PGM Working Group + Exposure Scenario Meeting

Brussels

6 November 2013

1. Welcome & Introduction

Dave Boyd

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Approval of the Agenda
- Approval of the minutes of the last meeting and status of action items (19 June 2013)

Agenda

1. Welcome and introduction
2. Substance identification and sameness of PGMs
3. PGM testing programme
4. Current status of PNEC and DNEL refinement
5. Environmental emissions Pd and Pd compounds
6. Occupational exposure Pd and Pd compounds
7. Launch of use and exposure/emission data collection for other PGMs
8. AOB, next meetings/calls and closing remarks

Actions 19 June (1)

Action	Who?	Status
Substance identification and sameness Pd substances		
Complete and return questionnaire on physical forms	PMC Members	Done
Organise expert meeting to clarify outstanding issues on sameness of PGM nitrates	PMC Sec	
Add Pd nitrate to genotox scope	PMC Sec	
Measure and report the ratio of DDP isomers; send IR spectrum of DDP	DDP registrants	
Final identified uses of Pd and Pd compounds		
Confirm if uses are in line with EuPhraC initiative	PMC/EBRC/WCA	Ongoing at EM level
PGM testing programme		
Provide outstanding CoAs to BSL	Sample providers	Done
PNECs / DNEL for diamminedichloropalladium (DDP)		
Consult with TAP on choice of Pd sulphate / Pd nitrate as alternative for Pd dihydroxide RDT testing / read across source for other Pd(II) substances	KR	Done
Environmental emissions of Pd and Pd compounds		
Companies to confirm if DUs are covered by Msafe calculations	PMC members	Postponed
Members to advise on existing company specific monitoring programmes, incl. which PGMs are covered and LODs for respective metals	PMC members	Ongoing
Draft outline for site-specific monitoring programme	WCA	Done
Check possibility for site-specific assessment of waste ES (int. landfills)	WCA	Done

Actions 19 June (2)

Action	Who?	Status
Occupational exposure of Pd and Pd compounds		
EBRC to update DDP ES to reflect drying of product	EBRC	Not needed
Request DDP samples (high and low moisture content) and initiate testing at DMT	PMC	Ongoing
Exchange latest classifications for PGMs and confirm required scope of occ. ES.	PMC/ EBRC	Ongoing
Final quality check of questionnaire data for other Pd compounds, and advise on potential additional data needs	EBRC	Ongoing
Advise on tentative DNELs to be used	PMC/ BIBRA	Done
Hold meeting PMC/ EBRC to discuss pros/cons of CHESAR. PMC to report back to PGM WG	EBRC/ WCA / PMC	Done
PMC to share aggregated occ. exp. data for Pt with EBRC	PMC	Done
Standard phrases		
Send list of metal standard phrases to EPMF to share with EBRC	R Winde	Ongoing at EM level
Check if metal standard phrases can be used for the ES of PGM	EBRC	
Consult with EM ES task force to check if there is an agreement between Umicore and EM to share metal standard phrases, and if this can be handled as a generic metals project	KR	
Water solubility paper		
Finalise water solubility paper following permission to publish data from external data holders. Acknowledge sample providers in paper.	PMC	Done
Circulate updated manuscript to PGM WG for commenting	PMC Sec	Done

2. Substance identification and sameness of PGMs

Klaus ROTHENBACHER
Katrien ARIJS

2.1. ID cards: how best to report the composition?

- Input ID cards variable:
  - Min-max concentrations
  - Typical concentrations
- Options to report in consolidated ID cards:
  - Report complete range of compositions reported by all registrants -> all companies covered?
  - Report the composition of the reference sample used for testing -> companies can check if the test results apply to their situation (e.g. classification)
- For practicality reasons, PMC's preference would be to limit the reported compositions to the reference samples.
- Note: in case of low LODs for impurities in the representative sample, some companies may need to re-analyze to confirm that their substance composition is within the defined boundaries.

2.2 Diammineplatinum (II) nitrite: UVCB status

- Also known as Platinum 'P' salt
- Used for plating
- Mono substance solid is explosive -> supplied as a solution (mostly in aqueous ammonia)
- In water it would convert to a mixture containing the diammine diaquo and in ammonia to a mixture of tetrammine species
- As a solid it is a mono-constituent substance, but as a solution it is a UVCB
- Any objections?

2.3. Sameness (1): Outcome PGM nitrates sameness discussions

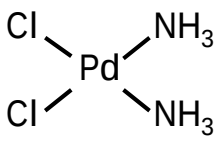
Final expert meeting 20th August 2013:

- Background
  - No feedback from 3 M/I received (despite several reminders)
  - Previous expert meeting could not conclude on sameness between solution and solid
    - Platinum nitrate
    - Rhodium nitrate
  - Additional analyses/spectra requested
- Conclusions
  - Need to document our rationale: "UVCB paper" by Dave Boyd
    - Proportions of any nitrato, nitrito and aqua ligands will vary
    - 'Platinum (II) nitrate' is Pt(IV); and contains no nitrate
    - Complex structures; varying composition; can form bridged polymers
  - Concluded on **sameness of solid/solution of both Pt- and Rh-nitrate**
  - Any objections?

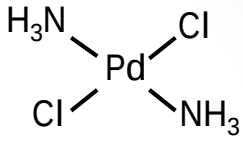
2.3. Sameness (2): Implications for registration strategy

- Main impact is on genotoxicity
- Expert meeting 7th Nov. 2013 to discuss way forward
  - Rh(III) genotoxicity
    - Conflicting results Rh(III) nitrate: no genotoxicity found; 'solid Rh nitrate' tested
    - All other Rh(III) substances: genotoxic
  - Selection of reference substance (UVCB = composition will vary)

2.3. Sameness (3): DDP isomers



cis



trans

- Isomer Ratio
  - Difficult to determine isomer ratios
  - Sameness meeting 20th Aug. 2013: Isomers have different IR fingerprint
  - Registrants were asked for IR spectra
- Evaluation of IR spectra
  - Mainly trans-isomer
- Proposed registration strategy
  - Register as monoconstituent substance (>80% t-DDP, with c-DDP as impurity)
  - **Any objections?**

3. PGM testing programme

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Klaus ROTHENBACHER

3.1. DDP ecotoxicity testing

- Scope
  - Sediment toxicity test (Chironomus, OECD 218)
  - Aquatic toxicity test (Daphnia, OECD 211)
  - DDP difficult to test, extensive prelim. testing required (stability, had to repeat both range finders, etc.)
- Chironomus study completed
  - NOEC > 57 mg DDP/kg
    - 2 range finders conducted
    - Highest achievable spiking rate used
    - Still unbounded NOEC
- Discussion
  - Unbounded NOECs not normally used in RA
  - No possibility for further refinement; we did everything we could
  - Recommend to stop testing at that stage
  - **Any objections?**

