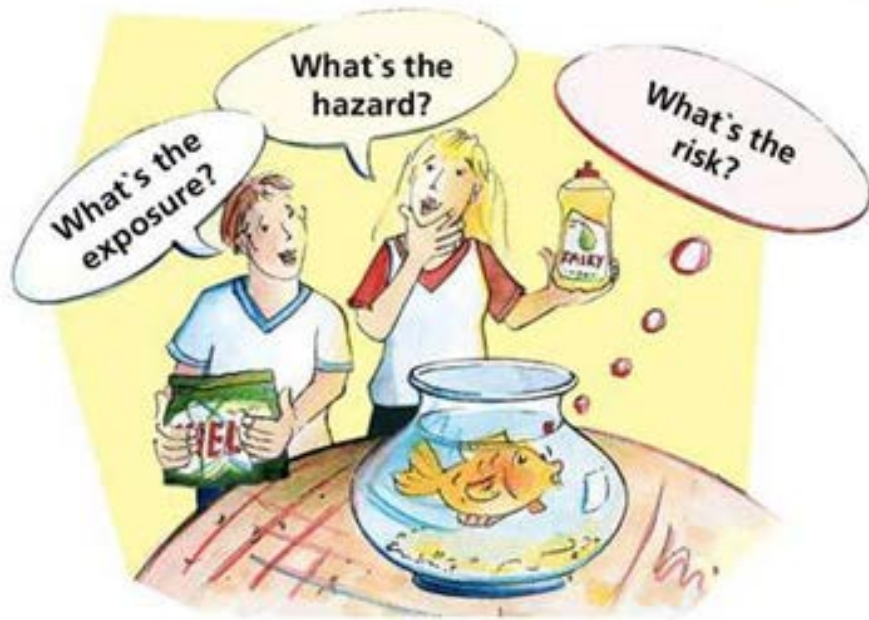




PGM Project Exposure Scenario Meeting

Brussels, 19 June 2013





1. Welcome & Introduction

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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 (12 December 2012)





Agenda

1. Welcome and introduction
2. Substance identification, sameness and tonnage of Pd substances
3. Final identified uses of Pd and Pd compounds
4. PGM testing programme
5. Current status of PNEC and DNEL refinement for DDP
6. Environmental emissions of Pd and Pd compounds
7. Occupational exposure scenarios for DDP
8. Next steps and timeline for dossier submission
9. AOB, next meetings/calls and closing remarks
10. *Optional: 1-to-1 sessions with WCA for those company representatives having queries on their site-specific environmental assessment*



Actions 12 December (1)

Action	Who?	Status
<i>Substance identification and sameness Pd substances</i>		
Circulate updated versions of the ID cards of prioritised PGMs	KA	Ongoing
Clarify outstanding issues on sameness of PGM nitrates	KA/KR with input from experts & PMC Members	Ongoing
<i>Identified uses of Pd and Pd compounds</i>		
Clarify remaining issues on uses with PMC Members (with focus on DDP first)	WCA	Done
Send input / comments on uses to WCA	PMC Members	Done
Once finalised, send list of Pd uses to downstream users clearly stating that non-reported uses may not be authorised and indicating that this is their last chance to respond (with deadline for response two weeks later)	PMC Sec through PMC Members	Done
Send input / comments on uses to PMC Sec	DUs through PMC Members	Done
<i>Environmental emissions of Pd and Pd compounds</i>		
If not done yet, send available data to WCA on: • Pd emissions to air; • Flow rate of receiving water bodies; • Process flow diagram indicating annual tonnage values for Pd processing starting materials, intermediates and final products.	PMC Members	Done
Refine Generic Exposure Scenario (GES) and site-specific risk assessment (SSA) for Pd and Pd substances based on extra data provided	WCA	Done
Based on results of the GES and SSA, decide whether or not there is a need for substance-specific refinement	WCA	Ongoing



Actions 12 December (2)

Action	Who?	Status
<i>Environmental emissions of Pd and Pd compounds (continued)</i>		
Based on results of the SSA, follow up need for monitoring programme with individual sites	WCA	Recommended for some sites in SSRA
Conduct additional testing for DDP to refine the PNECs (sediment toxicity test and aquatic toxicity test)	CRO through PMC Sec	Ongoing (results Jul 2013)
PNEC refinement	WCA	Aug-Oct 2013
<i>Occupational exposure of Pd and Pd compounds</i>		
Clarify remaining issues on occupational exposure and on monitoring data with PMC Members and further refine/update GES for DDP	EBRC	Done
Select 3 damp DDP solids with different known water content and perform dustiness testing	PMC Sec	Ongoing
Reflect results of the additional dustiness testing in the ES for DDP	EBRC	Ongoing
For each activity class, add a description of the involved tasks and a short name in the ES	EBRC	Done
<i>DNEL for diamminedichloropalladium (DDP)</i>		
Repeat RDT study (OECD TG422 combined toxicity/reproductive screen study) for DDP for final DNEL derivation	PMC Sec/ CiToxLAB	Ongoing (results Sep 2014)
DNEL refinement	WCA	Oct-Nov 2014
Check inhalation exposure data to see if peak exposures are relevant	EBRC	
<i>DDP dossier submission</i>		
Submit DDP registration dossier with tentative RMMs	PMC Sec/WCA	Dossier will be submitted with refined PNECs/DNELs early 2015
Update DDP registration dossier following PNEC refinement	PMC Sec/WCA	



2. Substance identification, sameness and tonnage of Pd substances

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Klaus ROTHENBACHER

Katrien ARIJS



2.1. ID cards

- ID cards have been circulated for prioritised PGM substances
- Aim
 - Clarify issues physical state/properties
 - Support the substance sameness discussions & other mandatory communication obligations with the SIEF (e.g. PdCl_2 in aq. HCl vs. H_2PdCl_4)
- Several questions still remain on the **physical state** and **composition** of some substances
- **Questionnaire** sent
 - To prepare substance sameness discussions
 - To help us decide how to properly register different forms of the same substance
 - Input to be used to further complete the ID cards
 - **Deadline today**





Questionnaire physical forms

COMPANY DATA															
Legal entity/site name:															
Contact person:															
Address:															
Tel:															
e-mail:															
Date of questionnaire completion:															

Substance	Manufactured as		Tonnage band		Description manufacturing process		Typical ratio of isomers (if applicable)	Solid		Solution			Method used to measure the composition/purity		Remarks
	Solid	Solution	Solid	Solution	Solid	Solution		Purity range (%)	Hydrated/anhydrous form	Concentration range of substance in solution (%)	Solvent	pH of solution	Solid	Solution	
Au - Tetrachloroauric acid															
Pd - Diammonium hexachloropalladate															
Pd - Dipotassium hexachloropalladate															
Pd - Palladium di(4-oxopent-2-en-2-oate)															
Pd - Palladium dihydroxide															
Pd - Palladium dinitrate															
Pd - Palladium sulphate															
Pd - Tetraamminepalladium(2+) dichloride															
Pd - Tetraamminepalladium(2+) diacetate															
Pt - Diammonium hexachloroplatinate															
Pt - Dihydrogen hexahydroxyplatinate															
Pt - Dihydrogen hexahydroxyplatinate, 2-aminoethanol															
Pt - Platinum dinitrate															
Pt - Tetraammineplatinum dinitrate															
Re - Perrhenic acid															
Rh - Dirhodium trisulphate															
Rh - Rhodium trinitrate															
Ru - Ruthenium trichloride															
Ru - Tris(nitrato-O)nitrosylruthenium															



2.2 Sameness

PGM nitrates

- Expert meeting 11th December 2012
- No sameness concluded between solution and solid of
 - o Platinum nitrate
 - o Rhodium nitrate
- Additional analyses/spectra requested (done)
- To be discussed at next expert meeting (date tbd)



2.2 Sameness

Implication on testing programme

- Sameness is pre-requisite for testing
- Genotoxicity
 - Testing of **Platinum nitrate** on hold until sameness discussion concluded
 - **Palladium nitrate** can now be added to gene. tox. scope
 - **Rh(III) genotoxicity**: conflicting results of existing tests
 - Rh(III) nitrate: no genotoxicity found; 'solid Rh nitrate' tested
 - Other Rh(III) substances: genotoxic effects found
 - Interpretation on hold until sameness discussion Rh nitrate completed
 - **Sameness crucial for testing programme**



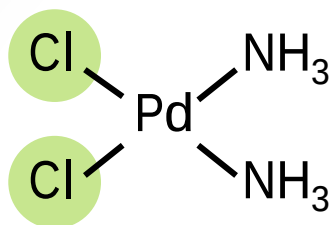
2.2 Sameness

DDP

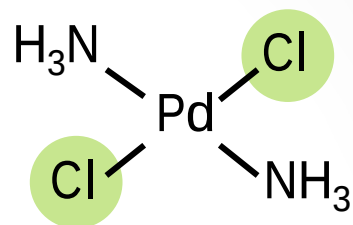
- o Consists of different isomers (cis/ trans/ others?)
- o PGM WG agreed on one CAS #: 14323-43-4
- o Need to discuss implications on
 - Sameness
 - Registration strategy
 - Read across strategy (agenda point 5.1)



