Precious Metals Consortium

Precious Metals & Rhenium Consortium

PGM Tox Experts & Work Group Meeting

18 October 2017 | Brussels

Precious Metals Consortium

1. Welcome and introduction

1.1 Confidentiality and Competition law

1.2 Tour-de-table and apologies

DO	DON'T
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.	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.
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.	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.
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.	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: - 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.
Exchange of Confidential Information	
Involve a Trustee for the exchange of Confidential Information.	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 : - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
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.	

1.3 Approval of the agenda

1. Welcome and Introduction (09:30 – 09:45)
    1. Reminder on Confidentiality and Competition Law
    2. Tour de table and apologies
    3. Approval of the agenda
    4. Approval of the minutes of the last meeting (22 March 2017) and status of action points

2. Palladium and compounds (09:45 – 10:45)
    1. Status registration dossiers
    2. Review of the OFI tracker and setting priorities for
        - Urgent work under current budget, and
        - Future work

3. Platinum and compounds (10:45 – 12:15)
    1. Status (ongoing) registration dossiers
    2. Karstedt Concentrate:
        - Leaching data (available data & need for further testing ?), and
        - dossier update
    3. HHPA/2AE: status & remaining work
    4. Pt genetox : status
    5. Review of the OFI tracker and setting priorities for :
        - Urgent work under current budget, and
        - Future work

Lunch break (12.15-13.30)

1.3 Approval of the agenda *(cont'd)*

4. Rhodium and compounds (13:30-14:45)
    1. Status (ongoing) registration dossiers
    2. Rh(III) genetox : testing status & further actions
    3. Review of the OFI tracker and setting priorities for :
        - Urgent work under current budget, and
        - Future work

5. Ruthenium and compounds (14:45 -15:30)
    1. Status (ongoing) registration dossiers
    2. Review of the OFI tracker and setting priorities for
        - Urgent work under current budget, and
        - Future work

6. PGM nanos : next steps ? (15:30 – 16:00)

7. Pt and Pd bars: article status? (16:00 – 16:15)

8. Workplan and budget (16:15 – 16:30)

9. AOB, next meeting(s) and closing remarks (16:30 – 16:45)

1.4 Approval of minutes & status action points

Final draft minutes of the meeting on 22 March, circulated on 29 March

Minutes approved?

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Organize a TE call 31 March 2017 on OECD422 Karstedt Conc & share the full draft report	PMC	w/e 24 March	✓
Agree on toxic thresholds and potential C&L of KC	Tox Experts	31 March	✓
Initiate derivation of KC DNELs afterwards	PMC & Bibra	ASAP after agreement TE	✓
Update slide 33 and stress the conclusions are tentative	PMC	Before circulating slides	✓
Communicate quickly with Reconsile and SIEF after KC C&L is agreed within PMC	PMC	ASAP after agreement TE	✓
Update slide 34 and highlight these are potential consequences if classification as CMR cat1.	PMC	Before circulating slides	✓

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Compare OECD422 of KC with OECD422 of ligand, and verify if observations might be related to the organic ligand;	PMC & consultants	Before TE meeting 31 March	✓
Investigate fate/presence of KC in articles, and cooperate with Reconsile when drafting exposure scenarios (to be initiated ASAP);	PMC & Reconsile	ASAP	✓
Liaise directly with chemical companies (eg DOW Chemicals) on CMR properties of siloxanes.	Companies	Before TE meeting 31 March	No input received
Provide input on similarities of required ES with other PGM dossiers	HHPA/2AE registrants	ASAP	✓
Develop occupational ES for HHPA/2AE once the DNELs are available.	PMC	Summer 2017	✓
Prepare overview of proposed changes for members (update AnnexIII to VII)	PMC	ASAP after having received Eurometaux' feedback from the Caracal meeting	✓ + *This meeting*

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Prepare an impact assessment of update Annex III to VII on the REACH dossiers	PMC	During GA in June	✓
IPA request: inform Mgt Cttee about PGM WG/TE recommendation	France	w/e 24 March	✓
Forward final Pt genetox review by Prof Kirkland to TE	PMC	ASAP	✓
Organize PhysChem testing for Rh sulphate and Rh tris(2-ethylhexanoate)	PMC	ASAP	✓
Circulate Rh metal draft dossier to WG for review	PMC	ASAP	✓
Circulate draft AnnexIII justification reports to WG for review after updating the mutagenicity sections.	PMC	ASAP	✓

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Organize bioelution testing Rh(III) cmpds	PMC	ASAP	✓
Revise grouping and testing/registration strategy Rh(III) dossiers	PGM TE	After bioelution test data are available	***This meeting***
Prepare Rh(III) registration dossiers without TP for in vivo mutagenicity, update the mutagenicity sections where relevant.	PMC and Bibra	<15 April	✓
Finalise occupational risk assessment Rh nitrito cmpd and circulate to the WG for review	PMC and Bibra	ASAP	✓
Check the need to include WP02 for Rh nitrito cmpd	Registrants Rh nitrito cmds	ASAP	✓
Organize PhysChem testing for Ru trihydroxide	PMC	ASAP	✓

1.4 Approval of minutes & status action points

Actions	Who?	When?	Status
Review and agree on RuCl3 mammalian tox assays	PGM TE	As soon as full draft report is available	✓
Review and agree on TetradoRu mammalian tox assay	PGM TE	As soon as full draft report is available	✓
Reserves: inform the Mgt Cttee on the WG opinion	France	ASAP	✓

Precious Metals Consortium

2. Palladium and compounds

2.1 Status registration dossiers

Name of the substance	Identification numbers		Tonnage band	LR	Registered by LR
	CAS	EC			
Palladium	7440-05-3	231-115-6	10-100 t/a	Umicore NV/SA	Jan 2017
Palladium dichloride	7647-10-1	231-596-2	10-100 t/a	BASF	Jan 2017
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	10-100 t/a	Heraeus	May 2017
Diamminedichloropalladium	14323-43-4	238-269-3	10-100 t/a	Heraeus	Jan 2017
Dichlorobis(triphenylphosphine)palladium	13965-03-2	237-744-2	1-10 t/a (Annex III)	Heraeus	Jan 2017
Palladium (II) di(4-oxopent-2-en-2-oate)	14024-61-4	237-859-8	10-100 t/a	Heraeus	Jan 2017
Palladium(II) acetate	3375-31-3	222-164-4	1-10 t/a (Annex III)	Heraeus	Oct 2016
Palladium monoxide	1314-08-5	215-218-3	1-10 t/a	Heraeus	Jan 2017
Tetraamminepalladium (II) nitrate	13601-08-6	237-078-2	1-10 t/a (Annex III)	Johnson Matthey	Jan 2017
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	10-100 t/a	Umicore AG&Co.KG	Mar 2017
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	1-10 t/a (Annex III)	Heraeus	May 2017
Tetrakis(triphenylphosphine)palladium	14221-01-3	238-086-9	1-10 t/a (Annex III)	Umicore AG&Co.KG	Mar 2017
Palladium sulphate	13566-03-5	236-957-8	1-10 t/a (Annex III)	Heraeus	May 2017
Tetraamminepalladium(2+) diacetate	61495-96-3	262-819-1	10-100 t/a	Umicore AG&Co.KG	Apr 2017
Disodium tetrachloropalladate	13820-53-6	237-502-6	10-100 t/a	BASF	Jan 2017
Palladium dinitrate *(UVCB!)*	10102-05-3	233-265-8	10-100 t/a	Heraeus	Apr 2017
Palladium dihydroxide	12135-22-7	235-219-2	10-100 t/a	Umicore AG&Co.KG	Apr 2017
Diammonium hexachloropalladate	19168-23-1	242-854-9	10-100 t/a	Johnson Matthey	Mar 2017
Dipotassium hexachloropalladate	16919-73-6	240-974-6	10-100 t/a	C. Hafner	Feb 2017

2.2 Review of the Pd OFI tracker and settings priorities for urgent work under current budget

- OFI (Opportunities For Improvement)-tracker in place since review/approval Pd files
- Excel-file, one per metal group

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	**Code**	**Name Point of Attention**	**Date added**	**Field** *(select from drop-down list)*	**Importance** *(select from drop-down list)*	**Action?**	ALL Ruthenium substances	Ruthenium	Ruthenium trichloride (hydrate)	Ruthenium (IV) oxide	Tris(nitrato-O,O')nitrosylruthenium	Hexakis[mu-(acetato-O:O')]-mu3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	Tetraammonium decachloro-mu-oxodiruthenate(4-)	Ruthenium trihydroxide	**Brief explanation**	**Further information of interest** *(potential partner, timing, budget…)*	***Status*** *(date + actions taken)*	**Linked folder(s)** *(add relevant information in new folder at H:\3 - PMC\7 - BUSINESS PLAN\Weaknesses tracker\Documents linked to points of attention, name new folder as 'Code_Name Point of Attention')*
2							*Select relevant substance (tickbox)*											
3	***Example***	*MeltingPoint*	*13/03/2016*	*Phys-Chem*	*Low*						✓				*Melting point waived, new test recommended*	*1500 euro/test*		*Pd0_MeltingPoint*
4	***Ru1***	RuAcRDT	13/12/2016	Mammalian tox	Low	No action			✓						BP owned RDT study has been reviewed by Mark R, but deemed not sufficient to cover relevant endpoints for RuCl3. So a new test was done with RuCl3, but the full study with RuAc is not reflected in the dossier (no LtU obtained)			Ru1_RuAcRDT

2.2 Review of the Pd OFI tracker and settings priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diamminedichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraamminepalladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraamminepalladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
Pd1	TK assessments	TK assessments are very conservative - might be refined - direct effects on DNELs - all uses are today safe	✓																			
Pd2	PdGenericPNECs	Pd PNECs are generic for entire group (reliance on DDP as a general read-across) – need to differentiate toxicity in a more rigorous grouping (cfr Pt dossiers) - further studies identified (~reduce AF and improved PNEC situation)	✓																			
Pd3	TAPdAc2STOTRE	STOT-RE2 classification source compound not read-across - conforming study/evidence can be requested															✓					
Pd4	OECD422	limited RDT / no Reprotox data available – conduct an OECD 422 pre-emptively or await potential ECHA follow up instead. Moore et al is poor quality study to fill endpoint.			✓	✓			✓									✓				
Pd5	PdOBioelution	bioelution data was not generated in the initial set of enabling studies - valuable for validating waiving and non-classification + significantly strengthen the PdO dossier (sensitization, acute tox, irritancy endpoints)									✓											
Pd6	ConservativeES	ES 'Use of process catalysts' is copied from 'use of inks and paints' from PdCl2 - Suggestion to verify (&gather more information if required) from relevant DU IND							✓													