3.1. DDP ecotoxicity testing (2)

- Daphnia study
  - More method development needed before study can start
    - Held expert call to discuss/ refine analytical method
    - Fraunhofer currently validating method
    - Main study planned for Q1 2014

3.2. DDP repeated dose testing

- OECD 422 study ongoing at CiToxLAB, HU
  - Extensive method development necessary; work still ongoing
    - Evaluated if formulations are stable over 1d: ✓
    - Conducted palatability study (to evaluate possibility for dosing via diet): ✓
  - Next steps
    - 1. Confirm stability of DDP in the diet over the course of the study (ongoing)
    - 2. Need to conduct extended range-finding study before main test
    - 3. Conduct main study
- Study completion expected Q3/4 2014
- Detailed review of study scheduled at tomorrow's expert meeting

3.3. PGM ecotoxicity testing

- Testing programme on hold due to capacity constraints PMC
- Suggest to start testing in Q1 2014
  - Diammonium sodium hexakis(nitro-N)rhodate
  - Diammonium hexachlororuthenate
  - Dihydrogen hexahydroxyplatinate
  - Diammonium hexachloroplatinate
- CROs
  - Previously agreed to work with Fraunhofer and Brixham
  - Good experience with Fraunhofer (DDP tests)
  - Brixham is closing down = need to find new CRO
  - Currently requesting/ discussing additional quotes
- Next Steps
  - Circulate updated quotes, final recommendation, for approval in November
  - Request/ ship test substances

3.4. PGM irritation/corrosion testing

- Testing programme at BSL completed
  - H_2PdCl_4 remains Cat 1A
  - Classification all other tested PGMs refined from Cat 1A to Cat 1B (incl. PGM-nitrates)
- Additional testing of proprietary materials
  - Was company responsibility
  - Above classifications confirmed
- Please let PMC know if additional tests available

3.5. PGM genotoxicity testing

- Testing ongoing at Covance
  - Palladium (II) di(4-oxopent-2-en-2-oate)
  - Dihydrogen tetrachloropalladate
  - Tetraamminepalladium(II) diacetate
  - Diammonium hexachloropalladate
  - Dihydrogen hexahydroxyplatinate
  - Diammonium sodium hexakis(nitro-N)rhodate
  - Diammonium hexachlororuthenate
- Testing summary: next slides
- TSCA 8(e) notification submitted
  - Dihydrogen hexahydroxyplatinate (mutagenicity)
- Detailed review of testing programme: expert meeting tomorrow

3.5. PGM genotoxicity testing (2)

Substance and Test	Result	Status	Comment
Diammonium hexachlororuthenate (CAS 18746-63-9)			
GLP Ames reverse mutation assay in 5 strains – OECD TG471			Discrepancies in TS description being investigated/confirmed by manufacturer.
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487			
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476			
Dihydrogen tetrachloropalladate (2-) (CAS 16970-55-1)			
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487			
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476			
Tetraamminepalladium(II) diacetate (CAS 61495-96-3)			
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476			
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)			
GLP Ames reverse mutation assay in 5 strains – OECD TG471	Negative	Complete	DMF as vehicle (suspension) . Range finder showed steep tox profile. Max doses for Expt 1 are solutions in DMF. Expt 2 - No evidence of Mutagenicity when tested up to toxic concentrations (9 Aug-13).
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Negative	Complete	DMF as vehicle (suspension) . Range finder showed steep tox profile. Max doses for Expt 1 are solutions in DMF (18 Jul-13). Tested at limit of solubility.
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476		In progress	Max conc. (based on solubility) = 150ug/mL in DMF. Range finder - toxicity at all concs -S9 and above 18.75 +S9. Repeat range finder needed in absence of S9. Sponsor confirmed.
Diammonium hexachloropalladate (CAS 19168-23-1)			
GLP Ames reverse mutation assay in 5 strains – OECD TG471	Negative	Draft report received (29-Oct-13)	Soluble in DMF at 1.1 mg/mL (Sponsor approved 16- Aug-13). RF complete. Doses for Expt 1 (up to 110ug/plate - limit of solubility) approved 3-Sep-13. Expt 1 complete - negative. Expt 2 - negative.
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Negative	Draft report in progress	Soluble in DMF at 1.1 mg/mL . RF complete. Doses for MN Expt up to 11ug/mL - limit of solubility. No toxicity. Study complete. No induction of micronuclei up to 11 ug/mL..
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476			Lab requested to proceed with assay (10/10/13)
Dihydrogen hexahydroxyplatinate (CAS 51850-20-5)			
GLP Ames reverse mutation assay in 5 strains – OECD TG471	Mutagenic	Draft report to Sponsor (14-Oct-13)	Suspension in DMF. Expt 1 - max dose of 5000 ug/plate. Expt 2 - MUTAGENIC - strains TA98 and TA100 (+/- S9), and TA1535 and TA102 (-S9). Queries re C of A analytical compliance resolved (9-Oct-13)
In vitro mammalian cell micronucleus test (chinese hamster ovary) – OECD TG487	Positive	In life complete	Insoluble so changed to CHO hamster cells and 1% methyl cellulose. PA signed 30-Jul-13. Range finder results to Sponsor 14-Aug-13. 2nd range finder 15-Aug-13. Main study showed TS . precipitate and will need to be repeated. Sponsor confirmation for repeat study - 24 Sept. ** Decide on need to repeat 24 hr -S9 expt **
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476			Decide on need for assay once CHO results are known
Diammonium sodium hexakis(nitro-N)rhodate (CAS 64164-17-6)			
GLP Ames reverse mutation assay in 5 strains – OECD TG471			draft protocol to Sponsor 30/20/13. Queries on Cof A & expiry date
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487			draft protocol to Sponsor 30/20/13. Queries on Cof A & expiry date
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476			
Palladadium nitrate (CAS 10102-05-3)			
In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487			
In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476			

3.6. PGM sensitisation testing

- TSCA 8(e) notifications based on test results
  - Diammonium hexachloropalladate
  - Palladium di(4-oxopent-2-en-2-oate)
- Detailed review of testing programme: expert meeting tomorrow
- Testing summary: next slide

