Precious Metals Consortium

Precious Metals & Rhenium Consortium

PGM Work Group Meeting

20 April 2016 | MCC, 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
2. Substance ID cards: update
3. PGM testing programme/summary PGM Tox Experts Group
    - 3.1.PGM phys.-chem. Testing
    - 3.2 PGM ecotox testing
    - 3.3 PGM HH testing
    - 3.4 PGM nanomaterials
4. PNEC and DNEL derivation
    - 4.1 PNEC derivation
    - 4.2 DNEL derivation
    - 4.3. PMC approach for chloroplatinates
    - 4.4. Read across approach
5. Exposure scenarios
    - 5.1 Life cycle trees Au/PMCN/Pt/Pd and identified uses Rh/Ru (PMC approach for plating/surface treatment)
    - 5.2 Exposure/risk assessment ENV/HH for Pd – final discussion
    - 5.3 “Man via environment” assessment
6. AoA Chloroplatinates
7. Timelines
8. Occupational Monitoring project: status
9. Workplan and budget
10. AOB, next meetings/calls and closing remarks

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2. Substance Id cards

2 Substance ID cards: update

- Definitions that will be used for defining substance composition in ID cards:
  - **Concentration ranges**: define the substance sameness criteria agreed by all Cs Members in preparation of the communication with other SIEF members
  - **Typical concentrations**: refer to the representative sample used for testing
- ID cards will include **spectral data** of the reference sample so registrants can make an informed decision on sameness (exception: Karstedt)
- ID cards will be circulated in **batches** and will only be sent to the relevant sub-assembly (e.g. all Ir ID cards will be sent to the Ir sub-assembly)
- ID cards circulated for:
  - Ir & Ir compounds
  - Karstedt
- Other ID cards ongoing - missing spectra/CoAs for:
  - 4/19 Pd substances
  - 4/13 Pt substances
  - 2/16 Rh substances
  - 3/7 Ru substances

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3. PGM Testing Programme/summary PGM tox experts group

3.1 Phys-Chem testing – outstanding tests of new solids

- Following substance identity discussions, some PGMs that were going to be registered as solutions will now be registered as solids
  - Solutions will be considered to be mixtures
- Additional phys-chem tests required for solid form for the following substances:
  - Pd: Palladium dinitrate, Tetraamminepalladium(2+) dihydroxide, Tetramminepalladium(2+) diacetate, Palladium sulphate (density)
  - Pt: Platinum dinitrate, Diammineplatinum (II) nitrite
  - Rh: Rhodium tris(2-ethylhexanoate)
- Quotes received from BAM, Siemens and Fraunhofer

Platinum Group Metals Ecotoxicity Testing

April 2016

Ecotoxicity Testing Programme: Progress April 2016

Metal	Compound	Test	Progress	Result	Notes
Platinum (cont.)	**Dihydrogen he[illegible]ahydroxyplatinate wit[illegible] 2-aminoethanol ([illegible]HPA-2AE)**	*Daphnia* Immobility (48 hours)	In Progress [Fraunhofer]	-	The two compounds separate in water and therefore the same issues as testing HHPA alone arise, with good recoveries on preparation (if stirred for 1-2 hours only in stock) and then loss of Pt from solution over test duration. Definitive tests will therefore be conducted as semi-static tests (stocks stirred for 1 hour) with filtration to allow mean measured concentrations of soluble Pt to be used in results (alongside measured 2-AE concentrations).
		Fish Mortality (96 hours)	In Progress [Fraunhofer]	-	
		Algae Inhibition of growth (72 hours)	In Progress [Fraunhofer]	-	
		[illegible]SRIT (3 hours)	Complete [Laus]	3hr EC50: Without ATU = 1100 mg/L With ATU = 1400 mg/L.	
	Hexachloroplatinic Acid (HCPA)	ASRIT (3 hours)	Complete [Laus]	3 hr EC50: Without ATU = 104 mg/L With ATU = 83 mg/L	-

Ecotoxicity Testing Programme: HHPA-2AE

- The two compounds separate in water and therefore the same issues as testing HHPA alone arise, with good recoveries on preparation (if stirred for 1-2 hours only in stock) and then loss of Pt from solution over test duration.

- Definitive fish & Daphnia tests will therefore be conducted as semi-static tests (stocks stirred for 1 hour) with filtration to allow mean measured concentrations of soluble Pt to be used in results (alongside measured 2-AE concentrations).

- Algae
  - Definitive test: Biology complete; Some analytical work still to complete.
  - Estimated completion in May/June 2016.

- Daphnia
  - Definitive test scheduled for April 2016
  - Estimated completion in June/ July 2016

- Fish
  - Definitive test scheduled for April 2016
  - Estimated completion in June/ July 2016

Ecotoxicity Testing Programme: Progress April 2016

Metal	Compound	Test	Progress	Result	Notes
Platinum (cont.)	**Karstedt Concentrate**	*Daphnia* Immobility (48 hours)	Not yet approved	-	-
		Fish Mortality (96 hours)	Not yet approved	-	
		Algae Inhibition of growth (72 hours)	Not yet approved	-	
		ASRIT (3 hours)	Not yet approved	-	
		Hydrolysis	Not yet approved	-	

Ecotoxicity Testing Programme: Karstedt Concentrate

- Substance is complex (Pt siloxane) and Pt
- Known to hydrolyse relatively quickly in water at neutral pH (a few hours) & extremely quickly as pH becomes (even slightly) acidic or alkaline (minutes).
- Analysis of complex not possible, but Fraunhofer have now developed method for detection of organic ligand.
- Preliminary hydrolysis testing conducted
  - Reducing concentrations of detectable Pt and organic ligand over time
  - Both still detectable after 96 hours (+/- 30% of added concentration)
- Primary ligand still detectable over period equivalent to acute ecotox tests
- May cause toxicity (in addition to Pt)

Tox Experts Group recommendation

- Ecotox testing approved
- More discussion required for hydrolysis
    - Perform pro - con assessment

Ecotoxicity Testing Programme: Progress April 2016

Metal	Compound	Test	Progress	Result	Notes
Ruthenium (cont)	**Ruthenium trichloride**	Algae Inhibition of Growth (72 hour)	In Progress [Fraunhofer]	-	Results of RF suggest effects at highest concentration only (approx 10% based on growth rate). Issues with solubility and maintenance of test concentrations during test. Discussion with manufacturer and PMRC suggests test item is highly soluble but hydrolyses rapidly to insoluble Ru(OH)3 and RuO2 in water. Range-finderswill be repeated. All samples to be filtered. Test solutions to be prepared directly (no stock solutions) and maintain a low pH to reduce hydrolysis rate.
		Fish Mortality (96 hours)	In Progress [Fraunhofer]	-	
		ASRIT (3 hours)	Complete	EC50 (without ATU) = 530 mg/L, EC50 (with ATU) = 330 mg/L	-

Ecotoxicity Testing Programme: Ruthenium Trichloride

- Results of RFs suggest issues with solubility and maintenance of test concentrations during test
- Discussion with manufacturer and PMRC suggests test item is highly soluble but hydrolyses rapidly to insoluble $Ru(OH)_3$ and RuO_2 in water. RuO_2 will also bind readily to surfaces

- Algae
  - Range-finder will be repeated.
- Fish
  - Range-finder repeated.
  - No effects.
  - Ru precipitates faster with higher concentrations. However, we still do not know the maximum achievable concentration, which is either between 1 mg/L and 10 mg/L, or between 10 mg/L and 100 mg/L.
  - 1. Another pre-test with two concentrations (5.0 and 50.0 mg test item/L) in order to determine the maximum achievable concentration of Ru in the test solutions, applying the same procedure as before. This pre-test would be performed without fish and only for two days. This pre-test would result in 4 further samples for analysis.
  - 2. Perform the definite test as a limit test with a concentration of 10 mg test item/L, as this concentration would lead to a maximum ruthenium concentration (as known so far).

Tox Experts Group recommendation

- Gather additional information on dissolution kinetics
- This information is basis for further decision

3.2 PGM Ecotox testing – proposed changes C&L

- Availability chronic Daphnia and algae data for DDP allowed recalculating M-factors for Pd substances
  - Diamminedichloropalladium: chronic M factor 100 → 10
  - Palladium dichloride: chronic M factor 100 → 10
  - Disodium tetrachloropalladate: chronic M factor 100 → 10

PGM WG Meeting

Brussels
20 April 2016

Karstedt Concentrate

Test	CRO	Status
Skin irritation in vitro Epiderm - OECD 439	LPT	Starts Apr 16
Eye irritation in vitro - OECD 437	LPT	Starts Apr 16
Local Lymph Node Assay - OECD 442B	LPT	Starts Apr 16
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD 487	Covance	Starts Apr 16
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD 476	Covance	Dependent on above
Acute oral toxicity Up-and-down procedure - OECD 425	LPT	Starts May 16
Acute dermal toxicity - OECD 402	LPT	Dependent on above
Preliminary repeat dose toxicity	LPT	Starts May 16
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test	LPT	Starts Jul 16

Initial formulation analysis demonstrates that Karstedt concentrate is stable in corn oil at 1 and 100 mg/mL for 7 days.

PMC note: could not wait for hydrolysis data, evaluated corn oil as vehicle

Tox Experts Group recommendation

- Stability testing
  - Developed for solids, considered not fully applicable to KC
  - Test results may not be conclusive – recommendation for an additional review of IR spectra

Dihydrogen hexahydroxyplatinate – 2AE

All studies at LPT

Test	Result	Status
Skin irritation in vitro Epiderm - OECD 439	Irritant Cat 2	Complete
Eye irritation in vitro - OECD 437	No prediction*	Complete
Local Lymph Node Assay - OECD 442B	Negative	Complete
Skin corrosion in vitro. Epiderm OECD 431	Corrosive Cat 1B/1C	Reporting
Preliminary repeat dose toxicity		Starts Jun 16
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test		Starts Jul 16

* Above cut-off for no classification and below cut-off for Cat 1

Initial formulation analysis demonstrates that HHPA-2AE is stable in corn oil at 125 mg/mL for 7 days.

