100-1000
9.2	Materials for reclaim, PM in bricks, crucibles, trays, etc.	931-674-2; None	N/A	N/A	Non-SCC intermediate	100-1000
9.3	Materials for reclaim, PM production by-products	931-663-2; None	N/A	N/A	Non-SCC intermediate	100-1000
10	Lead bullion, PGM rich	931-607-7; none	N/A	N/A	Non-SCC intermediate	10-100

* In light of Dec 2010 ECHA Guidance on intermediates, PMC has reviewed which Art 17/18 files submitted in 2010 required to be upgraded to Article 10 files. Tools and strategies suitable for UVCB intermediates have been developed, discussed and validated with Eurométaux.



3.4.1. PMC scope: freezing

FOR APPROVAL by the Assembly: freezing of the substances inventory as presented above until 2018.



3.4.2. PMC scope: SDS

Background:

- December 2011: proposal to draft SDS template for PMC substances BUT no formal agreement from Assembly
- 2012: SDS templates drafted for Ag
- December 2013: formal approval for draft SDS templates for Re
- SDS is not included into the scope of the Consortium agreement

Issue:

- No clear rules
- No dedicated budget
- No formal approval of the inclusion of SDS into PMC workplan



3.4.2. PMC scope: SDS

Impact on budget:

- PMC includes 100 substances
- Consultants costs estimated for SDS draft: $100 \times 2.000\text{€}$ (per SDS) = 200.000€
- Need to update the SDS: unknown costs

Impact on HR:

- 0,5 FTE to coordinate and review the exercise

This is not available in 2015 WP and is not foreseen so far in 2016 WP.



3.4.2. PMC scope: SDS

Pros and Cons: including SDS into PMC workplan

Pros	Cons
Guarantee consistency amongst SDS	SDS must be company specific
	Liability issue for the Secretariat (content, updates...)
	Additional workload and financial resources for PMC

FOR APPROVAL: the Secretariat recommends to not include SDS drafting into the PMC workplan 2016



4. PMC Finances

FRANCE CAPON



4.1. 2014 accounts audited

	2014 budget	2014 expenses	%
Generic costs	€ 745.140	€ 646.499	87
Ag-specific costs	€ 210.285	€ 220.615	105
Au-specific costs	€ 117.300	€ 160.433	137
PM CN- -specific costs	€ 165.300	€ 152.686	92
PGM-specific costs	€ 817.650	€ 1.295.919	158
Re-specific costs	€ 9.450	€ 7.268	77
Refinables-specific costs	€ 612.064	€ 318.800	52
Hydrazine-specific costs	€ 60.000	€ 5.543	9
TOTAL	€ 2.737.189	€ 2.807.763	103



4.1. 2014 accounts audited

- Generic costs: **underspent** - absence of PMC Trustee the last four months of 2014.
- Silver: **overspent** - unexpected increase of the costs related to the literature review.
- Gold: **overspent** - additional testing costs.
- PM Cyanides: **underspent** - delay in some testing
- PGM: **overspent** - study phasing cost calculation error in the original budget
- Re: **underspent** - lower activity in the literature review
- Refinables: **underspent** – no 2014 budget - not all the reserves were needed
- Hydrazine: **underspent** - delay in the exposure assessment which will only start in 2015.



4.1. 2014 accounts audited

PMC reserves after audit

	TOTAL RESERVES AFTER AUDIT	MINIMUM RESERVES TO BE RETAINED IN-HOUSE
Generic costs	€ 158.118,03	€ 167.412
Ag-specific costs	€ -3.180,85	€ 208.607
Au-specific costs	€ 38.693,76	€ 26.604
PM CN- -specific costs	€ 133.028,47	€ 37.468
PGM-specific costs	€ 1.103.390,47	€ 234.431
Re-specific costs	€ 168.626,86	€ 21.490
Refinables-specific costs	€ 293.263,94	€ 112.587
Hydrazine	€ 54.456,74	€ 2.591
	€ 1.946.397,26	€ 811.190



4.1. 2014 accounts audited

For recommendation of the Assembly to EPMF Plenary to approve the PMC 2014 audited accounts.



4.2. Q1 2015: actuals

	2015 Budget	Expenses by 30/04/2015	Difference	
2.1	Generic costs:	€ 789.928	€ 207.406	€ -582.522
2.2	Ag-specific costs	€ 241.415	€ 1.420	€ -239.995
2.3	Au-specific costs	€ 56.650	€ 12.967	€ -43.683
2.4	PM CN- -specific costs	€ 193.900	€ 99.752	€ -94.148
2.5	PGM-specific costs	€ 1.168.010	€ 159.815	€ -1.008.195
2.6	Re-specific costs	€ 9.450	€ 670	€ -8.780
2.7	Refinables-specific costs	€ 365.824	€ 12.065	€ -353.759
2.8	Hydrazine-specific costs	€ 78.000	€ 0	€ -78.000
	TOTAL	€2.903.177	€ 494.095	€ -2.409.082

- For most of the projects, invoices are lagging behind.
- The Secretariat will remind to the different labs and consultants to send their invoices on a regular basis.



4.2. 2015 forecast

Background – changes in PMC scope (cf. supra)

- Ru Cl3: moving from 1-10 to 10-100t/y (request from one company)
- PdCl2 and Na2PdCl4: moving from 1-10 to 10-100t/y (no implication on 2015 budget since read-across will be feasible) (request from one company)
- Karstedt (interest for 3 companies):
 - Current LR (from Reconcile) refuses to cover 10-100t/y tonnage band (relevant for PMC member)
 - Discussions are ongoing with Reconcile but work needs already to be done to avoid to miss the registration deadline.
 - Decision to include in the PMC scope this substance is a question of risk management and risk tolerance: taking into account the requirements related to this tonnage band postponing the testing programme, waiting for Reconcile decision, could jeopardize the compliance with the next registration deadline.
- HHPA compound is in the 10-100t/y tonnage band and not in the 1-10t/y. (mistake of the Secretariat)



4.2. 2015 forecast

Impact of the described changes on PMC budget and HR:

		RuCl3	HHPA compound	Karstedt	PdCl2 and Na2PdCl4	Forecast	PMC FTE
2015	External costs	262.600	259.600	333.800	0	856.000	
	Internal resources (days)	15	10	14	0		0,2
2016	External costs	79.200	79.200	79.200	40.000	277.600	
	Internal resources (days)	11	11	10	4		0,2
2017	External costs	0	186.000	0	0	186.000	
	Internal resources (days)		10				0,2
Total (€)						1.319.600	



4.2. 2015 forecast

Additional impact on 2015 forecast:

- 96.000€ in PGM (for invoices from 2014 not yet sent to the PMC and the Shadow RMO on chloroplatinates) have not been accrued properly in 2015 budget
- 112.177€ overspent is foreseen in Generic costs: Sec Gen salary, bonus of employees , leave of Renaud Nicolay and additional HR needed due to change in the scope of the Consortium.
- 39.000€ overspent is foreseen in Silver due to CLH and Evaluation.
- 22.000€ overspent is foreseen in Hydrazine project due to the refinement of the Occupational exposure campaign.



4.2. 2015 forecast

In summary...

2015 PMC Budget v/s forecast				
		2015 Budget	Forecast on 19 May 2015	Difference
2.1	Generic costs:	€ 789.928	€ 902.105	€112.177
2.2	Ag-specific costs	€ 241.415	€ 280.415	€39.000
2.3	Au-specific costs	€ 56.650	€ 56.650	€ 0
2.4	PM CN- -specific costs	€ 193.900	€ 193.900	€ 0
2.5	PGM-specific costs	€ 1.168.010	€ 2.120.010	€952.000
2.6	Re-specific costs	€ 9.450	€ 9.450	€ 0
2.7	Refinables-specific costs	€ 365.824	€ 365.824	€ 0
2.8	Hydrazine-specific costs	€ 78.000	€ 100.000	€22.000
	TOTAL	€2.903.177	€4.028.354	€1.125.177



4.2. 2015 forecast

Budget: Recommendations of the PMC Management Committee: exceptional situation requires the following exceptional approach

- **RuCl3 (262.600€):** in 2015, 80% of the costs will be bear by the company having requested the change in the tonnage band, the remaining 20% of the costs will be shared between the other co-registrants of the same substance. This amount will be invoiced to the relevant companies in Q3 2015.
- **PdCl2 and Na2PdCl4:** in 2015, there is no impact on the budget, therefore, the additional costs in 2016 will be included in 2016 budget.
- **Karstedt (333.800€):** due to the urgency of the work to be done and the fact that this situation is independent of the PMC members decision, it is suggested to invoice the related costs to the PGM projects members, following the usual cost-sharing rules of the PMC. This amount will be invoiced to the companies in the PGM WG in Q3 2015.
- **HPPA, accruals for 2014 invoices and RMO on chloroplatinates (355.600€):** PGM reserves will be used.
- **Generic costs (112.177€):** Generic costs reserves will be used.
- **Silver (39.000€):** Silver reserves will be used.
- **Hydrazine (22.000€):** Hydrazine reserves will be used.be included in 2016 budget.



4.2. 2015 forecast

In summary, a part of the overspend forecast (596.400€) will be invoiced following the above principles in Q3 2015, the rest will be taken from the reserves.



4.2. 2015 forecast

Impact of the Management Committee recommendation on PMC reserves

		SIMULATION TOTAL RESERVES END 2015 based on MC proposal	MINIMUM RESERVES TO BE RETAINED IN- HOUSE
1.2.1	Generic costs	€ 153.159,23	€ 167.412
1.2.2	Ag-specific costs	€ 201.347,87	€ 208.607
1.2.3	Au-specific costs	€ 80.263,37	€ 26.604
1.2.4	PM CN- -specific costs	€ 197.571,82	€ 37.468
1.2.5	PGM-specific costs	€ 347.790,47	€ 234.431
1.2.6	Re-specific costs	€ 159.176,86	€ 21.490
1.2.7	Refinables-specific costs	€ 293.263,94	€ 112.587
1.2.8	Hydrazine	€ 32.456,74	€ 2.591
	Total	€ 1.465.030,28	€ 811.190

In 2016, need to continue building the reserves in some areas.



4.2. 2015 forecast

Additional invoice in 2015 based on the PMC Management Cttee recommendation

ID Code	2015 Generic cost-share per Member	2015 Ag-specific cost-share per Member	2015 Au-specific cost-share per Member	2015 PM CN - specific cost-share per Member	2015 EXTRA PGM-specific cost-share per Member	2015 Re-specific cost-share per Member	2015 Ref-specific cost-share per Member	2015 Hz-specific cost-share per Member	EXTRA Amount to be invoiced in 2015
1	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
2	0,00 €	0,00 €	0,00 €	0,00 €	7.712,34 €	0,00 €	0,00 €	0,00 €	7.712,34 €
3	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
5	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
6	0,00 €	0,00 €	0,00 €	0,00 €	6.296,33 €	0,00 €	0,00 €	0,00 €	6.296,33 €
7	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
8	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
9	0,00 €	0,00 €	0,00 €	0,00 €	10.074,13 €	0,00 €	0,00 €	0,00 €	10.074,13 €
10	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
11	0,00 €	0,00 €	0,00 €	0,00 €	101.491,82 €	0,00 €	0,00 €	0,00 €	101.491,82 €
12	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
13	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
14	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
15	0,00 €	0,00 €	0,00 €	0,00 €	289.089,62 €	0,00 €	0,00 €	0,00 €	289.089,62 €
16	0,00 €	0,00 €	0,00 €	0,00 €	23.293,76 €	0,00 €	0,00 €	0,00 €	23.293,76 €
17	0,00 €	0,00 €	0,00 €	0,00 €	3.777,80 €	0,00 €	0,00 €	0,00 €	3.777,80 €
18	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
19	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
20	0,00 €	0,00 €	0,00 €	0,00 €	1.259,27 €	0,00 €	0,00 €	0,00 €	1.259,27 €