2.2 Review of the Pd OFI tracker and settings priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diamminedichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraamminepalladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraamminepalladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
Pd7	EnvRAAF	Env RAAF justification reports not included (framework not available)	✓																			
Pd8	PhysChemInputPGMs	additional input for PhysChem endpoints provided - might be included in other PGM dossiers	✓																			
Pd9	Waivers	Waiver in IU6 section 4.14 ('waiver is more applicable to organics') and section 5.1.2 ('waiver hydrolysis is weak') (+others - cfr doc)		✓																		
Pd10	PdCl2GenetoxTesting	Imperfect existing dataset and increased reliance on this compound as a source substance - suggestion to test OECD 471 and 476 - also covering dossiers of other RA group members			✓																	
Pd11	Pd(OH)2_EyeDam	classified as Eye Dam 1 (RA from Pd dichloride) – test required if classification needs to be removed [post meeting note Mark R: „*...based on what is known about Pd(II) and the bioleution nature of the compound, I consider it likely that it would test positive in the necessary in vivo assay. Hence a conservative approach is supported*.“]																		✓		
Pd12	PdO_OxidProp	PdO oxidising prop - suggestion to test instead of waiving (PtO = oxid cat1)									✓											

2.2 Review of the Pd OFI tracker and settings priorities for urgent work under current budget

Original dossier did not pass ECHA Manual Completeness Check: endpoint tested & dossier updated

Code	Name Point of Attention		Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diamminedichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraamminepalladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraamminepalladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
~~***Pd13***~~	~~TAPd(OH)2_WaterSol~~	~~non-standard waiver for water solubility - update~~												✓									
Pd14	DNELGenPop	for all except AnnexIII exempted dossiers - No DNEL for general population in dossiers - suggestion to derive a DNEL for general population although not used for any assessment	✓																				
Pd15	PdNO3&Cl2_DNEL	RA strategy has been revised, but the DNEL derivation has not been fully aligned. Modified strategy has been applied (Qual approach for Pd nitrate) to ensure conservatism, but further work is required. Align strategy of Pd dinitrate with Pt dinitrate!!			✓														✓				
Pd16	RAAF_PdAcAc	update report for 'category' instead of 'analogue'							✓														
Pd17	PdAcAc_DNEL	Allometric scaling factor=4 included to anticipate unknown effect of AcAc ligand - review approach and see if no-lower factor applies							✓														
Pd18	NaTClPd_SkinSens	Classified as Skin Sensit cat 1 based on RA, but substance specific testing shows negative outcome - retest?																✓					

2.2 Review of the Pd OFI tracker and settings priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diammine dichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraamminepalladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraamminepalladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
Pd19	TAPdAc2_PROCs	PROCs 5 and 26 need to be included in the manuf and intermediate use															✓					
Pd20	TAPdNitrate	update phys-chem waivers as done for TAPt dinitrate (use explosive nature rather than 'marketed as solution' as main waiving argument										✓										
Pd21	TAPd_Ames	For the Pd tetraammines, the existing AMES test lacks a bacterial strain susceptible to oxidative mutagenesis or cross-linking agents, and this test is therefore not in line with the ECHA testing requirements. Pd tetraammines are not expected to cause oxidative damage, and the TE consider the database and the proposal to not classify conclusive.										✓	✓	✓			✓					

2.2 Priorities under current budget
Pd PNEC Refinement

Current PNEC = DDP as ref substance

	DDP
algae	✓
Acute Daphnia	✓
Acute Fish	✓
LT Daphnia	✓
ASRIT	✓
Sediment	✓
	Basis Pd PNEC today

2.2 Priorities under current budget
Pd PNEC Refinement

Overview available data

	DDP	*H2PdCl4*	*TAPd(HCO3)2*	*Pd nitrate*	*Pdacac*	*Recent publications*
Algae	✓	✓	✓	✓		
Acute Daphnia	✓	✓	✓	✓	✓	*Undefined Pd species*
Acute Fish	✓		✓	✓		
LT Daphnia	✓					
ASRIT	✓					
Sediment	✓					*(Undefined Pd species)**
	Available data for Pd group substances					

* ISO 10872:2010 – 96h test, but can not be used in isolation to determine PNECsediment

2.2 Priorities under current budget
Pd PNEC Refinement

Threshold values acute endpoints

→ algae most sensitive, in [in mg/L]

	DDP	***H2PdCl4***	***TAPd(HCO3)2***	***Pd nitrate***	***Pdacac***	***Recent publications***
Algae (EC50/ NOEC)	0.003 / 0.0013	0.010 / 0.004	0.024 / 0.014	0.029 /0.023		
Acute Daphnia	0.035	0.045	0.079	0.785	0.076	*Undefined Pd species*
Acute Fish	0.154		0.190	53.6		
LT Daphnia	≥14					
ASRIT	14.6					
Sediment	≥27 mg/kg					*(Undefined Pd species)**
	Available data for Pd group substances					

2.2 Priorities under current budget
Pd PNEC Refinement

Considerations for grouping:

- Pd(IV) considered **unstable** – change to Pd(II) within minutes
- **Cl-coordinated** compounds considered **most potent**
- **TAPd** compounds considered **different** from Cl-coordinated compounds

PROPOSAL:

Group 1 = **Cl-coordinated Pd(II/IV) compounds** incl DDP
Group 2 = **Pd(II) tetraammine** compounds
Group 3 = **uncomplexed Pd(II)** compounds

Triphenyl phosphines?

2.2 Priorities under current budget
Pd PNEC Refinement

Palladium metal	10-100	
Tetrakis(triphenylphosphine)palladium	1-10 (AnnexIII)	?
Dichlorobis(triphenylphosphine)palladium	1-10(AnnexIII)	?
Dihydrogen tetrachloropalladate	10-100	group1
Disodium tetrachloropalladate	10-100	group1
(trans)Diamminedichloropalladium	10-100	group1
Dipotassium hexachloropalladate	10-100	group1
Diammonium hexachloropalladate	10-100	group1
Tetraamminepalladium (II) nitrate (in solution)	1-10 (AnnexIII)	group2
Tetraamminepalladium(2+) dichloride	10-100	group2
Tetraamminepalladium(2+) dihydroxide	1-10 (AnnexIII)	group2
Tetraamminepalladium(2+) diacetate	10-100	group2
Palladium dichloride	10-100	group3
Palladium monoxide	1-10	group3
Palladium sulphate	1-10 (AnnexIII)	group3
Palladium dinitrate	10-100	group3
Palladium dihydroxide	10-100	group3
Palladium di(4-oxopent-2-en-2-oate)	10-100	group3
Palladium(II) acetate	1-10 (AnnexIII)	group3

2.2 Priorities under current budget
Pd PNEC Refinement

TAPd(HCO3)2 ***no PMC substance!*** ***TIER0:*** *test* ***TAPdCl2 or TAPdAc2*** *for* ***algae tox*** *and use this cmpd for further testing?*

Proposed testing - 3TIERs

	DDP	***H2PdCl4***	***TAPd(HCO3)2***	***Pd nitrate***	***Pdacac***	***Recent publications***
Algae (EC50 / NOEC)	0.003 / 0.0013	0.010 / 0.004	0.024 / 0.014	0.029 /0.023	TIER0	
Acute Daphnia	0.035	0.045	0.079	0.785	0.076	*Undefined Pd species*
Acute Fish	0.154		0.190	53.6		
LT Daphnia			TIER1	TIER1		
ASRIT			TIER1	TIER1		
Sediment			TIER2	TIER2		*(Undefined Pd species)**
	Cl-coord. Pd(II/IV)		**TAPd**	**uncomplexed Pd(II)**		

2.2 Priorities under current budget
Pd PNEC Refinement

Proposed testing – estimated cost

	DDP	*H2PdCl4*	*TAPd(HCO3)2*		*Pd nitrate*	*Pdacac*	*Recent publications*
Algae (EC50 / NOEC)	0.003 / 0.0013	0.010 / 0.004	0.024 / 0.014	7.5 k€	0.029 /0.023	7.5 k€	
Acute Daphnia	0.035	0.045	0.079		0.785	0.076	*Undefined Pd species*
Acute Fish	0.154		0.190		53.6		
LT Daphnia			20 k€		20 k€		
ASRIT			10 k€		10 k€		
Sediment			30 k€		30 k€		*(Undefined Pd species)**
	Cl-coord. Pd(II/IV)		**TAPd**		**uncomplexed Pd(II)**		

2.2 Priorities under current budget
Pd PNEC Refinement – summary proposal

Group	Data available	Additional work	Budget proposal
Cl coordinated Pd(II/IV)	Ecotox data available – tetrachloroPd and DDP	No further work required	-
Pd(II) tetraammines	Acute ecotox data available with TAPd (HCO3)2	Tier 0: acute algae Tier 1: LT daphnia + ASRIT Tier 2: LT Sediment	Tier 0: 7.5 k€ Tier 1: 20K+10K Tier 2: 30K Admin: 5K
Uncomplexed Pd(II)	Acute ecotox data available with Pd nitrate (and acac for Daphnia)	Confirmatory algae test for Pdacac required	7.5K
		Tier 1: LT daphnia + ASRIT Tier 2: LT Sediment	Tier 1: 20K+10K Tier 2: 30K Admin: 5K

2.2 Priorities under current budget
PdO dossier improvements (Annex VII)

Priority: use in / emission from catalysts

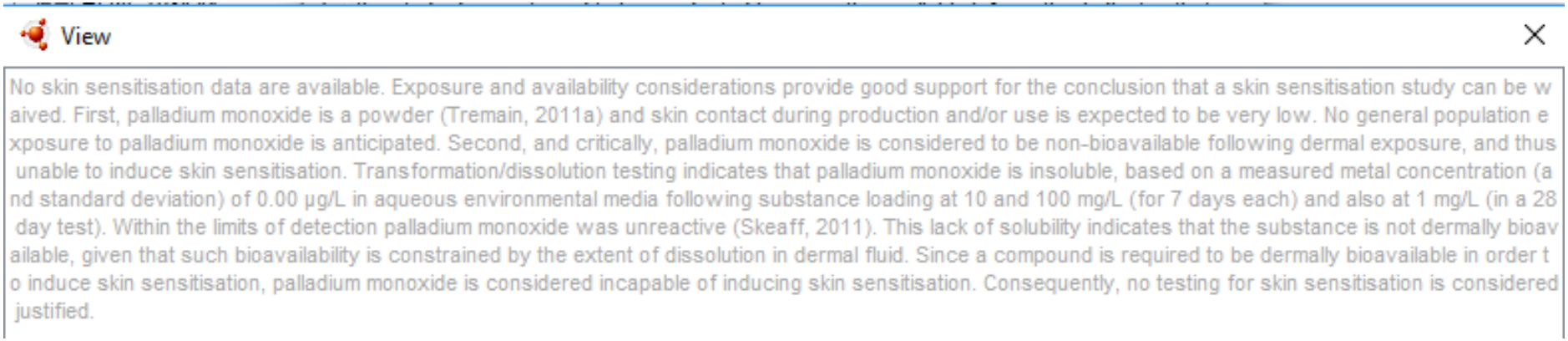
1/ Generate bioelution data

PdO currently without bioelution data

Generating bioelution data = **strengthening dossier**:

-acute tox + irritancy endpoints: key info = old studies

-skin sensitisation: waiver included based on TDp testing

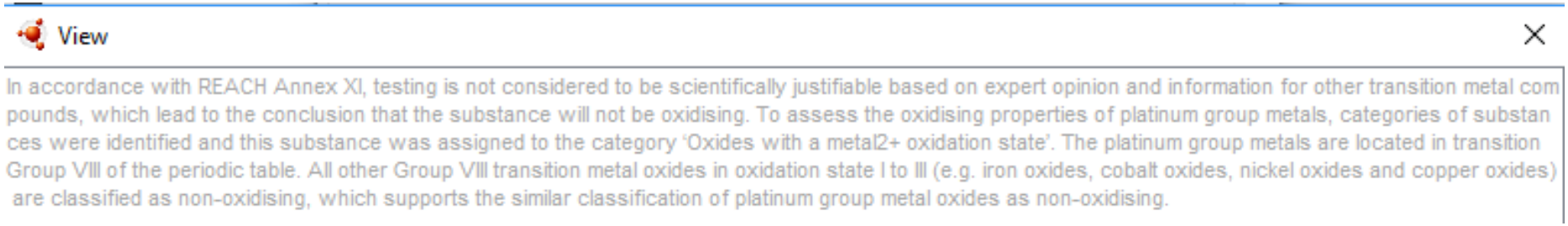


PROPOSAL: perform testing (gastric 2h + perspiration 168h)
estimated cost 8K €

2.2 Priorities under current budget
PdO dossier improvements (Annex VII)

2/ Oxidising properties

Currently **waiver** included based on expert judgement



Note: PtO2 is oxid solid cat 1, RuO2 oxid solid cat 2!

PROPOSAL: perform test
estimated cost: 4K €

2.2 Priorities under current budget
PdCl2 genetox testing

Mammalian **read-across group** '*uncomplexed Pd(II) compounds*' (PdO, Pd(OH)2, PdCl2)

PdCl2 = **ref compound** for genotoxicity, but…

-AMES: **missing strain** (susceptible to oxidative mutagenesis or cross-linking agents)

-OECD476 (hprt/tk): **WoE** argumentation (studies limited, non-guideline…)

	Palladium(II) monoxide	Palladium(II) dihydroxide	Palladium(II) dichloride
Genotoxicity			
In vitro bacterial mutation *(Annex VII)*	[*Read-across from palladium(II) dichloride*]	[*Read-across from palladium(II) dichloride*]	Tested form: unspecified. Mortelmans et al. (1986), Ames negative [does not include TA102 or E. coli].
In vitro (Annex VIII)	*[Not required at this tonnage]*	[*Read-across from palladium(II) dichloride*]	Tested form: unspecified. Gebel et al. (1997), micronucleus, negative. Tested form: solid. Migliore et al. (2002), micronucleus, weak positive. Tested form: unspecified. Gebel et al. (1997), SOS chromotest (DNA damage), negative. Tested form: solid Migliore et al. (2002), Comet assay (DNA damage), negative.

2.2 Priorities under current budget
PdCl2 genetox testing

Expected outcome: negative (no change to classification or testing strategy!)

PROPOSAL: perform OECD471 & 476 with PdCl2
estimated cost: 25K €

2.2 Priorities under current budget
TAPdCl2 genetox testing

Mammalian **read-across group** '*TAPd(II) compounds*' (acetate, Cl and HCO3 (source only) salts))

AMES testing: Cl and HCO3 salts as **source**, both **not compliant** with today's standards

-AMES: missing strain

	Tetraamminepalladium(II) diacetate	Tetraamminepalladium(II) dichloride	Tetraamminepalladium(II) hydrogen carbonate
Genotoxicity			
In vitro bacterial mutation	[*Read-across from tetraamminepalladium(II) hydrogen carbonate*]	Published data: Suraikina et al. (1979), limited Ames (two strains only), no metabolic activation, negative. [*Plus read-across from tetraamminepalladium(II) hydrogen carbonate*]	Tested form: powder. Thompson (1995), Ames (S. typhimurium), missing TA102 or E. coli, OECD 471, negative.

PROPOSAL: perform OECD471 with TAPdCl2
estimated cost: 5K €

2.2 Priorities under current budget disodium tetrachloroPd skin sensitisation

Mammalian **read-across group** 'tetrachloroPd(II) compounds' (hydrogen, sodium, potassium (source only) salts)

Disodium salt: -**substance specific** test data = **negative** (Guinea Pig Maximisation Test, pre-GLP, comparable to LLNA)

-**positive** data RA group member = **RA to sodium salt**

Skin sensitisation	Dihydrogen tetrachloropalladate(II)	Disodium tetrachloropalladate(II)	Dipotassium tetrachloropalladate(II)	DDP	Palladium(II) dihydroxide
In vivo	Tested form: liquid. van Huygevoort (2003b), GPMT OECD 406, sensitizing. **Proposed classification: Skin Sens. 1A**	Tested form: powder. Middleton & Hickey (1978), OECD 406, not sensitising. [*Plus read-across from dihydrogen tetrachloropalladate(II)*] **Proposed classification: Skin Sens. 1A**	"No sensitizing effect known"	Tested form: powder. Pooles (2012), LLNA, OECD 429, not sensitising.	[*Read-across not included in this report*] **Proposed classification: Skin Sens. 1**

2.2 Priorities under current budget disodium tetrachloroPd skin sensitisation

Expected outcome: negative (=remove Skin Sensit 1A classification)

QUESTION: Any experience with in vitro skin sensit test?

CitoxLab & ECHA guidance:

-DPRA (OECD442C) - not suited for metals

-KeratinoSens (OECD442D)

-h-CLAT (OECD442E) – best suited?

Assay		Test cost (CitoxLab)
In vitro	*DPRA (TG442C)*	*3.5K €*
	KeratinoSens (TG442D)	*3.5K €*
	h-CLAT (TG442E)	*4K €*
In vivo	*LLNA (TG429)*	*5K €*
	TOTAL	***Approx 16K €***

2.2 Priorities under current budget
disodium tetrachloroPd skin sensitisation

PROPOSAL: perform in vitro skin sensitisation test + develop WoE (if negative)
estimated cost: 20K € **(?)**

2.2 Priorities under current budget
OECD 422 with tetraClPd, Pdacac, PdCl2

OPTION1

TetraClPd RA group RDT:

-use of **low KL rank** Moore et al (1975) RDT study for potassium salt

-**supporting data/WoE** from DDP & Pd(OH)2 as Pd(II) other reference substances (including coverage of reprotox)

	Dihydrogen tetrachloropalladate(II)	Disodium tetrachloropalladate(II)	Dipotassium tetrachloropalladate(II)	DDP	Palladium(II) dihydroxide
	Category members			*Non-category members*	
Repeated-dose toxicity					
Short-term (28 d)	[*Read-across from dipotassium tetrachloropalladate(II). Additional weight-of-evidence read-across from DDP and palladium(II) dihydroxide*]	[Read-across from dipotassium tetrachloropalladate(II). Additional weight-of-evidence read-across from DDP and palladium(II) dihydroxide]	Tested form: solution (drinking water). Moore et al. (1975). Non-guideline repeated-dose study. No adverse effects in rats at concentrations of up to 194 ppm.	Tested form: powder. Török-Bathó (2015), OECD 422, combined repeated dose toxicity study with reproduction/ developmental toxicity screening test. NOAEL 373 mg/kg bw/day (mean achieved, systemic; repro-dev).	Tested form: powder. Török-Bathó (2015), OECD TG422, Combined repeated dose toxicity study with reproduction/developmental screening, systemic tox NOAEL 1000 mg/kg bw/day.
Reproductive and developmental toxicity					
Screening study	[*Weight-of-evidence read-across from DDP and palladium(II) dihydroxide*]	[*Weight-of-evidence read-across from DDP and palladium(II) hydroxide*]	"No effects known"	Tested form: powder. Török-Bathó (2015), OECD 422, combined repeated dose toxicity study with reproduction/ developmental toxicity screening test. NOAEL 373 mg/kg bw/day (mean achieved, systemic; repro-dev).	Tested form: powder. Török-Bathó (2015), OECD TG422, Combined repeated dose toxicity study with reproduction/developmental screening, repro/dev tox NOAEL 1000 mg/kg bw/day.

2.2 Priorities under current budget
OECD 422 with tetraClPd, Pdacac, PdCl2

OPTION2

Pdacac:

-atypical: **acac-ligand** can be **metabolized**, e.g. to 2-oxopropanal with potential for metabolite specific toxicity

-RDT and reprotox: **RA from Pd(OH)2** (OK if bioaccessibility Pd dihydroxide >> Pd(acac), and if acac-ligand does **not contribute** to RDT & reprotox (and thus Pd responsible for effects)

-in dossier: no mention of **acac chemistry/toxicology/metabolism**, RA justification report only discusses on expected similarity in behaviour of Pd(II) from Pd(OH)2 and Pd acac in gastric fluid.

	Palladium(II) acac	Palladium(II) dihydroxide
Repeated-dose toxicity		
Short-term (28 d)	[*Read-across from palladium dihydroxide*]	Tested form: powder. Török-Bathó (2015), OECD TG422, Combined repeated dose toxicity study with reproduction/developmental screening, systemic tox NOAEL 1000 mg/kg bw/day.
Reproductive and developmental toxicity		
Screening study	[*Read-across from palladium dihydroxide*]	Tested form: powder. Török-Bathó (2015), OECD TG422, Combined repeated dose toxicity study with reproduction/developmental screening, repro/dev tox NOAEL 1000 mg/kg bw/day.