PMC note: Classify (not label!) as causing serious eye damage, based on results of skin sorr. Cat. 1B/C

Ruthenium Chloride

Test	CRO	Result	Status
GLP Ames reverse mutation assay in 5 strains - OECD 471	Covance	Negative	Complete
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD 487	Covance	Negative	Complete
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD 476	Covance		Ongoing
Preliminary repeat dose toxicity	CiToxLAB		Starts May 16
28 day repeated dose toxicity (dietary) with recovery - OECD 407	CiToxLAB		Starts Jul 16
Reproduction/developmental toxicity screening test (dietary route) - OECD 421	CiToxLAB		Starts Aug 16

Preliminary analytical work has demonstrated stability in diet at 10,000 ppm For 14 days

Tetraammonium decachloro-mu-oxodiruthenate

Test	CRO	Result	Status
GLP Ames reverse mutation assay in 5 strains - OECD471	Covance	Negative	Complete
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD 487	Covance	Negative	Complete
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD 476	Covance	Negative	Reporting
Local Lymph node assay	CiToxLAB	Sensitiser	Complete
Acute oral toxicity – OECD 425	LPT	3110 mg/kg	Reporting
Preliminary repeat dose toxicity	LPT	* see next slide	Reporting
Repeated dose oral toxicity – OECD TG407	LPT	Decision on study types to be made	
Reproduction/developmental toxicity screening test – OECD TG421	LPT		
Combined repeat dose oral toxicity with reproduction/developmental toxicity screening test – OECD TG422	LPT		

Stability in corn oil at 1 and 100 mg/mL demonstrated.

PMC note: EC3 30.9% w/v

Tetraammonium decachloro-mu-oxodiruthenate

14 day preliminary repeat dose oral in rats:

- Dark faeces at 1000 mg/kg
- Dose-related reduction in body weight gain
- Lower food consumption in males at highest dose (week 1)
- Lower absolute and relative liver weights males all groups, not dose-related

Tox Experts Group recommendation

- Results of the acute and DRF discussed
- Recommendation: no separate studies required – combined study OECD 422

3.3 PGM HH testing – proposed changes C&L

- Pd(OH)2
  - not classified → Acute tox 4 (oral), Eye Dam. 1, Skin Sens. 1.

  N.B.: Now exposure scenarios needed for human health
- PdCl2
  - Additional classification as Acute tox 4 (oral),
- Na2PdCl4
  - Additional classification as Skin sens 1A,
- Diammonium hexachloropalladate
  - Additional classification as Acute tox 4 (dermal)
- Dipotassium hexachloropalladate
  - Additional classification as Acute tox 4 (dermal)

3.3 PGM HH testing – Rh(III) genotox classification

- Decisions PMC members:
  - Classify RhCl3 as Muta 2, read-across Muta2 classification to '*relevant soluble Rh(III) compounds in-scope*'

  → **how?**
- Informed with D Boyd on expected behavior via oral uptake(March 2016):
  - **groups according to their chemistry:**

    1/ metal, oxides, hydroxides

    2/ RhCl3, RhI3, triammonium hexachlororhodate

    3/ Rh trisulphate, -trinitrate, -acetate and –tris(2-ethylhexanoate)

    4/ Rh nitrite
  - All expected to dissolve / dissociate when brought in acidic medium (= conditions in stomach), except Rh metal

Tox Experts Group recommendation

1/ Rh sulphate, -trichloride, -nitrate, -acetate, triammonium hexachlororhodate: classify as Muta2

2/ Rh nitrite: classify as Muta2 (precautionary basis)

3/ Rh metal: do not classify

4/ poorly WS compounds (Rh tris(2-ethylhexanoate), Rh triiodide, -trioxide, -trihydroxide):

-further discussion required

-consider expert review (internal or external)

-decide where further in vivo testing is required, and for what compounds

3.4 PGM Nanomaterials – RuO2

- Potential to have nano RuO2
- Need to discuss:
  - Methodology
  - Way forward for update asap after registration
  - Interest of companies?

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4. PNEC and DNEL Derivation

Status of PNEC derivation

- Palladium substances:
  - PNECs agreed and entered into draft IUCLID files
- Rhodium:
  - Draft PNECs derived and report circulated for review
- Platinum
  - PNECs will be derived following completion of ecotox testing with HHPA-2AE
  - Aim to derive PNECs by 30 June '16
- Ruthenium:
  - PNECs will be derived following completion of ecotox testing with ruthenium trichloride
  - Aim to derive PNECs in July

DNEL (Derived No-Effect Level) approach for substances > 10 tpa

Palladium substances

- Genotoxicity
- Final draft DNELs

Platinum substances

- Genotoxicity/testing proposal
- Chloroplatinate DNELs
- Non-Cl Platinate DNELs

Read-across (RA) approach

DNEL (Derived No-Effect Level) approach for substances > 10 tpa

DNELs needed for each health effect and each relevant exposure pattern

Two main types:

$DNEL_{long\text{-}term}$

$DNEL_{acute}$

Systemic and local effects

Reproductive toxicity (fertility impairment and developmental toxicity)

However, lack of dose-descriptors generally precludes DNEL derivation for acute toxicity, irritation/corrosion, sensitization (i.e. (semi)qualitative assessment required)

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Exposure pattern	DNEL/DMEL (appropriate unit)	
	Workers	General population [3]
Acute – inhalation, systemic effects[1]	worker-DNEL acute for inhalation route-systemic	General population-DNEL acute for inhalation route-systemic
Acute – dermal, local effects[2]	worker-DNEL acute for dermal route-local	General population-DNEL acute for dermal route-local
Acute – inhalation, local effects[2]	worker-DNEL acute for inhalation route-local	General population-DNEL acute for inhalation route-local
Long-term – dermal, systemic effects[1]	worker-DNEL long-term for dermal route-systemic	General population-DNEL long-term for dermal route-systemic
Long-term – inhalation, systemic effects[1]	worker-DNEL long-term for inhalation route-systemic	General population-DNEL long-term for inhalation route-systemic
Long-term – oral, systemic effects[1]	Not relevant	General population-DNEL long-term for oral route-systemic
Long-term – dermal, local effects[2]	worker-DNEL long-term for dermal route-local	General population-DNEL long-term for dermal route-local
Long-term – inhalation, local effects[2]	worker-DNEL long-term for inhalation route-local	General population-DNEL long-term for inhalation route-local

1. Units for systemic exposure are mg/m3 for inhalation, and mg/kg bw for oral and dermal exposure

2. Units for local effects are mg/m3 for inhalation; and for dermal exposure: mg/cm2 skin, mg/person/day (e.g., calculated based on the deposited amount per cm2 times the actually exposed body area), or a measure of concentration (% or ppm)

3. General population includes consumers and humans via the environment. In rare cases it may also be relevant to derive a DNEL for specific subpopulations, such as children.

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Palladates genotoxicity

Overview

- complete negative dataset (in vitro/in vivo testing
- no testing/classification

Remark PMC Secretariat:

- Existing bacterial mutagenicity test Pd- tetraammines lacks a strain susceptible to oxidative mutagenesis
- Therefore, this test is not in line with formal ECHA test requirements, and ECHA may request new test (via SONC)

Recommendation Tox Experts

- Overall weight of evidence robust
- No need for action at that stage. Suggest to wait if ECHA comes back
- Be prepared to conduct new Ames test at later stage

Palladium DNELs

10 – 100 tpa

Final draft DNEL reports generated for 11 Pd substances (4 read-across "groups"):

- Diammonium hexachloropalladate
- Dipotassium hexachloropalladate

- Diamminedichloropalladium
- Palladium dichloride
- Dihydrogen tetrachloropalladate
- Disodium tetrachloropalladate

- Palladium dihydroxide
- Palladium dinitrate
- Palladium di(4-oxopent-2-en-2-oate)

- Tetraamminepalladium dichloride
- Tetraamminepalladium diacetate

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Palladium DNELs continued…

No general population exposure -> no DNELs (statement to satisfy IUCLID requirements)

Workers:

Quantitative assessment for systemic $DNEL_{long\text{-}term}$ for inhalation and dermal routes

- calculated from the oral dataset (RD/repro studies available for the "parent" compound in each group)
- REACH guidance regarding appropriate Assessment Factors (AFs) and route-to-route extrapolation (i.e. absorption differences)

No hazard identified for systemic $DNEL_{acute}$ since palladium compounds generally exhibit low acute oral/dermal toxicity, while inhalation is not considered a significant route of exposure

Qualitative assessment for local DNELs

- assess available data (irritation/sensitisation)
- hazard level/banding informs RMMs/OCs
- driven mainly by skin sensitisation potential (i.e. high hazard for strong sensitisers)

Qualitative assessment for hazard for the eyes

Palladium DNELs continued…

Summary of quantitative palladium DNELs

Substance	Systemic long-term hazard (DNEL)	
	Inhalation (mg/m^3)	Dermal (mg/kg bw/day)
Diammonium hexachloropalladate	4.70	1.33
Dipotassium hexachloropalladate	5.27	1.49
Diamminedichloropalladium	17.5	24.9
Palladium dichloride	14.7	4.17
Dihydrogen tetrachloropalladate	20.8	5.89
Disodium tetrachloropalladate	24.4	34.6
Palladium dihydroxide	47.0	66.7
Palladium dinitrate	77.2	21.9
Palladium di(4-oxopent-2-en-2-oate)	25.5	36.2
Tetraamminepalladium dichloride	0.19	0.27
Tetraamminepalladium diacetate	0.26	0.36