4.2. 2015 forecast

Additional invoice in 2015 based on the PMC Management Cttee recommendation

ID Code	2015 Generic cost-share per Member	2015 Ag-specific cost-share per Member	2015 Au-specific cost-share per Member	2015 PM CN - specific cost-share per Member	2015 EXTRA PGM-specific cost-share per Member	2015 Re-specific cost-share per Member	2015 Ref-specific cost-share per Member	2015 Hz-specific cost-share per Member	EXTRA Amount to be invoiced in 2015
21	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
23	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
24	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
25	0,00 €	0,00 €	0,00 €	0,00 €	66.583,24 €	0,00 €	0,00 €	0,00 €	66.583,24 €
27	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
28	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
29	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
30	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
31	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
32	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
33	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
34	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
35	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
36	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
39	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
40	0,00 €	0,00 €	0,00 €	0,00 €	7.963,48 €	0,00 €	0,00 €	0,00 €	7.963,48 €
41	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
42	0,00 €	0,00 €	0,00 €	0,00 €	1.259,27 €	0,00 €	0,00 €	0,00 €	1.259,27 €
43	0,00 €	0,00 €	0,00 €	0,00 €	3.934,54 €	0,00 €	0,00 €	0,00 €	3.934,54 €
44	0,00 €	0,00 €	0,00 €	0,00 €	8.814,86 €	0,00 €	0,00 €	0,00 €	8.814,86 €
45	0,00 €	0,00 €	0,00 €	0,00 €	16.683,94 €	0,00 €	0,00 €	0,00 €	16.683,94 €
46	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €	0,00 €
47	0,00 €	0,00 €	0,00 €	0,00 €	6.296,33 €	0,00 €	0,00 €	0,00 €	6.296,33 €
48	0,00 €	0,00 €	0,00 €	0,00 €	2.518,53 €	0,00 €	0,00 €	0,00 €	2.518,53 €
49	0,00 €	0,00 €	0,00 €	0,00 €	8.814,86 €	0,00 €	0,00 €	0,00 €	8.814,86 €
50	0,00 €	0,00 €	0,00 €	0,00 €	12.906,14 €	0,00 €	0,00 €	0,00 €	12.906,14 €
TPR 1	TPR 1					0,00 €			0,00 €
TOTAL	0,00 €	0,00 €	0,00 €	0,00 €	596.400,00 €	0,00 €	0,00 €	0,00 €	596.400,00 €



4.2. 2015 forecast

HR: Recommendations of the PMC Management Committee

Reorganisation PMC work to make it more efficient and increase of consultancy support

A review of the current working organisation has been done. Some areas of improvement have been identified:

- Streamlining and decreasing administrative burdens of the managers
- Increase the synergy between the different projects



4.2. 2015 forecast

For approval by the Assembly: recommendation of the PMC Management Committee:

- a part of the overspend forecast (596.400€) will be invoiced following the above principles in Q3 2015 (exceptional contribution of concerned companies and usual costs sharing for Karstedt), the rest will be taken from the reserves.
- Reorganisation of HR and additional consultancy support



4.3. PMC cost sharing

Principles used in PMC:

- **Fairness:** Same cost sharing formula to all potential registrants
 - Generic costs are shared equally among all potential registrants
 - Metal-specific costs are distributed per project or substance family as follows:
 - 50% is distributed by applying a weighted approach
 - 50% is distributed according to the total number of PMC substances (SCC intermediates are excluded) to be registered by each company in each project
- **Transparency:** predictions and calculations are based on clear, sound and objective hypotheses and assumptions
- **Non-discrimination**
- **Non profit**



4.3. PMC cost sharing

Data Sharing draft Implementing act

Implementing acts:

- To ensure uniform implementation across the EU
- Adopted by Ordinary Legislative Procedure: EP and EC on equal basis

In practice, « any person and/or entity required to share and submit information pursuant to the REACH Regulation shall comply with the provisions established by this Regulation.



4.3. PMC cost sharing

Data Sharing draft Implementing act

Proposal:

- **Transparent:**
 - Description of the study costs
 - Description of the administrative costs
 - The REACH requirements to which the study corresponds need to be added
 - If not done, existing data sharing agreement must be amended
 - Need to document yearly
 - further administrative or study costs
 - Compensation received from subsequent registrants
- **Fair and non-discriminatory:**
 - Take into account number of potential registrants and possibility of future additional information requirements (if well documented and justified separately from admin and study costs)
 - Reimbursement mechanism shall be envisaged: obligation can be waived if ALL parties consent (only for existing data sharing agreement) and new comer is not obliged to accept
- Dispute resolution



4.3. PMC cost sharing

- Based on the above, the Cost-Sharing WG reviewed on 29 April 2015 some principles of the PMC cost sharing formula.
- The recommended changes will be applicable in the future but not retroactively.
- The Cost-Sharing WG recommends the following changes to be implemented in the Appendices of the Cs agreement:
 - **Refinables:** It is recommended to apply to refinables the same cost sharing formula than for the other substances, **taking into account the SCC or non-SCC status**, based on members declaration. However, it is also recommended to not apply the differences in the tonnage band since this is not the main driver for the work done on refinables (no testing done – dossiers based on the components).

For approval by the Assembly and to be implemented in 2016



4.3. PMC cost sharing

- The Cost-Sharing WG recommends the following changes to be implemented in the Appendices of the Cs agreement:
 - **Nanos:** It is **premature to recommend a way forward** for the cost sharing between the registrants of nanos and non-nanos forms of the same substance. So far, it was agreed to have both forms in the same dossier because of no specific requirements for nanos. Now, with the ongoing Evaluation on silver, some additional requirements specific to nanos could be identified. **It will be therefore important to clarify if it is possible to differentiate what is specific to nanos or not.** Based on this, the recommendation of the cost-sharing WG is to review this issue when the outcome of the evaluation will be available. **The main driver for the cost sharing must be related to requirements** (as specified also in the Implementing act on data sharing).
 - Info from DD: “Only those registrants whose registration covers nanoforms of silver shall provide the information requested in this decision.”

For approval by the Assembly in December 2015 after clarifications of some pending issues



4.3. PMC cost sharing

- The Cost-Sharing WG recommends the following changes to be implemented in the Appendices of the Cs agreement:
 - **LoA:** It is recommended to have the **same cost sharing formula between all co-registrants.** The difference between PMC membership and LoA will be the scope of the data sharing. In the LoA, **only costs related to registration and other legal obligations** (e.g.: evaluation) can be shared with non PMC members. **It is therefore recommended to have a full review of the costs charged in the letter of access and to remove what is not explicitly mandatory to achieve the joint submission and further legal obligations.**
 - **LoA:** calculation based on **assumptions until 2020.** These assumptions can trigger difficult situations having a LoA buyer paying too much or less than needed. It is therefore recommended **to define LoA prices based on actuals and on the budget of the year and to update it on a yearly basis.** On an ad-hoc basis, additional costs will be invoiced to the LoA buyers when needed.

For approval by the Assembly that updated LoA prices can be available over Summer.



4.3. PMC cost sharing

- The Cost-Sharing WG recommends the following changes to be implemented in the Appendices of the Cs agreement:
 - **Generic costs:** for LoA as PMC members, the cost sharing WG recommends **to allocate the generics costs to each project when feasible** (e.g.: HR, meetings...) and to keep only in the equal shared costs the minimum benefitting clearly to all the projects (e.g.: Eurometaux fee).
 - **PGM:** It is recommended to change the cost sharing formula and apply it by group of substances and not to all the PGMs. It can be justified to have a group substance approach for read-across reasons.

N.B.: In the future, we could be obliged to review again the cost sharing formula and make it more substance specific.

For approval by the Assembly and to be implemented in 2016.



5. PMC Business Plan 2016-2019

FRANCE CAPON

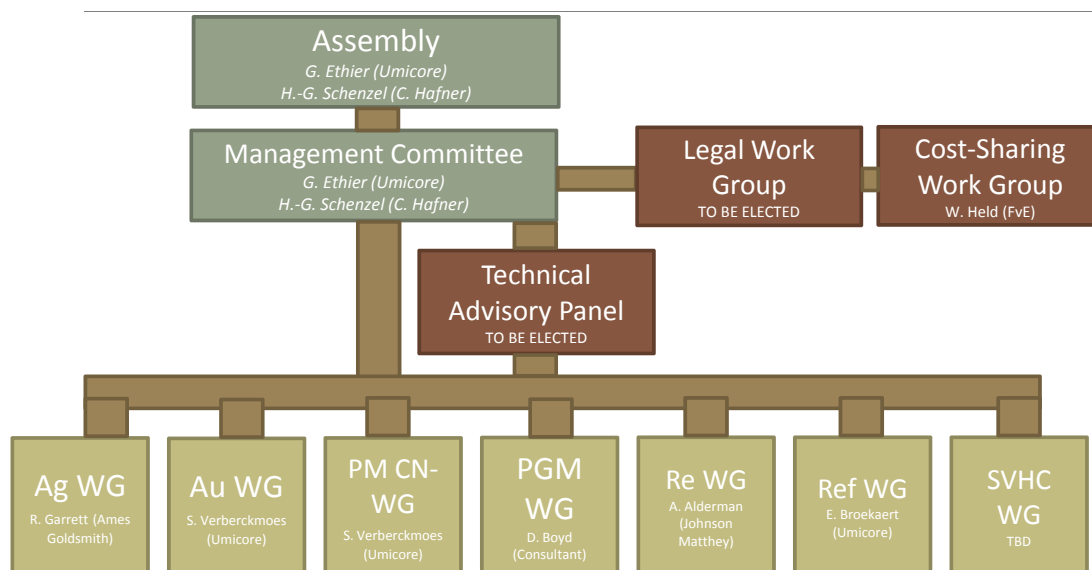


Introduction

- Aims of the workplan
 - Provide the MC and the Assembly with an overview of the projects including clear scope of the Cs (cf. list of substances)
 - Present in an integrated way the budget, HR and timeline of the PMC
 - Highlight the risks related to HR or timeline
 - Provide an outlook for the 5 coming years (to be developed)
- WP will be updated every year and approved by the Assembly in December of each year



Updated working structure





Updated working structure

- ❑ Each project (Except SVHC) is divided in sub-projects:
 - REACH Registration
 - REACH dossier maintenance
 - REACH Evaluation
 - REACH CI & Labelling
 - REACH Authorisation
- ❑ Projects activated when relevant
- ❑ SVHC project is covering all the monitoring activities related to Authorisation and Risk Management Measures in general



Draft 2016 WP

Ag project	Au project	CN project
<ul style="list-style-type: none">• Substance Evaluation (on Silver metal – nanoforms)• CLH under biocides• Maintenance of the dossiers: litterature review	<ul style="list-style-type: none">• Registration: submission of the dossiers	<ul style="list-style-type: none">• Registration: submission of 2 dossiers• Registration: testing of potassium docyanoargentate



Draft 2016 WP

PGM

Pt project	Pd project	Rh project
<ul style="list-style-type: none">• Registration: Envi and HH testing + IUCLID completion + exposure assessment	<ul style="list-style-type: none">• Registration: finalisation and submission of the 19 dossiers	<ul style="list-style-type: none">• Registration: Envi and HH testing + IUCLID completion + exposure assessment



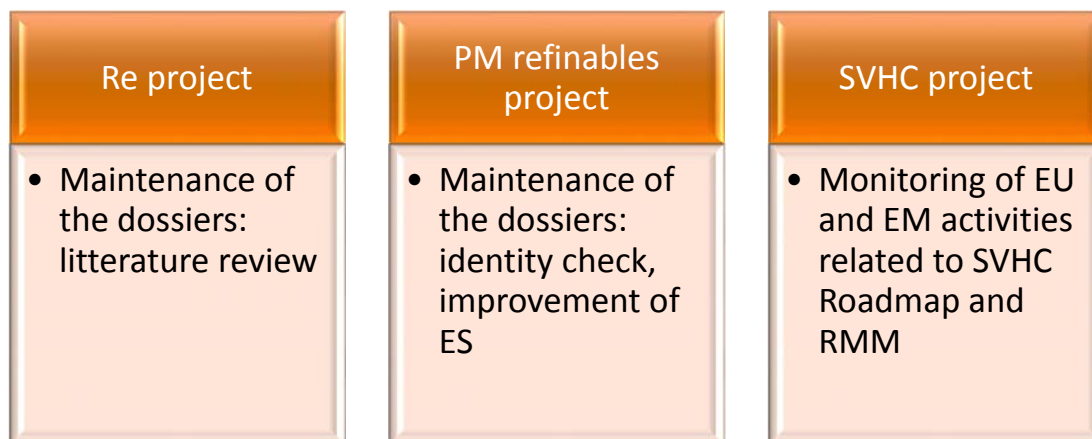
Draft 2016 WP

PGM

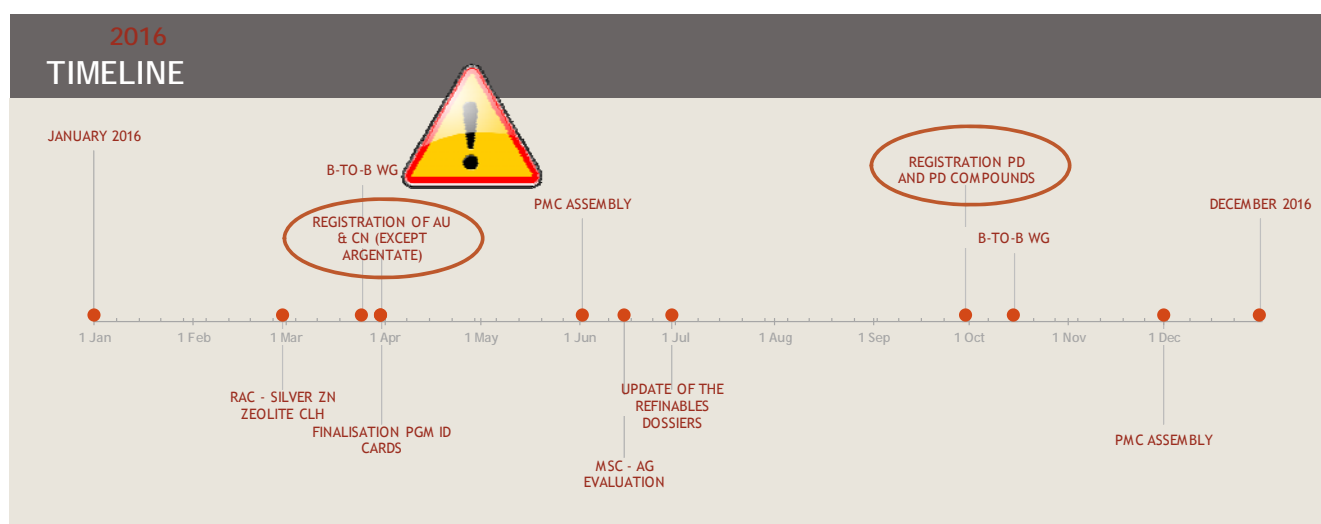
Ru project	Ir project
<ul style="list-style-type: none">• Registration: Envi and HH testing on Ruthenium trichloride + IUCLID completion + exposure assessment	<ul style="list-style-type: none">• Maintenance of the dossiers: literature review