2.2 Priorities under current budget
OECD 422 with tetraClPd, Pdacac, PdCl2

OPTION3

PdCl2:

-no RDT and reprotox available

-**RA from Pd(OH)2** – no effects up to 1000 mg/kg/d -> **conservative**?

	Palladium(II) monoxide	Palladium(II) dihydroxide	Palladium(II) dichloride
Repeated-dose toxicity			
Short-term (28 d)	*[Not required at this tonnage]*	Tested form: powder. Török-Bathó (2015), OECD TG422, Combined repeated dose toxicity study with reproduction/developmental screening, systemic tox NOAEL 1000 mg/kg bw/day.	*[Read-across from palladium(II) dihydroxide]*
Reproductive and developmental toxicity			
Screening study	*[Not required at this tonnage]*	Tested form: powder. Török-Bathó (2015), OECD TG422, Combined repeated dose toxicity study with reproduction/developmental screening, repro/dev tox NOAEL 1000 mg/kg bw/day.	*[Read-across from palladium(II) dihydroxide]*

QUESTION: do we pro-actively test (OECD422 or OECD407/421), or wait ECHA feedback? Cost: 160K €

2.2 Priorities under current budget
Overview - Pd

Remaining available budget:

Pd specific: 0 €

PGM Horizontal costs: 207K € (315K in total)

Proposal	Cost (€)	
PNEC refinement	Tier0	2 x 7.5K
	Tier1	2 x (30K +5K admin)
	Tier2	2 x 30K
PdO update	Bioelution	8K
	Oxid prop	4K
PdCl2	OECD471+476	25K
TAPdCl	OECD471	5K
NaTCPd	Skin sensit	20K
(RDT/Repro testing		*160K)*
Total		**367K (207K excl RDT/Repro)**

PROPOSAL: do not initiate RDT/Reprotox testing in 2017 – include in 2018 budget in case of pro-active testing approval

2.2 Review of the Pd OFI tracker and settings priorities for future work

Code	Name Point of Attention	Brief explanation	ALL Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diamminedichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraamminepalladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraammine palladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
Pd1	TK assessments	TK assessments are very conservative - might be refined - direct effects on DNELs - all uses are today safe	✓																			
Pd2	**PdGenericPNECs**	**Pd PNECs are generic for entire group (reliance on DDP as a general read-across) – need to differentiate toxicity in a more rigorous grouping (cfr Pt dossiers) - further studies identified (~reduce AF and improved PNEC situation)**	✓																			
Pd3	TAPdAc2STOTRE	STOT-RE2 classification source compound not read-across - conforming study/evidence can be requested															✓					
Pd4	**OECD422**	**limited RDT / no Reprotox data available – conduct an OECD 422 pre-emptively or await potential ECHA follow up instead. Moore et al is poor quality study to fill endpoint.**			✓	✓			✓									✓				
Pd5	**PdOBioelution**	**bioelution data was not generated in the initial set of enabling studies - valuable for validating waiving and non-classification + significantly strengthen the PdO dossier (sensitization, acute tox, irritancy endpoints)**									✓											
Pd6	ConservativeES	ES 'Use of process catalysts' is copied from 'use of inks and paints' from PdCl2 - Suggestion to verify (&gather more information if required) from relevant DU IND							✓													

2.2 Review of the Pd OFI tracker and settings priorities for future work

Code	Name Point of Attention	Brief explanation	ALL Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diamminedichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraamminepalladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraamminepalladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
Pd7	EnvRAAF	Env RAAF justification reports not included (framework not available)	✓																			
Pd8	PhysChemInputPGMs	additional input for PhysChem endpoints provided - might be included in other PGM dossiers	✓																			
Pd9	Waivers	Waiver in IU6 section 4.14 ('waiver is more applicable to organics') and section 5.1.2 ('waiver hydrolysis is weak') (+others - cfr doc)		✓																		
Pd10	**PdCl2GenetoxTesting**	**Imperfect existing dataset and increased reliance on this compound as a source substance - suggestion to test OECD 471 and 476 - also covering dossiers of other RA group members**			✓																	
Pd11	Pd(OH)2_EyeDam	classified as Eye Dam 1 (RA from Pd dichloride) – test required if classification needs to be removed [post meeting note Mark R: *„...based on what is known about Pd(II) and the bioleution nature of the compound, I consider it likely that it would test positive in the necessary in vivo assay. Hence a conservative approach is supported.*“]																		✓		
Pd12	**PdO_OxidProp**	**PdO oxidising prop - suggestion to test instead of waiving (PtO = oxid cat1)**									✓											

2.2 Review of the Pd OFI tracker and settings priorities for future work

Code	Name Point of Attention	Brief explanation	ALL Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diammine dichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraammine palladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraamminepalladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
~~***Pd13***~~	~~TAPd(OH)2_WaterSol~~	~~non-standard waiver for water solubility - update~~												✓								
Pd14	DNELGenPop	for all except AnnexIII exempted dossiers - No DNEL for general population in dossiers - suggestion to derive a DNEL for general population although not used for any assessment	✓																			
Pd15	PdNO3&Cl2_DNEL	RA strategy has been revised, but the DNEL derivation has not been fully aligned. Modified strategy has been applied (Qual approach for Pd nitrate) to ensure conservatism, but further work is required. Align strategy of Pd dinitrate with Pt dinitrate!!			✓														✓			
Pd16	RAAF_PdAcAc	update report for 'category' instead of 'analogue'							✓													
Pd17	PdAcAc_DNEL	Allometric scaling factor=4 included to anticipate unknown effect of AcAc ligand - review approach and see if no-lower factor applies							✓													
Pd18	**NaTClPd_SkinSens**	**Classified as Skin Sensit cat 1 based on RA, but substance specific testing shows negative outcome - retest?**																✓				

2.2 Review of the Pd OFI tracker and settings priorities for future work

Code	Name Point of Attention	Brief explanation	ALL Pd substances	Palladium	Palladium dichloride	Dihydrogen tetrachloropalladate(2-) (in solution)	Diamminedichloropalladium	Dichlorobis(triphenylphosphine)palladium	Palladium (II) di(4-oxopent-2-en-2-oate)	Palladium(II) acetate	Palladium monoxide	Tetraamminepalladium (II) nitrate	Tetraamminepalladium(2+) dichloride	Tetraamminepalladium(2+) dihydroxide	Tetrakis(triphenylphosphine)palladium	Palladium sulphate	Tetraamminepalladium(2+) diacetate	Disodium tetrachloropalladate	Palladium dinitrate	Palladium dihydroxide	Diammonium hexachloropalladate	Dipotassium hexachloropalladate
Pd19	TAPdAc2_PROCs	PROCs 5 and 26 need to be included in the manuf and intermediate use														✓						
Pd20	TAPdNitrate	update phys-chem waivers as done for TAPt dinitrate (use explosive nature rather than 'marketed as solution' as main waiving argument								✓												
Pd21	**TAPd_Ames**	**For the Pd tetraammines, the existing AMES test lacks a bacterial strain susceptible to oxidative mutagenesis or cross-linking agents, and this test is therefore not in line with the ECHA testing requirements. Pd tetraammines are not expected to cause oxidative damage, and the TE consider the database and the proposal to not classify conclusive.**								✓	✓	✓				✓						

2.2 Review of the OFI tracker and settings priorities for future work

Cfr. priority setting & OFI

Pro-active OECD422 testing

Precious Metals Consortium

3. Platinum and compounds

3.1 Status (ongoing) registration dossiers

Name of the substance	Identification numbers		Tonnage band	LR	Registered by LR
	CAS	EC			
Platinum	7440-06-4	231-116-1	10-100 t/a	Vale	Jun 2017
Hexachloroplatinic acid	16941-12-1	241-010-7	10-100 t/a	Johnson Matthey	
Tetraammineplatinum dichloride	13933-32-9	237-706-5	1-10 t/a (Annex III)	Johnson Matthey	Feb 2017
Tetraammineplatinum dinitrate (in solution)	20634-12-2	243-929-9	1-10t/a	Umicore AG&Co.KG	Aug 2017
Diammineplatinum (II) nitrite	14286-02-3	238-203-3	1-10 t/a (Annex III)	Heraeus	
Dipotassium tetrachloroplatinate	10025-99-7	233-050-9	1-10 t/a (Annex III)	Heraeus	
Platinum dioxide	1314-15-4	215-223-0	1-10 t/a (Annex III)	Umicore AG&Co.KG	Mar 2017
Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (in solution)	68133-90-4	268-717-3	10-100 t/a	BASF	
Dipotassium hexachloroplatinate	16921-30-5	240-979-3	10-100 t/a	Heraeus	
Platinum dinitrate *(UVCB!)*	18496-40-7	242-383-9	10-100 t/a	Heraeus	Jun 2017
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate *(UVCB!)*	68478-92-2	270-844-4	10-100 t/a	Heraeus	Feb 2017
Diammonium hexachloroplatinate	16919-58-7	240-973-0	10-100 t/a	Johnson Matthey	
Dihydrogen hexahydroxyplatinate	51850-20-5	257-471-2	10-100 t/a	Johnson Matthey	Jun 2017

3.1 Status (ongoing) registration dossiers

- **Diammineplatinum dinitrite** (Annex III exempted):
  - Dossier ready for review & approval
  - Will be circulated together with Rhodium trisulphate and Ruthenium trihydroxide

REMINDER:

Chloroplatinate dossiers: registration planned end 2017

→ ECHA communication about TAPtAc2 TP (cfr. discussion section 3.4), **submit earlier**?

3.2 HHPA/2AE : status & remaining work

- **HHPA/2AE (Annex VIII):**
  - OECD422 finalised (final report received w/c 2 Oct)
  - DNELs derived, ES finalised
  - Dossier **ready for review and approval**

  - **Additional Phys-Chem** testing initiated (cfr experience ECHA manual completeness checks: melting point, boiling point, density, flash point, vapour pressure, water solubility & autoflammability (depending on flash point) – ***results expected in Dec***

  - **Proposed way forward:**
    - Dossier review & approval launched October
    - Once available, PC data will be included, separate review & fast-track approval
    - Dossier available end 2017 – early 2018 for registration

3.3 Karstedt concentrate leaching data (available data & need for further testing ?)

- Reconsile study with **KC leaching** data from silicones
- Study forwarded to PMC secretariat (**confidential!**)
- Setup:
  - Determination **initial KC** content in silicone plates
  - Determination **Pt in DCM extracts**

Main finding: Pt in eluates <DL
Results **confirming assumptions** from ES

No determination of KC or ligand
Extraction only with DCM – what about saliva / heat / microwaving …?
Representativeness of sample ?