DDP isomers



cis



trans

- Isomer Ratio
 - o Not all registrants measured/provided input on ratio of isomers
 - o Those that did provide input: trans major
- All registrants are asked to measure & report ratio of isomers to decide on identification strategy



Isomers: registration under REACH

- REACH requires the registration of the **manufactured substance**. If a multi-constituent substance is produced, it has to be registered as such (unless it is covered by a registration of the individual constituents); e.g. a mixture (reaction mass) of two isomers formed during the manufacturing reaction.
 - Case by case decision to establish to what extent the different steps conducted while producing the substance are covered by the definition of 'manufacturing'.
- If an isomer mixture is registered as a multi-constituent substance, there is no need to **test** the substance as such, if the hazard profile of the substance can be sufficiently described by the information of the individual constituents.
- A registration of a multi-constituent substance does not cover the individual constituents



Isomers: options for ID/registration

- **Mono-constituent substance**

- o If main constituent *typical* content > 80%
- o “**Trans-DDP**” with cis-DDP as impurity

- **Multi-constituent substance**

- o Main constituents $\geq 10\%$ and $< 80\%$
- o “**DDP**” (unspecific IUPAC name acceptable if all isomers present as main constituents, i.e. $\geq 10\%$ but $< 80\%$)
- o (“Reaction mass of ...” if not all isomers present $\geq 10\%$)

- If composition very variable across registrants (e.g. isomer sometimes present as $\geq 10\%$ and sometimes $< 10\%$)

- o Register different qualities separately -> multiple registrations
- o One registration as a mono-constituent substance with sub-qualities deviating from the 80% rule (justification needed)
- o One registration as a multi-constituent substance with some constituents deviating from the 10-80% rule (justification needed)

- Discuss at next sameness expert meeting?



Sameness of solids vs. solutions

- PMC testing strategy
 - o Representative reference substance (mostly from LR)
 - o Test solid form if possible
 - o But sameness required
- Sameness is pre-requisite for testing
 - o No sameness = no extrapolation solid $\leftrightarrow$ solution
 - o PMG nitrates: currently no sameness of Pt and Rh nitrate solution vs. 'solid'
 - Important to clarify: e.g., see conflicting test results Rh genotoxicity
 - o PMG chlorides, - sulphates: sameness not clear
- Irritation testing: PMC recommendation to test both solids and solutions, if sameness not clear

Precious Metals and Rhenium Consortium

Sameness discussions

Introductory slide set aiming at obtaining a view
on the situation by the PGM WG

19 June 2013

Background

- **Dec 2010:**
 - In Dec 2010 some “pure” PM compounds were notified under CLP as skin corrosive 1A, primarily based on low pH.
 - Some of the PM compounds exist as substance as well as dissolved in diluted acids, wherein the acid acts as solvent/stabilizer.
- **Dec 2012**
 - Under the assumption that the acidic solutions are considered as mixtures, the classification by using the respective mixture rules for CLP and transport regulation and on the basis of already existing classifications of single components leads to divergent results.
 - Though original classifications were primarily based on low pH, it was suggested to actually test “pure” skin corrosive 1A substances to confirm/refine classification.
- **Jan 2013:**
 - PM compounds with more than one existing version (solid vs dissolved vs acidic solution, more or less concentrated) under the same EC number (and sometimes under different CAS numbers) were associated to ‘sameness’ discussions under PGM project.
 - PGM WG meeting agreed to test both solids and liquids for which a skin corrosion 1A classification needed to be demonstrated, including perhenic acid
- **Feb 2013:**
 - Testing programme was launched with companies requested to provide samples of solid and liquid
- **March 2013:**
 - Concern that testing both solid and liquid (mixture ?) will remove any flexibility to read-across from classification of solid (1B, hence packaging group II) and acid solvent in defined concentration (1A in pure form but packaging group II) to hopefully arrive at a more practical packaging group II

'Sameness' context and associated Registration options

Type	Description of PM compounds	Composition	Physical Form	REACH status	REACH Registration /CLP notification option 1	REACH Registration /CLP notification option 2
1	Reaction mass (the "solution") Compound, dissolved in diluted acid as a result of a chemical reaction	Compound (ion or complex species) + solvent/stabilizer in various concentration ranges	Liquid	UVCB substance	Register dissolved species as composition ID 2 of compound Type 2 and report solvent as stabiliser.	Register as compound Type 1, where solvent can be reported either as a stabiliser or as a constituent?
2	Compound, isolated from reaction mass Type 1	Compound (in hydrated or anhydrous form)	Solid	Mono-constituent substance	Register isolated species as composition ID 1	Register as compound Type 2
3	Compound Type 2, intentionally re-dissolved in diluted acid	Compound (ion or complex species) + solvent/stabilizer in various concentration ranges	Liquid	Mixture	Out of scope, not to be registered	Out of scope, not to be registered

Pros and cons of each Registration option

Registration option	Pros	Cons
1 Register dissolved and solid form together	• One dossier for all forms of the same chemical substance • Read-across easier to justify if within one same substance (double testing to validate read-across not excluded)	• Need to demonstrate same (varying) speciation • Duplicate testing for some endpoints to be diligent?
2 Register solution and solid form separately	• Sameness check simpler • Does not prevent reading-across from one another?	• Two dossiers: one for the solid form (= Mono const. subst.) and one for the solution (= UVCB) • Read-across from one another acceptable? Double testing? Expert judgement? • Triggers need for two EC numbers • Need to define each substance as well as possible to draw a line between the two

'Sameness' context and associated (skin corrosion) testing options

Type	Description	Composition	Physical Form	REACH status	Testing option 1	Testing option 2
1	Reaction mass (the "solution") PM compound, dissolved in diluted acid as a result of a chemical reaction	Compound (ion or complex species) + solvent/stabilizer in various concentration ranges	Liquid	UVCB substance	Test compound Type 1	Do not test and read-across from compound Type 2 applying mixture rule or expert judgement
2	PM compound, isolated from reaction mass Type 1	Compound (in hydrated or anhydrous form)	Solid	Mono-constituent substance	Test compound Type 2	Test compound Type 2
3	PM compound Type 2, intentionally re-dissolved in diluted acid	Compound (ion or complex species) + solvent/stabilizer in various concentration ranges	Liquid	Mixture	Use test information from compound Type 1	Do not test and read-across from compound Type 2 applying mixture rule or expert judgement

Pros and cons of each Registration option

Testing option	Pros	Cons
1 Test each substance form	• Recognises potential (varying) speciation differences • Fully transparent and diligent	• Leaves little room to expert judgement and practical assessment of handling measures • Dependant of number of different species extensive test scope
2 Test based on solid form and read-across to solution resp. mixture	• Leaves room to expert judgement and practical assessment of handling measures • Use of mixture rules replaces testing of various concentration ranges • Allows the use of already existing classifications under CLP and transport regulations	• May not fully acknowledge possible influence of (varying) speciation on effects • Requires to robustly document read-across strategy and underlying evidence • If effects were not properly assessed by expert judgement/read-across industry may be held responsible in the event of an accident

Key issues

- Unknown speciation will remain unknown: only theoretical prediction of speciation in which compound is in solid/liquid version can be achieved
- Register a UVCB and a mono-constituent version of the 'same' substance in one dossier: not sure IUCLID 5 allows this...
- Using mixture rule to classify the UVCB substance (whether in a standalone dossier or registered together with the mono-constituent version): mixture rules acceptable if information that constituents do not react together and retain their individual identity in the compound... cf. speciation question
- Need to agree on whether the solvent is:
 - a solvent (component of a mixture, or constituent of substance), or
 - a stabiliser (not a formal constituent, just needs to be reported for substance identification purposes)
- Because of hydrolysis of some PM compounds diluted acids are used as solvent as well as stabilizer. Unfortunately some PM compounds react with the solvent/stabilizer.
Need to agree on whether solid and dissolved version can be claimed to be identical.