Draft 2016 WP



Draft 2016 Timeline





Draft 2016 Budget

DRAFT BUDGET 2016		
	PMC 2016 Budget	PMC 2016 HR
2.1 Generic costs	1.018.760 €	1,49
2.2 Ag-specific costs	565.000 €	0,7945
2.3 Au-specific costs	23.000 €	0,2765
2.4 PM CN- -specific costs	295.000 €	0,4305
2.5 PGM-specific costs	1.586.000 €	2,0025
2.6 Re-specific costs	11.400 €	0,027
2.7 Refinables-specific costs	423.000 €	0,279
2.8 SVHC project (RMM, RMO, SVHC Roadmap...)	10.000 €	0,1
TOTAL	3.943.560 €	5,4



Budget comparaison 2014-2016

	2013 expenses	2014 expenses	2015 predicted expenses	2016 draft budget
Generic costs	€ 508.852	€ 646.499	€ 902.105	€ 1.018.760
Ag-specific costs	€ 657.369	€ 220.615	€ 280.415	€ 565.00
Au-specific costs	€ 156.734	€ 160.433	€ 56.650	€ 23.000
PM CN- -specific costs	€ 216.764	€ 152.686	€ 193.900	€ 295.000
PGM-specific costs	€ 727.626	€ 1.295.919	€ 2.120.010	€ 1.586.000
Re-specific costs	€ 26.422	€ 7.268	€ 9.450	€ 11.400
Refinables-specific costs	€ 248.332	€ 318.800	€ 365.824	€ 423.000
Hydrazine-specific costs	€ 45.588	€ 5.543	€ 100.000	€ 10.000
TOTAL	€ 2.587.687	€ 2.807.763	€ 4.028.354	€ 3.943.560



- Discussion and recommendation of the Assembly in preparation of the final WP 2016 to be approved in December 2015
- Approval of the additional HR (1 FTE – Regulaotry affairs manager)



6. Update on PMC Registration Projects

PMC TEAM



6.1. Ag Project (*K. Arijs*)

- a. Ag literature searches
- b. Ag Evaluation
- c. Ag Biocides
- d. Ag Roadmap



6.1.a. Ag literature searches

- **2014 budget:** overspent due to high costs for literature searches (unexpected high number of relevant publications).
- **2015 budget:** again high costs projected for literature searches → PMC Sec was asked at the 3 Dec 2014 GA to investigate options to limit costs.
- Several options investigated & compared: status quo, request new/revised offers, share efforts with other interested parties (Ag institute, EU Ag TF), internalisation of the work, ...
- Presented at 24 Feb PMC Mgmt Cttee meeting

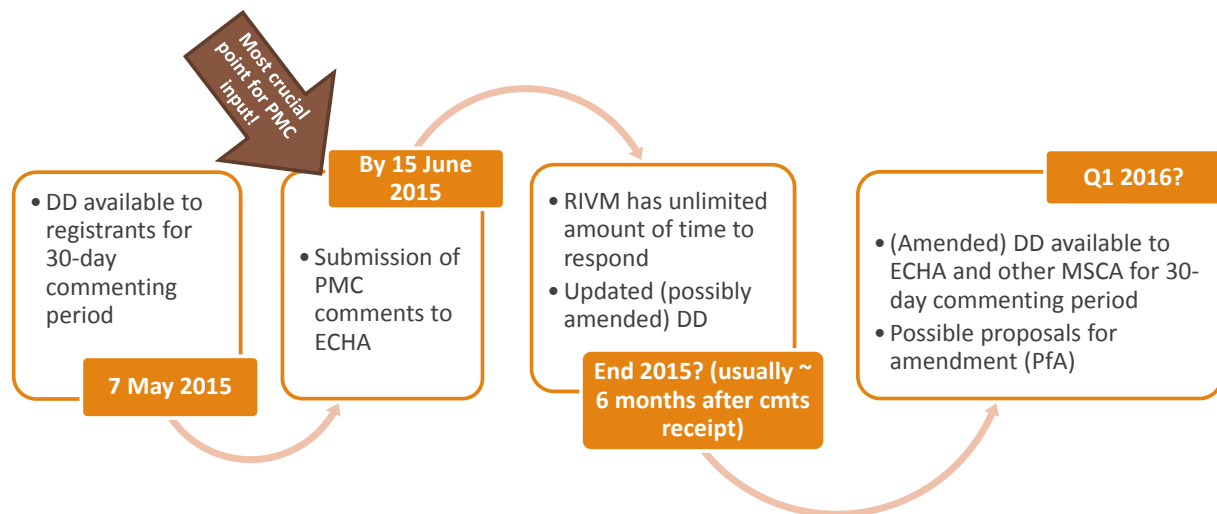
→ ***Environmental literature review will be performed in-house***

- Cost-sharing with EU Ag TF investigated:
 - no requirement under the BPR to keep dossiers up to date with latest available data → EU Ag TF has no strong interest to share costs with PMC

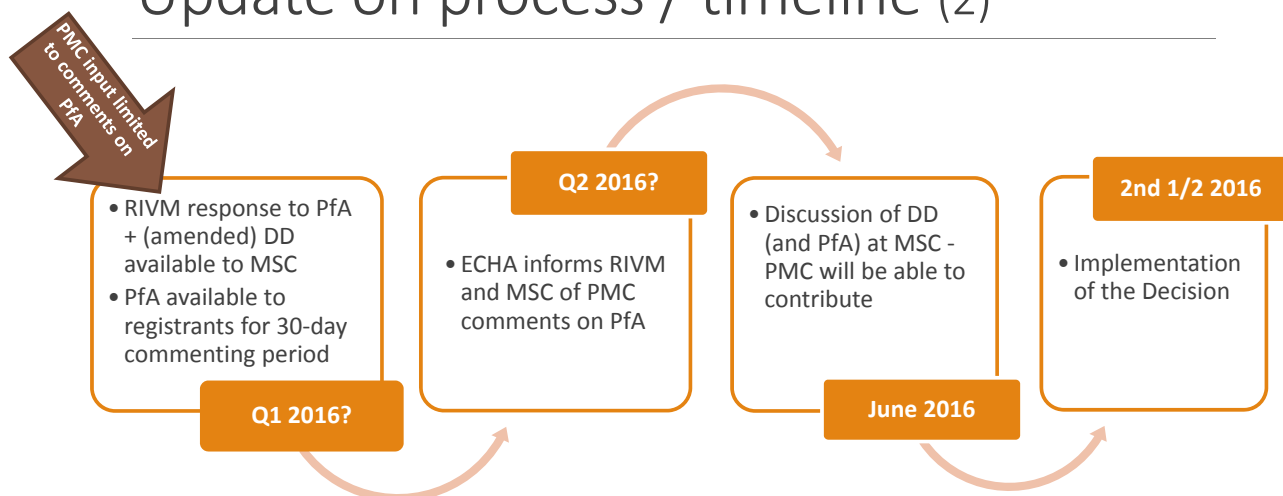


6.1.b. Ag Evaluation Update on process / timeline (1)

- Ag SEv started in 2014, by NL (RIVM)
- Based on registrations and other relevant and available information



6.1.b. Ag Evaluation Update on process / timeline (2)



- Updated registration to be submitted within **12 months** from the date of the final decision
- This decision does not imply that the info provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements
 - ➔ Still possibility of compliance checks on the dossier(s) or new SEv process!



6.1.b. Ag Evaluation Content Draft Decision (1)

- **Initial grounds for concern:** Nanoparticles/ Ecotoxicity of different forms of the substance; Environmental fate; Exposure/Wide dispersive use; aggregated tonnage
- Scope of SEv limited to the properties of and information on **nanofoms of Ag**: only those Registrants whose registration covers nanofoms of Ag shall provide the information requested in the DD
 - In case where a Registrant actually manufactures or imports nanofoms of Ag as defined in the Commission Recommendation (...), failure to report sufficient information on **each grade** of a substance in the registration dossier, including nanofoms, may result in these grades not being covered by this registration.
 - All Registrants of Ag shall therefore determine whether their individual registration dossier cover forms of nanoAg in order to establish certainty as to which manufacturer or importer will have to provide the information requested in the DD.



6.1.b. Ag Evaluation Content Draft Decision (2)

The eMSCA considered that further **information was required** to clarify the initial concerns:

1. Phys-chem properties of nanoAg
2. Fate in soil
3. Ecotoxicity studies
4. Uses

Registrant(s) invited to provide comments within 30 days of the receipt of the DD.



6.1.b. Ag Evaluation

General comments on Draft Decision

Overall, the DD is reasonable and in line with what was expected.

- 1. Timing:** only 12 months to perform testing and update the registration file → PMC will contest the time needed to conduct the request (ask for extension from 12 to 24 months) – needs to be well motivated!
 - Evidence that testing labs need more time (capacity issue given 2018 REACH deadline)
 - Soil testing: method development needed, need for extensive equilibrium times for soils
- 2. Grade/form:** unclear why sometimes the wording 'grade' is used and why sometimes 'form' → PMC to ask RIVM for clarification



6.1.b. Ag Evaluation

Further info on phys-chem properties (1)

Information on the phys-chem properties of **each individual form of nanoAg** that is manufactured, imported and/or placed on the market, using the indicated test method(s)

- A. Granulometry, incl. primary particle size and shape, aggregate/agglomerate size, and PSD
- B. Specific surface area (by volume)
- C. Surface treating agent(s)
- D. Dissolution rate
- E. Density
- F. Point of zero charge



6.1.b. Ag Evaluation

Further info on phys-chem properties (2)

56 Registrants, only 10 registered nanoAg

- only 2 provided data on the PSD that enables a proper comparison with the EU recommendation on the definition of nanomaterial
- 2 did not provide data on PSD of their nanoAg forms at all
- In all cases regarding impurities and additives, the general text of the J-CSR is copied in → info on specific surface modifications is not available

PMC is only aware of 3 nanoAg registrants! **How to identify the others?!**



Keep in mind: any non-reported nanoform/grade during this SEv decision follow-up, will not be covered by the joint registration and may be considered as a new substance meaning that a **full registration** may be required. **It is therefore critical that all registrants/ORs/importers submit the information requested for their forms/grades.**



6.1.b. Ag Evaluation

Further info on phys-chem properties (3)

PMC concerns:

1. PMC does not have information on the **total number of Ag nanoforms**
 - PMC agrees with the DD that each individual form of nanoAg is tested for their phys-chem properties: no evidence that grouping is needed / will be feasible
2. Registrants are responsible for phys-chem testing but '*LR shall ensure that each form of the substance is taken into account for all data included in sections 2-11 of the technical dossier as per REACH requirements*' → PMC Sec needs to be aware of **all** Ag nanoforms included in dossiers
 - PMC Sec will coordinate phys-chem testing (cf. PGM blacks) → lower variability in results, cost and time efficient



6.1.b. Ag Evaluation

Further info on phys-chem properties (4)

PMC comments:

1. **T/D testing:** deviation from standard protocol (adaptations to dissolution medium) is not acceptable (Mutual Acceptance of Data issue + precedence for all metals)
2. Suggestion to express T/D results in release per surface to be comparable with other metals



6.1.b. Ag Evaluation

Further info on fate in soil

Request: Quantitative info on nanoAg particles (3 representative forms) in soil pore water and soil solid fraction, following their introduction in 3 different soil types

PMC comments:

1. This is not routine testing, but **research...**
 - Time needed to identify organisation and methods to undertake work (cf. PMC comment on timing)
2. **Soils:**
 - Suggestion to use 3 soils from those that were used for previous Ag work in CSR
 - Aging of Ag in soils has considerable influence on behaviour, fate and ecotoxicity of the Ag salt



6.1.b. Ag Evaluation

Further info on ecotoxicity (1)

Request:

- New comparative ecotoxicity studies required for 3 nanoAg forms (cf. request 2):
 - 72-hour inhibition of algal growth (OECD 201)
 - 21-day *Daphnia magna* reproduction (OECD 211)
 - Toxicity to soil micro-organisms (OECD 216) – 3 soils (cf. request 2)
- Dissolution rates (T/D testing) required for the 3 nanomaterials in test media (cf. request 1)
- The concentrations of, and ratio between, nanoAg and ionic Ag should be monitored in exposures using appropriate analytical techniques
- A 'control' using AgNO₃ is to be included
 - Identical analytical procedures to be applied as in nanoAg tests to assess potential for 'formation' of nanoparticles



6.1.b. Ag Evaluation

Further info on ecotoxicity (2)

PMC comments:

1. DD states that modifications should be made to standard **test media** for algal and *Daphnia* tests: potential to affect growth / reproduction?
2. **Soils**: suggestion to use 3 soils from those that were used for previous Ag work in CSR
3. Analytical approaches will need to be investigated and trialled prior to implementation in the tests (cf. PMC comment on timing)
4. **'Control' exposure**: data already partly available so no need for full test but refer to existing dataset



6.1.b. Ag Evaluation

Further info on uses

Information on the uses of each individual form of nanoAg that is manufactured, imported and/or placed on the market

→ No PMC comments on this request



6.1.b. Ag Evaluation

Uses currently covered in Ag dossier

- Manufacture, refining and recycling of Ag metal
- Re-melting and alloying
- Production of batteries
- Electronics, contact materials and electroplating
- Production, preparation and use of chemicals, preparations or catalysts
- Welding in industrial settings
- Welding in professional settings
- Professional uses of Ag containing preparations (excluding alloys)
- Soldering and brazing in professional settings
- Service life for consumers of
 - Jewellery
 - Cutlery and Ag table ware
 - Installed dental appliances and fillings containing Ag
 - Massive objects containing Ag metal at ambient temperature
 - Articles containing Ag being encapsulated in the internal part of the product
 - Batteries

Uses in **orange** are relevant for both non-nano and nanoAg

No consumer use reported by nanoAg registrants and/or (nano)Ag registrants' DU



6.1.b. Ag Evaluation

Next steps

What?	Who?	Timeline
1. Drafting of comments on DD	PMC / WCA	By 2 June 2015
2. Approval of comments on DD	Ag registrants	By 8 June 2015
3. Submission of comments to ECHA	Heraeus	By 15 June 2015
4. Start implementation of the decision which is not challenged (data gathering on uses + characterisation work)	PMC / registrants	Q3 2015
5. Based on the PfAs, development of an advocacy strategy with MSCAs?	PMC	Q1 2016
6. Finalisation of the Decision	RIVM / ECHA	Summer 2016
7. Participation to the MSC hearing	PMC	June 2016
8. Implementation of the final decision	PMC	Q3 2016 and beyond



6.1.b. Ag Evaluation

Estimated costs (current assumption)

Additional work	Cost PMC (€)	Cost member company (€)	Comment
Phys-chem properties	Limited (only coordination)	T/D test only: ± 20 k€ per nanoform	This work will be covered by each member company having nanoAg. Work to be initiated Q3 2015.
Fate in soil	400-500 k€	-	
Ecotoxicity	± 300 k€ (excl. T/D tests)	-	Additional T/D tests to be undertaken in different test media; number of T/D tests still unclear
Uses	Limited	-	No testing; only data-gathering

- Total costs for PMC close to **1 million €**
- Costs will be incurred 2016 and 2017



6.1.c. Ag Biocides Background

	Ag REACH	Ag BPR
Scope	PMC Ag project includes eight substances/Dossiers: 1. Silver 2. Disilver oxide 3. Silver nitrate 4. Disilver sulphate 5. Disilver carbonate 6. Silver chloride 7. Silver bromide 8. Silver iodide	STF single core active substance dossier supporting eight substances: 1. Silver 2. Silver (reaction mass with SiO ₂ – nano?) 3. Silver chloride (reaction mass with TiO ₂) 4. Silver nitrate 5. Silver sodium hydrogen zirconium phosphate 6. Silver phosphate glass 7. Silver zinc zeolite 8. Silver copper zeolite
Prepared by	PMC	EU Silver Task Force (EU Ag TF)
Under review by	RIVM, Dutch CA	KEMI, Swedish CA
CLH	Not a requirement (only as a possible conclusion from the SEv itself)	Requirement

Proposed future entry in Annex VI of CLP Regulation

Carc. 2; H351; Repr. 1B; H360D STOT RE 2; H373 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 1; H410

Regulatory programme

BPD

Effects attributed to Ag ion → need to avoid domino effect on REACH Ag dossiers!



6.1.c. Ag Biocides Biocides vs CLP

Harmonisation of classification and labelling under CLP (article 36, CLP)

A substance that is an **active substance** (e.g. silver zinc zeolite) in the meaning of Directive 91/414/EEC or Directive 98/8/EC shall normally be subject to harmonised classification and labelling under CLP and to evaluation under BPR (Biocidal Products Regulation)

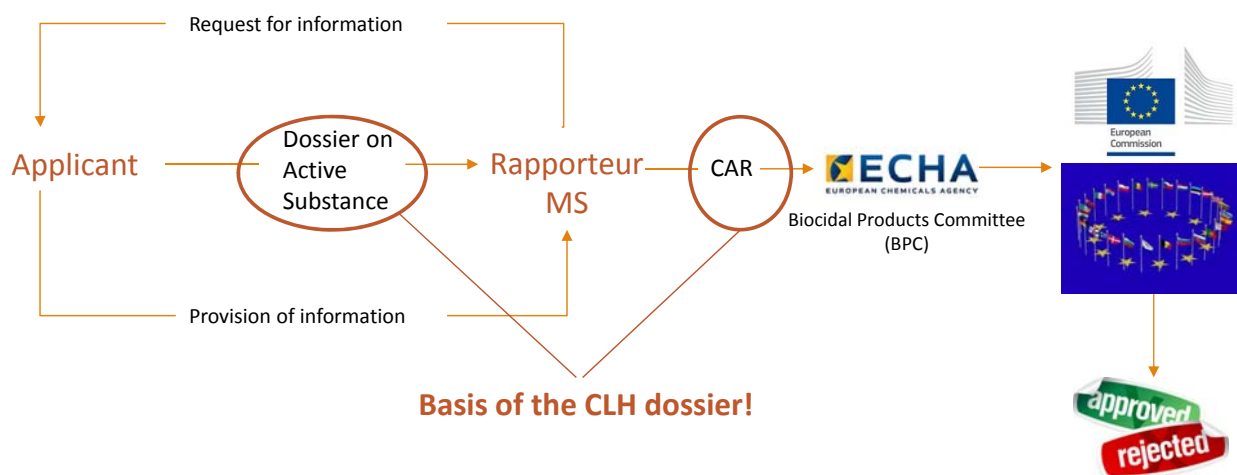
- CLH dossier: to be submitted to ECHA by the CA in the same MS than the RMS (Rapporteur Member State) preparing under biocides the DAR (Draft Assessment Report) or CAR (Competent Authority Report) for the active substance
- A specific justification that action is required at EU level is NOT needed
- CLH dossiers should address ALL hazard classes (except if an entry already exists in Annex VI to CLP)
- Even if the conclusion of the assessment is NO classification, a CLH dossier must be submitted. If RAC concludes that no classification is warranted, an opinion will be adopted BUT no entry into Annex VI.



6.1.c. Ag Biocides

How is a CLH dossier prepared?

Under BPR, approval of active substance:



6.1.c. Ag Biocides

Alignment CLH / BPR

- Roles of BPC and RAC: clearly defined
- Relationship between the approval of active substances in BPR and the harmonized classification and labelling process under CLP
 - E.g.: approval of the active substances and the identification of candidates for substitution are based also on the classification according to CLP criteria
 - E.g.: exclusion criteria described under BPR like CMR cat. 1A and 1B
→ Demonstrate the need for clear alignment!
- New active substances under BPR (article 7): CLH dossier must be submitted in advance of submission of CAR (2-3 months before)



6.1.c. Ag Biocides Update on timeline

- Silver zinc zeolite (SZZ):
 - ECHA and RAC received from KEMI the SZZ CLH dossier end of April
 - Accordance check now ongoing (~ 6 weeks)
 - Unlikely that the public consultation (45-day commenting period) starts before summer 2015
- Silver nitrate, silver chloride (reaction mass with TiO₂) and silver sodium hydrogen zirconium phosphate (SSHZP):
 - draft human health section for the CAR issued Jan 2015; full CAR expected end 2015
- Other Ag biocides: timing currently unknown



6.1.c. Ag Biocides Update on process

- Although essential, the CLH is not decided based on both the BPR and the REACH dossier
- No consensus between MS on SZZ CLH:
 - UK, France and the Netherlands disagree
 - PMC is considering advocacy with the Netherlands (RIVM/ctgb)
- PMC and EU Ag TF are exploring cooperation on an advocacy plan



6.1.c. Ag Biocides

PMC comments on SZZ CLH

Comments are being prepared by end of June:

- **Environment:** comments to be developed with Eurométaux (metals methodology not followed)
- **Human health:** comments under preparation by EBRC:
 - **Developmental tox (Repr. 1B):** key endpoint
1-gen tox study in rats with ionic Ag performed by the US FDA: some treatment related effects but no access to raw data yet → PMC requested copy of manuscript and Ag WG decided to update current waiver in Ag REACH dossier once results are available
 - **Carcinogenicity (Carc. 2)**
 - **STOT RE (STOT RE 2)**



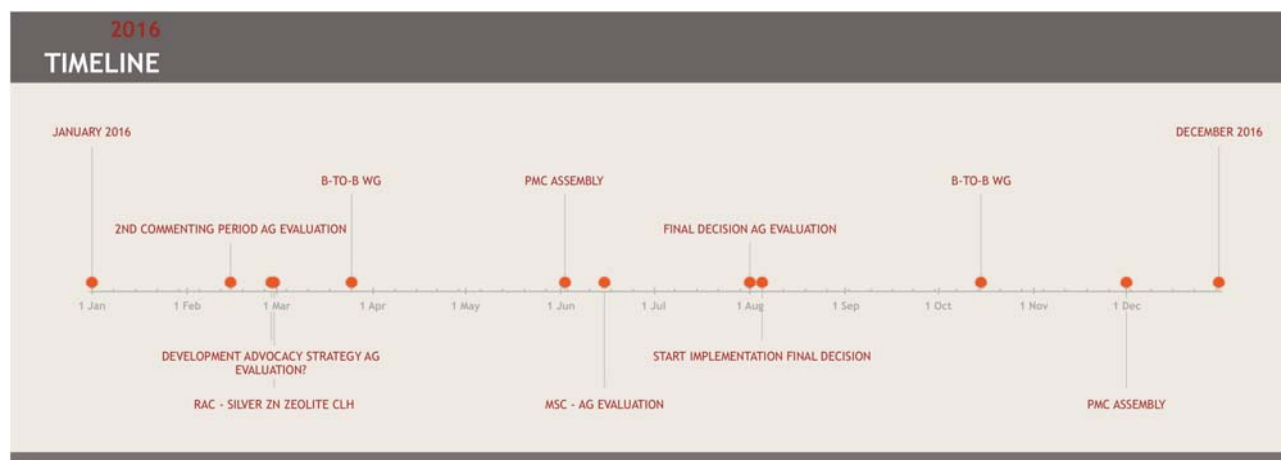
6.1.c. Ag Biocides

Potential interactions SEv and CLH

- **Impact KEMI on SEv:** The justification document for the selection of Ag for CoRAP inclusion only mentions ecotoxicity under the initial grounds for concern and no additional concerns than those listed in the CoRAP were identified → KEMI cannot comment on human health toxicity during this SEv.
- **Impact RIVM on CLH:** The consultation period on the SZZ CLH may be a good opportunity for The Netherlands (RIVM/ctgb) to comment. Ag TF suggested PMC to contact RIVM on this.