3.6. PGM sensitisation testing (2)

Substance	CRO	Result	Status	Comment
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)	CiToxLAB	**Sensitiser** based on RF studies	RF complete	Vehicle AOO. Prelim tox study - 25% & 10% = toxicity, 5% & 2.5% = toxicity. 3rd prelim at 1% and 0.5% to start 21 Aug 2013. Decision to be made about conduct of main study (27 Aug 2013)
Diammonium hexachlororopalladate (CAS 19168-23-1)	CiToxLAB	**Sensitiser**	2nd Draft report sent to Sponsor for review 23- Jul-13.	Max concentration achieved = 50% TS in propylene glycol. Solubility assessed in additional vehicles. Highest solution at 1.1 mg/ml in DMF. LLNA to proceed using suspensions with propylene glycol (50%, 25% and 10%). IR spectroscopy report issued 2-Jul -13 (13-102-929AN). **TS CONTAINS PLATINUM IMPURITIES WHICH MAY HVAE CONFOUNDED RESULT. REPEAT STUDY TO BE CONDUCTED**
Diammonium sodium hexakis(nitrito-N)rhodate (CAS 64164-17-6)	Harlan	Negative	Study complete and results received 19-Sep-13	Max concentration achieved = 25% TS in propylene glycol. IR analysis done in-house. Stability confirmed (23-Jul-13). Main study conducted at 25%, 10% and 5%.
Diammonium hexachlororuthenate (CAS 18746-63-9)	CiToxLAB		TS at LPT. Confirming substance identity	Discrepancies in TS description undergoing investigation/confirmation by manufacturer. Sample shipped back to manufacturer 30-Oct-13.
Repeat study - Diammonium hexachlororopalladate (CAS 19168-23-1)	CiToxLAB		In Life complete	Repeat study - main study only. 50%, 25% and 10% in DMF. Draft comments to SD 22-Aug-13. Start date changed in PA1. Sponsor to confirm that study is complete & report can be written (29 Oct 13)

3.7. PGM acute/repeated dose testing

Substance and test	CRO	Status	Comment
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)			
1. Acute oral toxicity (OECD 425)	CiToxLAB	In progress	Vehicle water (suspension). Protocol signed by Sponsor (27 Aug -13)
Diammonium sodium hexakis(nitro-N)rhodate (CAS 64164-17-6)			
2. Acute oral toxicity (OECD 425)	CiToxLAB		
3. Preliminary repeat dose oral toxicity including	CiToxLAB		
analytical method development and validation	CiToxLAB		Awaiting decision on vehicle
4. Repeated dose oral toxicity – OECD TG407			
5. Reproduction/developmental toxicity screening test – OECD TG421			
6. Combined repeat dose oral toxicity with reproduction/developmental toxicity screening test – OECD TG422			
Diammonium hexachlororuthenate (CAS 18746-63-9)			Received test substance is not as described. Need to ship back to supplier and confirm identity
7. Acute oral toxicity (OECD 425)	LPT		
8. Preliminary repeat dose oral toxicity including analytical method development and validation	LPT		
9. Repeated dose oral toxicity – OECD TG407			
10. Reproduction/developmental toxicity screening test – OECD TG421			
11. Combined repeat dose oral toxicity with reproduction/developmental toxicity screening test – OECD TG422			
Palladium dihydroxide			
12. Preliminary repeat dose oral toxicity including	CiToxLAB		
analytical method development and validation	CiToxLAB		
13. Combined repeat dose oral toxicity with reproduction/developmental toxicity screening test – OECD TG422	CiToxLAB		
Dihydrogen hexahydroxyplatinate (CAS 51850-20-5)			Held pending results of genotoxicity studies at Covance (Ames Positive)
14. Preliminary repeat dose oral toxicity including analytical method development and validation	LPT		
15. Combined repeat dose oral toxicity with reproduction/developmental toxicity screening test – OECD TG422	LPT		
Diammonium hexachloropalladate (CAS 19168-23-1)			
16. Preliminary repeat dose oral toxicity including	CiToxLAB		
analytical method development and validation	CiToxLAB		To proceed with oral route using propylene glycol as vehicle. Need to confirm stability in PG (IR and potentially ICP). Study plan pending.
17. Repeated dose oral toxicity – OECD TG407	CiToxLAB		
18. Reproduction/developmental toxicity screening test – OECD TG421	CiToxLAB		
Diammonium hexachloroplatinate			
19. Preliminary repeat dose oral toxicity including analytical method development and validation	LPT		Draft protocol received 29-Oct-13
20. Repeated dose oral toxicity – OECD TG407	LPT		
21. Reproduction/developmental toxicity screening test – OECD TG421	LPT		
Tetraamminepalladium(2+) dichloride			
22. Preliminary repeat dose oral toxicity including	CiToxLAB		
analytical method development and validation	CiToxLAB		
23. Reproduction/developmental toxicity screening test – OECD TG421	CiToxLAB		
Tetraammineplatinum dinitrate			
24. Preliminary repeat dose oral toxicity including analytical method development and validation	LPT		
25. Reproduction/developmental toxicity screening test – OECD TG421	LPT		

- Studies ongoing at CitToxLAB and LPT
- Testing at LPT
  - Need to reconfirm identity of received Ru compound
  - Suggest to start with AHCPt

4. Current status of PNEC and DNEL refinement

Klaus ROTHENBACHER

4.1. PNEC derivation DDP

Agreed at last meeting on

- Read across strategy (based on Pd2+) – *s. background paper*
- DDP PNECs will apply for all Pd compounds (worst case)
- No need to derive tentative (= uncertain) PNECs/DNELs
- Complete ongoing studies asap and derive robust PNEC
- Will allow to refine ES (e.g., conduct site-specific monitoring)

Timing

- Data from aquatic tox test still pending
- Results expected in Q1 2014 => PNECs can be derived then, and ES can be updated

4.1. PNEC Derivation other PGMs

Other PNECs

- Ecotox studies for other PGMS to be started in Q1 2014
  - Diammonium sodium hexakis(nitro-N)rhodate
  - Diammonium hexachlororuthenate
  - Dihydrogen hexahydroxyplatinate
  - Diammonium hexachloroplatinate
- Results expected from Q2-4 2014 => PNECs can be derived then
- Next Steps
  - Circulate updated quotes, final recommendation for approval in November
  - Likely CRO: Fraunhofer + evt. 1 additional lab
  - Request/ ship test substances

4.2. DNEL derivation

DDP DNEL

- Repeated dose tox. study (OECD 422) ongoing at CiToxLAB, HU
  - Extensive method development work ongoing
- Study completion expected Q4 2014 => DNEL can be derived when study is completed

Other DNELs

- Acute/ repeated dose/ reprotox studies initiated for
  - Palladium (II) di(4-oxopent-2-en-2-oate)
  - Palladium dihydroxide
  - Diammonium hexachloropalladate
  - Tetraamminepalladium(2+) dichloride
  - Diammonium sodium hexakis(nitro-N)rhodate
  - Diammonium hexachlororuthenate
  - Dihydrogen hexahydroxyplatinate
  - Diammonium hexachloroplatinate
  - Tetraammineplatinum dinitrate
- Studies to be conducted at 2 CROs over 2 years