Possible solutions for discussion

1. Register each form separately

- Precedent-setting, different EC numbers
- Some companies manufacture both types indistinctively on customer's demand
- How to define each form individually?
- Whose composition should appear as:
 - Compound X: e.g. 50-100 % (using minimum concentration range in liquid form up to concentration in solid form)
 - Solvent/Stabiliser: e.g. 0-50% (using minimum and maximum concentration range of solvent in liquid form)
- Whose classification would be:
 - Derived on the basis of mixture rules (e.g. using MeClas) using the classification of the solid and the solvent, or
 - The one of the liquid form, when available

2. Register both mono-constituent (solid, isolated) and UVCB (dissolved) species in one dossier

- How to describe substance sameness between solid and dissolved species

3. Other?



Sameness of solids vs. solutions

- Conclusions/ Next Steps



2.3 Updated tonnage bands

- Purification/ re-dissolution counted as 1 process step (was: 2)
- Implications

	Tonnage band old	Tonnage band new	REACH deadline
Diamine dichloropalladium	100-1000 tpa	10-100 tpa	5/2013 => 2018
Diammonium hexachloropalladate	100-1000 tpa	10-100 tpa	5/2013 => 2018
Diammonium hexachloroplatinate	100-1000 tpa	10-100 tpa	5/2013 => 2018

- Further discussion: slides agenda point 4 (testing programme)

3. Identified uses of Palladium and Palladium compounds

Becky Marks, Claire Massey, Iain Wilson, Ed Stutt

Palladium Uses

- Uses identified from PMRC member companies and downstream users
- Uses and their descriptors grouped where possible
- Presented at last meeting
 - » Some clarification points raised with respondents
- All uses and use titles are unchanged since the slides presented at the last meeting except for;

Changes to use titles

- Processing aid – Industrial changed to Catalyst – industrial
 - » Dichlorobistriphenyl phosphine
 - » Palladium (II) diacetate
 - » Palladium (II) di(4-oxopent-2-en-2-oate)
- Processing aid – Industrial moved under the title Catalyst – Industrial
 - » Terakis(triphenylphosphine)palladium

Changes to use titles

- Manufacture of inks and paints – Industrial added
- Use of inks and paints – Consumer added
- Use of Inks and paints – Professional removed
- Service life of metal surface treated objects – Industrial/Professional/Consumer removed
- Service life of non-metal surface treated objects – Industrial/Professional/Consumer removed
 - » Palladium chloride

Changes to use titles

- Service life of galvanised or metal surface treated objects - Industrial/Professional/Consumer – removed
 - » Palladium Sulphate
 - » Tetraammine Palladium dichloride

Changes to use titles

- Industrial use resulting in inclusion to the matrix changed to Manufacture of Pd oxide containing catalyst
- Service life after inclusion onto matrix - Industrial/Professional/Consumer changed to Use of Pd oxide containing catalyst – Industrial/Professional/Consumer
 - » Palladium Oxide

Changes to use descriptors

- Additionally, wca removed some PROC codes from intermediate uses that are deemed by ECHA to be incompatible for intermediate uses
- And noted those that ECHA consider inappropriate for SCC intermediate use

Process to define final list of uses

- Updated and circulated for review and comment by Katrien (07/02/2013)
- After review by PMRC member companies
 - » Only 1 additional use identified:

Dihydrogen tetrachloropalladate Metal surface treatment – Industrial

- » Some additional SU, PROC and ERC codes were identified
- » Some SU and ERC removed from intermediate use based on ECHA guidance
- A final list of declared uses and descriptors has been circulated



4. PGM testing programme

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Klaus ROTHENBACHER



4.1 DDP ecotoxicity testing

- Agreed (PGM ES mtg. 12th Dec. 2012) to conduct
 - o Sediment toxicity test (Chironomus, OECD 218)
 - o Aquatic toxicity test (Daphnia, OECD 211)
- Status
 - o Tests ongoing (at Fraunhofer Inst. Schmallenberg, D)
 - o DDP difficult to test, extensive prelim. testing required (stability, had to repeat both range finders, etc.)
 - o Range finders completed, main studies to start in June
 - o Results expected in July 2013



4.2 DDP Repeated Dose Testing

- OECD 422 study ongoing at CiToxLAB, HU
 - o Overall, slow progress
 - o Extensive method development necessary; work ongoing
 - Formulations not stable over 7d (reason why previous study failed?)
 - o Next Steps
 - Evaluating if formulations are stable over 1d
 - Evaluating in parallel possibility for dietary study (palatability study)
 - Conduct detailed range-finding study before main test
- Study completion expected 2014



4.3 PGM ecotoxicity testing

- Agreed CROs: Brixham (UK) and Fraunhofer Inst. Schmallenberg (D)
- Scope agreed
- Currently paused due to workload considerations



4.4 PGM irritation/corrosion testing

Substance	CRO	Availability of results	Result	Final Report Issued	Comment
2. Platinum dinitrate (EC No. 242-383-9)	BSL	24. Mai 13	1B		
3. Platinum dinitrate (EC No. 242-383-9)	BSL	24. Mai 13	1B		
~~4. Platinum dinitrate (EC No. 242-383-9) - company 3~~	BSL				Substance not supplied
5. Dihydrogen tetrachloropalladate (EC No. 241-047-9) - solution PMRC	BSL	24. Mai 13	1A		
~~6. Palladium sulphate (EC No. 236-957-8) - solid~~	BSL				Substance not available in solid form
7. Palladium sulphate (EC No. 236-957-8) - solution PMRC	BSL	24. Mai 13	1B		
8. Palladium dinitrate (EC No. 233-265-8)	BSL	24. Mai 13	1B		
9. Palladium dinitrate (EC No. 233-265-8)	BSL	24. Mai 13	1B		
~~10. Palladium dinitrate (EC No. 233-265-8) - company 3~~	BSL				Substance not supplied
11. Dirhodium trisulphate (EC No. 234-014-5) - solid	BSL	24. Mai 13	1B		
12. Dirhodium trisulphate (EC No. 234-014-5) - solution PMRC	BSL	24. Mai 13	1B		
13. Rhodium trinitrate (EC No. 233-397-6)	BSL	24. Mai 13	1B		
14. Rhodium trinitrate (EC No. 233-397-6)	BSL	24. Mai 13	1B		
~~15. Rhodium trinitrate (EC No. 233-397-6) - company 3~~	BSL				Substance not supplied
16. Ruthenium trichloride (EC No. 233-167-5) - solid PMRC	BSL	24. Mai 13	1B		
17. Ruthenium trichloride (EC No. 233-167-5) - solution	BSL	24. Mai 13	1B		
18. Tris(nitrato-O)nitrosylruthenium (EC No. 252-068-8) - solid PMRC	BSL	24. Mai 13	1B		
20. Tris(nitrato-O)nitrosylruthenium (EC No. 252-068-8) - aqueous solution PMRC	BSL	24. Mai 13	1B		

- To refine transport classification
- Sameness solids vs. solutions
- CoAs missing: draft reports cannot be issued yet



4.5 PGM genotoxicity testing

Substance and Test	CRO	Proposed start date
<u>Diammonium hexachlororuthenate (CAS 18746-63-9)</u>		
1. GLP Ames reverse mutation assay in 5 strains – OECD TG471	Covance	17. Jun 13
2. In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Covance	17. Jun 13
3. In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476	Covance	29. Jul 13
<u>Dihydrogen tetrachloropalladate (2-) (CAS 16970-55-1)</u>		
4. In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Covance	04. Jul 14
5. In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476	Covance	
<u>Tetraamminepalladium(II) diacetate (CAS 61495-96-3)</u>		
6. In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476	Covance	04. Jul 14
<u>Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)</u>		
7. GLP Ames reverse mutation assay in 5 strains – OECD TG471	Covance	17. Jun 13
8. In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Covance	17. Jun 13
9. In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476	Covance	29. Jul 13
<u>Diammonium hexachloropalladate (CAS 19168-23-1)</u>		
10. GLP Ames reverse mutation assay in 5 strains – OECD TG471	Covance	10. Jan 14
11. In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Covance	10. Jan 14
12. In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476	Covance	11. Jul 14
<u>Dihydrogen hexahydroxyplatinate (CAS 51850-20-5)</u>		
13. GLP Ames reverse mutation assay in 5 strains – OECD TG471	Covance	19. Jul 13
14. In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Covance	19. Jul 13
15. In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476	Covance	10. Jan 14
<u>Diammonium sodium hexakis(nitro-N)rhodate (CAS 64164-17-6)</u>		
16. GLP Ames reverse mutation assay in 5 strains – OECD TG471	Covance	10. Jan 14
17. In vitro mammalian cell micronucleus test (human lymphocytes) – OECD TG487	Covance	10. Jan 14
18. In vitro gene mutation in mammalian cells (hrpt assay in mouse lymphoma cells) – OECD TG476	Covance	11. Jul 14

- Contracts signed
- Test substances requested
- Tests starting now



4.6 PGM sensitisation testing

Substance	CRO	Status	Comment
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)	CiToxLAB	TS not delivered yet	
Diammonium hexachlororopalladate (CAS 19168-23-1)	CiToxLAB	ongoing	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 completed and shows stability.
Diammonium sodium hexakis(nitrito-N)rhodate (CAS 64164-17-6)	Harlan	ongoing	Max concentration achieved = 25% TS in propylene glycol. (Additional vehicles and concentrations assessed -Feb 2013). Quote for analysis by IR spectroscopy received 25 Feb 2013 - need to confirm acceptability (28 Feb). IR analysis to be done in-house on suspensions only w/c 22 Apr 2013. Awaiting progress report (requested 21 & 29 May).
Diammonium hexachlororuthenate (CAS 18746-63-9)	CiToxLAB	TS not delivered yet	

- Carried out solubility/stability pre-tests prior to definitive tests
- Two test substances not delivered yet
- Again, bad experience with Harlan (no progress yet: fire in test facility, study director resigned, etc.)