6.1.d. Ag Roadmap



6.2. Au Project (*M. Eliat*) Scope

Substances included in the scope:

- Gold
- Tetrachloroauric acid
- Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate
- Balsams, copaiba, sulfurized, mixed with turpentine, gold salts



6.2. Au Project *Scope*

Nanogold

- 3 surveys (Members and DU) did not conclude on the significant presence of nanogold on the market. Less than 10% of members have informally reported nanogold.
- On the basis of these results, PMC will not include nanogold in the scope.

Tetrachloroauric Acid forms

- TCA aq solution is the form that PMC was aware of and planned to register
- Pure forms have been identified
- Intention to register pure TCA and consider the solution as a mixture



6.2. Au Project *Classification*

IUPAC Name	Gold	Tetrachloroauric acid (in aq. solution)	Aurio(1+) 2,6,6-trimethylbicyclo [3.1.1]heptanet hiolate	Balsams, copaiba, sulfurized, mixed with turpentine, gold salts
Classification	None	Acute tox. 4 (H302: Harmful if swallowed)	Flam. Solid Cat 1 (H228)	Flam. Solid Cat 1 (H228)
		Skin corr. 1B (H314: Causes severe skin burns and eye damage)		
		Eye dam. 1 (H318: Causes serious eye damage)		
		Aquatic chronic 2 (H411)		
		Met. Corr. 1 (H290: May be corrosive to metals)		



6.2. Au Project *Identified uses*

Tetrachloroauric acid:

- Manufacture of TCA
- Use as an intermediate

Gold (survey not completed):

- Manufacture of gold
- Use of gold as an intermediate
- Use of gold in jewelry

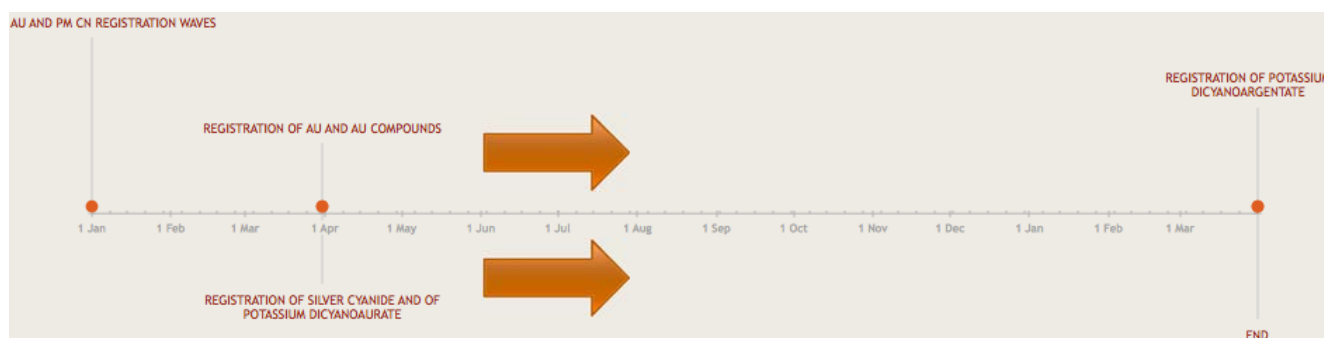
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate & Balsams, copaiba, sulfurized, mixed with turpentine, gold salts (survey not completed):

- **No Identified uses reported!**



6.2. Au Project *Timing*

- Testing phase reaching an end
- Interim DNELs available, PNECs almost available
- Uses available for TCA and Gold but not for the other 2 gold substances
- Environmental risk assessment will be ready by Q1 2016
- Occupational risk assessment might not be ready by Q1 2016 due to potential site visits and monitoring program





6.2. PM CN-Project (*M. Eliat*) *Scope*

Substances included in the scope:

- Potassium dicyanoargentate
- Silver cyanide
- Potassium dicyanoaurate



6.3. PM CN- Project *Classification*

IUPAC Name	Potassium dicyanoargentate	Silver cyanide	Potassium dicyanoaurate
Classification	Acute tox. 2 (H330: Fatal if inhaled)		
	Acute tox. 1 (H310: Fatal in contact with skin)		Skin sens. 1
	Acute tox. 2 (H300: Fatal if swallowed)	Acute tox. 3 (H301)	Acute tox. 2 (H300: Fatal if swallowed)
	EUH032: contact with acids liberates very toxic gas		
	Skin Corr. 1A	Skin Irrit. 2 (H315)	
	Eye dam. 1 (H318)		
	Aquatic acute 1 (H400)		
	Aquatic chronic 1 (H410)		
	Met. Corr. 1 (H290)		



6.3. PM CN- Project

Potential classification

Potential classification for potassium dicyanoaurate:

- Mutagenicity:
 - Positive results in the Annex VII/VIII tests
 - Testing proposal for Annex IX test (OECD 474)
 - Only when OECD 474 has been approved and completed a conclusion can be taken

- STOT-RE
 - Based on OECD 422 test
 - Waiting on clarification of the pathologist



6.3. PM CN- Project

Identified uses

- Manufacture of the substance
- Formulation of the substance
- Use as an intermediate
- Use in electroplating or metal surface treatment
- Use in non-metal surface treatment
- Use as reactive processing aid
- Article service life of surface treated products (substance not expected to remain as metal cyanide in articles)



6.3. PM CN- Project *Timing*

AgCN and KAu(CN)₂

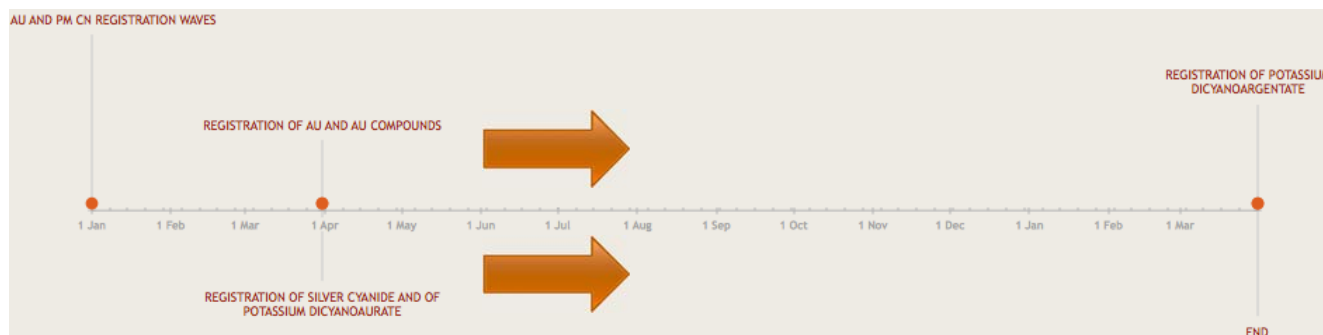
- Testing phase of AgCN and KAu(CN)₂ reaching an end
- Interim DNELs available, PNECs almost available
- Uses are available
- Environmental risk assessment will be ready by Q1 2016
- Occupational risk assessment might not be ready by Q1 2016 due to potential site visits and monitoring program

KAg(CN)₂

- First batch of testing finished
- Second batch of tox. testing will be started beginning of 2016
- Uses are available
- Risk assessments can not start before the testing is finished



6.3. PM CN- Project *Timing*





6.4. Refinables Project (K. Arijs)

- a. Refinables Classification & Uses
- b. Refinables Project status
- c. Refinables Roadmap

6.4.a. Refinables Classification & Uses



Group	Name	Type of registration dossier prepared by PMC	Classification notified (Apr 2014)
1	Doré	Non-SCC intermediate	1 No classification
			2 Repto. 1A, ENV Ch 3
			3 Repto. 1A, STOT Rep 2, ENV Ch 3
			4 Carc. 2, Repto. 1A, STOT Rep 2, Skin sens. 1, ENV Ch 3
			5 Carc. 2, Repto. 1A, STOT Rep 2, Skin sens. 1, Acute tox oral 4, ENV Ch 2
2	Matte, PM	Non-SCC intermediate	1 Carc. 1B, Repto. 1A, STOT Rep 2 (driver: CdS), ENV Ch 2
			2 Carc. 2, Repto. 1A, STOT Rep 1 (driver: Ni), ENV Ch 2, Skin sens. 1
			3 Carc. 2, Repto. 1A, STOT Rep 1 (driver: Ni), ENV Ac 1, ENV Ch 1, Skin sens. 1, Acute tox oral+inh 4
3	Slags, PM refining	Non-SCC intermediate	1 (slags, doré furnace) ENV Ac 1, ENV Ch 1, STOT Rep 1, Repto. 1A, Carc. 1A, Skin sens. 1, Eye dam. 1, Skin corr/IRR 1B, Acute tox oral 3, Acute tox inh 4
			2 (slags, production of PM containing materials other than) ENV Ac 1, ENV Ch 1, STOT Rep 1, STOT Se 3, Repto. 1A, Carc. 1A, Eye dam. 1, Skin corr/IRR 2
4	Slimes and sludges, PM refining	Non-SCC intermediate	1 ENV Ac 1, ENV Ch 1
			2 (low Ni, As, Pb) ENV Ac 1, ENV Ch 1, Acute tox oral 4, Skin sens 1
			3 (med Ni, As, Pb) ENV Ac 1, ENV Ch 1, Acute tox oral+inh 4, Skin corr/IRR 2, Eye dam. 2, Resp/skin sens 1, Muta 2, Carc. 1A, STOT Rep 1 (driver: NiCl ₂ or Pb comp)
			4 (high Ni, As, Pb) ENV Ac 1, ENV Ch 1, Acute tox oral 3, Acute tox inh 4, Skin corr 1A, Eye dam. 1, Resp/skin 1, Muta 1B, Carc. 1A, Repto. 1A, STOT Rep 1 (driver: Pb comp)
5.1	Matte leaching residue	Non-SCC intermediate	1 Carc. 1A, Repto. 1A, Muta 2, STOT Rep 1, ENV Ac 1, ENV Ch 1, Resp/Skin sens. 1, Skin corr. 2, Acute tox oral 3, Eye dam. 1
			2 Carc. 1A, Repto. 1A, Muta 2, STOT Rep 1, ENV Ac 1, ENV Ch 1, Resp/Skin sens. 1, Skin corr. 2, Acute tox oral 3, Eye Irrit. 2
			3 Carc. 1A, Repto. 1A, Muta 2, STOT Rep 1, ENV Ac 1, ENV Ch 1, Resp/Skin sens. 1, Skin corr. 2, Eye dam. 1, Acute tox oral 3, Acute tox inh 4
5.2	Speiss leaching residue	REACH exempt	1 Skin Irr 2, Eye Dam 1, Carc. 1A, Repto. 1A, Muta 2, STOT Rep 2, ENV Ac 1, ENV Ch 1, Skin sens. 1, Acute tox oral+inh 4
6.1	Ag electrolyte	SCC intermediate	1 Repto. 1A, STOT Rep 1, ENV Ac 1, ENV Ch 1, Skin corr. 1B, Eye dam. 1, Skin sens 1
2	Acute tox oral 4, ENV Ac 1, ENV Ch 1, Skin corr. 1B, Eye dam. 1, Skin sens 1, STOT Rep 2		
6.2	Au electrolyte	SCC intermediate	1 ENV Ac 1, ENV Ch 1, Skin corr 1A, Resp/Skin sens. 1, Eye dam. 1, Acute tox oral+inh 4
7	Flue dust, PM refining	Non-SCC intermediate	1 Skin sens 1, Carc. 1A, Repto. 1A, STOT Rep 1, ENV Ac 1, ENV Ch 1
			2 (high Ag/Pb) Carc. 1A, Repto. 1A, Muta 2, STOT Rep 1, ENV Ac 1, ENV Ch 1, Resp/Skin sens. 1, Skin corr. 2, Acute tox oral 3, Eye dam. 1
			3 (high Ni/ As/Cu) Acute tox oral+inh 3, Skin corr/IRR 1B, Eye dam. 1, Resp/Skin sens 1, Carc. 1A, Muta 1B, Repto. 1A, STOT Rep 1, ENV Ac 1, ENV Ch 1
8	Residues cementation and reduction, PM refining	Non-SCC intermediate	1 Acute tox oral+inh 4, Skin sens 1, ENV Ac 1, ENV Ch 1, STOT Rep 2
			2 Acute tox oral+inh 3, Skin 1B, Eye dam. 1, Resp/skin sens 1, Muta 2, Repto. 1A, Carc. 1A, STOT SE 3, STOT Rep 1, ENV Ac 1, ENV Ch 1
9.1	Materials for reclaim, PM with or without support	Non-SCC intermediate	1 (low Pb/Ni) Carc. 1A, Repto. 1A, ENV Ac 1, ENV Ch 1
			2 (med Pb/Ni) Acute tox oral 4, Acute tox inh 4, Resp/skin sens 1, Carc. 1A, Repto. 1A, STOT Rep 2, ENV Ac 1, ENV Ch 1
			3 (high Pb/Ni) Acute tox oral 4, Acute tox inh 3, Resp/skin sens 1, Carc. 1A, Repto. 1A, Muta 2, STOT Rep 1, ENV Ac 1, ENV Ch 1
9.2	Materials for reclaim, PM in bricks, crucibles, trays, etc.	Non-SCC intermediate	1 (low Ni/Pb) ENV Ch 3
			2 (med Ni/high Pb) Carc. 1A, Repto. 1A, STOT Rep 1 (driver: Pb comp), ENV Ac 1, ENV Ch 1
			3 (high Ni/Pb) Acute tox inh+oral 4, Skin sens 1, Carc. 1A, Repto. 1A, STOT Rep 1 (driver: NiO), ENV Ac 1, ENV Ch 1
9.3	Materials for reclaim, PM production by-products	Non-SCC intermediate	1 No classification
			2 Carc. 2, Repto. 1A, STOT Rep 2 (driver: Ni or Pb), ENV Ac 1, ENV Ch 1, Skin sens. 1
			3 Carc. 2, Repto. 1A, STOT Rep 1 (driver: Ni or Pb), ENV Ac 1, ENV Ch 1, Skin sens. 1, Acute tox oral+inh 4
			4 Carc. 2, STOT Rep 2 (driver: Ni), ENV Ac 1, ENV Ch 1, Resp/Skin sens. 1
10	Lead bullion, PGM rich	Non-SCC intermediate	1 Carc. 2, Repto. 1A, STOT Rep 1 (driver: Ni or Pb), ENV Ac 1, ENV Ch 1, Skin sens. 1, Acute tox oral 4