EBRC

4.3. Scope of exposure assessment I/IV

- ESs are required for hazardous substances that are manufactured and/or imported at or above 10 t/a
- Substances m/i above 10 t/a (irrespective of hazardous properties):
  - No iridium substance
  - 2 rhodium substances (rhodium (substance), diammonium sodium hexakis(nitrito-N)rhodate (non-SCC intermediate))
  - 2 ruthenium substances (ruthenium (substance), diammonium hexachlororuthenate (non-SCC intermediate))
  - 8 platinum substances
  - 11 palladium substances (including 3 non-SCC intermediates)

Scope of exposure assessment II/IV

- Definition of “Scope of Exposure Assessment” provided in ECHA guidance*:
  - 35 types of exposure assessment can be considered, for HH:
    - different target groups (i.e. workers, consumers & man via environment)
    - different routes of exposure (i.e. inhalation, dermal, eyes & oral), and
    - different types of effects (i.e. acute & chronic, local & systemic)
  - → exposure assessment/risk characterisation only required if a hazard is identified (assessed for each route/endpoint separately)
  - → scope of exp. assessment to be clarified for PGM substances, taking into account recent guidance

*ECHA Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment (v. 2.1, Dec. 2011, ECHA-11-G-16-EN), in particular Chapter B.8 thereof (Scope of Exposure Assessment)

Scope of exposure assessment III/IV

- Prerequisites for defining the “Scope of Exposure Assessment”:
  - Information on **hazardous properties** of the substance(s) for different routes of exposure (i.e. inhalation, dermal, eyes and oral) and types of effects (i.e. acute and chronic, local and systemic)
- Currently available information (inventory, 29 Oct 2013):
  - **Classification** of aforementioned 23 substances:
    - some have no classification, e.g. Pd
    - some have only ENV classification, e.g. Pd dihydroxide
    - some have only HH classification, e.g. diammonium hexachloropalladate

    → different scopes of exposure

Scope of exposure assessment IV/IV

- Example substance: **DDP**, **classified** as:
  - acute tox. 4 (oral)
  - aquatic chronic 4
  - eye damaging
- However, additional **hazards** not addressed in the overview on the website seem to be identified, e.g.:
  - Inhalation DNEL derived for long-term systemic effects at a relatively low level, suggesting systemic effects by **inhalation** of DDP

→ **Hazards** to be identified by toxicologists, taking into account all relevant information

→ Identification of scope of assessment, taking into account all potential **hazards** of a substance

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PGM Environmental Exposure Modelling, Risk Assessment & Monitoring

Ed Stutt & Adam Peters

Content

- Recap
- Pd sampling programme
  - Rationale for monitoring programme
  - Measurement of partitioning and removal in STP
  - Sediment sampling programme
  - Analytical requirements
  - Provisional costing
- Sampling and monitoring of other PGMs
- Assessment of waste stage

Recap - Generic Exposure Scenario

- Derivation of sector-wide Pd Generic Exposure Scenario (GES)
  - » Sector-wide approach to exposure assessment (consistent and harmonised approach across the industry)
  - » Covers manufacture and use as on-site intermediate for all Pd compounds
  - » GES is therefore not specific to individual palladium compounds, but instead demonstrates whether the emissions from all sources of palladium result in safe use.
- Msafe approach to developing GES
  - » Calculated the tonnage that can be safely processed (manufactured or used) WITHOUT posing a risk to environment (RCR<1)

Msafe GES for DDP manufacture

- ERC 1 (Manufacture of substances);
- Msafe tonnage = 11 tonnes DDP per annum (**5.5 t Pd**)

Compartment	PNEC	PEC	RCR
Discharge to STP (ES 1.1 & 1.3)	1.46 mg/L as Pd(II)	9.9×10^{-5} mg/L as Pd(II)	6.8×10^{-5}
ES 1.1 Freshwater via STP	1.33×10^{-5} mg/L as Pd(II)	9.87×10^{6} mg/L as Pd(II)	0.74
ES 1.2 Freshwater following direct discharge	1.33×10^{-5} mg/L as Pd(II)	1.23×10^{-5} mg/L as Pd(II)	0.92
ES 1.3 Marine water via STP	1.33×10^{-6} mg/L as Pd(II)	8.42×10^{-7} mg/L as Pd(II)	0.65
Terrestrial (all scenarios)	0.0117 mg/kg as Pd(II)	1.89×10^{-3} mg/kg as Pd(II)	0.16
Air (MvE) (all scenarios)	0.5 µg Pd/m³	1.3×10^{-3} µg Pd/m³	3.1×10^{-3}

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Results of site-specific risk assessment

Site Ref	Receiving water body	Release factor to water	RCR STP	RCR Receiving water body	RCR Receiving water body sediment	Release factor to air	RCR Local Air	RCR Local soil (no sludge)
		g/T				g/T		
Site A	Freshwater via STP	5.8	3.00×10^{-7}	0.0528	**1.50**	1.1	1.1×10^{-5}	0.161
Site B	Freshwater via STP	109.5	4.41×10^{-4}	**45.0**	**451**	300	1.5×10^{-2}	0.163
Site C	Freshwater via STP	0.9	2.03×10^{-7}	0.0513	**1.48**	300	4.6×10^{-3}	0.162
Site D	Freshwater via STP	62.5	2.71×10^{-5}	0.327	**4.23**	300	7.3×10^{-3}	0.162
Site E	Freshwater	25.3	NR	0.084	**1.81**	61.0	1.7×10^{-3}	0.161
Site F	Freshwater via STP	0.2	5.17×10^{-9}	0.0493	**1.46**	158	1.4×10^{-4}	0.161
Site G	Marine water	68.2	NR	**21.2**	**208**	300	4.1×10^{-3}	0.162
Site H	Freshwater via STP	68.2	3.39×10^{-7}	0.0527	**1.50**	300	5.6×10^{-3}	0.162
Site I	**No emissions**							
Site J	Freshwater via STP	357.1	1.13×10^{-4}	**1.20**	**13.0**	300	9.7×10^{-3}	0.162
Site K	Freshwater via STP	833.3	9.04×10^{-4}	**9.29**	**93.9**	300	3.3×10^{-3}	0.162
Site L	Freshwater via STP	78.0	1.63×10^{-6}	0.0659	**1.63**	300	5.6×10^{-4}	0.161
Site M	Freshwater via STP	68.2	9.25×10^{-5}	0.995	**10.9**	300	5.6×10^{-4}	0.161
Site N	Marine water via STP	180.0	5.55×10^{-4}	**5.05**	**50**	300	5.6×10^{-3}	0.162