- In **REACH dossier**, all uses **safe**

Question: do we want to re-do leaching tests?

3.3 Karstedt concentrate dossier update

- **Karstedt Concentrate (Annex VIII):**
  - OECD422 finalised (final report received w/c 2 Oct)
  - DNELs derived, ES finalised
  - **Input** received from **Reconsile**:
    - Water solubility – solubility trial data will be included as supporting data
    - logKow – value from OECD SIDS will be included next to QSAR value
    - **Bioaccumulation**:
      - some concerns on Reconsile argumentation
      - Mark Raffray reviewed
      - Wording redrafted by PMC Secretariat:
        - Focus on
          - water solubility & hydrolysis (KC) and
          - Kow & BCF (ligand)
        - **BCF < 2000 L/kg** as main argument for '**not B**'

! REQUEST TO REVIEW BY REGISTRANTS !

Next steps (tentative):

Dossier review & approval launched October

Dossier available end 2017 – early 2018 for registration

3.4 Pt genetox : status

- **Recap**:
  - **Pt genetox review** performed by Prof Kirkland
  - Tier0 test: **repeat** in vitro mouse lymphoma tk assay with **TAPt dichloride** – not clearly negative
  - Agreement to **include TP in vivo Comet / MN with TK** in dossiers (x5)

    -remember: discussion about in vivo Comet/MN vs TGR assay

    -cfr ILSI publication: status = seriously delayed
  - Agreement for **Tiered approach**, starting with ClPt dossiers
  - Once Tier1 testing finalised, reconsider other Tiers & dossiers

- **KC**: in vivo MN combined with OECD422 – **negative** outcome!

3.4 Pt genetox : status

- Umicore draft decision on **TP TAPt diacetate** :
  - registration March 2017
  - TP for ‘in vivo mammalian alkaline Comet assay **(OECD489)’** included – PMC RA strategy followed
  - ECHA **draft decision** (end Sept 2017):
    - RA not accepted
    - Obliged to test
    - Proposed assay “*not appropriate to follow up the observed in vitro gene mutation concern […] it is at discretion of registration to perform in vivo MN & TK assay, additionally and in combination to the comet assay*.”

3.4 Pt genetox : status

- **IPA testing plans**:
  - Discussed within PMC
    - Keep PMC timing unchanged and keep TP in dossiers
    - IPA to make own decisions and develop workplan, but ensure to not hamper PMC workplan/deadlines
    - Evaluate need to update PMC dossiers once data get available

Need now to take into account the latest developments on Umicore's TP and ensure no conflicts between IPA workplan and ECHA requests

  - **Status** IPA discussions?

3.5 Review of the Pt OFI tracker and settings priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Pt substances	Platinum	Hexachloroplatinic acid	Tetraammineplatinum dichloride	Tetraammineplatinum dinitrate (in solution)	Dipotassium tetrachloroplatinate	Platinum dioxide	Dihydrogen hexahydroxyplatinate,	Dipotassium hexachloroplatinate	Platinum dinitrate	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt	Diammonium hexachloroplatinate	Dihydrogen hexahydroxyplatinate	Diammineplatinum (II) nitrite
			Select relevant substance (tickbox)													
Pt1	Dermal Monitoring	Analogous data are used for dermal exposure assessment (Ni data) – dermal exposure data need to be gathered urgently (cfr. Induction resp sensit via dermal exposure)	✓													
Pt2	Dermal Toxicokinetics	Experimental dermal uptake data are not available (cfr TK section in dossiers). This information is required for refining dermal DNELs for non ClPt (HHPA, Pt nitrate is corrosive!).	✓													
Pt3	PNEC ChronicERV	PNEC derivation Pt(IV) substances uses literature reference for chronic ecotox test. Test is not according current guidelines (Biesinger and Christensen (1972). New test can be considered			✓				✓	✓	✓	✓		✓	✓	
Pt4	Waivers Acute Mammalian tox	Waivers are included for many HH endpoints, mainly based on substance inertness (water solub, bioelution) and data other Pt cmpds. Revisions are encouraged if additional data get available		✓												
Pt5	AnnexIII vs WDU	Registered as AnnexIII exempted dossier, but might potentially be emitted from car exhaust catalysts. Suggestion to assess emissions, or register as AnnexVII dossier							✓							

3.5 Review of the Pt OFI tracker and settings priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Pt substances	Platinum	Hexachloroplatinic acid	Tetraammineplatinum dichloride	Tetraammineplatinum dinitrate (in solution)	Dipotassium tetrachloroplatinate	Platinum dioxide	Dihydrogen hexahydroxyplatinate,	Dipotassium hexachloroplatinate	Platinum dinitrate	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt	Diammonium hexachloroplatinate	Dihydrogen hexahydroxyplatinate	Diammineplatinum (II) nitrite
			Select relevant substance (tick box)													
Pt6	RelativeDensitiy	Rel density endpoint is filled with information from secondary source – perform test									✓					
Pt7	KC_LLNA	in vivo LLNA was borderline negative – retest can be considered. Ensure low Cl concentration in test sample											✓			
Pt8	Karstedt waivers	Waivers have been included for ecotox (cfr prelim tests, low conc in solution) & hydrolysis (low concentrations in solution, not able to monitor hydrolysis products). Full testing can be considered, but will imply significant costs (especially hydrolysis). Additional solubility testing (TDp testing incl 28d testing to compare solubility with chronic ERV) can be considered to strenghten waiver											✓			
Pt9	Karstedt PBT	currently not considered PBT, but QSAR of ligand indicates potential P and B. Study of ligand bioaccumulation available within Reconsile (cfr ECHA WS) – consider getting access?											✓			
Pt10	AnnexIII Genetox	AnnexIII exempted dossier considered not CMR, but TP included in dossiers for in vivo genetox. Might trigger update classification for Mutagenicity, and potentially imply Annex VII registration dossier				✓	✓	✓	✓							
Pt11	KC_AcuteToxInhal	A rationale on data waiver due to absence of inhalation exposure potential for an organic substance is valid provided the substance is not appreciably volatile. However, this specific is not addressed in the justification, e.g. on the basis of vapour pressure etc.											✓			

3.5 Review of the Pt OFI tracker and settings priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Pt substances	Platinum	Hexachloroplatinic acid	Tetraammineplatinum dichloride	Tetraammineplatinum dinitrate (in solution)	Dipotassium tetrachloroplatinate	Platinum dioxide	Dihydrogen hexahydroxyplatinate,	Dipotassium hexachloroplatinate	Platinum dinitrate	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt	Diammonium hexachloroplatinate	Dihydrogen hexahydroxyplatinate	Diammineplatinum (II) nitrite
			Select relevant substance (tickbox)													
Pt12	QualOccupAssess	Exposure estimates based on Table R14-2 of old ECHA Guidance - Table not in new guidance anymore, advisable to update accordingly. Alternative is MLE approach as used by Nickel Institute			✓						✓	✓		✓	✓	
Pt13	KC_UpdateDossier	Update of dossier required as summarized by Bibra											✓			
Pt14	PtNO3_Waivers	waiver included for RDT, Reprotox and in vivo genotox based on low pH - update required as testing can be done at lower conc than those triggering irritation, and in vivo genotox depends in practice on outcome other substances										✓				
Pt15	PtNO3_OccupExpAssess	Exposure and Risk Assessment done as combination qual & quant approach. This is different from Pd dinitrate, and it is recommended to streamline both dossiers for consistency (maybe best both qualititative with some BV (IPA BV, Pd(OH)2 DNEL...)										✓				
Pt16	ClPt_SecondaryPoisoning	ClPt substances are classified as STOT-RE cat1, but secondary poisoning assessment for Pt dossiers is waived because of non CMR/STOTRE. This assessment is currently waived because no data available + no exposure, but needs to be revised. - suggestion from Steven V: check with IPA			✓			✓						✓		
Pt17	InvivoGenetox_include platin as p	suggestion Mark Raffray to include a platin compound as positive control when doing in vivo genetox testing - might increase credibility of the assays when doing MN/TK rather than transgenic MA	✓													
Pt18	InVitroGenetoxTAPtCl2_include	in vitro genetox test TAPtCl2 not yet included in dossier (was already registered when report got available) - include in dossier + include in TAPtNO3 + update RAAF&TP accordingly				✓	✓									

3.5 Review of the Pt OFI tracker and settings priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Pt substances	Platinum	Hexachloroplatinic acid	Tetraammineplatinum dichloride	Tetraammineplatinum dinitrate (in solution)	Dipotassium tetrachloroplatinate	Platinum dioxide	Dihydrogen hexahydroxyplatinate,	Dipotassium hexachloroplatinate	Platinum dinitrate	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt	Diammonium hexachloroplatinate	Dihydrogen hexahydroxyplatinate	Diammineplatinum (II) nitrite
			Select relevant substance (tickbox)													
Pt19	Reference substance Pt	1. Table 1.1. IUPAC name should be Platinum – not platinum(2+). The latter implies the ion. 2. The molecular weight reference we have is 195.084 – not 195.083.		✓												
Pt20	Perform inh adsorption test	The DNELs for Pt are artificially lowered because Pt inh adsorption data is lacking. Instead of the default factor 2 (100%/50%) Bibra applies a factor of 200 (100%/0,5%). By refining the absorption via inhalation all DNELs will increase.	✓													

3.5 Priorities under current budget
PtO2 update to AnnexVII

Priority:

- use in / emission from **catalysts**
- Greenscreen program: get rid of AnnexIII & update to at least Annex VII

(https://chemicalwatch.com/crmhub/58431/greenscreen-process-aims-to-resolve-conflicting-assessment-results?pa=true)

Datagaps identified for AMES test and skin sensitisation

	PtO2
Skin irrit/corr	In vivo data
Eye irrit/corr	In vivo data
In vitro genotox (AMES)	**NO DATA**
Skin sensitisation	**NO DATA**
Acute tox (oral)	Data available
Acute tox Algae	TD data
Acute tox Daphnia	TD data

Proposal: perform testing to fill datagaps
estimated budget 30K € (15K € for skin sensit?)

3.5 Priorities under current budget
ClPts - Secondary Poisoning Assessment

Secondary poisoning **triggers**:

- indication for **bioaccumulation** potential (e.g. logKow ≥ 3 & MW < 700)
- potential to cause **toxic effects** if substance is accumulated via food chain (based on classifications like H360-2, H373)

ClPt dossier (STOT-RE1): **waiving** argumentation included

- only intermediate use
- stringent WP controls
- limited ENV exposure to ClPt

PMC secretariat considers this not sustainable!