4.7 PGM acute/repeated dose testing

Substance and test	CRO
Palladium (II) di(4-oxopent-2-en-2-oate) (CAS 14024-61-4)	
1. Acute oral toxicity	CiToxLAB
Diammonium sodium hexakis(nitro-N)rhodate (CAS 64164-17-6)	
2. Acute oral toxicity	CiToxLAB
3. Preliminary repeat dose oral toxicity including analytical method development and validation	CiToxLAB
4. Repeated dose oral toxicity - OECD TG407	CiToxLAB
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)	
7. Acute oral toxicity	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 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)	
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 analytical method development and validation	CiToxLAB
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
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 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

- Agreed on CROs: CiToxLAB and LPT
- Contracts signed
- Test substances requested
- Tests starting now
- Need to revisit scope (agenda point 5.2)



5. Current status of PNEC and DNEL refinement for DDP

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Klaus ROTHENBACHER



Timeline

Revised timing: Registration deadline for all Pd compounds is 2018 now

- No need to derive tentative (= uncertain) PNECs/ DNELs/ interim RMM, and submit incomplete dossiers in May 2013
- But: suggest to keep up momentum
- Proposed next steps
 - o Complete ongoing studies asap
 - o Derive robust PNEC, DNEL
 - o Update ES
- Will allow for time to refine ES (e.g., conduct site-specific monitoring, if required)



5.1 PNEC Derivation

Read across approach for Pd compounds

- ‘Grouping approach’
 - o Pd(IV): not stable, will hydrolyse rapidly to Pd(II) = use Pd(II) PNECs
 - o Use worst-case PNECs for Pd(II) compounds = **read across from DDP**

Test	Palladium dinitrate	Tetraammine palladium hydrogen carbonate	Dihydrogen tetrachloro palladate	Diammine dichloro palladium
	mg Pd/L	mg Pd/L	mg Pd/L	mg Pd/L
Acute Algae	0.029	0.024	0.010	0.003
Acute Invert	0.785	0.079	0.045	0.035
Acute Fish	53.569	0.190	NA	0.154



5.1 PNEC Derivation

DDP is not perfect for read across (different isomers)

- But other PGM may have different isomers too
- Additional tests to refine DDP PNEC currently ongoing = robust data set
- DDP represents a worst-case = other substances are all less toxic than DDP

Conclusion: DDP still suited for conservative, pragmatic read across approach

- Any objections?



5.2 DNEL Derivation

DDP DNEL

- No need to derive tentative DNEL
- Repeated dose tox. study (OECD 422) ongoing at CiToxLAB, HU
- Study completion expected 2014
- DNEL derivation/ update occ. ES once study results available



5.2 DNEL Derivation

Other DNELs

- Agreed testing strategy RDT in Jan. 2013 PGM WG mtg.
 - DDP (OECD 422 – ongoing at CiToxLAB)
 - Palladium dihydroxide* (OECD 422 – CiToxLAB)
 - Tetraamminepalladium(2+) dichloride (OECD 421 – CiToxLAB)
 - Diammonium hexachloropalladate (OECD 407/421 – CiToxLAB)
- Palladium dihydroxide is poorly soluble – test more soluble Pd(II) form?**

	7647-10-1 Palladium dichloride (1-10 tonne substance)	13566-03-5 Palladium sulphate (1-10 tonne substance)	10102-05-3 Palladium dinitrate (and solution) (10-100 tonne substance)	12135-22-7 Palladium dihydroxide (10-100 tonne intermediate)
Water solubility	33.4 g/l of solution at 20.0 ± 0.5°C monitoring the palladium concentration of the sample solutions; equivalent to a palladium dichloride solubility of 55.6 g/l of solution at 20.0 ± 0.5°C (Harlan, 2010), 32g/l (prop.), 4.03g/l (JM 2011)	280g/l (hydrate)(prop), only available as a solution	Expert statement. substance hydrolyses in water and precipitates after time (prop), soluble (prop) - Clarification Required re Palladium concentration in resulting solution. Test - Modified shake flask. 30331 mg/l (> 10 g/l) (JM 2012)	max Pd concentration over the 7 and 28 days of T/D testing of all three loadings of Pd(OH) ₂ , was the 6 hr value of the 100 mg/L loading: 1.02 ug/L (σ% = 13). CANMET 2012

6. Pd Environmental Exposure Modelling & Risk Assessment

Ed Stutt, Dawn Maycock & Adam Peters

Content

- 'Final' update on use of data from exposure questionnaire & follow-ups
- Development of Generic Exposure Scenario (GES) for total Pd
- GES for DDP manufacture and use as intermediate
- GES for downstream use of DDP in electroplating
- Site-specific risk assessment
- Monitoring
- Assessment of waste stage

Follow-up to the questionnaire

- Tonnage data and flow diagrams
 - thanks for very useful data
 - helped identify issue with tonnage band of DDP
- Consideration of 'net Pd tonnage' and calculation of emission factors from this were final stage in development of the GES

Generic Exposure Scenario

- GES details exposure assessment and risk characterisation
- Exposure assessment describes exposure characteristics (including RMMs) and parameter values that cover majority of Pd sector; these are used in calculation of PEC
- Risk characterisation: $RCR = PEC / PNEC$
- GES for the manufacture and downstream use of diamminedichloropalladium (DDP) will be included in Sections 9 and 10 of the CSR

Generic Exposure Scenario

- Derivation of sector-wide Pd Generic Exposure Scenario (GES)
 - » Representative ('reasonable worst case') GES for all Pd compounds based on values calculated from compiled dataset
 - » 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

Generic Exposure Scenario

- Derivation of sector-wide Pd Generic Exposure Scenario (GES)
 - » is based on the total amount of palladium used at the site, and the total emissions of palladium. The GES is therefore not specific to the individual palladium compounds, but instead demonstrates whether the emissions from all sources of palladium result in safe use.

Generic Exposure Scenario (GES)

- GES for overall Pd (complete dataset)

Parameter	Value	
Tonnage	20.3 T/a (as Pd)	90P
EF water	68.2 g/T	50P
Emission days to water	250 d	50P
WWTP flow rate	120 m ³ /d	50P
STP flow rate	3000 m ³ /d	10P
Freshwater dilution	10x	Default
Marine water dilution	100x	Default
EF air	300 g/T	SpERC
Emission days to air	300 d	Mean

Generic Exposure Scenario (GES)

- Multiple scenarios required for emissions to water
 - » Freshwater without STP
 - » Freshwater via STP
 - » Marine without STP
 - » Marine via STP
- Emission factors are constants but dilution factors etc. are adjusted for these sub-scenarios

DDP Manufacturing GES sub-scenarios	
ES 1.1	Freshwater with STP
ES 1.2	Freshwater direct discharge
ES 1.3	Marine water with STP

GES Risk Characterisation

Compartment	PEC	PNEC	RCR
Air	$4.6 \times 10^{-6} \text{ mg/m}^3$	$5.0 \times 10^{-4} \text{ mg/m}^3$	0.011
STP	$5.4 \times 10^{-4} \text{ mg/L}$	1.46 mg/L	3.8×10^{-4}
Freshwater via STP	$5.2 \times 10^{-5} \text{ mg/L}$	$1.33 \times 10^{-5} \text{ mg/L}$	3.89
Freshwater direct	$4.3 \times 10^{-3} \text{ mg/L}$		323
FW sediment via STP	$5.8 \times 10^{-2} \text{ mg/kg}$		39.9
FW sediment direct	4.68		3235
Seawater via STP	$3.5 \times 10^{-6} \text{ mg/L}$	$1.33 \times 10^{-6} \text{ mg/L}$	3.35
Seawater direct	$3.7 \times 10^{-4} \text{ mg/L}$		285
Soil w/o sludge spreading	$1.9 \times 10^{-3} \text{ mg/L}$	0.0117 mg/kg	0.16
Soil with sludge	0.011		0.95

Msafe GES

- CSR requires exposure scenario demonstrating no risk to the environment
 - GES to be updated and RCRs re-calculated with revised PNECs from on-going testing programme
 - Alternative is to use sector-specific EFs & other GES exposure parameter values in conjunction with PNECs to calculate the tonnage of a substance that can be safely processed (manufactured or used) WITHOUT posing a risk to environment ($RCR < 1$)
- Msafe approach