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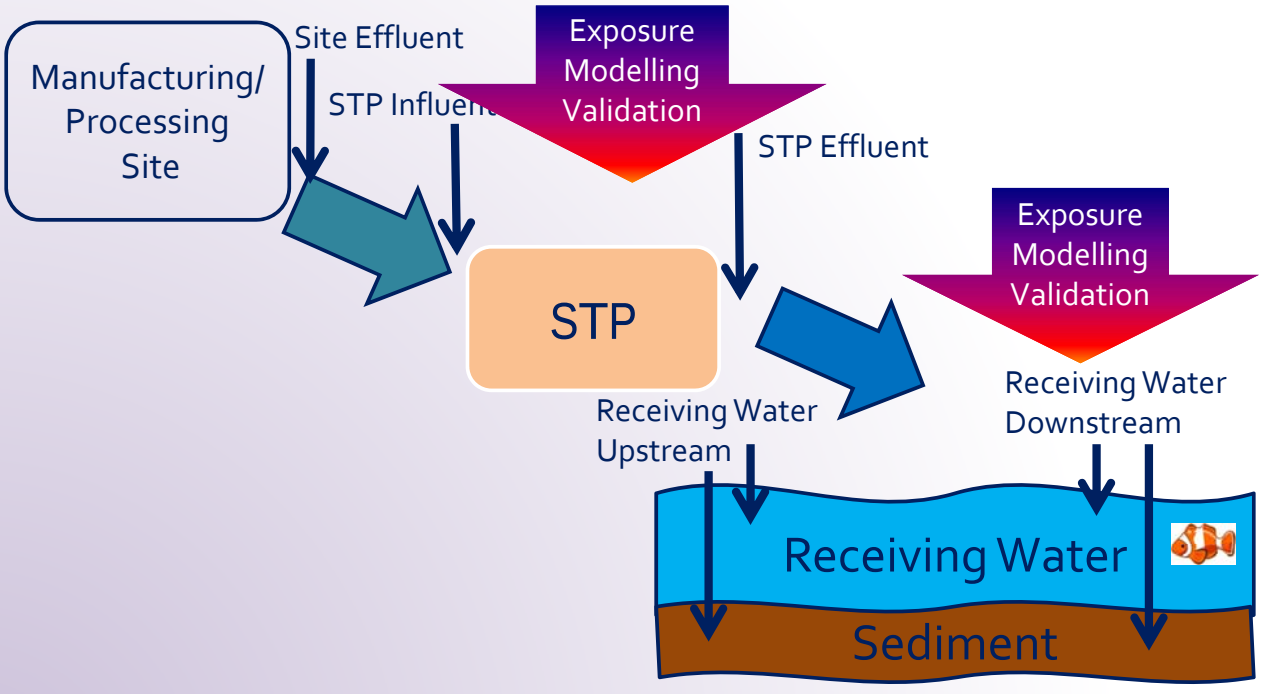
Rationale for Monitoring Programme

- Where aquatic and sediment RCRs >1 there will be a requirement to undertake monitoring to demonstrate safe production/use (based on revised PNECs)
- Current aquatic exposure estimates are based on:
  - » the quantities of Pd substances produced and emissions data from the site (known)..... +
  - » Numerous assumptions on environmental fate and behaviour of Pd (and for some sites, dilution in receiving water body)
- Exposure can be refined on the basis of monitoring for:
  - » Pd removal rate in STP (sector initiative)
  - » Concentrations in receiving water body and sediment downstream of discharge (site specific)

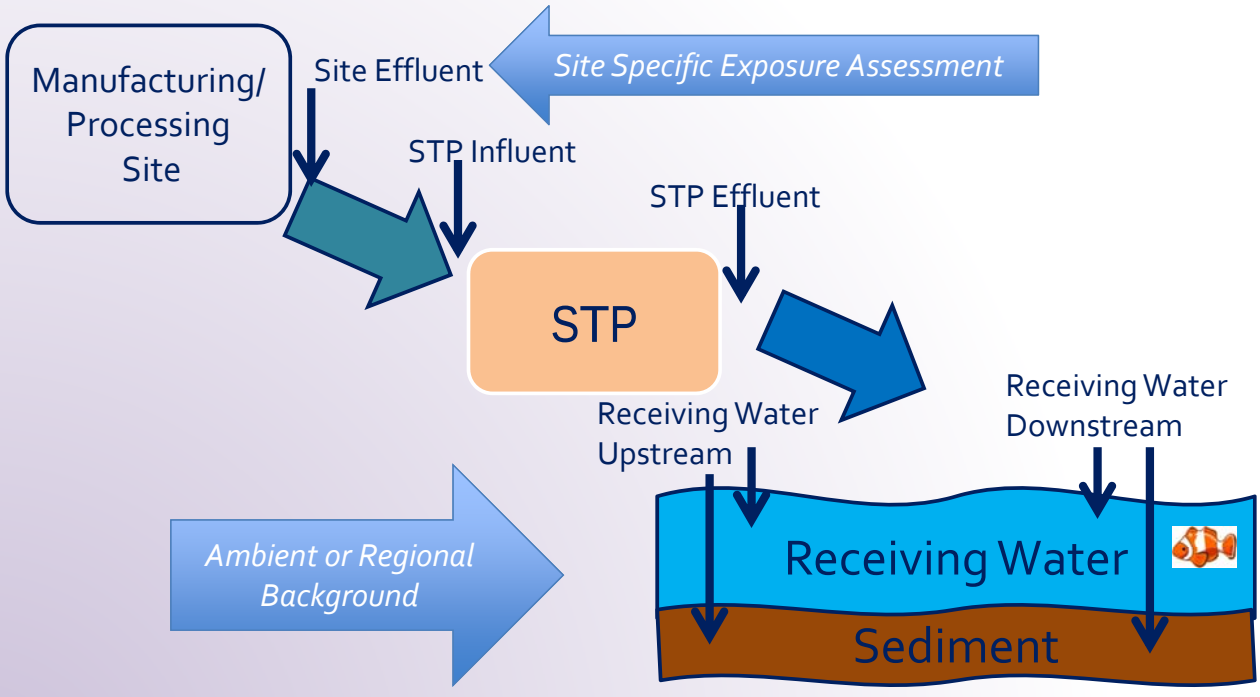
Required Monitoring Points



Rationale for Monitoring Programme

- Additional information can be provided from measurement of:
  - » Site effluent concentration (on the basis of lower LoD)
  - » Concentrations in receiving water body and sediment upstream of discharge (ambient or regional background)
  - » Supporting parameters such as pH, dissolved organic carbon (DOC), calcium (or hardness) and conductivity
- Non-essential 'desirable' monitoring points can be sampled less frequently

Desirable Monitoring Points



Pd Removal in STPs

- No quantification for removal rate of Pd in sewage treatment plants (STPs)
- STP removal rate in current exposure assessment estimated from information on partitioning to suspended particulate matter
  - » controlled by partitioning to organic carbon
- Significant uncertainty regarding this assumption
- Removal rate can only be quantified by measuring Pd in sewage influent and effluent

