MINUTES

AP refer to Action Points listed at the end of this document.

1. **Welcome and introduction.**
   - 1.1. **Confidentiality and Competition Law.** Participants were reminded on their obligation to comply with Confidentiality and Competition Law.
   - 1.2. **Tour de table and apologies.** The list of participants is available in Annex 1.
   - 1.3. **Approval of the agenda.** The agenda is available in Annex 1. No remarks / additions; agenda approved.
   - 1.4. **Approval of the minutes of the last meeting (9 October 2012).** A table with the status of the action points from the last meeting is available in Annex 2 – slide 5-6. Several action items are on the agenda for discussion today. No remarks on the minutes; minutes approved.

2. **Substance identification and sameness of Pd substances**

In order to clarify several issues on physical state/properties (e.g. PdCl2 in aqueous HCl vs. H2PdCl4) and to support the substance sameness discussions and other mandatory communication obligations with the SIEF, ID cards have been circulated for the following Pd substances:

- Diamminedichloropalladium (DDP)
- Diammonium hexachloropalladate
- Dihydrogen tetrachloropalladate
- Palladium dichloride
- Palladium dinitrate

Currently the feedback is being evaluated and further clarified. Updated consolidated ID cards will be sent around in January 2013. AP1

An expert meeting was held 11 December on the sameness of the PGM nitrates. Some issues are to be further clarified but good progress was made. AP2

3. **Identified uses of Pd and Pd compounds**

Cf. slides 10-33 in Annex 2. Additions/comments:

- It is noted that the complete service life should be covered in the CSR and the ES.
- WCA is asked to provide PMC Members with a definition of intermediate - industrial use versus intermediate - professional use as PMC Members have difficulties to make this distinction.
- Dichlorobistriphenylphosphine palladium, palladium (II) diacetate, tetrakis(triphenylphosphine) palladium and palladium (II) di(4-oxopent-2-en-2oate) might be catalysts instead of processing aids (cf. definition of catalyst in factsheet intermediates).
- It was queried whether respondants may have reported Pd chloride under dihydrogen tetrachloropalladate and vice versa. Currently it is assumed that responding companies have responded with uses for the substances they intend to register. If this alters after finalisation of the ID cards, member companies should inform WCA.
- For palladium, no relevant use descriptors were supplied for handling and use of Pd containing materials, however, uses in Trading, Surface treated materials, Technical Products, Precious metal products, Coins, Medals, Electronics, Dental alloys and Jewellery were indicated. PMC Members should clarify/add.
- PMC Members agreed that an exposure scenario for service life is currently not required for palladium compounds used in surface treatment (cf. also 5.3).
- Palladium dinitrate is sold in relatively small quantities to academia for small-scale chemistry research. WCA will check if this is what is meant by 'intermediate - professional use'.
- For palladium oxide, WCA will check if the declared uses cover catalyst use.
- For DDP, it is assumed for now that the two identified uses cover the full life cycle and that there is no subsequent service life.
- PROCs 13 and 23 have been reported under intermediate use for some compounds but have been identified by ECHA as incompatible with the intermediate definition. Furthermore, PROCs 4 and 5

were also reported under intermediate use for some compounds but are incompatible with SCC requirements. PROCs 8a, 14, 19, 21, 22, 24, 26, 27a and 27b can be compatible with the intermediate definition/SCC requirements but justification will be needed in Appendix 3. WCA will note on the updated lists of identified uses and use descriptors where PROCs have been removed for these reasons, or will need further justification by individual member companies.

WCA will follow up individual responses and outstanding issues. **AP3-4**

Once finalised, the list of uses for palladium and palladium compounds will be sent 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). **AP5-6**

4. Environmental emissions Pd and Pd compounds *(Cf. slides 36-54 in Annex 2)*

4.1. Environmental ES building approach

The data compiled through the environmental emissions questionnaire will be used:

- To develop a Generic Exposure Scenario (GES) for use in the CSA/CSR. The GES is a sector-wide approach (not compound-specific) to exposure assessment and represents a reasonable worst-case scenario.
- As initial dataset for the site-specific risk assessment (SSA). If Tier 1 assessment indicates a risk (i.e. if RCR > 1 or close to 1), additional data may be required for higher tier modelling or substance-specific refinement may be needed. Monitoring may also be required in order to establish RCR < 1, but there is not much time left for this (long-term monitoring will not be possible before dossier submission for DDP but initial data may be presented alongside a long-term monitoring plan).

4.2. Environmental emissions questionnaire: additional data since last meeting

WCA has now received 14 questionnaires from 12 companies with an improved level of detail but:

- There are very little data for emissions to air (the use of the limit of detection led to very high emission estimates, hence the SpERC value was used);
- Additional data on receiving water bodies (especially the flow rate) would be helpful (otherwise conservative default values from ECHA will have to be used);
- Further follow-up is needed on tonnage.

AP7-8

It is noted that as much refinement as possible will be needed due to the low PNECs for the aquatic environment.