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 $\mu\text{g Pd/m}^3$	1.3×10^{-3} $\mu\text{g Pd/m}^3$	3.1×10^{-3}

Msafe GES for DDP use as intermediate

- ERC 1 (Manufacture of substances); ERC 6A (Use as Intermediate)
- Environmental GES is identical to that for manufacture of DDP
 - » Pd emission data used to quantify GES includes emissions due to both manufacture of DDP AND downstream use as an on-site intermediate (NB. GES covers all industrial Pd processing)
 - » GES based on data for use as on-site intermediate is also applied to use as chemical intermediate off-site in the absence of data from non-PMC member companies (this may need checking)

Msafe GES for DDP use in electroplating

- ERC 5 (Industrial use resulting in inclusion into or onto a matrix)
- No emission data for environmental GES so based on SpERC for 'Industrial use of metals and metal compounds in metallic coating'

Maximum annual safe use at a site (Msafe)	1 tonne DDP (500 kg Pd metal equivalent)
Pattern of release to the environment	220 days per year per site
EF to water	500 g/T (modified SpERC EF)
EF to air	200 g/T (modified SpERC EF)
Dilution factors	TGD defaults

Msafe GES for DDP use in electroplating

- SpERC EFs have been reduced by an order of magnitude
 - » EFs were derived from industry data in base metal electroplating sector (e.g. Zn, Ni, Sn)
 - » Reasonably anticipated to be much lower emissions of Pd due to higher monetary value
- GES currently assumes discharge to freshwater via STP
- Option of 'scaling' but GES assumptions and parameter values will need to be checked with DUsers
- GES will be updated with revised PNECs

Msafe GES for DDP use in electroplating

Compartment	PNEC	PEC	RCR
ES Discharge to STP	1.46 mg/L as Pd(II)	1.13×10^{-4} mg/L as Pd(II)	7.7×10^{-5}
ES Freshwater via STP	1.33×10^{-5} mg/L as Pd(II)	1.11×10^{-5} mg/L as Pd(II)	0.84
Terrestrial	0.0117 mg/kg as Pd(II)	1.89×10^{-3} mg/kg as Pd(II)	0.16
Air	0.5 $\mu\text{g Pd/m}^3$	7.6×10^{-5} $\mu\text{g Pd/m}^3$	1.9×10^{-4}

Site specific risk assessment

- Based on site-specific data wherever possible, supplemented by GES parameter values where necessary
- Currently calculating exceedances ($RCR > 1$) for several sites for fresh & sea-water & all for sediment
- Further refinement possible in some cases (i.e. dilution factor in receiving water body) but not in others. Options to refine risk assessment include:
 - » Refinement of PEC based on exposure data (if possible)
 - » PNEC refinement
 - » Higher tier modelling or monitoring of local environment (aquatic and sediment)

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

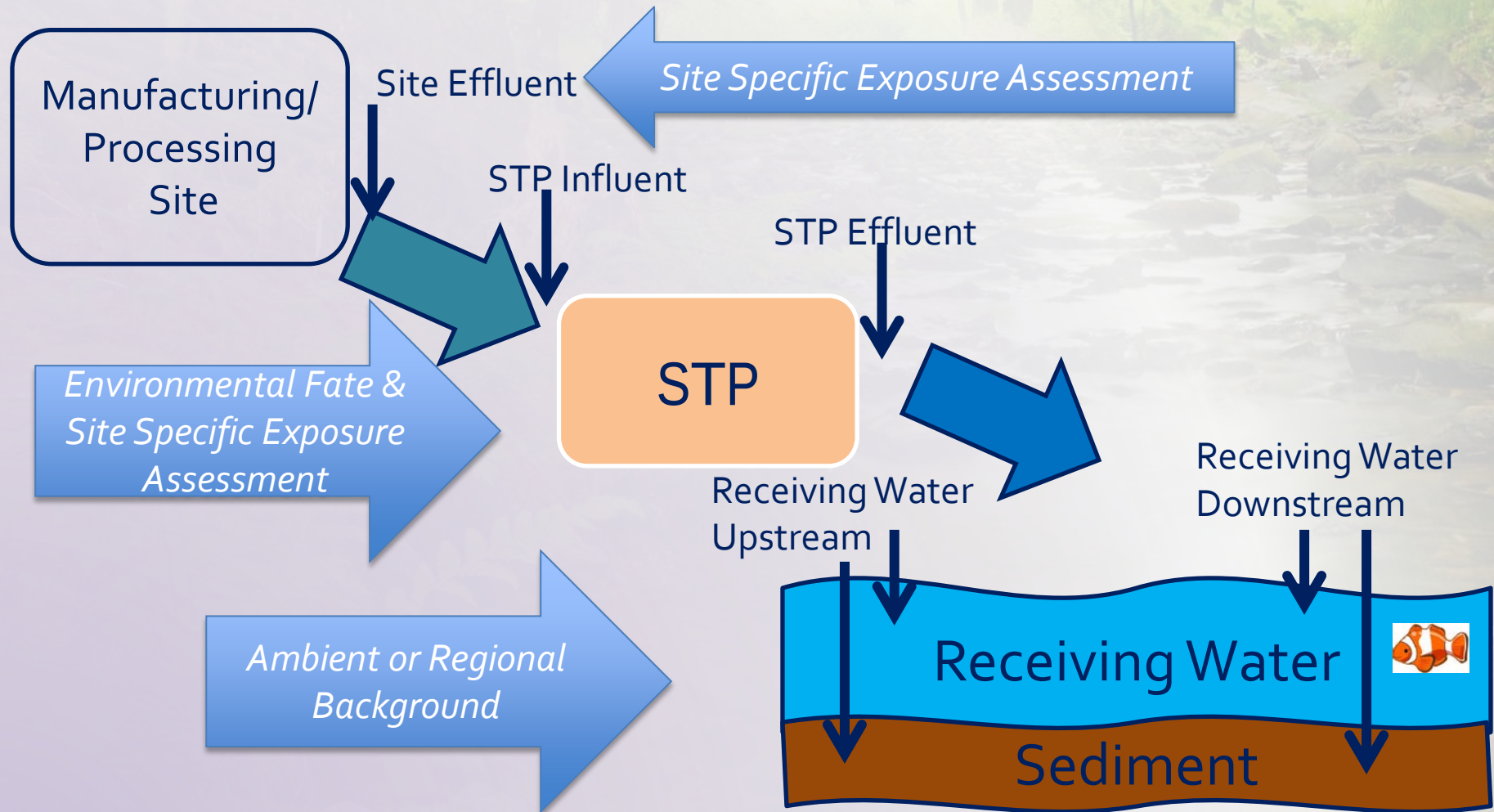
Site-specific risk assessment

- Calculation of sediment RCR
 - » an additional factor of 10 is included in the RCR calculation because of the way in which the PNEC was calculated (equilibrium partitioning, EqP)
 - » ECHA guidance doc R.10, Section R.10.5.2.1
 - the $PEC_{sed}/PNEC_{sed}$ ratio is increased by an order of 10 in order to take into account uptake via ingestion of sediment
 - If with this method a $PEC/PNEC$ ratio > 1 is derived, the testing strategy developed in Section R.7.8.12 should be applied