PMC comment: many DNELs > nuisance dust limits; ES will assume max. 10 mg/ m3

Palladium DNELs continued…

Summary of qualitative palladium DNELs

Substance	Qualitative hazard conclusion (no threshold derived)						
	Inhalation			Dermal			Eyes
	Systemic acute	Local long-term	Local acute	Systemic acute	Local long-term	Local acute	Local effects
Diammonium hexachloropalladate	-	Medium	Medium	-	Medium	Medium	Medium
Dipotassium hexachloropalladate	-	Medium	Medium	-	Medium	Medium	Medium
Diamminedichloropalladium	-	-	-	-	-	-	Medium
Palladium dichloride	-	High	High	-	High	High	Medium
Dihydrogen tetrachloropalladate	-	Medium	Medium	-	High	High	Medium
Disodium tetrachloropalladate	-	High	High	-	High	High	Low
Palladium dihydroxide	-	Medium	Medium	-	High	High	Medium
Palladium dinitrate	-	Medium	Medium	-	Medium	Medium	Medium
Palladium di(4-oxopent-2-en-2-oate)	-	High	High	-	High	High	Medium
Tetraamminepalladium dichloride	-	Medium	Medium	-	High	High	Low
Tetraamminepalladium diacetate	-	Medium	Medium	-	High	High	Low

- = No hazard identified

Tox Experts Group recommendation

- Moderate hazard suggested for skin sensitizers (for inhalation)
- Check qualitative hazard conclusions “High” and “Moderate” :
  - What is underlying endpoint (skin sensitization vs skin irritation/corrosion)?
  - If applicable, change to lower category

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Platinates genotoxicity

- A number of the in vitro genotoxicity assays for platinum compounds have been positive
- Lack of good quality in vivo data impedes robust classification on germ cell mutagenicity

Tetraammineplatinum dinitrate: in vivo data available - negative results (not full guideline/REACH recommended studies)

However, clear positive evidence exists for cisplatin (and some other platins), but this is expected considering its molecular characteristics and mechanistically is of uncertain predictive value for genotoxic effects of other Pt compounds

Platinates genotoxicity continued…

AGREED DURING TE MEETING? Do not classify those Pt substances with positive in vitro assays as genotoxic

AGREED DURING TE MEETING? Include **in vivo genotoxicity test proposal(s)** on suitable Pt salt(s) in the REACH dossier

- Diammonium hexachloroplatinate
- Dipotassium hexachloroplatinate
- Hexachloroplatinic acid
- Dihydrogen hexahydroxyplatinate

Platinum dinitrate (Waive on basis of technical and scientific non-justification; possibility to use results from dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2) (HHPA) in vivo test)

Following the results of the in vivo genotoxicity testing, need to reconsider

- Mutagenicity classification & labelling
- DNELs vs DMELs
- Hazard banding (RMMs/OCs)

Tox Experts Group recommendation

- Complicated dataset with potential big implications
- Most Pt(II/IV) compounds tested positive in vitro
- In vivo data:
  - "limited"
  - old/non-conform
  - mixed outcome (some negative, some positive)
- Proposal Tox Experts not classify as cat2 at this time (do more in vivo testing)

- ECHA may question this decision based on:
  - Consistent positive in vitro
  - Fragmentary/contradictory in vivo
  - May link to platins (potent mutagens, probable carcinogens)

- External review recommended
- Determine cost-effective and scientifically defensible TP-program
- Genotox pattern matching "platins" and other Pt compounds?

Chloroplatinate DNELs

10 – 100 tpa

Draft DNEL reports generated for the following chloroplatinates in Q1:

- Diammonium hexachloroplatinate
- Dipotassium hexachloroplatinate
- Hexachloroplatinic acid

Well established reports of respiratory sensitisation with this sub-category (critical difference to Pd DNELs)

Systemic $DNEL_{long\text{-}term}$ initially calculated by analogous method to Pd compounds

- Determined inhalation values higher (>2 orders of magnitude) than the existing Occupational Exposure Limit (OEL) of 2 µg/m^3 for soluble Pt salts (expressed as Pt metal)
- OEL informs systemic $DNEL_{long\text{-}term}$ for inhalation and dermal routes (non-standard, but more precautionary) after accounting for absorption differences
- Potential for molecular weight extrapolation (i.e. substance specific DNELs)?

Chloroplatinate DNELs

10 – 100 tpa

Key differences from Pd reports

Medium/high hazard identified for systemic $DNEL_{acute}$ since these compounds are classified for Acute toxicity in category 2/3

Inhalation local DNELs

- Classification as respiratory sensitiser 1A necessitates allocation to the high hazard band
- Epidemiology literature (Heederik et al., 2016; Merget et al., 2000) indicates respiratory tract (RT) effects at levels lower than the OEL
- As such, the suitability of the OEL for protecting workers from potential RT sensitisation to be further investigated

DNEL reports to be reviewed and subsequently finalised in the coming weeks

DNELs for non-Cl Platinates

10 – 100 tpa

Draft DNEL reports generated for three non-chloroplatinates in Q1:

- Dihydrogen hexahydroxyplatinate
- Tetraammineplatinum dinitrate
- Platinum dinitrate (UVCB)

Systemic $DNEL_{long\text{-}term}$ approach was similar to the chloroplatinates

Key differences from chloroplatinate reports

Platinum dinitrate

- hazard unknown for systemic $DNEL_{acute}$ since this compound involved waiving of all acute toxicity testing on the basis of a low pH
- Non-sensitising to skin/RT, but skin corrosive -> high hazard band for local DNELs

Dihydrogen hexahydroxyplatinate and tetraammineplatinum dinitrate generally exhibited much “cleaner” profiles (i.e. no hazard identified for majority of qualitative endpoints)

Platinum DNELs

Summary of quantitative platinum DNELs

Substance	Systemic long-term hazard (other toxicological threshold)	
	Inhalation ($\mu g/m^3$)	Dermal (µg/kg bw/day)
Diammonium hexachloroplatinate	2	1.43
Dipotassium hexachloroplatinate	2	1.43
Hexachloroplatinic acid	2	1.43
Dihydrogen hexahydroxyplatinate	2	2.86
Tetraammineplatinum dinitrate	2	2.86
Platinum dinitrate	2	1.43

PMC remark: calculated DNELs >> official OEL (2 ug/m3)
Replaced calculated DNELs by OEL
Official OEL recognized as not protective – s. discussions chloroplatinates

Platinum DNELs continued…

Summary of qualitative platinum DNELs

Substance	Qualitative hazard conclusion (no threshold derived)						
	Inhalation			Dermal			Eyes
	Systemic acute	Local long-term	Local acute	Systemic acute	Local long-term	Local acute	Local effects
Diammonium hexachloroplatinate	Medium	High	High	Medium	Medium	Medium	Medium
Dipotassium hexachloroplatinate	Medium	High	High	Medium	Medium	Medium	Medium
Hexachloroplatinic acid	High	High	High	High	Medium	Medium	Medium
Dihydrogen hexahydroxyplatinate	-	-	-	-	-	-	Low
Tetraammineplatinum dinitrate	-	-	-	-	-	-	-
Platinum dinitrate	Unknown	High	High	Unknown	High	High	Medium

- = No hazard identified
Unknown = Hazard unknown (no further information necessary)

PMC approach for chloroplatinates - background

- Outcome PGM WG conf call (February 2016)
  - Qualitative approach
  - Sub-group to steer the project

- Outcome CPs Sub-group
  - Draft rationale for REACH dossier
  - Oversee relevant part of CSR
  - Consider impact on DUs
  - Coordinate with IPA/STF

PMC approach for chloroplatinates - considerations

- Qualitative approach: acceptable but not at a long term
  - Need a semi-quantitative assessment in addition?
- ECHA screening expected 2018
- Ensure no clash between IPA/STF work focus on long term project on acceptable OEL and REACH requirements/regulatory pressure

- Need for additional face-to-face meeting to discuss qualitative approach in detail

Read-across (RA) approach

1) ESR- and ES-specific RA justifications
- Amend ESR with RA details as appropriate
- Required to pass TCC
- Include brief RA justification text in ES

2) Overall substance-specific RA justification report
- Robust document attached separately to IUCLID
- Detailed comparison between target and RA substance (data matrix and discussion)

3) ESRs included in target dossier for all studies on surrogate referred to in the data matrix
- Not current practice
- Potentially significant undertaking/impracticalities (ownership, resource, CSR)
- ECHA have confirmed this is the required approach

Read-across (RA) approach

Draft RA justification report (2) on dipotassium hexachloropalladate produced last week

- Heavily based on ECHA (2015) RAAF
- Data matrix for source and target substances to cover all key endpoints (phys-chem, environ fate, ecotox and HH)
- Discussion of the similarity in the matrix endpoints on the target and source compound(s) (and the reasons for/consequences of any significant differences)
- Consideration of the structural similarity (and implications of any differences wrt to the particular endpoint)
- Formation of common breakdown products and the potential impact of non-common breakdown products to the prediction

Recommended that similar reports for the remaining compounds involving RA should be drafted and attached to each dossier

Bibra toxicology advice & consulting Ltd

www.bibra-information.co.uk

Precious Metals Consortium

5. Exposure Scenarios

5.1 Life Cycle Trees and Identified uses

- PMC approach for Plating / Surface treatment
  - Use for 'Plating' and/or 'surface treatment' included in many PMC REACH dossiers
  - In this use, a metal compound is transformed into the metallic form
  - During further life-cycle, no exposure to the metal compound anymore

  PROPOSAL:

  -stop lifecycle at this use:

  › REACH dossier = substance specific, further lifecycle steps included in respective metal dossier.