- Several grades/classifications for most Refinables
- Only intermediate use



6.4.b. Refinables Project status (1)

- Non-waste UVCB substances used as intermediates in the PM sector
- Refinables dossiers have been submitted in 2010 as SCC intermediate dossiers and most of them have been upgraded to full registration dossiers in 2014.
- Update of the Refinables dossiers foreseen in 2016:
 - Include results of the 2015 substance identity check and subsequent classification updates
 - Refine the Exposure Scenarios (e.g.: combined toxicity assessment, reducing uncertainties, ...)
- Additional (speciation/validation) testing will only be performed if required by ECHA

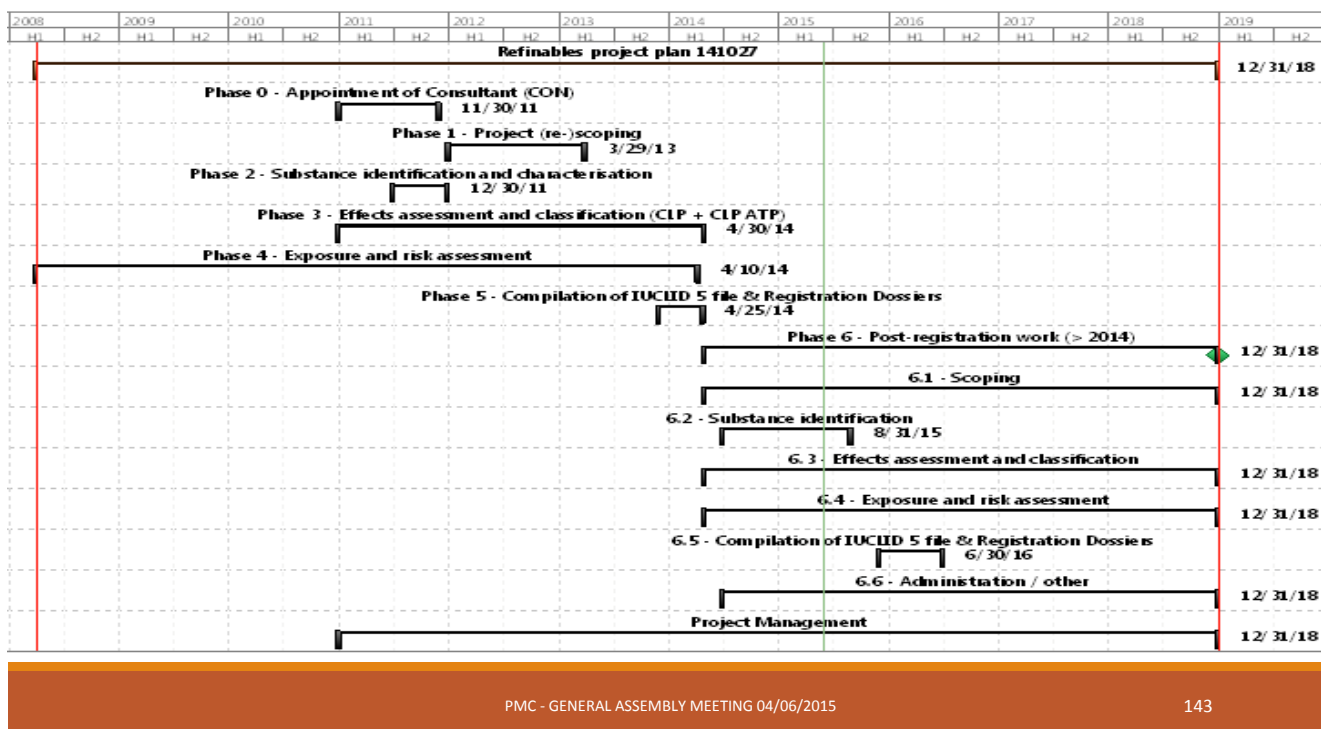


6.4.b. Refinables Project status (2)

- **Substance identity (SID):**
 - Clear signals received from ECHA that further justification of our SID approach and splitting for some Ref will be needed
 - SID decision tree has been developed, complemented with list of PM refining processes and definitions
 - SID check ongoing for all Refinables taking into account the recent ECHA 3-step sameness methodology for UVCBs, which requires considerations on the description of the composition to be made first
 - SID approach will be documented in an internal report
 - Dossiers will be split and (phys-chem) testing initiated where needed



6.4.c. Refinables Roadmap



6.5. PGM Project (K. Rothenbacher)

Summary:

- a. PGM Substance identity / scope
- b. Classification/ Uses
- c. Testing programme
- d. Hazard assessment
- e. Exposure assessment
- f. Registration timeline



Scope and Substance identification

•Scope

- Several changes before closure of PMC inventory (cf. next slide)
- Increase in tonnage band = additional data requirements = more tests
- Further characterization work on PGM blacks ongoing (nano materials?)
- 65 PGM compounds

•Substance ID/ Sameness

- Sameness experts group meeting (29 June 2015) to clarify remaining open issues
- ID cards will be finalised in Q3/4 2015
- Karstedt concentrate
 - Sameness discussions ongoing with Reconsile consortium (LR)
 - LR issue



Scope and Substance identification

•Increases in tonnage band

- Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2): 10-100t/y
- Karstedt Concentrate: 10-100 tpa
- Ruthenium trichloride: 10-100t/y
- Palladium dichloride: 10-100t/y
- Disodium tetrachloropalladate: 10-100t/y

=> **Will require additional testing!**

•No more registrants for

- Dichlorotris(triphenylphosphine)ruthenium (CAS 15529-49-4)
- Diammoniumhexachloro ruthenate
- Iridium dioxide (CAS 12030-49-8)
- Di- μ -chlorobis((1,2,5,6-eta)cycloocta-1,5-diene))diiridium (CAS 12112-67-3)
- Iridium dioxide (CAS 12030-49-8)
- Palladium dioxide (CAS 12036-04-3)

=> **Removed from the scope!**



Classification

- Updated classifications shared with registrants (PGM WG) March 2015
- Testing still ongoing: classifications may still change. Recommend to update classifications only once all data are available
- Exception: classifications that require action 'without undue delay'
 - E.g.: STOT RE1 for Hexachloroplatinates



Classification Pt and Pt compounds

	7440-06-4 Platinum metal	10025-99-7 Dipotassium tetrachloroplatinate	13933-32-9 Tetraammineplatin um dichloride (and hydrate)	20634-12-2 Tetraammineplatinum dinitrate (in solution)	14286-02-3 Diammineplatinum (II)	16941-12-1 Hexachloroplatinic acid (and hydrate 26023-84-7 or 18497-13-7)	1314-15-4 Platinum dioxide (and hydrate)
Physico-chemical classification		Metal corrosivity 1 (H290)	Metal corrosivity 1 (H290)	Self reactive type A (H240) EUH001 Explosive when dry EUH044 Risk of explosion if heated under confinement	EUH001 Explosive when dry	Metal corrosivity 1 (H290)	Oxidising solid 1 (H272)
Environmental classification			Aquatic chronic 3 (H412)	Aquatic chronic 3 (H412)		Aquatic acute 1 Aquatic chronic 1 Acute M factor 10 Chronic M factor 10	
Human Health classification		Acute tox. 3 (H301) (oral) Skin Irrit. 2 (H315) Eye Dam 1 (H318) Skin sens. 1B (H317) Resp. Sens. 1A (H334) Resp. Sens. 1 (Annex VI)	Skin Irrit. 2 (H315) Eye Dam 2 (H319)		Eye Dam 1 (H318)	Acute tox. 2 (H300) (oral) Skin corr. 1B (H314) Eye dam 1 (H318) Skin sens. 1B (H317) Resp. Sens. 1A (H334) STOT RE1 Resp. Sens. 1 (Annex VI)	



Classification Pt and Pt compounds

	16921-30-5 Dipotassium hexachloroplatinate	51850-20-5 Dihydrogen hexahydroxyplatinate	16919-58-7 Diammonium hexachloroplati- nate	18496-40-7 Platinum dinitrate (and solution)	68133-90-4 Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)	68478-92-2 Platinum, 1,3-diethenyl- 1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate
Physico-chemical classification	Metal corrosivity 1 (H290)		Metal corrosivity 1 (H290)	Oxidising liquid 3 (H272) Metal corrosivity 1 (H290)		
Environmental classification	Aquatic acute 1 Aquatic chronic 1 Acute M factor 10 Chronic M factor 10	No classification currently notified. Classification of Aquatic acute 1 Aquatic chronic 1 Acute M factor 10 Chronic M factor 10 proposed based on Daphnia result	Read across to be agreed by Working Group, then updated classification will be required (Aquatic acute 1, aquatic chronic 1)			
Human Health classification	Acute tox. 3 (H301) (oral) Eye dam 1 (H318) Skin sens. 1B (H317) Resp. Sens. 1A (H334) STOT RE1 Resp. Sens. 1 (Annex VI)	Eye Irrit. 2 (H319)	Acute tox. 3 (H301) (oral) Eye dam 1 (H318) Skin sens. 1B (H317) Resp. Sens. 1A (H334) STOT RE1 Resp. Sens. 1 (Annex VI)	Skin corr. 1A (H314) Eye dam 1 (H318)	Eye Irrit. 2 (H319)	



Classification Pd and Pd compounds

	7440-05-3 Palladium metal	14221-01-3 Tetrakis(triphe- nylphosphine) palladium	7647-10-1 Palladium dichloride	16970-55-1 Dihydrogen tetrachloropallada- te	1314-08-5 Palladium monoxide	13566-03-5 Palladium sulphate	13820-53-6 Disodium tetrachloropalladate	10102-05-3 Palladium dinitrate (and solution))	12135-22-7 Palladium dihydroxide	13782-33-7 Diamminedichlorop- alladium
Physico- chemical classification			Metal corrosivity 1 (H290)	Metal corrosivity 1 (H290)		Metal corrosivity 1 (H290)	Metal corrosivity 1 (H290)	Metal corrosivity 1 (H290)		
Environment classification		Aquatic chronic 4 (H413)		Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10				Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10		Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 100 M factor chronic 100
Human Health classification			Eye Dam. 1 (H318) Skin Sens. 1A (H317)	Acute tox. 4 (H302) (oral) Skin Corr. 1A (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317)		Acute tox. 4 (H302) (oral) Skin Corr. 1B (H314) Eye Dam. 1 (H318)	Acute tox. 4 (H302) (oral) Eye Dam. 2 (H319)	Acute tox. 4 (H302) (oral) Skin Corr. 1B (H314) Eye Dam. 1 (H318)		Acute tox. 4 (H302) (oral) Eye Dam. 1 (H318)