3.5 Priorities under current budget
KC - Secondary Poisoning Assessment

KC (LogKow > 3, Repr2):

-**Screening assessment** by WCA

-PEC different from other Pt cmpds due to organic ligand?

-BCF estimated:

°QSAR from logKow	*23400 L/kg*
°TGD default value	*>5000 L/kg*
°measured BCF for organic ligand	*1800 L/kg*

-$PNEC_{oral}$ derived from NOAEL OECD422 (125 mg/kg/d) *4,17 mg/kg*

-freshwater PEC intermediate use *9,5x(10-6) mg/L*

formulation *2,1x10(-5) mg/L*

3.5 Priorities under current budget
KC - Secondary Poisoning Assessment

SECONDARY POISONING – aquatic foodchain	QSAR-calc BCF (from CSR log Kow)	TGD default BCF	Ligand BCF (measured)
BCF (L/kg)	23442	>5000	1800
Use as Intermediate			
PECoral local (mg/kg ww)	2.23	>0.475	0.171
RCR Aquatic mammal PNEC=4.17 mg/kg ww	0.53	>0.11	0.041
Formulation			
PECoral local (mg/kg ww)	4.92	>1.05	0.378
RCR Aquatic mammal PNEC=4.17 mg/kg ww	**1.18**	>0.252	0.091

- **Overconservative** (?) BCF associated with risk – Remove?
- Highest weight to measured BCF?
- PEC based on 'generic' Pt data – assumed to be similar for KC?

3.5 Priorities under current budget
ClPts & KC - Secondary Poisoning Assessment

Proposal:

TIER1

- KC: do NOT include report in dossier (cfr. not B!), but keep in case questions come
- ClPt: -literature search for available data on Pt
  -compile prelim screening for ClPt with available data + data gaps
  -update KC & ClPt dossier <u>if needed</u>

Estimated cost: 25 k€

TIER2

- perform test with ClPt (OECD305)
- update dossiers

Estimated cost: 60 k€

3.5 Priorities under current budget
Pt compounds - TK refinement

Tox database – mainly **oral admin**

DNEL derivation: **oral → inhalation**

TK aspects to consider:

- oral absorption: 0,5% (Moore et al 1975)
- inhalation absorption: 100% (no data, cfr ECHA guidance)

→ **correction factor NOAEC** = 100:0,5 = 200 !

Any value gives rise to increasing DNEL and decreasing RCR

Relevant dossiers: **HHPA, HHPA/2AE and PtN**

Proposal: refine inhalation absorption

- acute exposure, inhalation, single dose
- Pt in blood
- male + female animals
- blood sampling at 5 timepoints (cfr. KC testing; 0-3-6-12-24h)
- Test substance: KC, HHPA, HHPA/2AE, PtN (or …?)

Estimated cost: 40K € per test item (quotation CitoxLab) **– *setup (& cost estimate) SUFFICIENT??***

3.5 Priorities under current budget
Pt compounds - TK refinement

Dermal absorption data **missing** for soluble Pt (only data for ClPt)

Cfr previous slide: DNEL **oral** → **dermal** considers TK

Currently: 10% dermal absorption (cfr ClPt data)

Any measured value will likely improve situation

In vitro assays developed in S-African lab

Cost estimate: 20K € (not GLP)
vs
OECD408 (at BASF / TNO) – 50K €

3.5 Priorities under current budget
Pt nitrate

In dossier: **waivers** included for RDT, Reprotox and in vivo genotox based on **low pH**

Earlier discussions: low pH / corrosivity **no valid reason to waive** testing

RDT/Reprotox

- testing at lower conc than those triggering irritation
- administration via diet (cfr RuCl3)

In vivo genotox:

- wait outcome tiered testing (TIER1 = ClPt)

For consideration: proactively test RDT/Reprotox via OECD422 or 421/407?
Estimated cost: 160K €

3.5 Priorities under current budget
Pt (IV) long-term Daphnia test

PNEC derivation **Pt(IV)** includes literature ref for **LT Daphnia**

- Biesinger et al (1972), hexaClPt acid
- not according current guidelines
- NOEC assessed as reported EC16/2

Review: '*The reported **nominal** 21d-EC_{16} of 14 µg/L is **sufficiently reliable** for hazard and risk assessment purposes, and that the value 7 µg/L can be used as a **surrogate NOEC** according to ECHA Guidance*.'

Option to repeat study, and strenghten dossier
No RCR improvement expected, but reliability of PNEC improves

Estimated costs: 25K €

3.5 Priorities under current budget
Pt Overview

Remaining available budget:

Pt specific: 350K €

PGM Horizontal costs: 0K €

Proposal	Cost (€)	
PtO2 update		30K
Sec Poisoning	TIER1	25K
	TIER2	60K
TK Refinement	inhal	40K *(sufficient?)*
NaTCPd	dermal	20 – 50K
Pt nitrate	OECD422 or 421/407	160K
LT Daphnia		25K
Total		**360-390K €**

Proposal: include Secondary Poisoning TIER2 in 2018 budget

3.5 Review of the OFI tracker and settings Pt priorities for future work

- Pt genotox testing proposals (x5)

- KC
  - EOGRTS
  - PBT assessment

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4. Rhodium and compounds

4.1 Status (ongoing) registration dossiers

Name of the substance	Identification numbers		Tonnage band	LR	Registered by LR
	CAS	EC			
Rhodium	7440-16-6	231-125-0	1-10 t/a	Johnson Matthey	Ongoing
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	25470-96-6	247-015-0	1-10 t/a (Annex III)	Johnson Matthey	Oct 2016
Carbonylhydrotris(triphenylphosphine)rhodium	17185-29-4	241-230-3	1-10 t/a (Annex III)	Umicore AG&Co.KG	Mar 2017
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	14874-82-9	238-947-9	1-10 t/a (Annex III)	Umicore AG&Co.KG	Sep 2017
Rhodium tris(2-ethylhexanoate) (in solution)	20845-92-5	244-079-1	1-10 t/a (Annex III)	Umicore AG&Co.KG	
Rhodium trichloride, hydrate	20765-98-4	606-630-8	1-10 t/a (Annex III)	Heraeus	Sep 2017
Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	12092-47-6	235-157-6	1-10 t/a (Annex III)	Heraeus	Sept 2016
Tris(triphenylphosphine) rhodium (I) chloride	14694-95-2	238-744-5	1-10 t/a (Annex III)	Umicore AG&Co.KG	Mar 2017
Rhodium triiodide	15492-38-3	239-521-5	1-10 t/a (Annex III)	Umicore AG&Co.KG	July 2017
Dirhodium trisulphate	10489-46-0	234-014-5	1-10 t/a (Annex III)	Umicore AG&Co.KG	
Dirhodium trioxide	12036-35-0	234-846-9	1-10 t/a (Annex III)	Umicore AG&Co.KG	July 2017
Rhodium (III) acetate *(UVCB!)*	42204-14-8	255-707-9	1-10 t/a (Annex III)	Umicore AG&Co.KG	July 2017
Rhodium trinitrate *(UVCB!)*	10139-58-9	233-397-6	1-10 t/a	Johnson Matthey	Ongoing
Rhodium trihydroxide	21656-02-0	244-508-2	1-10 t/a (Annex III)	Heraeus	July 2017
Triammonium hexachlororhodate	15336-18-2	239-364-2	1-10 t/a (Annex III)	Vale	July 2017
Diammonium sodium hexakis(nitrito-N)rhodate	64164-17-6	264-713-0	10-100 t/a	Vale	July 2017

4.1 Status (ongoing) registration dossiers

- **Rhodium sulphate** (Annex III exempted):
  - Dossier being finalised – water solubility testing report still pending
  - Will be circulated together with DiamminePt nitrite and Ruthenium trihydroxide

- **Rhodium tris(2-ethylhexanoate)** (Annex III exempted, in solution):
  - PC testing running (MP/BP, vapour pressure, flashpoint, rel density, (autoflamm depending on flashpoint)
  - Test substance: 2-ethylhexanol as solvent

! two solvents possible:

- 2-ethylhexanol or 2-ethylhexanoic acid
- concentration ranges similar (roughly 40-50%)

Both will be included in **single dossier** (registration as mono-constituent substance)

- **two compositions**
- **two classifications** (cfr classifications of solvents; Acute tox 4 (H332), Skin Irrit 2 (H315), Eye Irrit 2 (H319), STOT SE 3 (H335) vs Repr2 (H361d))
- **second batch of PC testing** with Rh tris(2-ethylhexanol) in 2-ethylhexanoic acid

4.2 Rh(III) genetox : testing status & further actions

- **Recap**: Actions from previous BtB meetings:
  - Organize bioelution testing Rh(III) cmpds
  - Revise grouping and testing/registration strategy Rh(III) dossiers
  - Prepare Rh(III) registration dossiers without TP for in vivo mutagenicity, update the mutagenicity sections where relevant.

- **AMES testing** (approved in Autumn '16 BtB meeting)

  3 cmpds scheduled
  - Rh(OH)3 tested – negative
  - Rh2O3 – DRF test finalised, full test on hold
  - Rh tris(2EH) – not initiated yet

PROPOSAL: finalise full test Rh2O3 (cfr further – update annex III to VII)

4.2 Rh(III) genetox : testing status & further actions

- **Bioelution testing**:
  - Artificial gastric fluid (HCl, pH 1.5, 2h)
  - 5 cmpds:
    - Rh trichloride
    - Diammonium sodium hexakis (nitrito-N) rhodate
    - Rhodium trihydroxide
    - Rhodium trioxide
    - Rhodium triiodide

Element eluted per g TI (µg/g)	Available element eluted (%)	Element eluted per surface (mg/m²)
402027	101	NR
158156	95	NR
2027	0,30	8,1
1,1	0,00013	0,0043
26	0,014	0,0043

  - Bioaccessibility **supports grouping**:

    WS & MWS Rh(III) compounds

    vs

    PWS Rh(III) compounds

4.2 Rh(III) genetox : testing status & further actions

- **Proposed next steps:**

  TIER1

  - Proposal to **continue Rh2O3 Ames** to strengthen database PWS Rh(III)

  

  - **Rh tris(2EH)** (solution): proposal to test **AMES** (cfr PWS grouping)

    ? For two compositions ? ***cost: 5K € (x2?)***

  - **RhI3**: -proposal to **redo Ames** in water (cfr positive test in DMSO)? ***cost: 5K €***

    -proposal to **test solubility** in water vs DMSO? ***cost: <5K €***

  - Bioelution: assumption gastric is '*worst case*', no further testing proposed

  - **In vitro MN assay**: **WS Rh(III) cmpd** (eg sulphate), confirmation of **clastogenic** activity (not investigated with RhCl3) ***cost: 20K €***

4.2 Rh(III) genetox : testing status & further actions

- **Proposed next steps:**

  TIER2

  - **In vitro assay (MLA, HLM): PWS** Rh(III) cmpd (eg hydroxide), strengthen grouping

    cost: 20K €

  - **Include in vivo TP**: OECD489 as for Pt? What compound(s)?