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Monitoring Pd Removal in STPs

- Recommended that a monitoring programme be undertaken at STPs that are receiving discharges from palladium operations
- Conditions (and removal rates) can vary between STPs and over time

➢ 2 sampling regimes at 3 STPs

➢ Use average removal rate in exposure assessment

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Site Specific Monitoring Programme

- Regular sampling for receiving water body
- Prolonged time period (minimum 6 months)
- Monitoring paper circulated in last week
- Sampling recommendations tailored to processes operating on site (e.g. batch or continuous)
- Accounting for variation in time and conditions (i.e. daily sampling over a week on two occasions)
- Sample collection undertaken by site operatives and handling fully recorded

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Sediment Sampling Programme

- Sediment samples do not need to be measured with the same frequency as aqueous samples
  - » Several samples x2 per year
- Preferable that all sediment samples are taken in the same way
  - » Recommended that one company is used to take sediment samples from all sites
  - » Consistency and some cost-saving if commissioned as a European sampling project
  - » ExCal consultancy recommended for sediment sampling programme on the basis of accreditation and price

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Analytical Considerations

- $PNEC_{Aqua}$ currently 13 ng l^{-1} (as dissolved Pd)
  - » Equivalent to 26 ng l^{-1} as DDP
- Quantitation limit not more than 3.9 ng l^{-1} (Pd)
  - » Achievable at some labs (but not many)
- $PNEC_{Sed}$ currently 14.5 µg kg^{-1} (wwt, Pd)

- Adequate detection limits are relatively difficult to achieve
- Numerous laboratories approached to provide analytical capabilities and cost

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Analytical Considerations

- Only 2 laboratories could achieve adequate LoQ and LoD
- Environmental Sciences Group (ESG) were considerably cheaper and are recommended for analysis of all samples
  - » Additional PGMs can be measured at minimal additional cost (€5.50 per metal per sample)
  - » UK based so this will involve transport costs

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Approximate Costings

- Excluding transport costs (for samples and samplers!)
- STP monitoring programme: >€5.5k (shared)
- Site-specific monitoring programme:

— ***minimum*** analytical costs of €7k for continuously operating site and €4k for batch processing site (total and dissolved Pd only in downstream receiving water)

— considerably more if also sampling site effluent and analysing for supporting parameters

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Other precious metals

- Minimal additional cost to analyse for additional precious metals (Rh, Pd, Ag, Pt, Au, etc. as appropriate for the site concerned)
- Freshwater and sediment PNECs for other precious metals may be similarly low as for Pd...to be confirmed with on-going test programme
- Exposure data for other PGMs to be collected in the new year

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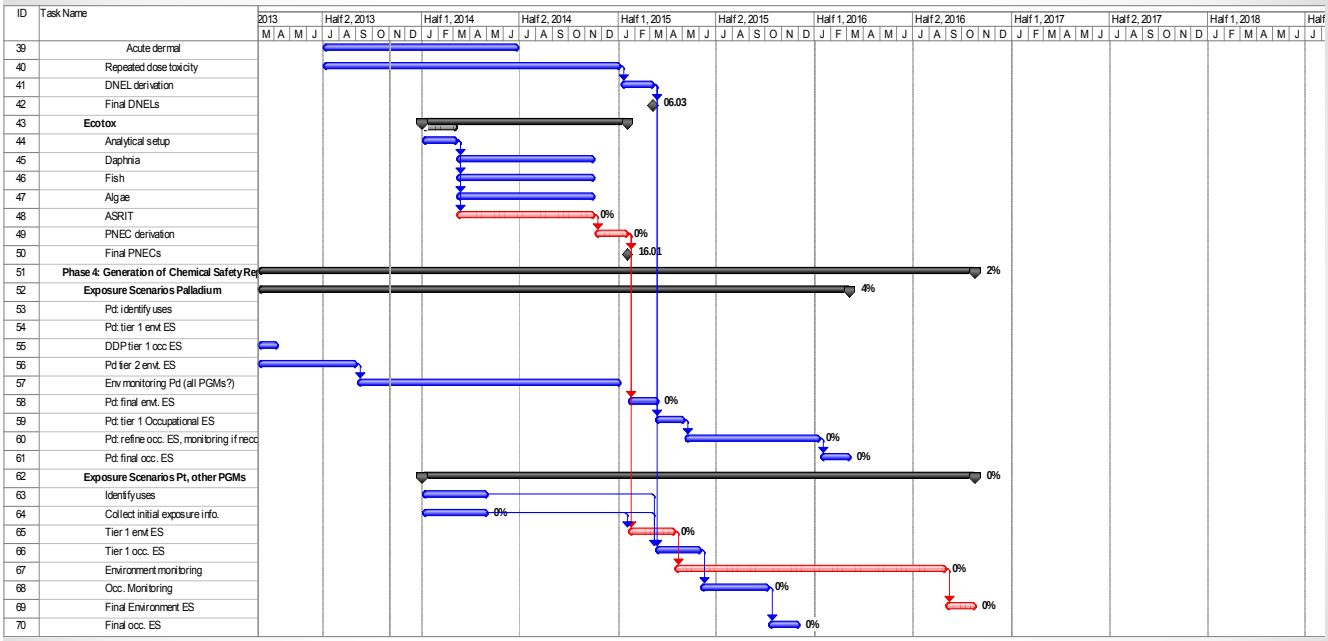
Timing planning other PGMs: "Textbook scenario"



If done sequentially, env. monitoring (Pt, other PGMs) can only start in 2015, and will be time critical (red bars)

Timing planning other PGMs

Ideal workflow *("textbook scenario")*

- Ecotox testing
- Derive PNECs
- Launch monitoring programme other PGMs
- Env. monitoring (Pt, other PGMs): will be time critical (red bars)

Pragmatic approach proposed

- Combine other PGMs with Pd monitoring programme
- LODs: as low as technically feasible = should cover PNECs
- Sites: WCA to make proposal based on existing data

Assessment of waste

- Basic information on waste needs to be included for all tonnage bands - a waste exposure assessment is now required in the CSR for substances >10tpa.
- Requirement for several exposure scenarios based on different waste options identified (e.g. Recycling and landfill)
- ECHA Guidance R18 details default release fractions for waste stages
  - » Input to EUSES modelling

Assessment of waste (recycling)

- Recycling of metals is considered to be a thermal treatment as a default.
  - » *Default EF for air = 0.005*
  - » *Default EF for water = 0.00005*
- Assuming 1000 t of Pd containing waste for recycling, with an average Pd content of 0.1%, (i.e 1 tpa)
- Input to EUSES modelling

Compartment	RCR
Surface water	0.039
Freshwater sediment	0.39
Marine water	0.18
Marine sediment	1.8
STP	3.4×10^{-6}