  › not in line with ECHA Guidance

  › same strategy followed by some other metal consortia

  -address service-life in dossier, as selected use descriptors require them (e.g. ERC 4, 5)

  › include generic title (e.g. 'Service life of plated article')

  › assign a tonnage of '0'

  › include brief explanation in 'Remarks' field

5.2 Environmental Exposure Assessment for Pd compounds

- Sector approach developed for production and processing (intermediate use) of Pd compounds
- Reasonable worst case (RWC) exposure scenario (ES) based on tonnage values and site emission data provided in questionnaires
- Sufficient information to develop a robust dataset (14 sites across Europe) for discharge to aquatic environment and to support use of adjusted SpERC for emissions to air

Environmental Exposure Assessment for Pd compounds

- RWC ES for processing (manufacture and industrial use as intermediate) based on:
  - 90P net site tonnage of Pd
  - 50P site emission factor (EF) for aquatic discharge
  - 10% of SpERC EF for emissions to air (supported by limited amount of site data available)
  - 50P emission days per year & typical RMMs
- Processing sub-scenarios for:
  - Discharge to freshwater via STP
  - Direct discharge to freshwater
  - Direct discharge to marine water

Environmental Exposure Assessment for Pd compounds

- Exposure modelling undertaken using algorithms from ECHA technical guidance (EUSES)
  - » Minimum STP size from sector data
  - » 50P dilution factor from sector data for receiving water body
  - » Measured and literature partitioning coefficients
  - » Default values for other parameters

- All RCRs <1 indicating an acceptable level of risk to the environment

Environmental Exposure Assessment for Downstream Use

- In the absence of measured emissions data from downstream users of Pd compounds a tiered approach has been applied to calculate the maximum safe tonnage (Msafe) of each Pd compound that can be used in a specific sector without risk to the environment
- ESs primarily based on SpERCs with EFs adjusted down by an order of magnitude based on the monetary value of Pd
- All downstream users of Pd compounds assumed to discharge wastewater emissions via an STP

Environmental Exposure Assessment for Downstream Use

- Default assumptions from ECHA technical guidance (R16) used for size of STP and dilution factors
- Msafe tonnage calculated based on environmental modelling to give RCR <1 (~0.8 for most sensitive compartment, usually freshwater)

- Please check that Msafe tonnages for Pd compounds are reasonable for each sector use

Monitoring PGM Removal in STPs

- A monitoring programme was established at STPs that are receiving discharges from plants processing effluent containing PGMs
- Conditions (and removal rates) can vary between STPs and over time
  - » Sampling at 3 STPs in two different countries
  - » Sampling to address seasonal variation (specifically, high and low flow conditions)
  - » Average removal rate taken forward to use in exposure assessment
- STP Influent, effluent and STP sludge sampled

Site specific risk assessment (SSRA)

- SSRAs for environmental emissions of Pd during processing have been prepared for all sites providing data
- Initially based on measured emission data, supplemented by GES values
- Site-specific monitoring of receiving environment (i.e. freshwater and sediment) has also been undertaken and used to demonstrate absence of risk
- Majority of sites able to demonstrate RCR<1 for all environmental compartments

PGM Removal in STPs

- Previously there was no reported measurement of removal efficiency of Pd and other PGMs in sewage treatment plants (STPs)
- Initial modelling was based on estimate of 80% removal efficiency based on extrapolation from partitioning data
- Majority of manufacturing sites discharge to freshwater via STP so project set up to measure removal of PGMs at 3 STPs across Europe

Monitoring PGM Removal in STPs

- First round of monitoring was November-December 2014
  - » Assumed to be medium flow conditions based on rainfall (dependent on local conditions)
- Second round of monitoring was in April – May 2015
  - » High flow conditions
- Third round of monitoring was in September – October 2015
  - » Low flow conditions
- Samples analysed for Pd, Pt, Rh and Ru in influent and effluent

PGM Removal in STPs

- Removal rates were calculated as % for each site and sampling occasion
  - » = [Influent conc – effluent conc] / influent conc
- The median removal rate was then calculated for each metal across the 3 STPs for use in environmental exposure assessment

Metal	Pd	Pt	Rh	Ru
Removal Efficiency ± MAD (No. of datapoints*)	79 ± 6 % (9)	57 ± 7 % (7)	48 ± 19 % (5)	46 ± 19 % (6)

MAD = Median absolute deviation

*On several occasions effluent concentrations were significantly higher than influent concentrations, probably indicating variable input of PGMs, or more probably, changes in rainfall or STP operation affecting influent and/or effluent concentrations on these occasion. These data were removed from consideration

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5.2 Exposure/Risk Assessment ENV/HH

Occupational exposure scenarios for Pd substances

PGM Meetings

Brussels

April 2016

Daniel Vetter
EBRC Consulting
Hannover, Germany

Available information for occ. ES

- Responses to occupational exposure questionnaire from manufacturers
- Inhalation monitoring data from manufacturers
- Use nominations
- Scope of occ. exposure assessment provided by secretariat / IUCLID files with hazard conclusions for workers

  → 11 Pd substances in scope
- Telephone interviews with manufacturers of 2 substances not covered in occ. questionnaire

Pd substances in scope for occ. ES

Substance	Inhalation				Dermal				Eyes
	systemic		local		systemic		local		
	LT [mg/m³]	acute	LT	acute	LT [mg/kg bw/d]	acute	LT	acute	
Palladium dichloride	14.70	NHI	med	med	4.17	NHI	high	high	med
Dihydrogen tetrachloropalladate(2-)	20.80	NHI	med	med	5.89	NHI	high	high	med
Diamminedichloropalladium	17.50	NHI	NHI	NHI	24.90	NHI	NHI	NHI	med
Palladium (II) di(4-oxopent-2-en-2-oate)	25.50	NHI	med	med	36.20	NHI	high	high	med
Tetraamminepalladium(2+) dichloride	0.19	NHI	med	med	0.27	NHI	high	high	low
Tetraamminepalladium(2+) diacetate	0.26	NHI	med	med	0.36	NHI	high	high	low
Disodium tetrachloropalladate	24.40	NHI	med	med	34.60	NHI	high	high	low
Palladium dinitrate	77.20	NHI	med	med	21.90	NHI	med	med	med
Palladium dihydroxide	47.00	NHI	med	med	66.70	NHI	high	high	med
Diammonium hexachloropalladate	4.70	NHI	med	med	1.33	NHI	med	med	med
Dipotassium hexachloropalladate	5.27	NHI	med	med	1.49	NHI	med	med	med

LT: long-term, NHI: No hazard identified

Further information

- Dustiness tests available for a subset of substances
- Chesar used for generation of occ. ES
- Scope of assessments (substances hazardous to HH)
- Use description and exposure assessment to stop after transformation of substances, this affects:
  - Manufacture
  - Intermediate uses
  - Further downstream uses such as surface treatment
  - Corresponding life cycle trees
- Potential deletion of ES without PROC nominations (confirmation or non-confirmation by commenting)

Deliverables on 1st April 2016

- Draft occ. ES in Section 9/10 for the CSR provided for
  - 11 Pd substances
  - total of 26-30 ES (4 ES will be deleted in case no further information is provided → all formulation uses)
  - total of 274 contributing occ. ES
- 1 methodology document for occ. exposure assessment (15 pages)
- 1 commenting form for all provided documents (Microsoft Excel based)

Comments on occ. ES

- Please read the occ. ES together with the methodology document thoroughly
- Please note that ES without PROC nominations will be deleted in the next version
- Please provide further information on sections highlighted in yellow background colour
- Please inform us on relevance/non-relevance of occ. ES
- Please also inform us whether you agree with content of occ. ES (e.g. physical forms, localised controls, RMMs, PPE)
- Any remaining comments/questions on first drafts?

Occupational exposure scenarios for Pt substances

PGM Meetings

Brussels

April 2016

Daniel Vetter
EBRC Consulting
Hannover, Germany

Introduction

- Varying hazard potential of Pt substance groups (Oct 2014)
- Agreement to follow workplace-specific approach for manufacturing ES (April 2015)
- Common workplaces defined, draft publication of IPA data received for comparison of workplaces (Sept 2015)
- EBRC request for further information on IPA data (Nov 2015, still pending)
- Meeting for discussion of risk assessment (Feb 2016)

Available information for occ. ES

- Responses to occupational exposure questionnaire from manufacturers
- Use nominations
- Scope of occ. exposure assessment provided by secretariat (June 2015)
- IUCLID files with hazard conclusions for workers for 6 Pt substances (April 2016)

HC for workers for 6 Pt substances

Substance	Inhalation				Dermal				Eyes
	systemic		local		systemic		local		
	LT [µg/m³]*	acute	LT	acute	LT [µg/kg bw/d]*	acute	LT	acute	
Hexachloroplatinic acid	2	high	high	high	1.43	high	med	med	med
Tetraammineplatinum dinitrate (in solution)***	2	NHI	NHI	NHI	2.86	NHI	NHI	NHI	NHI
Dipotassium hexachloroplatinate (solid only)	2	med	high	high	1.43	med	med	med	med
Platinum dinitrate (UVCB)	2	HU**	high	high	1.43	HU**	high	high	med
Diammonium hexachloroplatinate	2	med	high	high	1.43	med	med	med	med
Dihydrogen hexahydroxyplatinate (solid only)	2	NHI	NHI	NHI	2.86	NHI	NHI	NHI	low

LT: long-term, NHI: No hazard identified
*: Other toxicological threshold (semi-quantitative assessment required)
HU**: Hazard unknown, no further information available (qualitative assessment required)

***Substance not covered in occ. exp. questionnaire →further information urgently required!

Overview of activity classes

- Activity classes assigned by manufacturing companies on a substance-specific basis:

AC	Title
AC1	Remote handling of dusty materials (including automated operations)
AC2	Direct handling (including hand-held tools) of dusty materials at ambient temperature (non-abrasive tasks)
AC3	Handling of non-/very low dusty granulates/objects at ambient temperature
AC4	Handling/manipulation of solutions/suspensions in not-closed processes
AC5	Spraying operations with powders or solutions/suspensions in not-closed processes
AC6	Operations at furnaces/smelters/ovens in not-closed process at substantially elevated temperatures (e.g. casting)
AC7	Closed processes at substantially elevated temperatures (e.g. sintering, smelting)
AC8	Mechanical operations in not-closed processes
AC9	Supervision of completely closed processes (not including any furnace operations)
AC10	Non-routine work (excluding cleaning)
AC11	Cleaning tasks not part of standard operations

- Re-assignment of ACs to workplaces

Overview of workplaces

- Generic workplaces relevant for all Pt activities:

WP	Title
WP1	Raw material handling
WP2	Sampling/Evaluation
WP3	Wet processing
WP4	Separation/Filtration
WP5	Washing/Drying
WP6	Calcination
WP7	Milling/Grinding/Sieving
WP8	Re-melting/Casting
WP9	Packaging/Filling
WP10	Cleaning and maintenance
WP11	Other, please specify

Overview of exposure categories

- exclusively poorly sol/insol. Pt
- mostly poorly sol/insol. Pt, traces of solPt, no hexPt
- mostly poorly sol/insol. Pt, traces of solPt and/or hexPt
- poorly sol/insol. Pt, solPt, hexPt, equal parts
- exclusively solPt and/or hexPt
- no exposure to any Pt form

Live presentation – Online Survey

Availability of inhalation monitoring data

- IPA data and publication available:
  - Job/workplace description not available
  - Some processes may not be relevant for EU (primary production), only subset of data obtained in EU (only UK)
  - Additional data gaps / open questions:
    - 2 data sets only partly overlapping
    - Conditions of use not reported
    - Sampling duration/TWA values
    - Additional data available (2012-2015)? Older data (e.g. from 2000) still relevant?
- Original EU data submitter identifiable?
- Data set(s) to be assigned to workplaces to be surveyed

Availability of dermal monitoring data?