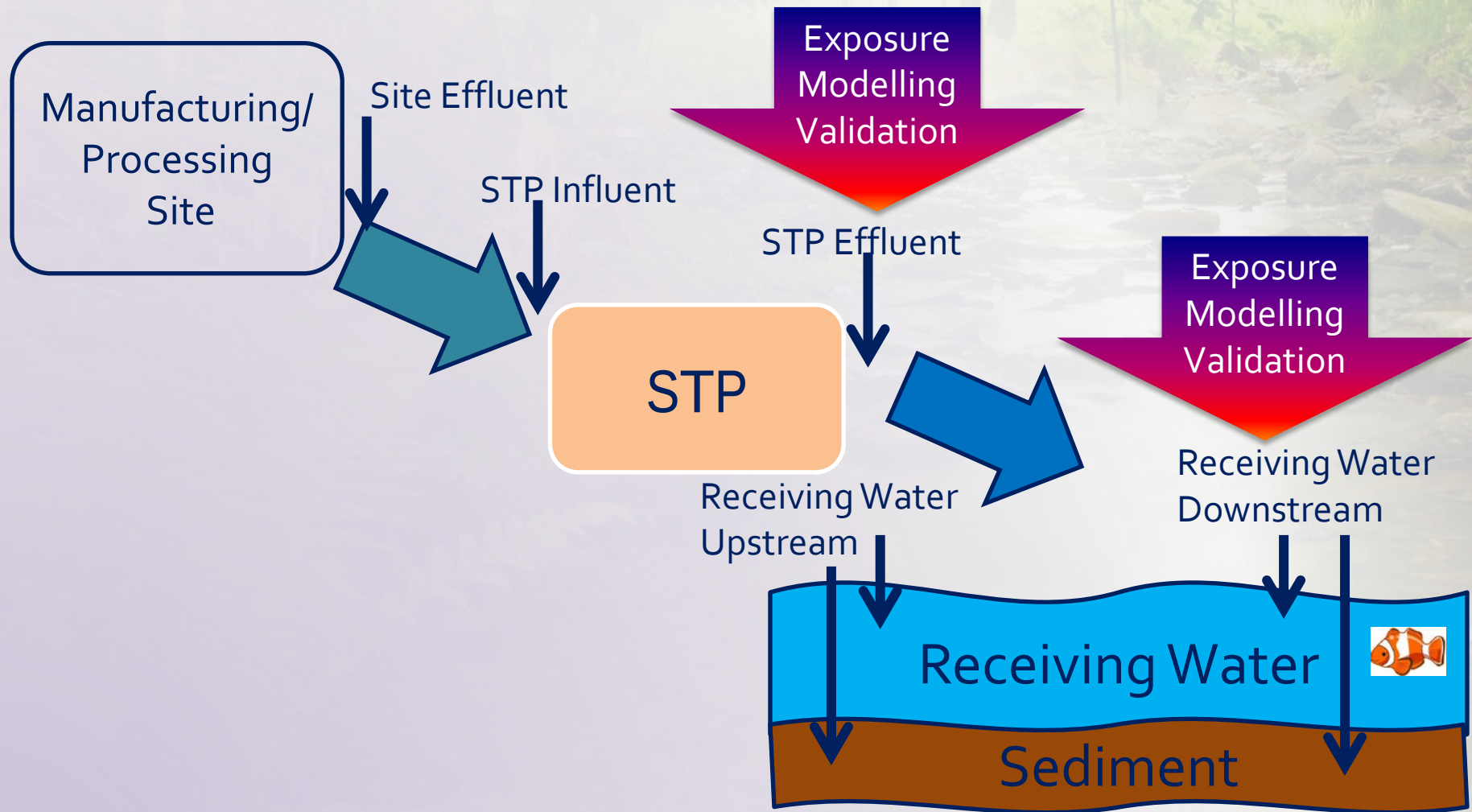
Monitoring

- Where aquatic RCR > 5 and/or sediment RCR > 10 there may be a requirement to undertake monitoring to demonstrate safe production/use
- Programme of regular sampling
- Prolonged time period (minimum 6 months)
- Tailored to processes operating on site (e.g. Batch or continuous)
- Accounting for variation in time and conditions
- Sample collection and handling fully recorded

Desirable Monitoring Points



Required Monitoring Points



Required Limit of Quantitation

- $PNEC_{Aqua}$ 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)
 - » May be achievable at some labs
- $PNEC_{Sed}$ currently $14.5 \mu\text{g kg}^{-1}$ (wwt, Pd)
- $PNEC_{Marine}$ currently 1.3 ng l^{-1} (as dissolved Pd)
- $PNEC_{MarSed}$ currently $4.7 \mu\text{g kg}^{-1}$ (wwt, Pd)
 - » Adequate detection limits may not be achievable

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.
- Exemptions from qualitative exposure assessment include:
 - Waste stage includes, or exclusively consists of recycling processes (waste entering the recycling process is part of the first life cycle)
 - The conditions in the waste stage are already covered in the exposure assessment for other life cycle stages. It can be concluded that the expected releases to the environment from the waste stage are significantly lower than those from the previous life cycle stages.
 - Only small fractions of the mass flow of the substance end up in the waste stage. This consideration should take into account the initial quantities of the substance placed on the market and the outcome of the assessment for the previous life stages.
 - the concentration of the substance at the waste stage falls below the cut-off in article 14(2) of REACH (e.g. 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII of the Registration of substances regulation)

Assessment of Waste

- o Waste generally in the form of sludges or filter cakes/press cakes but some other materials as well
- o 10 respondents recycle their waste, vast majority of whom recycle for re-use (1 on-site, 7 off-site, others unknown)
- o 3 respondents send waste to landfill (1 on-site, 2 off-site)

Assessment of waste

- Requirement for several exposure scenarios based on different waste options identified
- Assessment for recycling consists of three steps:
 1. Assessment of relevance of recycling and justification of no relevance.
 - » Note: Recycling processes should only be excluded after careful consideration
 2. Checking if recycling process is already covered by earlier assessments
 3. Estimation of released amounts from relevant recycling processes
- ECHA Guidance R18 details default release fractions for waste stages

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}

The background of the slide is a photograph of a shallow, rocky stream flowing through a dense forest. Sunlight filters through the trees, creating a dappled light effect on the water and rocks. The water is clear, revealing the smooth, grey stones beneath. The surrounding trees are lush with green foliage.

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7. Occupational exposure scenarios for DDP, outstanding issues and proposed way forward

Platinum Group Metals Meeting

Brussels

19 June 2013

Jutta Schade & Daniel Vetter

EBRC Consulting

Hannover, Germany

Status in March I/III

- Clarification on monitoring data and occupational exposure questionnaires received
 - Comments on 1st draft occupational exposure scenario (ES) received from 1 additional company (4 companies in total)
 - 2 additional companies indicated that they agree with the occ. ESs
 - Identified uses:
 - all relevant use descriptors included
 - clarification on potential additional uses and physical forms
- Information used for development of final draft ES for DDP

Status in March II/III

- Text passages highlighted in yellow background colour in ES replaced/amended
- Some further editorial changes done
- Table “Scope and type of exposure assessment for DDP” included
- Comments reflected and/or responses to comments provided
- Occupational ESs for DDP were at a final stage and ready for submission in March

Status in March III/III

- Some open issues
 - some discussions on-going with regard to interim DNEL levels
 - dustiness testing of DDP with different moisture content may require further discussion
- Due to new information on tonnage and therefore new registration deadline for DDP → proposal to wait for further study results to have:
 - final DNELs and
 - relevant dustiness covered

Progress since March/Way forward I/II

- Discussion on compatible SUs (Sectors of End-use) for intermediates:
 - due to the definition of intermediates, SUs that describe the manufacture of articles cannot be used
 - it is proposed to replace SU15 (Manufacture of fabricated metal products, ...) by SU14 (Manufacture of basic metals, ...) in ES 9.2
- It is proposed to delete PCs 20 (pH regulators,...) and 21 (laboratory chemicals) for ES 9.2 and only keep PC 19 (intermediate)
- It is proposed to change the title of ES 9.3 to “Industrial use of DDP for surface treatment”

Progress since March/Way forward II/II

- No further information on occ. ESs received via commenting form (including clarification on the drying of DDP)
- Results (n=2) from additional air-monitoring received from one company
- Additional dustiness test with DDP conducted indicating low dustiness
- Further confirmation received that DDP is dried during manufacture, yielding a lower moisture content → update of occ. ESs is required (process/activity and dustiness)
- Proposal to “upgrade” information on cleaning & maintenance workplaces
- Proposal for further dustiness testing & monitoring

Relevance of dustiness tests for EA I/III

- Dustiness potential of a substance is a crucial parameter in the assessment of occupational exposure
 - Exposure modelling (e.g. with MEASE): different dustiness classes lead to considerable differences in exposure estimates that may be up to 2 order of magnitude comparing estimates for low and high dusty solids
 - Measured exposure: dustiness has to be known to facilitate read-across between different workplaces or similar workplaces at different companies
- Proposal (2012) to conduct 3 dustiness tests with DDP:
 - low moisture content
 - typical moisture content
 - high moisture content
 - to establish moisture-dustiness-relationship
 - to extrapolate to other Pd substances (having less data on dustiness)

Relevance of dustiness tests for EA II/III

- Available results of dustiness tests with DDP:
 - High dustiness (22 % total dustiness) for dried DDP (moisture content <0.01 %)
 - Low dustiness (0.7 % total dustiness) for 20.1 % moisture content
 - Indication that moisture content ranges from 15 to 40 %
- Additional questions to manufacturers of DDP:
 - Indication received that DDP is dried during manufacture
 - Dried to which moisture content and resulting dustiness of DDP?
- Potentially different dustiness classes to be reflected in EA:
 - additional inhalation monitoring measurements could be conducted to reflect actual conditions in the occ. exposure scenarios
 - results could also be used for other Pd substances

Relevance of dustiness tests for EA III/III

- Sample selection: Clarification required which factors mainly determine the variability in the moisture content, e.g.:
 - a) Variability determined by process (required output specifications)?
 - b) Variability due to varying times between digging off filters and sample preparation?
 - low and high moisture containing samples may be obtained when such specifications are produced (relevant for a))
 - taking high moisture content sample right after digging off the filter and lower sample shortly before packaging (relevant for b))
 - to cover all handled materials: lower moisture content sample from company with lowest lower range limit (currently reported with 15 %) and the high moisture content sample from company with highest upper range limit (currently reported with 40 %) to be taken