Assessment of waste (landfill)

- Assumption that 1000 tonnes of solid waste are produced at a single site & sent to landfill for disposal. The concentration of palladium in the waste is 1 g/T (fraction of Pd in waste = 0.00001).
- Default EF = 0.032
- Input to EUSES modelling

Compartment	RCR
Surface water	0.0388
Freshwater sediment	0.388
Marine water	**3.16**
Marine sediment	**31.6**
STP	1.5×10^{-6}

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Assessment of waste

- Metal specific refinement of waste exposure scenarios with values from literature (precedents from Ag waste exposure scenarios)
- Site-specific exposure assessment
  - » Needs monitoring data to be provided

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6. Occupational exposure Pd and Pd compounds

Daniel VETTER
Jutta SCHADE

DDP – status update

- Refinement of Occupational ES on hold until further information is available:
  - 2 additional dustiness tests → draft report of 1 dustiness test received, 2nd test not yet conducted
  - Clarification on drying of DDP → site visit conducted during which this question was clarified among others
  - Final DNEL report → relevant study on-going

(Other) Pd substances – status update

- Occ. exp. Q. & submission form for inhalation monitoring data for 12 Pd substances manufactured/ imported at or above 10 tonnes per year circulated in 2012
  - Quality check done over summer
  - Emails send for further clarification → awaiting response from 1 company
  - Manufacturers were asked to provide short process overviews for manufacturing processes to indicate chronological order of activities → awaiting responses from multiple companies
  - Since information above and on hazard profiles is not yet complete and to avoid duplication of work: wait for finalisation of DNELs and conclusive hazard assessment to develop occ. ES

7. Launch of use and exposure/ emission data collection for other PGMs

Klaus ROTHENBACHER
Katrien ARIJS

7.1. Pt and Pt substances – status update

- First set of occ. exposure monitoring data received
  - First evaluation of data set done, evaluation/clarification on-going
  - Currently, only a subset may be suitable for use in REACH ES
  - Questionnaire on identified uses to be launched for all substances (for inclusion in IUCLID Section 3.5 and for potential development of ES for hazardous substances m/i ≥10 t/a)
- Development of occ. exp. questionnaire and submission form for additional inhalation monitoring data based on initial information, e.g.:
  - Results from dustiness tests
  - Information on identified uses
  - Site visits/process overviews provided by industry experts

7.2. Timing planning other PGMs - Scope

PMC Indicative List

Name of the substance	CAS	Highest tonnage band*	Classification notified (Feb 2012)
Platinum (solid only)	7440-06-4	10-100 t/a	None
Hexachloroplatinic acid	16941-12-1	10-100 t/a	Acute tox. 2 (H300) (oral)*** Skin corr. 1B (H314) Skin sens. 1B (H317) Eye dam. 1 (H318) Resp. Sens. 1A (H334) Aquatic acute 1 (H400) Aquatic chronic 1 (H410) Met. Corr. 1 (H290) Acute M-factor 10 Chronic M-factor 10
Tetraammineplatinum dinitrate (in solution)	20634-12-2	10-100 t/a	Self-reactive Type A (H240) Skin Irrit. 2 (H315) Eye Dam. 2 (H319) EUH001: Explosive when dry*** EUH044: Risk of explosion if heated under confinement*** Aquatic chronic 3 (H412)
Dipotassium hexachloroplatinate (solid only)	16921-30-5	10-100 t/a	Acute tox. 3 (H301) (oral) Skin sens. 1B (H317) Eye dam. 1 (H318) Resp. Sens. 1A (H334) Met. Corr. 1 (H290) Aquatic acute 1 (H400) Aquatic chronic 1 (H410) Acute M-factor 10 Chronic M-factor 10
Platinum dinitrate	18496-40-7	10-100 t/a	Oxid. Liq 3 (H272) Skin Corr. 1A (H314) Eye dam. 1 (H318) Met. Corr. 1 (H290)
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (in solution)	68478-92-2	10-100 t/a	Flam. Liquid 2 (H225) Aquatic Chronic 4 (H413)

7.2. Timing planning other PGMs - Scope

Name of the substance	CAS	Highest tonnage band*	Classification notified (Feb 2012)
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate (in solution)	68478-92-2	10-100 t/a	Flam. Liquid 2 (H225) Aquatic Chronic 4 (H413)
Diammonium hexachloroplatinate	16919-58-7	10-100 t/a	Acute tox. 3 (H301) (oral) Skin sens. 1B (H317) Eye dam. 1 (H318) Resp. Sens. 1A (H334) Met. Corr. 1 (H290)
Dihydrogen hexahydroxyplatinate (solid only)	51850-20-5	10-100 t/a	Eye Irrit. 2 (H319)
Palladium (solid only)	7440-05-3	10-100 t/a	None
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	10-100 t/a	Acute Tox. 4 (H302) (oral) Skin Corr. 1A (H314) Skin Sens 1A (H317) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Met. Corr. 1 (H290) Acute M-factor 10 Chronic M-factor 10
Diamminedichloropalladium	14323-43-4	10-100 t/a	Acute Tox. 4 (H302) (oral) Aquatic Chronic 4 (H413) Eye Dam 1 (H318)
Palladium (II) di(4-oxopent-2-en-2-oate) (solid only)	14024-61-4	10-100 t/a	Flam. Solid 1 (H228) Self heat. 1 (H251) Aquatic Chronic 4 (H413)
Palladium monoxide (solid only)	1314-08-5	10-100 t/a	None
Tetraamminepalladium(2+) dichloride	13815-17-3	10-100 t/a	Acute Tox. 4 (oral) (H302) Skin Sens 1A (H317) Eye Dam. 2 (H319) Aquatic acute 1 (H400) Aquatic Chronic 1 (H410) Met. Corr.1 (H290) Acute M-factor 1 Chronic M-factor 1

7.2. Timing planning other PGMs - Scope

Name of the substance	CAS	Highest tonnage band*	Classification notified (Feb 2012)
Tetraamminepalladium(2+) diacetate (in solution)	61495-96-3	10-100 t/a	Acute Tox. 4 (H302) (oral) Skin Sens 1A (H317) Eye Dam. 2 (H319) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Acute M-factor 1 Chronic M-factor 1
Palladium dinitrate (in solution)	10102-05-3	10-100 t/a	Acute Tox. 4 (H302) (oral) Skin Corr. 1A (H314) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Met. Corr. 1 (H290) Acute M-factor 10 Chronic M-factor 10
Palladium dihydroxide (solid only)	12135-22-7	10-100 t/a	Aquatic Chronic 4 (H413)
Diammonium hexachloropalladate (solid only)	19168-23-1	10-100 t/a	Acute Tox. 4 (H302) (oral) Skin Irrit. 2 (H315) Eye Dam. 1 (H318)
Dipotassium hexachloropalladate (solid only)	16919-73-6	10-100 t/a	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Dam. 1 (H318)
Rhodium (solid only)	7440-16-6	10-100 t/a	None
Diammonium sodium hexakis(nitrito-N)rhodate (solid only)	64164-17-6	10-100 t/a	Oxid. Solid 3 (H272) Self heat. Cat. 1 (H251)
Ruthenium (solid only)	7440-18-8	10-100 t/a	None
Diammonium hexachlororuthenate (solid only)	18746-63-9	10-100 t/a	Eye Dam 1 (H318)