- Provided reference values for dermal, long-term systemic effects:
  - 1.43 µg soluble Pt/kg bw/d
  - 2.86 µg soluble Pt/kg bw/d
- Initial exposure estimate for handling of metal powders at ambient temperature: 0.14 mg/kg bw/d (RCR: 98.9)
- Refinement possible: Non-dispersive use, non-direct handling, use of protective gloves: 1.41 µg/kg bw/d

→ Minimum dermal RCR: 0.99 (100 %, 480 minutes)

→ Dermal RCR has to be summed up with inhalation RCR…

Way forward

- Webex planned in the coming weeks (delay due to technical problems, parallel discussions) for workplace assignment
- Monitoring data from IPA (once clarification available) to be assigned to workplaces → urgent!
- Occ. ES to be developed without Chesar 2.3
- Potentially to be updated once Chesar 3 is available
- Monitoring data to be read-across to DUs (or monitoring data to be submitted if available)
- Categorisation of substances into poorly soluble and soluble substances (based on solubility threshold?)

5.3 ‘Man via Environment’ assessment

- ECHA (2012) R16 guidance:

  Assessment of indirect exposure is generally only conducted if:

  • the tonnage >1,000 t/y or

  • the tonnage >100 t/Y and the substance is classified

  o as “Toxic” with a risk phrase “R48”; or

  o as a carcinogen or mutagen (of any category); or

  o as toxic to reproduction (category 1 or 2).

- All PGM dossiers <100 tpa, so no MvE assessment required / performed

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6. Analysis of Alternatives (AoA) of Chloroplatinates

AoA chloroplatinates - Why?

- Our 4 chloroplatinates have an harmonised classification as **respiratory sensitisers with high potency**
  - => Potential SVHC - “respiratory sensitization” is considered as an “equivalent concern” (article. 57f)
- To be registered by PMC **4Q 2017 (LR)**
- **Regulatory action may be launched quickly after registration** following ECHA IT screening (as early as 2018)
- Regulatory action likely to consist in:
  - RMOA
  - “Soft letter”, selection for dossier compliance check
- **Substitution, intermediate status, tonnages: key criteria for RMO selection**

AoA chloroplatinates – the project

- Pt Sub-Assembly decided to launch an AoA this year
- DHI Appointed as consultant
  - DHI Team leader: Jens Torslov
  - Experts: Dr Martin Lok (catalysts) and Dr Hubert Schmidbaur (refining, plating)
- Approach in line with our needs and regulatory timeline
  - We are in a preliminary phase where focus should be on understanding knowledge status including beyond members

AoA chloroplatinates – scope and objectives

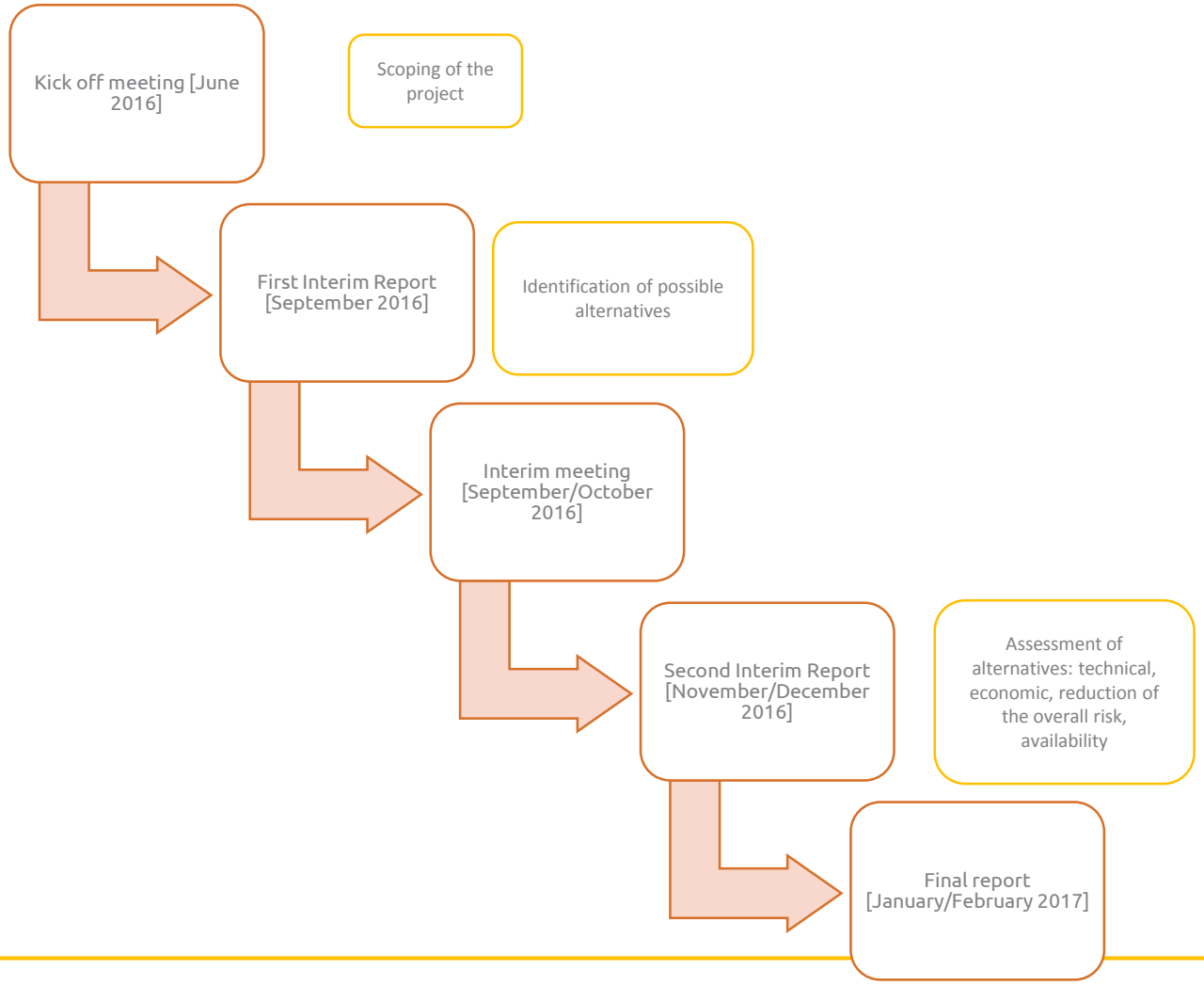
- Identified uses in the RMOA

Declared Uses	Non-declared Uses
Refining of platinum (intermediate use?)	Plating
Catalysis (intermediate use?)	Photographic films, Ceramic colouring

- Objectives of the AoA:

1. Complement RMOA / clarify substitution status and potential for the different uses
2. Progress on identification of indermediate status of certain uses
3. Support registration dossier update for non-declared uses