Occ. ESs for other Pd substances I/IV

- Data gathering in 2012:
 - occupational exposure questionnaire & submission form for inhalation monitoring data
 - for 12 Pd substances manufactured/imported at or above 10 tonnes per year
 - decision taken to also develop ES for Pd metal (not classified)
 - all information received included in database (questionnaire information and inhalation monitoring data)
 - decision taken to prioritise DDP due to 2013 REACH deadline
 - Information on other Pd substances checked at the time for completeness, but no final quality check done at that time

Occ. ESs for other Pd substances II/IV

- Exposure scenarios (ESs) are only required for hazardous substances that are manufactured and/or imported at or above 10 tonnes
- The recent version of the Chesar tool provides a “scope” for exposure assessment/risk characterisation:
 - exposure assessment/risk characterisation only required if a hazard is identified (assessed for each route/endpoint separately)
 - e.g.: no HH hazard identified → risk characterisation for HH not needed
 - scope of exposure assessment to be clarified for Pd (and Pt) substances, taking into account recent guidance

Occ. ESs for other Pd substances III/IV

- DNELs required for all relevant Pd substances
 - inhalation & dermal, acute DNELs required?
 - additional (dermal) DNELs for general population required (if consumer uses are relevant (→ data gathering for consumer uses not yet started))
- Further information on physical forms may be available soon (new questionnaire sent out by PMC secretariat)
 - dustiness tests for other Pd substances available (potential for read-across to DDP on the basis of their moisture contents?)

Occ. ESs for other Pd substances IV/IV

- Timing depends on:
 - availability of required information (e.g. DNELs) and
 - agreement on e.g. dustiness testing, monitoring campaign, ...
- Proposal for way forward:
 - final quality check of questionnaire information over summer
 - data gathering (additional monitoring data?, additional dustiness tests?, additional study results (e.g. skin corrosion?)) over summer
 - decision on scope of exposure assessment/risk characterisation
 - interim DNELs for relevant Pd substances to be used
 - development of occ. exposure scenarios after summer

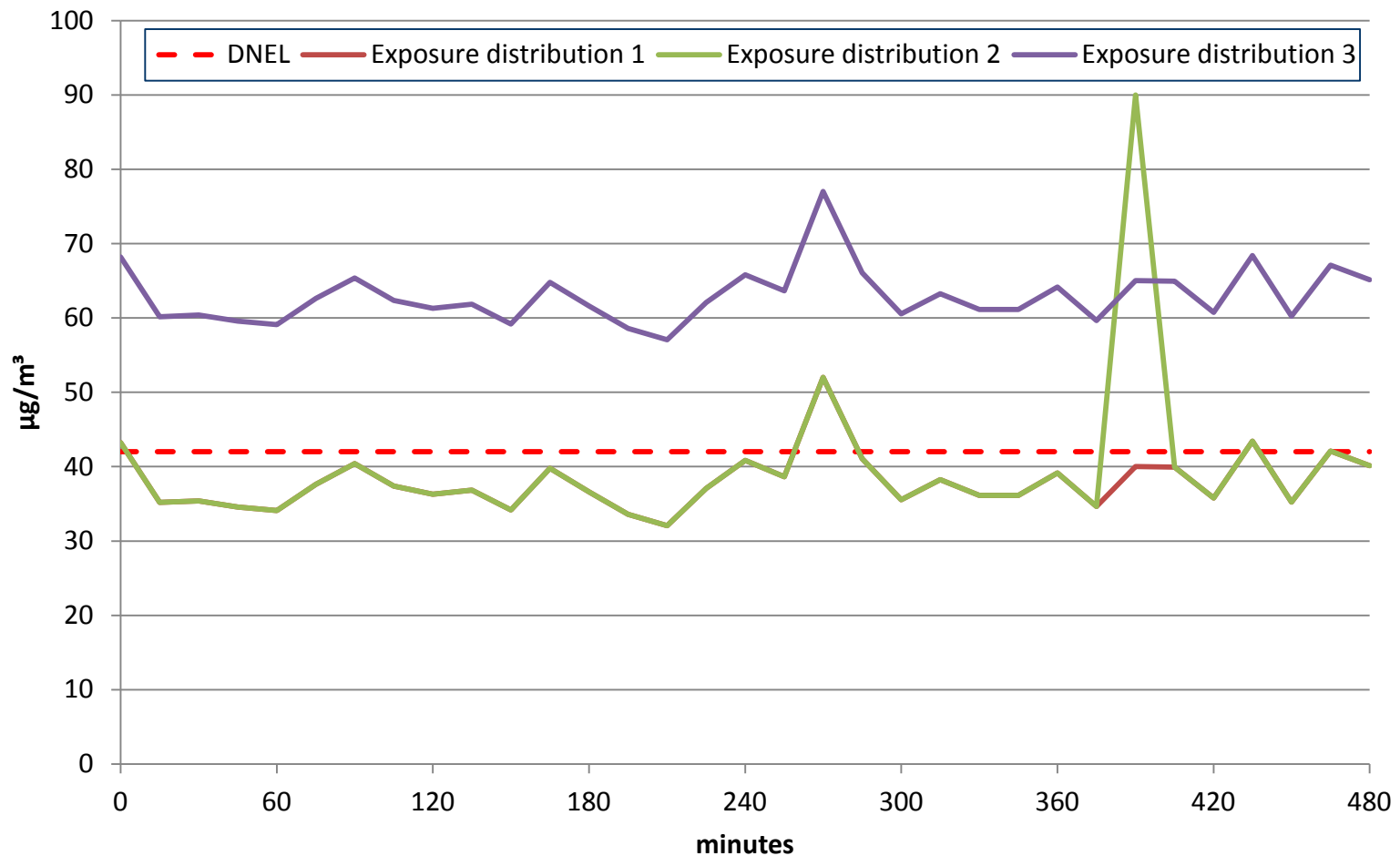
Occ. ESs for Pt substances

- Same information required as for Pd substances
 - Use of the same occ. exposure questionnaire and submission form for monitoring data
 - Downstream uses already identified?
 - Consumer uses relevant?
- Data-sharing agreement between EPMF and IPA has been signed
- Collation and aggregation of Pt workplace exposure data is on-going
- Data will be sent for review/use under REACH as soon as possible (no later than 1-2 October)

Definition of peak exposures I/III

- ECHA Guidance R.14:
 - Peak exposure = an acute exposure level clearly higher than the related full-shift exposure level
- Guidance R.8:
 - For acute toxicity hazard: DNEL for acute toxicity established for the effects of peak exposures as these peaks can be significantly higher than the average daily exposure and the long-term DNEL
 - Guidance provides an approach of using factors to extrapolate from long-term DNELs to acute DNELs (R.8: the acute DNEL can be set as 1-5 times the long-term DNEL)
 - Substances classified as Acute Tox 1 and 2 or Specific target organ toxicity – single exposure category 1: qualitative risk characterisation recommended

Definition of peak exposures II/III – Example!



Definition of peak exposures III/III

- Estimation of acute exposure levels (according to R.14): multiplying long-term exposure estimates by a factor of 1.5-10 (depending on used percentile and GSD)
- For DDP:
 - 90th percentile value for AC2 (Manual handling of dusty materials at ambient temperature) = 146 $\mu\text{g DDP}/\text{m}^3$ (by a factor of 3.5 above the DNEL of 42 $\mu\text{g DDP}/\text{m}^3$)
 - 1 short-term (20 min) exposure value available of 262 $\mu\text{g DDP}/\text{m}^3$
 - Clearly higher than related full-shift exposure level (nearly a factor of 2)
 - Clearly higher than long-term DNEL (factor 6)
- Maximum value of all received measurements: 967 $\mu\text{g Pd}/\text{m}^3$

Next steps/open points

- Use of Chesar for the 2018 registration? Advantages:
 - ECHA approved “scope of assessment”
 - Automated generation of IUCLID sections 3.5 and 3.7 (via export)
 - Facilitating the use of standard phrases for ESs
 - Automated generation of ESs for the CSR and the eSDS
 - Avoidance of updating partly redundant documents: ES for CSR, ES for eSDS, sections 3.7
- Initiation of inhalation monitoring campaigns?
 - Depending on DNEL levels and physical forms of the substances
- ESs for further substances required:
 - Pd & Pt substances
 - Rhodium, Ruthenium, Iridium (<10 t and/or not hazardous)



Thank you for your attention!