All our PGMs >10 tpa, except metals and PdO, are classified

7.2. Timing planning other PGMs

Ideal workflow *(in that order)*

- Hazard assessment
- Classification; Scope of exposure assessment
- Exposure assessment (EA) 1st tier
- Monitoring (if required)
- Exposure assessment (EA) 2nd tier

7.2. Timing planning other PGMs

Ideal workflow (in that order)

• Hazard assessment	by Q1 2015
• Classification, Scope of EA	Q1/2 2015
• Exposure assessment (EA) 1st tier	Start Q1/2 2015
• Monitoring (if required)	Start Q2/3 2015
• Exposure assessment (EA) 2nd tier	By end 2016?

7.2. Timing planning other PGMs

Ideal workflow (in that order)

• Hazard assessment	by Q1 2015
• Classification -> scope of EA	Q1/2 2015
• Exposure assessment (EA)	Start Q1/2 2015
• Monitoring	Start Q2/3 2015
• Exposure assessment (EA) 2nd tier	By end 2016?

Pragmatic approach proposed

- All PGMs >10 tpa (except metals and PdO) are classified
- Assume EA needed for all of them
- Start collecting information in Q1 2014 (uses, env/ occ emissions, OC, RMMs, etc.)
- Conduct testing programme/hazard assessment in parallel
- Launch EA after completion of hazard assessment
- Additional monitoring (env./ occ.) to refine EA may be necessary
- **Any objections?**

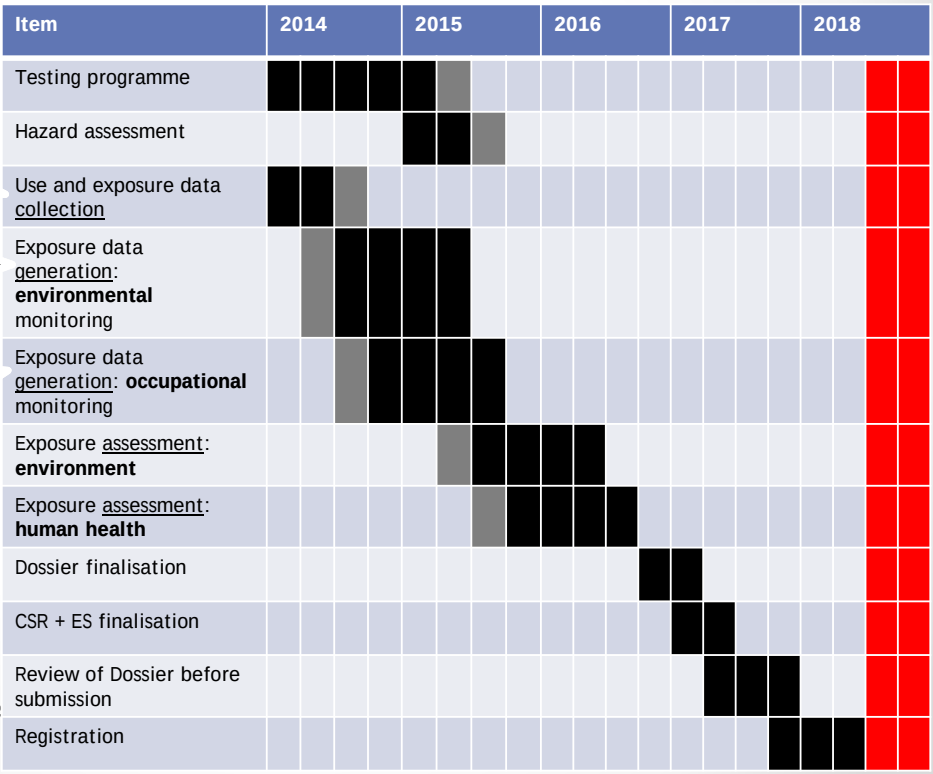
7.2. Timing planning other PGMs

Assumed to take place in parallel (use and exposure) and for al PGM

Need to decide whether to proceed with Pd first, and then other PGM (once PNECs known), or all PGM in parallel (using lowest LoD for all)

After IPA's Pt exposure dataset has been checked, determine for which PGM monitoring is needed

Other PGM besides Pt and Pd
=
2 Rh and 2 Ru compounds



8. AOB, next meetings/calls and closing remarks

8.1. Use of standard phrases

- Currently: extensive ES used in CSR to explain all details to regulators = not very user-friendly
- Standard phrases would make communication with DU easier
  - Currently: many companies need to translate manually to their prop. systems
  - Time/ resource intensive
- EM Project Standard Phrases
  - Planned for 2014
  - Build on existing catalogues (EUPHRAC or EsCom)?
  - Use CHESAR as reporting tool for stand. phrases

8.2. Use of CHESAR

- Other Functionalities
  - integrate the substance properties from IUCLID
  - confirm when no ES is needed, only qualitative ES, etc.
  - reflect complex life cycle trees
  - conduct and/or report on exposure assessments
  - generate Sections 9 and 10 of the CSR
  - generate ES for communication
  - harmonise ES information through a determinant library
  - export information to IUCLID via CSR-plugin
- Currently under evaluation by EM ES working group

Advantages of the use of Chesar

- ECHA's official "Chemical Safety Assessment and Reporting" tool
- Automated completion of IUCLID Section 3.5 based on life cycle tree defined:
  - Feasibility to nominate PROCs multiple times in an occ. ES
- "Scope of assessment" defined by Chesar
- Automated generation of IUCLID Section 3.7
- Facilitating the use of standard phrases for ES for eSDS
- Automated generation of ESs for CSR and eSDS
- Avoidance of updating partly redundant documents: ES for CSR, ES for eSDS, Sections 3.7

8.4. TSCA 8(e) notifications

- TSCA 8(e)
  - US process (US EPA)
  - Requirement to notify any 'significant new information' within 30d
- PGM testing programme generating significant amount of new data
- PMC submitting TSCA 8(e) notifications on behalf of its members
- Recent notifications
  - Dihydrogen hexahydroxyplatinate (mutagenicity)
  - Diammonium hexachloropalladate (sensitisation)
  - Palladium di(4-oxopent-2-en-2-oate) (sensitisation)

Thank you!