AoA chloroplatinates – draft timeline



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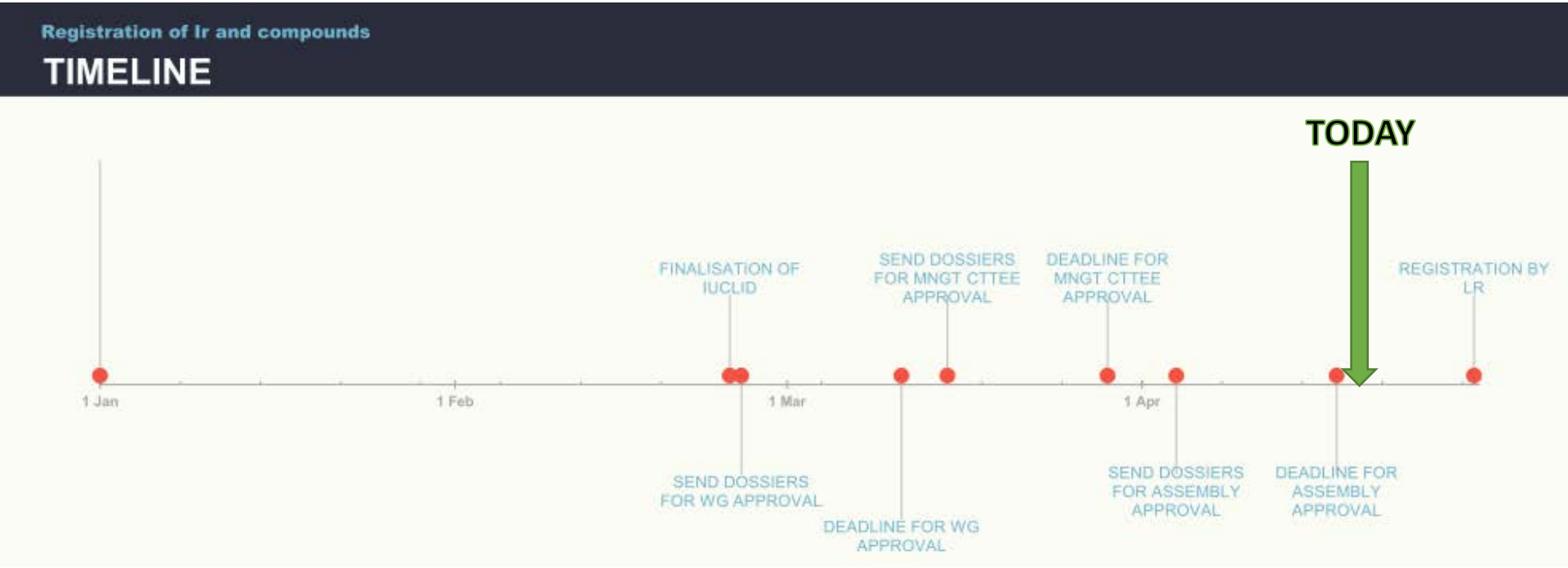
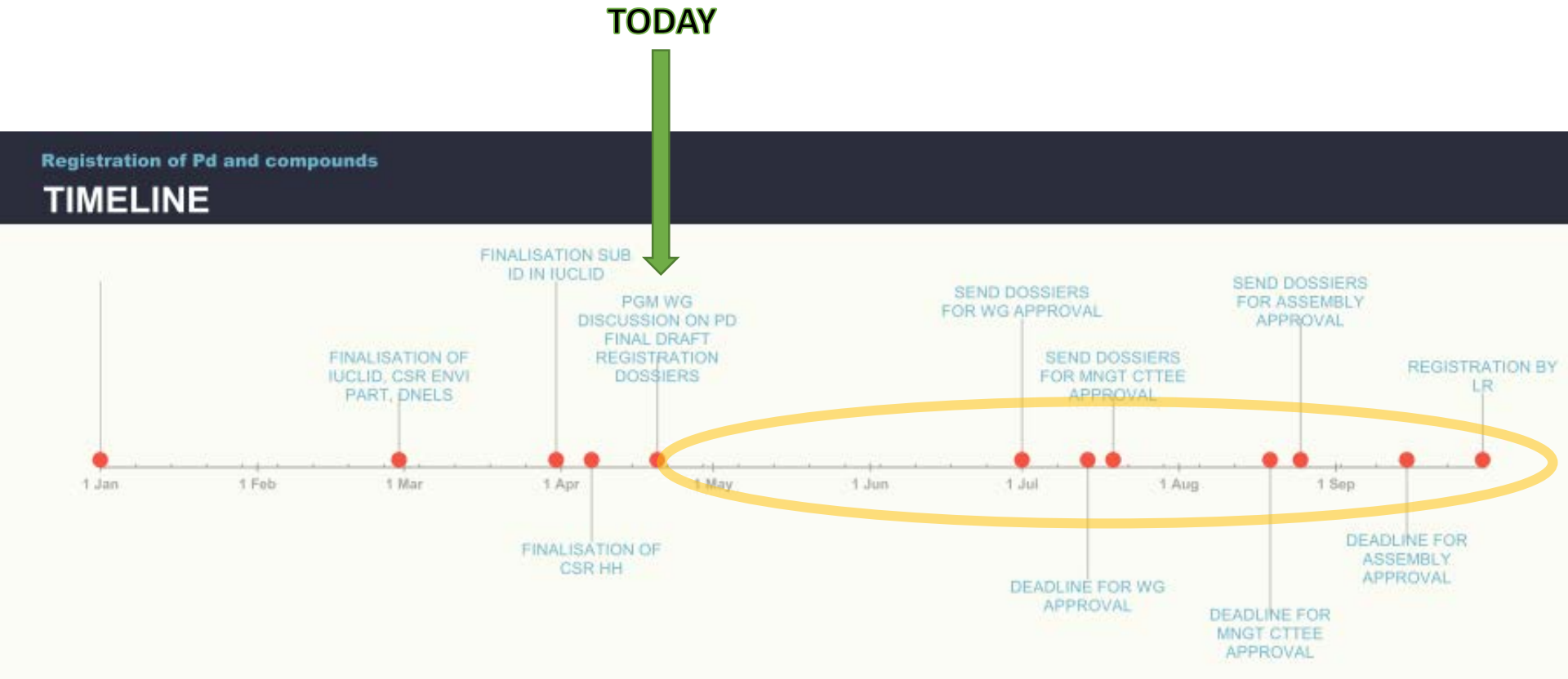
7. Timelines

7. Timelines


Registration of Ir and compounds
TIMELINE
TODAY
FINALISATION OF IUCLID
SEND DOSSIERS FOR MNGT CTTEE APPROVAL
DEADLINE FOR MNGT CTTEE APPROVAL
REGISTRATION BY LR
1 Jan
1 Feb
1 Mar
1 Apr
SEND DOSSIERS FOR WG APPROVAL
DEADLINE FOR WG APPROVAL
SEND DOSSIERS FOR ASSEMBLY APPROVAL
DEADLINE FOR ASSEMBLY APPROVAL

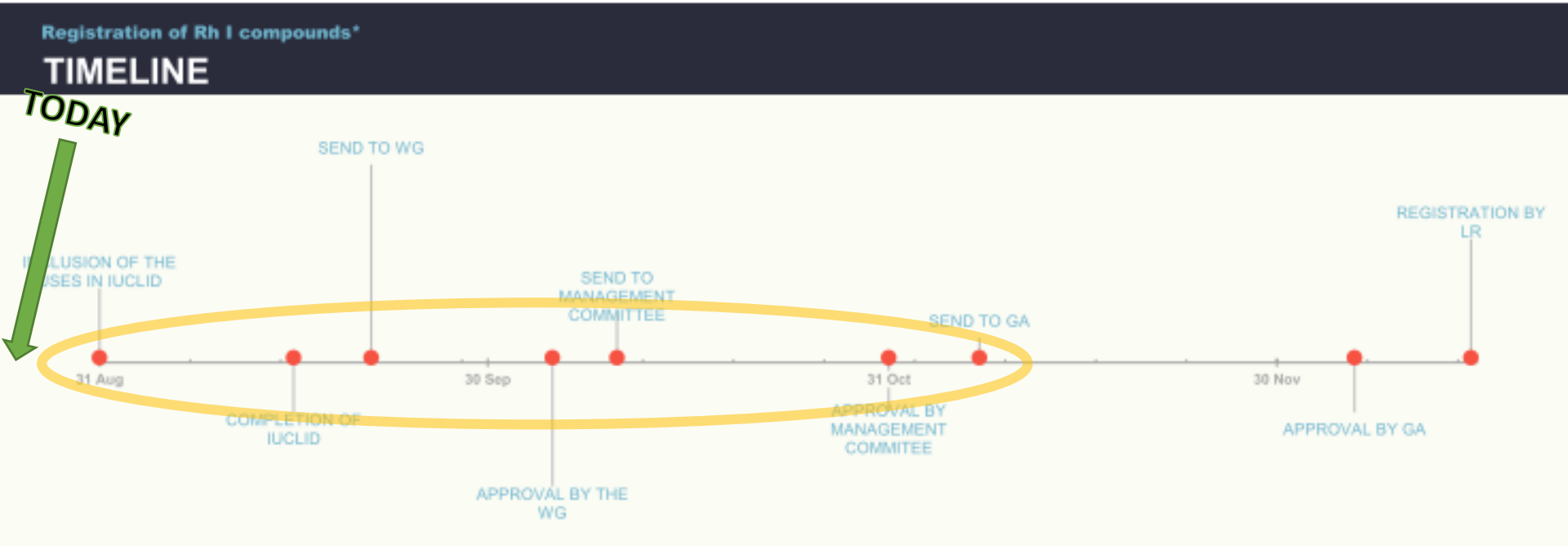
7. Timelines


TODAY
Registration of Pd and compounds
TIMELINE
FINALISATION SUB ID IN IUCLID
PGM WG DISCUSSION ON PD FINAL DRAFT REGISTRATION DOSSIERS
FINALISATION OF IUCLID, CSR ENVI PART, DNELS
SEND DOSSIERS FOR WG APPROVAL
SEND DOSSIERS FOR ASSEMBLY APPROVAL
SEND DOSSIERS FOR MNGT CTTEE APPROVAL
REGISTRATION BY LR
1 Jan
1 Feb
1 Mar
1 Apr
1 May
1 Jun
1 Jul
1 Aug
1 Sep
FINALISATION OF CSR HH
DEADLINE FOR WG APPROVAL
DEADLINE FOR MNGT CTTEE APPROVAL
DEADLINE FOR ASSEMBLY APPROVAL

7. Timelines

- Proposal to split Pd approval process:
  - start with Annex III exempted substances end April – can be approved by end June 2016
  - continue with others as scheduled