Classification Pd and Pd compounds

	13601-08-6 Tetraamminepalladium (II) nitrate (in solution)	13815-17-3 Tetraamminepalladium(2+) dichloride	68413-68-3 Tetraamminepalladium(2+) dihydroxide	61495-96-3 Tetraamminepalladium(2+) diacetate	13965-03-2 Dichlorobis(triphenylphosphine)palladium	14024-61-4 Palladium di(4-oxopent-2-en-2-oate)	3375-31-3 Palladium(II) acetate	16919-73-6 Dipotassium hexachloropalladate	19168-23-1 Diammonium hexachloropalladate
Physico-chemical classification	Self-reactive Type A (H240) EUH044: Risk of explosion if heated under confinement	Metal corrosivity 1 (H290)				Flammable solid 1 (H228) Self heating 1 (H251)			
Environment classification	Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10	Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10	Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10	Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10	Aquatic chronic 4 (H413)	Aquatic chronic 4 (H413) currently notified. Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10 recommended based on acute Daphnia result (Fraunhofer 2014) and read across	Aquatic chronic 4 (H413)	Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10	Aquatic acute 1 (H400) Aquatic chronic 1 (H410) M factor acute 10 M factor chronic 10
Human Health classification	Acute tox. 4 (H302) (oral) Eye Dam. 2 (H319) Skin Sens. 1A (H317)	Acute tox. 4 (H302) (oral) Eye Dam. 2 (H319) Skin Sens. 1A (H317)	Acute tox. 4 (H302) (oral) Eye Dam. 2 (H319) Skin Sens. 1A (H317)	Acute tox. 4 (H302) (oral) Eye Dam. 2 (H319) Skin Sens. 1A (H317)		Acute tox. 4 (H302) (oral) Eye Dam. 1 (H318) Skin Sens. 1A (H317)	Eye Dam. 1 (H318)	Acute tox. 4 (H302) (oral) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Skin Sens. 1B (H317)	Acute tox. 4 (H302) (oral) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Skin Sens. 1B (H317)



Classification Rh and Rh compounds

	Rhodium 7440-16-6	Di-μ-chlorobis(hapto-1,5-cyclooctadiene)dirhodium(I) 12092-47-6	Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium 25470-96-6	Dicarbonyl(pentane-2,4-dionato-O,O')rhodium 14874-82-9	Carbonylhydrottris(triphenylphosphine)rhodium 17185-29-4	Tris(triphenylphosphine)rhodium(I) chloride 14694-95-2	Dirhodium trisulphate 10489-46-0	Rhodium trichloride (Hydrate) 20765-98-4/13569-65-8	Rhodium triiodide 15492-38-3	Dirhodium trioxide 12036-35-0
Physico-chemical classification				Flammable solid 1 (H228) EUH044: Risk of explosion if heated under confinement			Metal corrosivity 1 (H290)	Hydrate: Metal corrosivity 1 (H290)		
Environment classification			Aquatic chronic 4 (H413)	Aquatic chronic 3 (H412)	Aquatic chronic 4 (H413)	Aquatic chronic 4 (H413)		Anhydrous: Aquatic chronic 4 (H413)	Aquatic chronic 4 (H413)	
Human Health classification				Acute tox. 3 (H301) (oral) Eye Irrit. 2 (H319) Skin sens. 1 (H317)			Skin Corr. 1B (H314) Eye Dam. 1 (H318)	Acute tox. 4 (H302) (oral) Eye Dam. 1 (H318) Muta. 2 (H341)		



Classification Rh and Rh compounds

	Rhodium trinitrate 10139-58-9 (and hydrate 13465-43-5)	Rhodium trihydroxide 21656-02-0	Triammonium hexachlororhodate 15336-18-2	Diammonium sodium hexakis(nitrito-N)rhodate 64164-17-6	Rhodium acetate 42204-14-8	Rhodium tris(2-ethylhexanoate) 20845-92-5
Physico-chemical classification	Oxidising solid 1 (H272) Metal corrosivity 1 (H290)			Oxidising solid 3 (H272) Self heating category 1 (H251)		
Environment classification	Aquatic acute 1 (H400) Aquatic chronic (H410) Acute M factor 1 Chronic M factor 1	Aquatic chronic 4 (H413)		Classification to be confirmed following result of algal test (Aquatic chronic 3 based on Daphnia result)		Aquatic chronic 4 (H413)
Human Health classification	Acute tox. 4 (H302) (oral) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317)		Eye Dam. 1 (H318)		Eye Dam. 2 (H319)	



Classification Ru and Ru compounds

	Ruthenium 7440-18-8	Ruthenium trichloride hydrate (14898-67-0)	Ruthenium trihydroxide 12135-42-1	Hexakis[μ-(acetato-O,O')]-μ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate 55466-76-7	Tris(nitratato-O)nitrosylruthenium 34513-98-9	Ruthenium (IV) oxide 12036-10-1 (Ruthenium (IV) oxide hydrate 32740-79-7)	Tetraammonium decachloro-mu-oxodiruthenate(4-) 85392-65-0	Potassium tetraoxoruthenate 31111-21-4
Physico-chemical classification		Hydrate: Metal corrosivity 1 (H290)			Oxidising solid 1 (H272) Metal corrosivity 1 (H290)	Oxidising solid 2 (H271)		
Environment classification		Anhydrous: Aquatic chronic 4 (H413) Hydrate: Aquatic chronic 3 (H412)	Aquatic chronic 4 (H413)	Aquatic acute 1 (M factor 1), Aquatic chronic 1 (M factor 1)				
Human Health classification		Acute tox. 4 (H302) (oral) Skin Corr. 1B (H314) Eye Dam. 1 (H318)		Eye Dam. 1 (H318)	Skin Corr. 1B (H314) Eye Dam. 1 (H318)		Eye Dam. 1 (H318)	



Classification Ir and Ir compounds

	Iridium 7439-88-5	Iridium trichloride (and hydrate) 10025-83-9	Hexachloroiridic acid, Hydrogen hexachloroiridate (IV) (and hydrate) 16941-92-7	Reaction mass of iridium tetrachloride and iridium trichloride	Diammonium hexachloroiridate 16940-92-4
Physico-chemical classification		Metal corrosivity 1 (H290)	Metal corrosivity 1 (H290)		Metal corrosivity 1 (H290)
Environment classification					
Human Health classification		Skin Corr. 1A (H314) Eye Dam. 1 (H318)	Acute tox. 4 (H302) (oral) Skin Corr. 1C (H314) Eye Dam. 1 (H318)		Acute tox. 4 (H302)



PGM Uses

- Pd: information collected, uses finalised
- Pt: information collected, currently finalising
- Rh, Ru, and Ir: currently collecting information



Pt and Pt compounds Uses

	7440-06-4 Platinum metal	10025-99-7 Dipotassium tetrachloroplatinate	13933-32-9 Tetraammineplatinum dichloride (and hydrate)	20634-12-2 Tetraammineplatinum dinitrate (in solution)	14286-02-3 Diammineplatinum (II) nitrite (in suspension)	16941-12-1 Hexachloroplatinic acid (and hydrate) 26023-84-7 or 18497-13-7	1314-15-4 Platinum dioxide (and hydrate)
Identified Uses	<ul style="list-style-type: none"> Alloy production Reshaping and reforming of Pt metal and alloys Formulation of catalysts Downstream use of catalysts Use as a catalyst in contact lens solutions Inclusion into matrix Intermediate Pt metal and alloys in devices used by consumers Pt metal and alloys in jewellery and investment products Production of Dental alloy Production of precious metal containing products 	<ul style="list-style-type: none"> Intermediate Alloy production Production of catalysts Formulation of catalysts Downstream use of catalysts 	<ul style="list-style-type: none"> Downstream use of catalysts 	<ul style="list-style-type: none"> Formulation of preparations Downstream use of catalysts Intermediate 	<ul style="list-style-type: none"> Surface treatment 	<ul style="list-style-type: none"> Intermediate Production of catalysts 	<ul style="list-style-type: none"> Formulation of catalysts Downstream use of catalysts Use in automotive catalysts



Pt and Pt compounds uses

	16921-30-5 Dipotassium hexachloroplatinate	51850-20-5 Dihydrogen hexahydroxyplatinate	16919-58-7 Diammonium hexachloroplatinate	18496-40-7 Platinum dinitrate (and solution)	68133-90-4 Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2)	68478-92-2 Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate
Identified uses	<ul style="list-style-type: none"> Intermediate 	<ul style="list-style-type: none"> Intermediate 	<ul style="list-style-type: none"> Intermediate 	<ul style="list-style-type: none"> Intermediate 	<ul style="list-style-type: none"> Formulation of catalysts Downstream use of catalysts Intermediate 	<ul style="list-style-type: none"> Formulation of preparations Downstream use of catalysts Use of catalysts (ind. + prof.) Use of silicones (consumer)



Pd and Pd compounds uses (draft)

	7440-05-3 Palladium metal	14221-01-3 Tetrakis(triphenylphosphine)palladium	7647-10-1 Palladium dichloride	16970-55-1 Dihydrogen tetrachloropalladate	1314-08-5 Palladium monoxide	13566-03-5 Palladium sulphate	13820-53-6 Disodium tetrachloropalladate	10102-05-3 Palladium dinitrate (and solution))	12135-22-7 Palladium dihydroxide	13782-33-7 Diamminedichloropalladium
Identified Uses	<ul style="list-style-type: none"> Formulation of preparations Intermediate Production and use of Pd metal containing catalysts Metal Surface treatment Reforming and reshaping of Pd metal (ind./prof.) Alloy production 	<ul style="list-style-type: none"> Formulation of preparations Intermediate Production and use of catalysts 	<ul style="list-style-type: none"> Formulation of preparations Intermediate Production and use of catalysts Metal Surface Treatment Non-metal Surface Treatment Production of Inks and paints Use of Inks and paints (ind./cons.) Laboratory reagent 	<ul style="list-style-type: none"> Formulation of preparations Intermediate Metal Surface Treatment 	<ul style="list-style-type: none"> Formulation of preparations Intermediate Manufacture of Pd oxide containing catalysts 	<ul style="list-style-type: none"> Formulation of preparations Intermediate Metal Surface Treatment 	Intermediate	<ul style="list-style-type: none"> Formulation of preparations Intermediate Manufacture of Pd nitrate containing catalysts 	<ul style="list-style-type: none"> Formulation of preparations Intermediate 	<ul style="list-style-type: none"> Formulation of preparations Intermediate Electroplating/ metal surface treatment



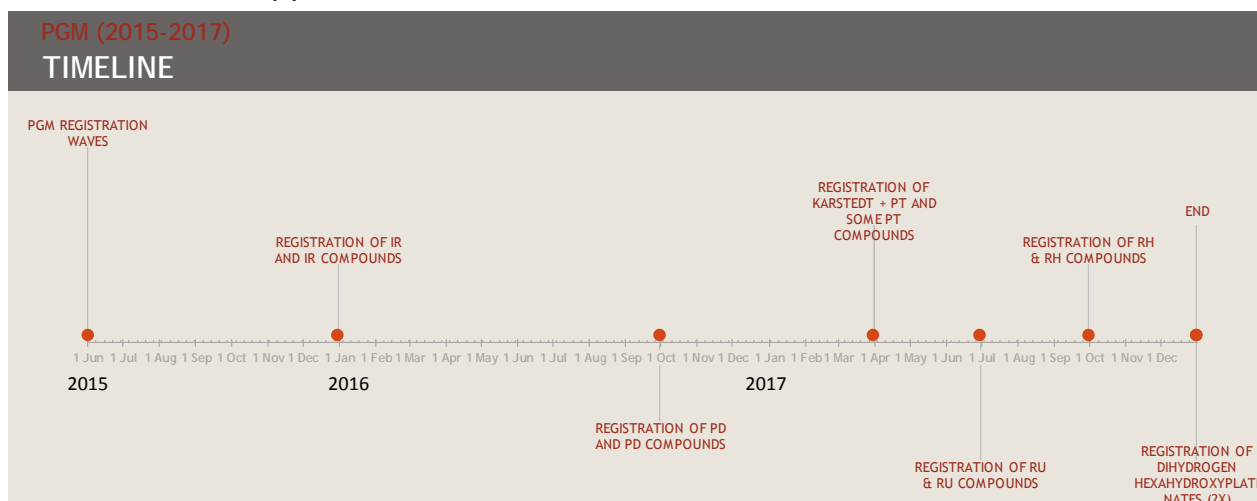
Pd and Pd compounds uses (draft)

	13601-08-6 Tetraamminepalladium (II) nitrate (in solution)	13815-17-3 Tetraamminepalladium(2+) dichloride	68413-68-3 Tetraamminepalladium(2+) dihydroxide	61495-96-3 Tetraamminepalladium(2+) diacetate	13965-03-2 Dichlorobis(triphenylphosphine)palladium	14024-61-4 Palladium di(4-oxopent-2-en-2-oate)	3375-31-3 Palladium(II) acetate	16919-73-6 Dipotassium hexachloropalladate	19168-23-1 Diammonium hexachloropalladate
Identified Uses	<ul style="list-style-type: none"> Formulation of preparations Intermediate 	<ul style="list-style-type: none"> Intermediate Metal Surface Treatment 	Intermediate	<ul style="list-style-type: none"> Formulation of preparations Intermediate 	<ul style="list-style-type: none"> Intermediate Production and use of catalysts 	<ul style="list-style-type: none"> Intermediate Production and use of catalysts 	<ul style="list-style-type: none"> Intermediate Production and use of catalysts Reactive processing aid 	Intermediate	Intermediate



Registration strategy

- Phased approach:



All PGMS must be registered end of 2017!