  Proposal to consider TP

  - **once additional in vitro testing WS Rh(III) is finalised**
  - **once we learned more about TP TAPtAc2**

4.3 Review of the Rh OFI tracker and setting priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Rhodium substances	Rhodium	Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	Carbonylhydrotris(triphenylphosphine)rhodium	Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	Rhodium tris(2-ethylhexanoate) (in solution)	Rhodium trichloride (hydrate)	Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	Tris(triphenylphosphine) rhodium (I) chloride	Rhodium triiodide	Dirhodium trisulphate	Dirhodium trioxide	Rhodium (III) acetate	Rhodium trinitrate	Rhodium trihydroxide	Triammonium hexachlororhodate	Diammonium sodium hexakis(nitrito-N)rhodate
			Select relevant substance (tickbox)																
Rh1	Rh2O3_AnnexIIItoVII	Rh trioxide is now annex III, but has WDU (automotive catalysts) and C&L inventory suggests acute tox classif. Suggested to register as AnnexVII, but no substance specific data avail. Missing (tentative): acute tox oral, in vitro AMES, in vitro skin/eye irrit, skin sensit												✓					
Rh2	Rh(III)genetox	cfr Rh(III) genetox review and actions agreed at BtB meeting 22/3/17						✓	✓			✓	✓	✓	✓	✓	✓	✓	✓
Rh3	Reference substance Rh	1. Table 1.1. IUPAC name should be Rhodium - not rhodium(x+). The latter implies the ion.		✓															

4.3 Priorities under current budget
Rh2O3 update to AnnexVII

Priority: use in / emission from catalysts

Datagaps identified for all mammalian endpoints

	Rh2O3
Skin irrit/corr	**NO DATA**
Eye irrit/corr	**NO DATA**
In vitro genotox (AMES)	**NO DATA (test on hold)**
Skin sensitisation	**NO DATA**
Acute tox (oral)	**NO DATA**
Acute tox Algae	TD data
Acute tox Daphnia	TD data

Proposal: perform testing to fill datagaps
estimated budget 50K € (15 k€ for skin sensit?)

4.3 Priorities under current budget
Rh2O3 Oxid Prop

Oxidising properties

Currently **waiver** included based on expert judgement

Cfr. Earlier proposal to test PdO

Note: PtO2 is oxid solid cat 1, RuO2 oxid solid cat 2!

PROPOSAL: perform test
estimated cost: 4K €

3.5 Priorities under current budget
Rh Overview

Remaining available budget:

Rh specific: 0 €

PGM Horizontal costs: approx. 115K € (total: 315K€)

Proposal	Cost (€)	
Rh(III) genetox – TIER1	AMES Rh2O3	-
	AMES Rh tris(2EH)	2x5K
	AMES RhI3	5K
	RhI3 solub	<5K
	In vitro HLM WS Rh(III)	20K
Rh(III) genetox – TIER2	In vitro HLM/MLA PWS Rh(III)	20K
Rh2O3	AnnexIII to VII	50K
	Oxid prop	4K
Total		**114K**

4.3 Review of the Rh OFI tracker and setting priorities for future work

- Cfr Rh(III) genotoxicity discussion – TP in vivo genetox

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5. Ruthenium and compounds

5.1 Status (ongoing) registration dossiers

Name of the substance	Identification numbers		Tonnage band	LR	Registered by LR
	CAS	EC			
Ruthenium	7440-18-8	231-127-1	10-100 t/a	Heraeus	
Ruthenium trichloride, hydrate	14898-67-0	604-667-4	10-100 t/a	Heraeus	
Ruthenium (IV) oxide	12036-10-1	234-840-6	1-10 t/a (Annex III)	Heraeus	
Tris(nitrato-O)nitrosylruthenium	34513-98-9	252-068-8	1-10 t/a (Annex III)	Umicore AG&Co.KG	Feb 2017
Hexakis[mu-(acetato-O:O')]-µ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	55466-76-7	259-653-7	1-10 t/a (Annex III)	Johnson Matthey	
Tetraammonium decachloro-mu-oxodiruthenate(4-)	85392-65-0	286-924-7	10-100 t/a	Heraeus	
Ruthenium trihydroxide	12135-42-1	235-221-3	1-10 t/a (Annex III)	Umicore NV/SA	

5.1 Status (ongoing) registration dossiers

- **Ruthenium dihydroxide** (Annex III exempted):
  - Dossier ready for review & approval
  - Will be circulated together with diamminePt nitrite and Rhodium trioxide

5.2 Review of the Ru OFI tracker and setting priorities for urgent work under current budget

Code	Name Point of Attention	Brief explanation	ALL Ruthenium substances	Ruthenium	Ruthenium trichloride (hydrate)	Ruthenium (IV) oxide	Tris(nitrato-O)nitrosylruthenium	Hexakis[mu-(acetato-O:O')]-µ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	Tetraammonium decachloro-mu-oxodiruthenate(4-)	Ruthenium trihydroxide
			Select relevant substance (tick box)							
Ru1	RuAcRDT	BP owned RDT study has been reviewed by Mark R, but deemed not sufficient to cover relevant endpoints for RuCl3. So a new test was done with RuCl3, but the full study with RuAc is not reflected in the dossier (no LtU obtained)			✓					
Ru2	RuCl3_MoALiver	Effects were identified on T4 hormone analysis during OECD421 study. Further hormone analysis will be done, but it might be considered to investigate MoA of liver enzymes / hormones								
Ru3	Reference substance Ru	Table 1.1. IUPAC name should be Ruthenium – not ruthenium(x+). The latter implies the ion.		✓						
Ru4	Labelling ENV acute1&Chronic1	when classified as Aq acute1&chronic1, former is obsolete. Suggestion to modify in CSR, or include a sentence refering to corresponding Guidance text			✓					

5.2 Review of the Ru OFI tracker and setting priorities for urgent work under current budget

- **Need to update RuO2 AnnexIII to Annex VII?**

  (Used in automotive catalysts???)

	RuO2
Skin irrit/corr	**NO DATA**
Eye irrit/corr	**DATA**
In vitro genotox (AMES)	**NO DATA**
Skin sensitisation	**NO DATA**
Acute tox (oral)	**DATA**
Acute tox Algae	TD data
Acute tox Daphnia	TD data

Proposal: perform testing to fill datagaps
estimated budget 35K € (15 k€ for skin sensit?)

5.2 Review of the Ru OFI tracker and setting priorities for urgent work under current budget

Remaining available budget:

Ru specific: 127K €

PGM Horizontal costs: approx. 0K €

	Cost €
RuO2 annexIII-VI	**35K**

5.2 Review of the Ru OFI tracker and setting priorities for future work

- **Usual maintenance** foreseen, no immediate concerns

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6. PGM nanos : next steps ?

PGM Nanos : next steps

- Nano meeting prior to GA meeting in Pforzheim
- 2018 workplan: **literature review** for nanoAu and nanoPGMs included
- EU Commission just released *Roadmap on Revision of Commission Recommendation 2011/698/EU on the definition of nanomaterial* (cfr. attachment).
  - threshold cited in the nanomaterial definition
  - the specific surface area criterion
  - concept of constituent particles

    …

PMC actions:
- No PMC specific input submitted, monitor and comment Eurometaux'
- Monitor further developments and consider commenting future recommendations (e.g.: new definition), guidances etc.
- In line with ECMA position

- Recent publication KULeuven: nanoCu effects in soil ~ Cu ion effect

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7. Pt and Pd bars: articles?

Background

- 2010: position paper LBMA-PMC (EPMF): clarifications on Imported Good Delivery Bars in relation to REACH

- Conclusions:

  Imported Good Delivery bars fulfil the definition of "Article" under REACH. The gold they are made is not subject to registration, and should be excluded from the calculation of a potential registrant's tonnage band of gold imported into the EEA.

- LBMA/LPPM is now looking at the import of Good Delivery platinum and palladium plates and ingots.

  QUESTION: does PMC support this assessment?

How to define if an object is an article or not?

- Based on ECHA guidance on requirements for substances in articles (June 2017)

- Key questions to be answered:
  - What is the **function** of an object? Meaning the “intended purpose”
  - What is the **shape, surface and design** of an object? These are not to be confused with physical characteristics that result from the chemistry of the material(s) the object is made of.

  N.B.: it is to be noted that an article is an object which “during the production” is given a special shape, surface, or design which determines its function to a greater degree than its chemical composition

How to define if an object is an article or not?