7. Timelines

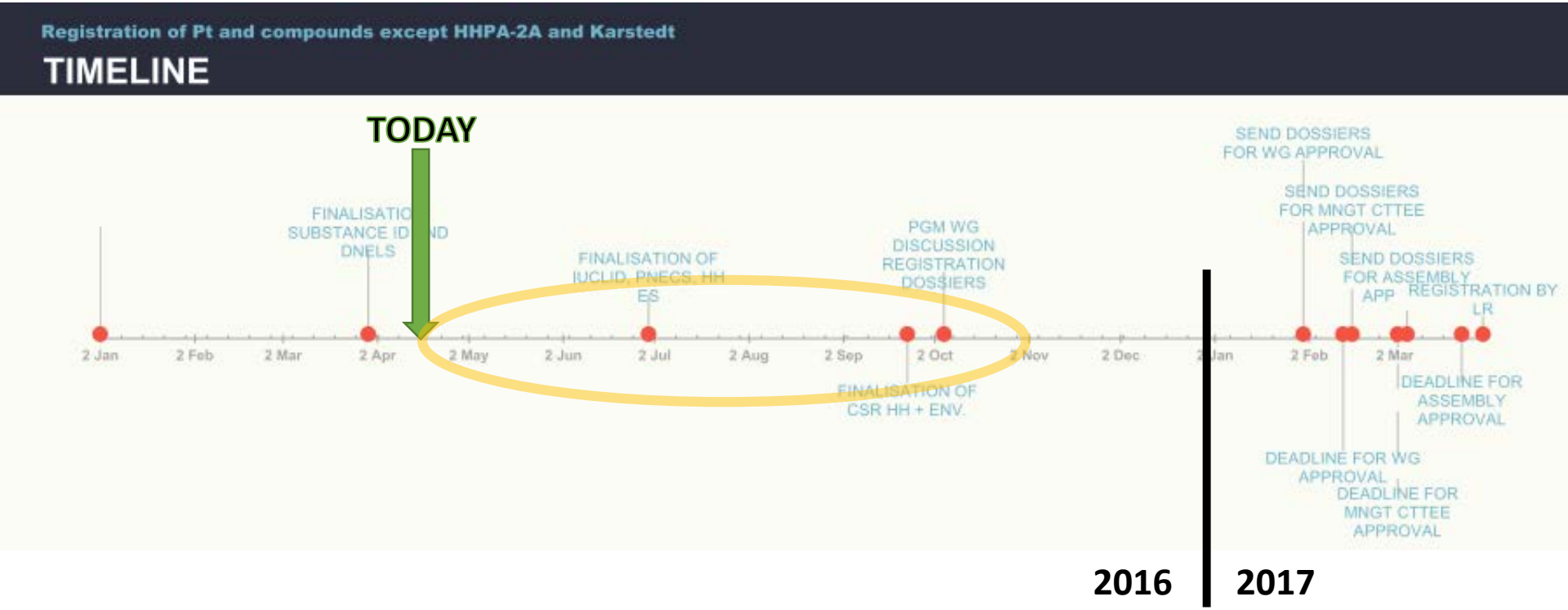


*Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I) 12092-47-6 (1-10 tonne substance)
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium 25470-96-6 (1-10 tonne substance)
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium 14874-82-9 (1-10 tonne substance)
Carbonylhydrotris(triphenylphosphine)rhodium 17185-29-4 (1-10 tonne substance)
Tris(triphenylphosphine) rhodium (I) chloride 14694-95-2 (1-10 tonne substance)

7. Timelines


Registration of Rh and Rh(III) compounds
TIMELINE
TODAY
2016
AGREEMENT ON MUTA TESTING
FINALISATION OF MUTA TESTING OR AGREEMENT ON CLASSIFICATION
15 Mar
15 Apr
15 May
15 Jun
15 Jul
15 Aug
15 Sep
15 Oct
15 Nov
15 Dec
FINALISATION ENVI ASSESSMENT
2017
CLASSIFICATION AND DNELS DERIVATION
REGISTRATION BY LR
SEND TO WG
FINALISATION CSR
SEND TO THE MANAGEMENT CTTEE
SEND TO GA
25 Jan
25 Feb
25 Mar
25 Apr
25 May
25 Jun
DNELS AVAILABLE
APPROVAL OF MANAGEMENT CTTEE
APPROVAL OF THE GA
APPROVAL OF THE WG

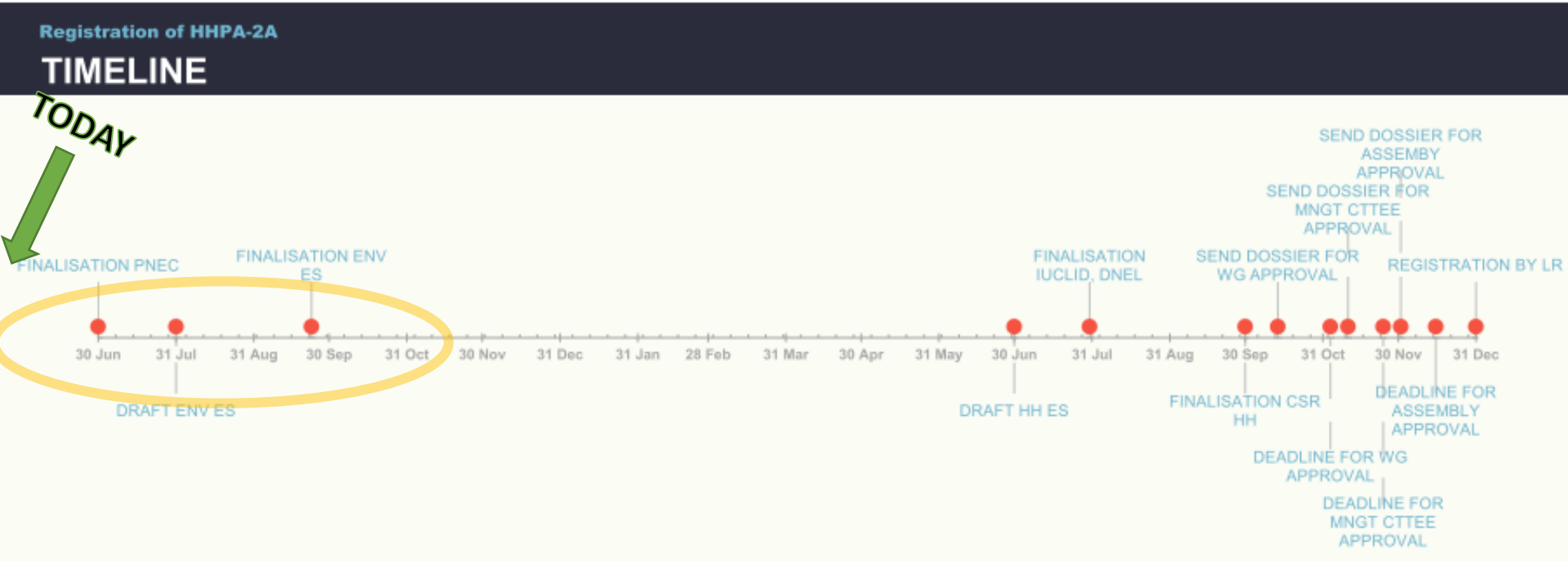
7. Timelines


Registration of Pt and compounds except HHPA-2A and Karstedt
TIMELINE
TODAY
FINALISATIO
SUBSTANCE ID ND
DNELS
FINALISATION OF
IUCLID, PNECS, HH
ES
PGM WG
DISCUSSION
REGISTRATION
DOSSIERS
FINALISATION OF
CSR HH + ENV.
SEND DOSSIERS
FOR WG APPROVAL
SEND DOSSIERS
FOR MNGT CTTEE
APPROVAL
SEND DOSSIERS
FOR ASSEMBLY
APP
REGISTRATION BY
LR
DEADLINE FOR
ASSEMBLY
APPROVAL
DEADLINE FOR WG
APPROVAL
DEADLINE FOR
MNGT CTTEE
APPROVAL
2 Jan
2 Feb
2 Mar
2 Apr
2 May
2 Jun
2 Jul
2 Aug
2 Sep
2 Oct
2 Nov
2 Dec
2 Jan
2 Feb
2 Mar
2016
2017

7. Timelines


Registration of Karstedt
TIMELINE
TODAY
DRAFT PNECS PT (INCL. KARSTEDT)
GATHER USE AND EXPOSURE INFORMATION
DRAFT HH ES
REACH DOSSIER READY
DRAFT DNEL KARSTEDT
FINAL IUCLID
SEND DOSSIERS FOR WG APPROVAL
SEND DOSSIERS FOR MNGT CTTEE APPROVAL
SEND DOSSIERS FOR ASSEMBLY APPROVAL
DEADLINE FOR WG APPROVAL
DEADLINE FOR MNGT CTTEE APPROVAL
REGISTRATION BY LR
DEADLINE FOR ASSEMBLY APPROVAL
30 Apr
31 May
30 Jun
31 Jul
31 Aug
30 Sep
31 Oct
30 Nov
31 Dec
31 Jan
28 Feb
31 Mar

7. Timelines


Registration of HHPA-2A
TIMELINE
TODAY
FINALISATION PNEC
FINALISATION ENV ES
FINALISATION IUCLID, DNEL
SEND DOSSIER FOR WG APPROVAL
SEND DOSSIER FOR MNGT CTTEE APPROVAL
SEND DOSSIER FOR ASSEMBY APPROVAL
REGISTRATION BY LR
30 Jun
31 Jul
31 Aug
30 Sep
31 Oct
30 Nov
31 Dec
31 Jan
28 Feb
31 Mar
30 Apr
31 May
30 Jun
31 Jul
31 Aug
30 Sep
31 Oct
30 Nov
31 Dec
DRAFT ENV ES
DRAFT HH ES
FINALISATION CSR HH
DEADLINE FOR WG APPROVAL
DEADLINE FOR MNGT CTTEE APPROVAL
DEADLINE FOR ASSEMBLY APPROVAL

7. Timelines


Registration of Ru and compounds
TIMELINE
TODAY
END OF ENVI TESTING PROGRAMME
END OF HH TESTING PROGRAMME
DNELS AVAILABLE
SEND TO WG
FINALISATION OF DOSSIER
SEND TO THE MANAGEMENT CTTEE
SEND TO GA
30 Sep
31 Oct
30 Nov
31 Dec
31 Jan
28 Feb
31 Mar
30 Apr
31 May
30 Jun
31 Jul
31 Aug
FINALISATION OF ENVI ASS INCLUDING CSR
FINALISATION OF HH ASS INCLUDING CSR
APPROVAL OF THE WG
CTTEE
GA

Precious Metals Consortium

8. Occupational Monitoring Project - Status

8. Occupational Monitoring Project

- Project agreed during December ‘15 GA meeting
  - Large number of REACH registrations <2018
  - DNELs expected to be (relatively) low
  - Limited n° of exposure data available
- AIM = collect/gather exposure data at representative workplaces of PGM Industry
- Timing: finalise <end 2016
- Metals under scope = as wide as possible (Rh, Ru, Pt, Pd…)
- EBRC contracted
- So far:
  - Kick-of meeting 18 February in Bxl
  - Participating companies: BASF, Chafner, Chimet, Heraeus, Johnson Matthey, Umicore, Vale
  - Engagement for sharing exposure data and/or site visits
  - 4 site visits scheduled so far (13-14 April and 11-12 May)
- Next steps…cfr proposed timing