PGM testing programme

Key Messages

- Tests on schedule, except for Ru-compound *
 - Ru delayed due to substance availability/ sameness discussion
 - Ru results by Q3 2016 = 1 year behind schedule
- Additional tests necessary due to tonnage band increases
- Classification of Hexachloroplatinates as STOT RE1 required
 - Alerted registrants
 - TSCA 8(e) notification in December 2014

*Tetraammonium decachloro-mu-oxodiruthenate



PGM testing programme

Phys.-chem. Testing

- Outstanding tests completed

Ecotoxicology

- Scheduled tests completed except Ru-compound *
- Tests on Ru-compound initiated in May 2015 (awaiting test substance)
- Additional tests recommended by PGM WG (March 2015) ongoing; to be completed in Q3 2015
- Tonnage increases – additional data requirements
 - Data requirements discussed with PGM WG
 - Contracts ready for signature
 - Test substances in preparation
 - Little impact on overall timing
 - Work can be completed by Q1 2016

*Tetraammonium decachloro-mu-oxodiruthenate



PGM testing programme

Human Health

- Scheduled testing completed/ reporting phase, except Ru-compound *
 - Tests on Ru-compound initiated March 2015
 - Results by Q3 2016 = 1 year behind schedule
- Tonnage increases – additional data requirements
 - Data requirements discussed with PGM WG
 - Includes repeated dose studies; > 1 year duration
 - Quotes requested/ Contracts ready for signature
 - Test substance in preparation
 - Work can be completed by end 2016
- *Tetraammonium decachloro-mu-oxodiruthenate



PGM Exposure assessment

- Conducting most time-consuming work now
 - Questionnaires (uses, occ./env. exposure)
 - Env. emission monitoring programme (site-specific + STPs, all PGMs). Will be completed by end 2015
- Definitive ES once final PNECs/ DNELs available (2016)



Registration Timeline



Ir and Ir compounds Registration timeline

	2015				2016				2017				2018
	1	2	3	4	1	2	3	4	1	2	3	4	1
Testing													
PNEC/ DNEL													
ES													
Commenting													
Registration													

- No PNECs/DNELs required
- No ES required
- Currently mapping uses
- Dossier completion by Q4 2015



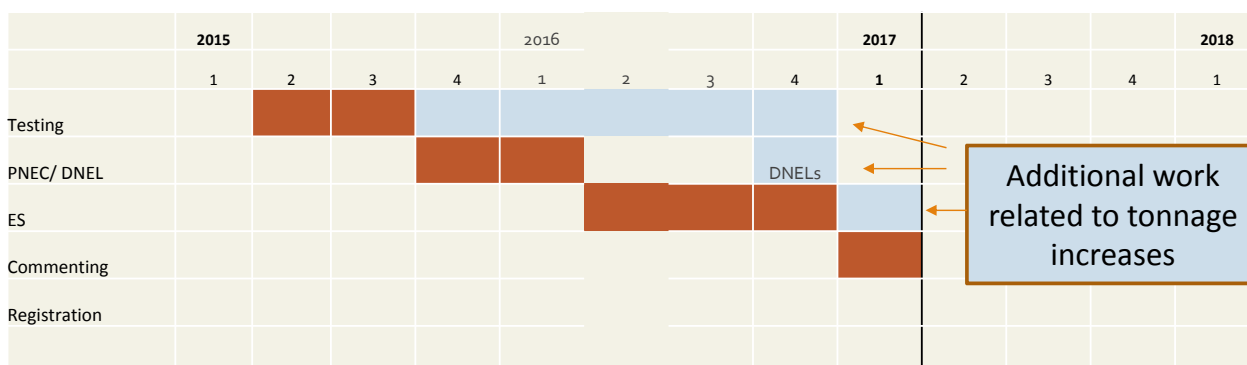
Pd and Pd compounds Registration timeline

	2015				2016				2017				2018
	1	2	3	4	1	2	3	4	1	2	3	4	1
Testing													
PNEC/ DNEL													
ES													
Commenting													
Registration													

- Testing completed
- PNEC derivation completed, DNEL derivation ongoing (by end 2015)
- ES will be completed once final DNELs available
- Dossier completion by Q2 2016



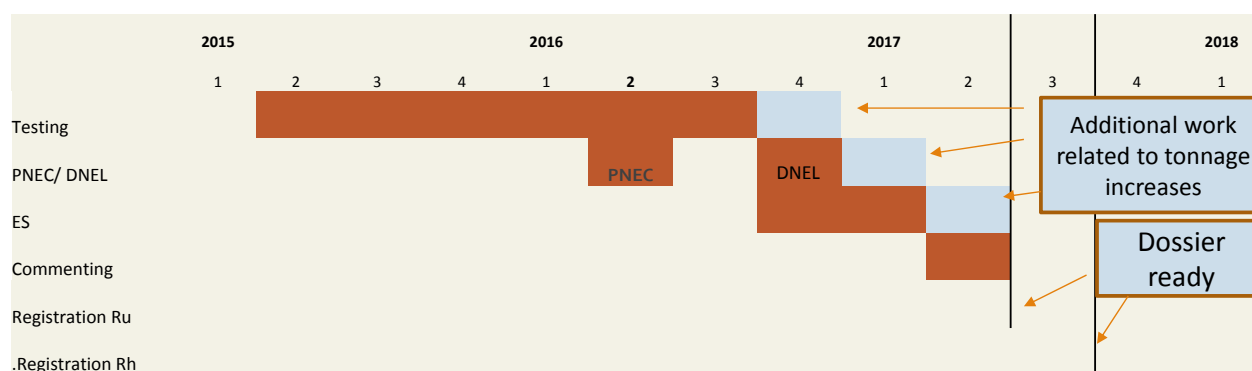
Pt and Pt compounds Registration timeline



- Additional testing required due to tonnage increases (Karstedt, HHPA-2AE)
- PNEC/ DNEL derivation and ES can only be finalised after tests completed
- Dossier completion by Q1 2017
- **Optimistic timing = no room for unexpected developments = need for all to stick to deadlines**



Ru/Rh and Ru/Rh compounds Registration timeline



- Delay in testing of Tetraammonium decachloro-mu-oxodiruthenate
- Additional testing required due to tonnage increases (RuCl₃)
- PNEC/ DNEL derivation and ES after tests are completed
- Dossiers will be ready as planned, no overall delay



6.6. Re Project (*K. Arijs*)

- a. Re Classification
- b. Re Uses
- c. Re Project status
- d. Re Roadmap



6.6.a. Re Classification

Name of the substance	Identification		REACH Category	Type of registration dossier prepared by PMC	Highest tonnage band*	Registration submission deadline**	Classification notified (Feb 2012)
	CAS	EC					
Rhenium	7440-15-5	231-124-5	Mono-constituent	Substance	1-10 t/a	2018	None
Perrhenic acid (in solution)	13768-11-1	237-380-4	Mono-constituent	Substance	1-10 t/a	2018	Acute tox. 4 (H302) Skin Corr. 1A (H314) Eye Dam. 1 (H318) Met. Corr. 1 (H290)
Ammonium perrhenate	13598-65-7	237-075-6	Mono-constituent	Substance	10-100 t/a	2018	None
Sodium rhenate (in aq. solution)	13472-33-8	236-742-9	Mono-constituent	SCC Intermediate	1-10 t/a	2018	None
Potassium perrhenate	10466-65-6	233-953-8	Mono-constituent	Non-SCC Intermediate	1-10 t/a	2018	None
Dirhenium heptasulphide	12038-67-4	234-882-5	Mono-constituent	SCC intermediate	1-10 t/a	2018	None



6.6.b. Re Uses

Substance name	Use
Rhenium	Manufacture
	Manufacture of alloys
	Formation of fabricated metal products
	Manufacture of computer, electronic and optical products, electronic equipment
Perrhenic acid	Manufacture
	Use as an intermediate
	Use as a catalyst
Ammonium perrhenate	Manufacture
	Use as an intermediate
Sodium rhenate	Use as an intermediate under SCC
Potassium perrhenate	Manufacture
	Use as an intermediate
Dirhenium heptasulphide	Manufacture
	Use as an intermediate under SCC



6.6.c. Re Project status

- 5/6 dossiers (sodium rhenate, ammonium perrhenate, perrhenic acid, potassium perrhenate and rhenium) completed and submitted in 2013 and 2014
- 1 remaining dossier (dirhenium heptasulphide) to be submitted now that registration interest is confirmed
- Except for some light dossier maintenance work (literature review and subsequent update of dossiers), no further work anticipated



6.6.d. Re Roadmap

	2008	2009	2010	2011	2012	2013	2014 - 2018
Phase 0 - Identification of CRO + contract	■						
Phase I - Literature search & data gap analysis	■						
Phase II - Read-across / grouping approach & testing strategy		■	■ Phys-chem/Env	■ MamTox			
Phase III - Testing programme			■ Phys-chem/Env		■ MamTox, PSD & bio-elution		
Phase IV - CSA/CSR			■	■	■	■	
Phase V - IUCLID 5 file preparation			■	■	■	■ ID cards	
Phase VI - Post-registration / dossier maintenance work						■ Revie	■ Submit



7. Authorisation

FRANCE CAPON



7.1. Hydrazine: regulatory status

Indicative time plan for ECHA opinion on 7th priority list adopted

Process starts early 2015

- **Feb 2015** scoring of all new substances (incl. new Borates and Cd compounds)
- Allowing all to **update Registration file until March**
- In **MAY** the release of "*the first integrated scoring list*": hydrazine is still scoring very low
- MSC Discussion on **draft prioritisation results in June**
- Discussion on draft **7th recommendation in MSC-43, Sept 2015**
- **Public Consultation Oct-Dec 2015**
- SVHC's included in Dec.'14 and June '15 will be assessed in the 8th round
- **Adoption** 7th list June 2016.

Conclusion: process takes 1,5 y so overlapping 6 months with previous list. Aim is to maintain the one release/year.



7.1. Hydrazine: workplace exposure assessment

An important part of the Authorisation defence plan!

Background

- In previous ECHA consultation PM sector asserted workplace exposures to hydrazine are well controlled
- Company datasets limited and techniques vary
=> not consistent with latest expectations of what is 'negligible exposure'
- If hydrazine is prioritised in future: a more robust exposure dataset is a clear need
- Could be also useful for other regulatory purposes



7.1. Hydrazine: workplace exposure assessment

Workplace exposure assessment project

2-Step approach:

- Step 1 – High exposure risk exposure assessment : appropriate more highly exposed activities
→ Critical for the calibration of the exercise
- Step 2 – Complete exposure characterization: representative monitoring of all similar exposure groups/jobs with potential exposure

Jobs tasks lists have been developed and validated by the Hydrazine Task Force

Target LOQ

- Half of proposed German OEL
- Alternatively, half of the proposed EU OEL if technical or economic limitations: TBC

Consultant in charge: WES (Workplace Environment solutions Limited, UK)

Timeline:

- Phase 1: May-June 2015
- Phase 2: July-August 2015
- Draft report: September 2015
- Final report: October 2015



7.2. RMO on chloroplatinates

Background:

- Chloroplatinates – respiratory sensitizer
- Respiratory sensitizer is considered as an « equivalent concern » under REACH to be identified as relevant SVHC and included into the Candidate List
- In 2014: RMO (Risk Management Option) project on chloroplatinates has been approved

Shadow RMO exercise on chloroplatinates is ongoing:

- Consultant: Michel Vander Straeten
- Timeline: April-October 2015
- Eurometaux RMO mock up is available
- 3 steps:
 - RMO scoping: ongoing
 - RMO identification
 - RMO refinements and identification of the data gaps



8. AOB, next meetings and closing remarks



Next meetings

- 2015 PMC Assembly meeting: Brussels, Belgium, 2 December 2015
- 2016 PMC Assembly meeting: Poland, city to be confirmed, 2 June 2016