8. Next steps and timeline for dossier submission

• • •

Klaus ROTHENBACHER

Katrien ARIJS



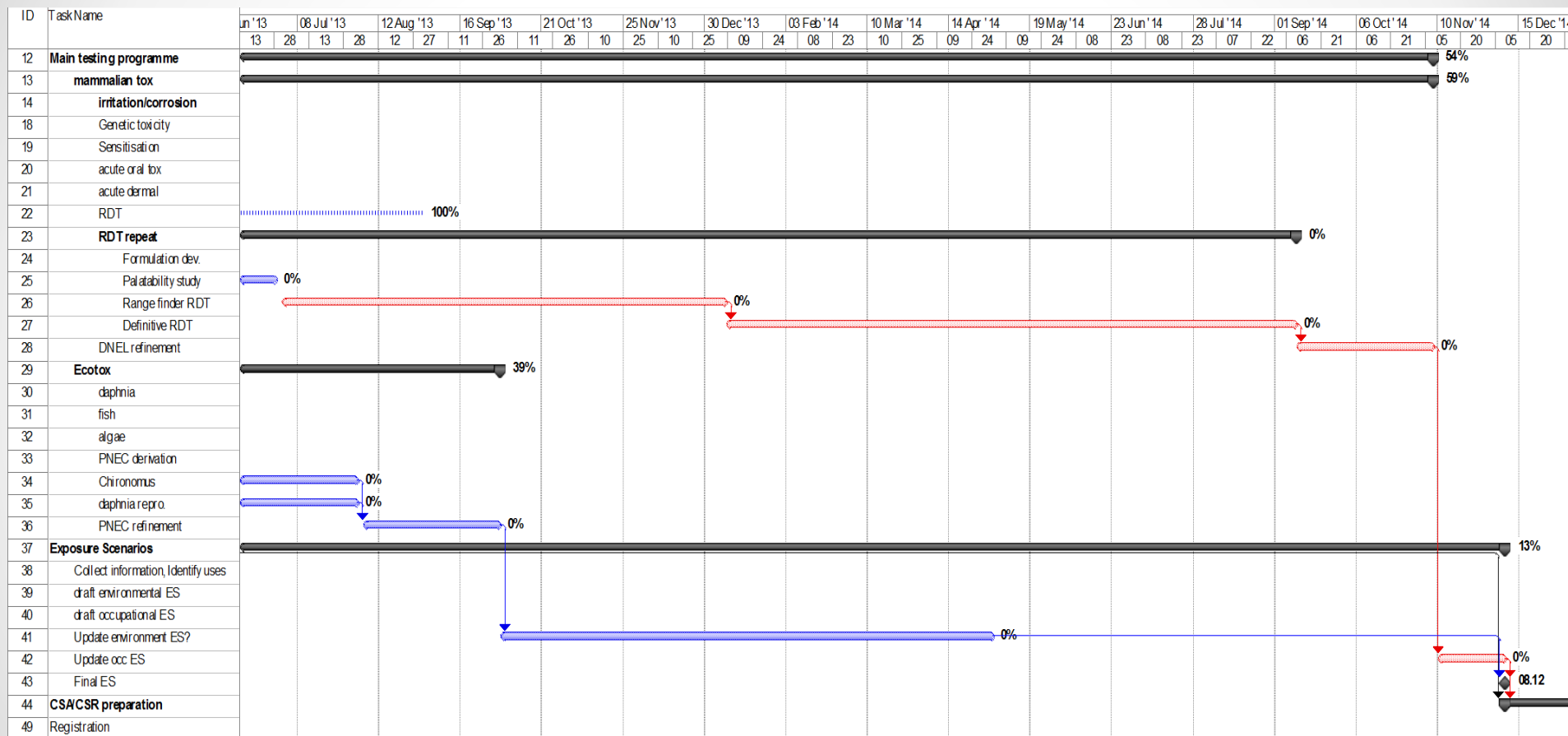
Updated timeline DDP

	Previous timeline	Updated timeline
RDT	Dec 2013	Sep 2014
DNEL	Jan/Feb 2014	Oct/Nov 2014
Occ. ES	Mar 2014	Nov/Dec 2014
Registration	Apr 2014	Dec 2014/Jan 2015

- Critical path projects
 - o Repeated dose testing (RDT)
 - o DNEL derivation
 - o Update occupational ES
 - o Registration
 - o Highlighted in red in the following project scheme



Updated timeline DDP





8.1 ES for other Pd substances

- Current environmental ES covers all Pd substances
- Current occupational ES covers DDP
 - Timing occupational ES for other Pd substances: see slides EBRC



8.2 Launch of data collection for Pt substances and intermediates

- On-going workplace exposure + data collection and assessment at IPA level
 - Data-sharing agreement EPMF/IPA signed
 - Collation and aggregation of the Pt workplace exposure data currently ongoing
 - Aggregated data to be sent to EBRC for review/use under REACH by early Oct at the latest
- Questionnaires to collect data on uses/exposure/emission to be circulated to Members Q3/Q4 2013 (pending access to /review of IPA data and discussions EBRC on data requirements)



9. AOB, Next Meetings/Calls & Closing Remarks

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David BOYD



9.1. Translation of eSDS to other languages, use of standard phrases

- At the Dec PGM ES meeting, it was advised not to use standard phrases in the ES because of the anticipated close registration deadline May 2013
- It was however indicated that the occ. ESs could be translated to standard phrases (consortium decision)
- Issues:
 - o Standard phrases not clearly applicable for metals
 - o Metal phrases under development/to be developed
 - o CSR not readable for regulators -> use CHESAR?



9.2. Water solubility paper

- Agreed to publish results of WS testing programme in peer-reviewed journal
- Manuscript drafted by JM
- Pending actions
 - Waiting for permission to publish data from external data holders (WS measurements not carried out at JM)
 - Can we mention names of sample providers (in acknowledgment)?
- Next Steps
 - Complete pending actions
 - Circulate updated manuscript to PGM WG for commenting



Thank you!

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10. Optional Slides

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	7647-10-1 Palladium dichloride (1-10 tonne substance)	13566-03-5 Palladium sulphate (1-10 tonne substance)	10102-05-3 Palladium dinitrate (and solution) (10-100 tonne substance)	12135-22-7 Palladium dihydroxide (10-100 tonne intermediate)	3375-31-3 Palladium(II) acetate (1-10 tonne substance)
pH	pH 2.15 (JM 2011 as part of water solubility testing), pH1.4 (Harlan 2010 as part of water solubility testing)	Hydrate: pH0.67. Acid/alkaline reserve: 15ml of a 10%solution of the substance was titrated with 5.70ml of 2N NaOH to reach a pH of 4.00. Calculated acid reserve: 30.10g NaOH (prop., 2011)	pH value = 0.77, 0.73; Reserve = 27.8,27.7; Result = -1.547, -1.578. Corrosive = yes (prop, 2011) [pH 1.23 (JM 2012, solubility test)]	pH 9.95 Acid/alkaline reserve: not executed since no extreme pH (prop., 2011)	
Skin sensitisation	Skin Sens. 1 (based on weight of evidence)	Endpoint can be waived based on skin corrosivity; although published data available	van Huygevoort (2003b), OECD 406, not sensitizing	Read across/WoE from available data - no classification	
Acute toxicity, oral route	Allen (1994b), OECD 401, LD50 > 2000 mg/kg bw Additional supporting published data	Acute Tox . 4 (oral) based on weight of evidence	Huygevoort (2003d), OECD 401, LD50 = 200-2000 mg/kg bw. Acute Tox. 4 (oral)	Read across/WoE from available data - no classification	Berthold (1989), OECD 401, LD50 > 5110 mg/kg bw
Skin irritation in vivo	Allen (1994a), OECD 404, primary dermal irritation index (PDII) score = ca. 3, not irritant	not required at this tonnage Skin Corr. 1A (based on extreme pH)	Skin Corr. 1A (based on extreme pH)	Requirement can be fulfilled by validated in vitro test	Zechel (1989c), OECD 404, primary dermal irritation index (PDII) = 1.3, not irritant
Eye irritation in vivo	not required at this tonnage Eye Dam. 1 (based on extreme pH)	not required at this tonnage Eye Dam. 1 (based on extreme pH)	Eye Dam. 1 (based on extreme pH)	Read across/WoE from available data - no classification	Jahn (1989), OECD 405, Overall irritation score = 40, corrosive Eye Dam. 1



Sameness

Implication on testing programme: Rh genotoxicity

Substance	Existing endpoints	pH value
CASRN 20765-98-4. Rhodium trichloride “hydrate”	Positive in vitro Ames test	<2
	Positive in vitro mouse lymphoma assay	
	Positive in vitro micronucleus assay	
	Positive in vivo mouse micronucleus assay	
CASRN 10139-58-9. Rhodium trinitrate	Negative in vitro Ames test	1.3 (hydrate)
	Negative in vivo mouse micronucleus assay	