8. Occupational Monitoring Project – proposed timing

Action	By whom	Duration	Time
Agree on date for site visit	Companies / EBRC	1 month	Mid March 2016
Easter break	*All*		
Perform site visit	Companies / EBRC (/EPMF)	2 weeks	Mid April 2016
Draft site visit report	EBRC	2 weeks	End April 2016
Revise / approve site visit report	Companies	1 month	End May 2016
Develop data submission form	EBRC	1 month	End June 2016
Summer break	*All*		
Submit monitoring data	Companies	1 month	Mid Aug 2016
Generate database	EBRC	2 weeks	End Aug 2016
Conduct sampling	Sampling institute / Companies	2 weeks	Mid Sep 2016
Sample analysis & drafting report	Sampling institute / EBRC	1.5 month	End Oct 2016
Finalisation of database	EBRC	2 weeks	Mid Nov 2016

ONGOING

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9. Workplan and budget

2015 finances after audit

		PMC Budget	PMC Real	Delta
2.5	***PGM-specific costs***	***1.168.010 €***	***699.018 €***	***468.992 €***
2.5.1	**PGM REACH registration and CLP notification work programme**	**1.168.010 €**	**699.018 €**	**468.992 €**
2.5.1.1	*Phase 1: Literature search, data gap analysis and recommendations (e.g. C&L update)*	15.750 €	6.684 €	*9.066 €*
2.5.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	2.625 €	10.674 €	*-8.049 €*
2.5.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	762.109 €	482.889 €	*279.220 €*
2.5.1.4	*Phase 4: Generation of Chemical Safety Reports*	242.032 €	101.007 €	*141.026 €*
2.5.1.5	*Phase 5: Generation of IUCLID 5 Files and Registration Dossiers*	142.343 €	63.809 €	*78.534 €*
	IUCLID 5 Hosting System	3.150 €	2.665 €	*485 €*
2.5.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*	0 €	10.604 €	*-10.604 €*
2.5.5	**PGM REACH authorisation**	**0 €**	**20.686 €**	**-20.686 €**
2.5.5.1.	*Chloroplatinates*	0 €	20.686 €	*-20.686 €*

2017 draft budget - Pt

		PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR
2.5.A	***Platinum-specific costs***	***89.650 €***	***74.150 €***	***0,3***
2.5.A.1	**Pt REACH registration**	**89.650 €**	**74.150 €**	
2.5.A.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	4.000 €	4.000 €	
2.5.A.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €	
2.5.A.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	15.500 €	0 €	
2.5.A.1.4	*Phase 4: Generation of Chemical Safety Reports*	69.150 €	69.150 €	
2.5.A.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €	
2.5.A.1.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €	
2.5.A.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*			
2.5.A.2	**Pt REACH dossier maintenance**	**0 €**	**0 €**	
2.5.A.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €	
2.5.A.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €	
2.5.A.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €	
2.5.A.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €	
2.5.A.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €	
2.5.A.2.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €	
2.5.A.3	**Pt REACH evaluation**	**0 €**	**0 €**	
2.5.A.3.1	*Dossier evaluation*	0 €	0 €	
2.5.A.3.2	*Substance evaluation*	0 €	0 €	
2.5.A.4	**Pt REACH classification & labelling**	**0 €**	**0 €**	
2.5.A.5	**Pt REACH authorisation**	**0 €**	**0 €**	
2.5.A.5.1.	*Chloroplatinates*	0 €	0 €	
2.5.A.6	**Pt internal and external fixed Scientific Managers**	**67.800 €**	**67.800 €**	
2.5.A.7	**Pt Building reserves**			

2017 draft budget - Pd

	PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR
2.5.B Palladium-specific costs	***88.800 €***	***88.800 €***	***0,3***
2.5.B.1 Pd REACH registration	**0 €**	**0 €**	
2.5.B.2 Pd REACH dossier maintenance	**1.000 €**	**1.000 €**	
2.5.B.2.1 Phase 1: Literature search, data gap analysis and recommendations	0 €	0 €	
2.5.B.2.2 Phase 2: In-depth data gap analysis and integrated testing strategy	0 €	0 €	
2.5.B.2.3 Phase 3: Experimental studies (testing programme including cost of samples)	0 €	0 €	
2.5.B.2.4 Phase 4: Generation of Chemical Safety Report	0 €	0 €	
2.5.B.2.5a Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers	0 €	0 €	
2.5.B.2.5b Phase 5b: IUCLID 5 Hosting System	1.000 €	1.000 €	
2.5.B.3 Pd REACH evaluation	**0 €**	**0 €**	
2.5.B.3.1 Dossier evaluation	0 €	0 €	
2.5.B.3.2 Substance evaluation	0 €	0 €	
2.5.B.4 Pd REACH classification & labelling	**0 €**	**0 €**	
2.5.B.5 Pd REACH authorisation	**0 €**	**0 €**	
2.5.B.6 Pd internal and external fixed Scientific Managers	**67.800 €**	**67.800 €**	
2.5.B.7 Pd Building reserves			
2.5.B.8 Chloropalladates	**20.000 €**	**20.000 €**	

2017 draft budget - Rh

		PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR
2.5.C	***Rhodium-specific costs***	***127.700 €***	***110.200 €***	***0,7***
2.5.C.1	**Rh REACH registration**	**79.400 €**	**61.900 €**	
2.5.C.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €	
2.5.C.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €	
2.5.C.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	17.500 €	0 €	
2.5.C.1.4	*Phase 4: Generation of Chemical Safety Reports*	38.850 €	38.850 €	
2.5.C.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	22.050 €	22.050 €	
2.5.C.1.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €	
2.5.C.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*			
2.5.C.2	**Rh REACH dossier maintenance**	**0 €**	**0 €**	
2.5.C.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €	
2.5.C.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €	
2.5.C.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €	
2.5.C.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €	
2.5.C.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €	
2.5.C.2.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €	
2.5.C.3	**Rh REACH evaluation**	**0 €**	**0 €**	
2.5.C.3.1	*Dossier evaluation*	0 €	0 €	
2.5.C.3.2	*Substance evaluation*	0 €	0 €	
2.5.C.4	**Rh REACH classification & labelling**	**0 €**	**0 €**	
2.5.C.5	**Rh REACH authorisation**	**0 €**	**0 €**	
2.5.C.6	**Rh internal and external fixed Scientific Managers**	**48.300 €**	**48.300 €**	
2.5.C.7	**Rh Building reserves**			

2017 draft budget - Ru

		PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR
2.5.D	***Ruthenium-specific costs***	***151.850 €***	***134.350 €***	***0,5***
2.5.D.1	**Ru REACH registration**	**103.550 €**	**86.050 €**	
2.5.D.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €	
2.5.D.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €	
2.5.D.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	17.500 €	0 €	
2.5.D.1.4	*Phase 4: Generation of Chemical Safety Reports*	63.000 €	63.000 €	
2.5.D.1.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	22.050 €	22.050 €	
2.5.D.1.5b	*Phase 5b: IUCLID 5 Hosting System*	1.000 €	1.000 €	
2.5.D.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*			
2.5.D.2	**Ru REACH dossier maintenance**	**0 €**	**0 €**	
2.5.D.2.1	*Phase 1: Literature search, data gap analysis and recommendations*	0 €	0 €	
2.5.D.2.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	0 €	0 €	
2.5.D.2.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	0 €	0 €	
2.5.D.2.4	*Phase 4: Generation of Chemical Safety Report*	0 €	0 €	
2.5.D.2.5a	*Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers*	0 €	0 €	
2.5.D.2.5b	*Phase 5b: IUCLID 5 Hosting System*	0 €	0 €	
2.5.D.3	**Ru REACH evaluation**	**0 €**	**0 €**	
2.5.D.3.1	*Dossier evaluation*	0 €	0 €	
2.5.D.3.2	*Substance evaluation*	0 €	0 €	
2.5.D.4	**Ru REACH classification & labelling**	**0 €**	**0 €**	
2.5.D.5	**Ru REACH authorisation**	**0 €**	**0 €**	
2.5.D.6	**Ru internal and external fixed Scientific Managers**	**48.300 €**	**48.300 €**	
2.5.D.7	**Ru Building reserves**			

2017 draft budget - Ir

	PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR
2.5.E Iridium-specific costs	***1.000 €***	***1.000 €***	***0,1***
2.5.E.1 Ir REACH registration	**0 €**	**0 €**	
2.5.E.2 Ir REACH dossier maintenance	**1.000 €**	**1.000 €**	
2.5.E.2.1 Phase 1: Literature search, data gap analysis and recommendations	0 €	0 €	
2.5.E.2.2 Phase 2: In-depth data gap analysis and integrated testing strategy	0 €	0 €	
2.5.E.2.3 Phase 3: Experimental studies (testing programme including cost of samples)	0 €	0 €	
2.5.E.2.4 Phase 4: Generation of Chemical Safety Report	0 €	0 €	
2.5.E.2.5a Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers	0 €	0 €	
2.5.E.2.5b Phase 5b: IUCLID 5 Hosting System	1.000 €	1.000 €	
2.5.E.3 Ir REACH evaluation	**0 €**	**0 €**	
2.5.A.3.1 Dossier evaluation	0 €	0 €	
2.5.A.3.2 Substance evaluation	0 €	0 €	
2.5.E.4 Ir REACH classification & labelling	**0 €**	**0 €**	
2.5.E.5 Ir REACH authorisation	**0 €**	**0 €**	
2.5.E.6 Ir internal and external fixed Scientific Managers	**0 €**	**0 €**	
2.5.E.7 Ir Building reserves			

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

AOB

- Update REACH IT tools:
  - IUCLID 6/CHESAR3 available 29th April
  - REACH-IT 3 scheduled for the 21st June

Precious Metals Consortium

THANK YOU

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