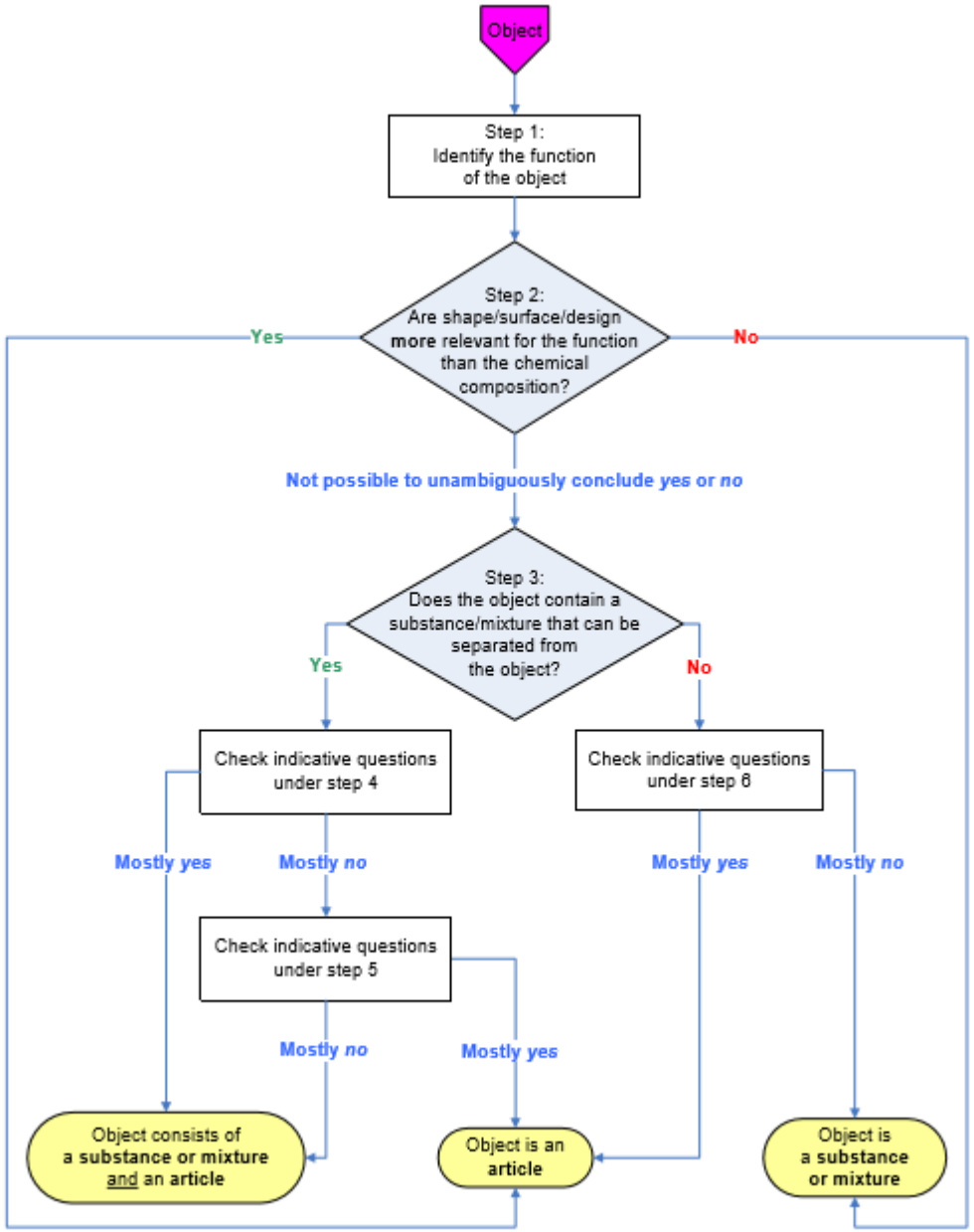

Figure 2: Decision-making on whether an object is an article or not

LPPM/LBMA conclusions

- Pt and Pd are regarded as substance when the GD standards are not met e.g.: in case of industrial use
- GD Pt and Pd plates and ingots ought to be regarded as an article
- Importers of GD Pt and Pd plates and ingots for investment are regarded as importers of articles and exempted from registration

PMC position?

- Are the GD Pt and Pd plates and ingots comparable to GD Au bars in the standards setting?
- Can we follow the decision tree and conclude undoubtly that GD Pt and Pd plates and ingots are articles?
- The Secretariat has some concerns regarding some of the statements (e.g.: an article is an object which "during the production" is given a special shape, surface, or design which determines its function to a greater degree than its chemical composition

Recommendation to the Management Committee?

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8. Workplan and budget

Workplan

- Cfr decisions for Pd – Pt – Rh – Ru in previous points

- Budget included for **review of dossiers**
  Proposal: 2 for Pd, 4 for Pt
  Suggestion for consultants (ex-PMC)?

- Proposal for **future meetings**:
  - Spring: define priority project(s) for next year
  - Autumn: status update + confirm priority project(s)

2018 Budget

Pt metal	10.264 €
Chloroplatinates	59.927 €
Karstedt	50.047 €
Pt compounds (others)	296.393 €
Pd metal	10.097 €
Pd compounds	380.001 €
Rh metal	8.020 €
Rh III compounds	203.740 €
Rh compounds (others)	26.140 €
Ru metal	9.627 €
Ru compounds	55.773 €
Ir metal	6.180 €
Ir compounds	27.620 €

2017 Expenses - Ir

2017 Budget to be spent	Expenses by 31/08/2017
13 850 €	9 893 €

2018 Draft budget - Ir

	Ir metal	Ir compounds
Total Budget	**€ 6.180,00**	**€ 27.620,00**
REACH PLATFORMS		
REACH registration		
Phase 1: Literature search, data gap analysis and recommendations		
Phase 2: In-depth data gap analysis and integrated testing strategy		
Phase 3: Experimental studies (testing programme including cost of samples)		
Phase 4: Generation of Chemical Safety Reports		
Phase 5a: Generation of IUCLID Files and Registration Dossiers		
Phase 5b: IUCLID Hosting System		
REACH dossier maintenance	**€ 5.000,00**	**€ 17.000,00**
Rolling maintenance	€ 3.000,00	€ 6.000,00
Further improvement	€ 2.000,00	€ 11.000,00
REACH evaluation	**€ -**	**€ -**
REACH classification & labelling		
REACH authorisation		
Internal and external fixed Scientific Managers	**€ 1.180,00**	**€ 10.620,00**

2017 Expenses - Pd

2017 Budget to be spent	Expenses by 31/08/2017
25 200€	38 369 €

2018 Draft budget - Pd

	Pd metal	Pd compounds
Total Budget	**€ 10.097,01**	**€ 380.000,99**
REACH PLATFORMS		
REACH registration	**€ -**	**€ -**
Phase 1: Literature search, data gap analysis and recommendations		
Phase 2: In-depth data gap analysis and integrated testing strategy		
Phase 3: Experimental studies (testing programme including cost of samples)		
Phase 4: Generation of Chemical Safety Reports		
Phase 5a: Generation of IUCLID Files and Registration Dossiers		
Phase 5b: IUCLID Hosting System		
REACH dossier maintenance	**€ 6.842,11**	**€ 318.157,89**
Rolling maintenance	€ 1.842,11	€ 33.157,89
Further improvement	€ 5.000,00	€ 285.000,00
REACH evaluation	**€ -**	**€ -**
REACH classification & labelling	**€ -**	€ -
REACH authorisation	**€ -**	€ -
Internal and external fixed Scientific Managers	**€ 3.254,90**	**€ 61.843,10**

2017 Expenses - Pt

2017 Budget to be spent	Expenses by 31/08/2017
763 900 €	315 815 €

2018 Draft budget - Pt

	Pt metal	Chloroplatinates	Karstedt	Pt compounds (others)
Total Budget	**€ 10.264,29**	**€ 59.926,97**	**€ 50.047,29**	**€ 296.393,45**
REACH PLATFORMS				
REACH registration	**€ -**	**€ -**	**€ -**	**€ 15.000,00**
Phase 1: Literature search, data gap analysis and recommendations				
Phase 2: In-depth data gap analysis and integrated testing strategy				
Phase 3: Experimental studies (testing programme including cost of samples)				€ 15.000,00
Phase 4: Generation of Chemical Safety Reports				
Phase 5a: Generation of IUCLID Files and Registration Dossiers				
Phase 5b: IUCLID Hosting System				
REACH dossier maintenance	**€ 7.307,69**	**€ 29.230,77**	**€ 32.307,69**	**€ 263.653,85**
Rolling maintenance	€ 2.307,69	€ 9.230,77	€ 2.307,69	€ 16.153,85
Further improvement	€ 5.000,00	€ 20.000,00	€ 30.000,00	€ 247.500,00
REACH evaluation	**€ -**	**€ -**	**€ -**	**€ -**
REACH classification & labelling				
REACH authorisation	**€ -**	**€ 10.000,00**	**€ -**	**€ -**
Internal and external fixed Scientific Managers	**€ 2.956,60**	**€ 20.696,20**	**€ 17.739,60**	**€ 17.739,60**

2017 Expenses - Rh

2017 Budget to be spent	Expenses by 31/08/2017
171 050€	90 666 €

2018 Draft budget - Rh

	Rh metal	Rh III compounds	Rh compounds (others)
Total Budget	**€ 8.020,00**	**€ 203.740,00**	**€ 26.140,00**
REACH PLATFORMS			
REACH registration	**€ -**	**€ 7.500,00**	**€ 7.500,00**
Phase 1: Literature search, data gap analysis and recommendations			
Phase 2: In-depth data gap analysis and integrated testing strategy			
Phase 3: Experimental studies (testing programme including cost of samples)			
Phase 4: Generation of Chemical Safety Reports			
Phase 5a: Generation of IUCLID Files and Registration Dossiers			
Phase 5b: IUCLID Hosting System			
REACH dossier maintenance	**€ 6.250,00**	**€ 75.000,00**	**€ 6.250,00**
Rolling maintenance	€ 1.250,00	€ 12.500,00	€ 6.250,00
Further improvement	€ 5.000,00	€ 62.500,00	€ -
REACH evaluation	**€ -**	**€ 100.000,00**	**€ -**
REACH classification & labelling			
REACH authorisation	**€ -**	**€ -**	**€ -**
Internal and external fixed Scientific Managers	**€ 1.770,00**	**€ 21.240,00**	**€ 12.390,00**

2017 Expenses - Ru

2017 Budget to be spent	Expenses by 31/08/2017
501 700 €	161 313 €

2018 Draft budget - Ru

	Ru metal	Ru compounds
Total Budget	**€ 9.627,14**	**€ 55.772,86**
REACH PLATFORMS		
REACH registration		
Phase 1: Literature search, data gap analysis and recommendations		
Phase 2: In-depth data gap analysis and integrated testing strategy		
Phase 3: Experimental studies (testing programme including cost of samples)		
Phase 4: Generation of Chemical Safety Reports		
Phase 5a: Generation of IUCLID Files and Registration Dossiers		
Phase 5b: IUCLID Hosting System		
REACH dossier maintenance	**€ 7.857,14**	**€ 22.142,86**
Rolling maintenance	€ 2.857,14	€ 17.142,86
Further improvement	€ 5.000,00	€ 5.000,00
REACH evaluation	**€ -**	**€ -**
REACH classification & labelling		
REACH authorisation	**€ -**	**€ -**
Internal and external fixed Scientific Managers	**€ 1.770,00**	**€ 33.630,00**

Precious Metals Consortium

9. AOB, Next meeting(s) and closing remarks

Next meeting(s)

- **2017 PMC General Assembly**:
  - 5-6 December, Brussels (*Marivaux Hotel Congress & Seminar Centre – Boulevard A. Max 98 – 1000 Bruxelles*)

- **2018 PMC BtB meetings** :
  - Spring : 13-15 March, Brussels (PGM WG 14/03)
  - Autumn : 9-11 October, Brussels (PGM WG 10/10)

Precious Metals Consortium

THANK YOU

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