4.3. Draft Generic Exposure Scenario (GES) for Pd and Pd substances

- The parameter values for the environmental GES for overall Pd (metal equivalent) are summarised on slide 39 in Annex 2.
- Multiple scenarios are needed for emissions to water (freshwater/marine, with/without STP). The emission factors will remain the same, but tonnage, dilution factors etc. can be adjusted.
- Regional background concentrations for air, freshwater, sediment and soil (to be added to local GES PECs and for SSA) were calculated using EUSES and are summarised on slide 42 in Annex 2. Background concentrations for sediment and soil are high (RCR close to 1).
- PNECs were re-calculated because of an error made with the units and an error in identifying the most sensitive study in the previous calculation. The re-calculation resulted in a lower PNEC for freshwater, which had a knock-on effect on the other PNECs (cf. list of PNECs on slide 67 in Annex 2).
- New RCR calculations for the GES using the re-calculated PNECs are available on slide 43 in Annex 2 (overall Pd; background + calculated local contribution). Whereas at the last meeting, the risk for sediment was particularly high, there is now a potential risk for freshwater, marine water, sediment, marine sediment and soil.
- Substance-specific refinement alone of the GES will not be sufficient to bring the RCR to an acceptable level (< 1) but it is an option if RCR < 1 cannot be achieved by other refinements.

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AP9

Site-specific risk assessment (SSA)
WCA is currently calculating exceedances (RCR > 1) for several sites for freshwater, seawater and sediment. Further refinement is possible in some cases but not in others. Options include:

- Refinement of PEC based on exposure data (if possible);
- PNEC refinement;
- Monitoring of local environment (specifically freshwater (dissolved and sediment)). This has to be a long-term programme, but will not be necessary for all sites. **AP10**

4.4. ES refinement and potential testing strategies

Additional data are needed on:

- Pd emissions to air, to refine the EF in the GES or to further justify the use of SpERC for production of metals and metal compounds;
- Receiving water flow rate (or dilution factor), to refine the SSA;
- RMMs and efficiency for emissions to air;
- Tonnage: it is unclear if all sites have provided data for 'total Pd tonnage' in the same way. WCA needs to know the net Pd tonnage (i.e. Initial Pd feedstock processed or amount sold/stockpiled + discharge).

AP7-8

Furthermore, PMC Members agree that extra (chronic) testing will be needed to refine the PNECs and lower the RCRs (now only acute tests are available, resulting in a high assessment factor). Just improving the freshwater PNEC (with knock-on effect on other PNECs) will not be sufficient; all PNECS will need to be refined. Hence, aquatic and sediment testing will be required (**AP11-12**). It is noted that if sediment testing is performed, the additional factor of 10 in the RCR calculation will not be needed anymore.

Two approaches are possible for PNEC refinement:

1. Substance grouping approach: a PNEC is derived for each substance group/category;
2. Single assessment of all Pd substances: only a single reasonable worst-case PNEC is required, covering all forms of palladium.

WCA recommends the second approach, potentially using the PNEC derived for DDP if a limited amount of confirmatory testing could confirm that it is appropriate to use this compound as worst case.

There is some discussion on which approach to use and whether DDP is really the worst case Pd substance, but since DDP will have to be registered by 31 May 2013, testing and PNEC refinement will be done for DDP first anyway. The PGM WG will discuss at their next meeting whether we use the DDP PNECs as reasonable worst-case for all Pd substances.
(***Post-meeting note:*** *At the PGM WG meeting of 17 Jan 2013, it was agreed to use DDP as basis for read across to other Pd(II) substances (a decision will be taken on Pd(IV) substances later). The testing carried out on DDP will thus be directly relevant also for the other Pd dossiers.)*

Since DDP testing results are not expected to be available in time for the May registration deadline, it is suggested to submit the dossier with low PNECs and an M_{safe} GES (based on tonnage that would give RCR < 1) and update it later if we have test results. Following a strict interpretation of ECHA guidance this means RMMs will be needed between registration and the dossier update. **AP20-21**

4.5. Pd in waste

Basic information on waste needs to be included in the ES for all tonnage bands. A waste exposure assessment is now required in the CSR for substances > 10 t/a (only qualitative for substances < 10

t/a). The majority of Pd sites recycle their waste for re-use, some send their waste to landfill. The waste is generally in the form of sludges or filter cakes, or press cakes.

The potential requirement for several ESs is based on the different waste options identified. Assessment for recycling consists of three steps:
1) Assessment of relevance of recycling and justification of no relevance (recycling processes should only be excluded after careful consideration);
2) Checking if recycling process is already covered by earlier assessments (might be already covered for DDP);
3) Estimation of released amounts from relevant recycling processes.

ECHA Guidance R18 details default release fractions for landfill.

5. Occupational exposure Pd and Pd compounds *(Cf. Annex 3 and slides 57-64 in Annex 2)*

5.1. Occupational ES building approach

The occupational ES building approach is summarised on slide 58 in Annex 2.

5.2. Occupational exposure questionnaire: additional data since last meeting

Since the last meeting, EBRC received additional (clarification on) occupational exposure questionnaires but is still awaiting further information, to be included in the next version of the ES. **AP13**

5.3. Draft occupational exposure assessment for DDP

EBRC presented the draft exposure assessment for DDP (cf. Annex 3 and slides 59-64 in Annex 2). Additions/comments:

- DDP is used for electroplating of massive objects, but it is unclear if it is used for treatment solution and chemically transformed before plating or if it is still available in the solution and directly used for surface treatment. The point in time when DDP is transformed into palladium metal is important because:
  - If transformation occurs before the surface treatment process, all treatment shops operating with tonnages at or above 1 per year would have to register palladium metal.
  - If transformation occurs during the surface treatment process, a decision would have to be taken whether or not the treated surface represents a part of the life cycle of DDP.

  PMC Members agreed that an exposure scenario for service life is **currently** not required for DDP, but the final decision will be postponed until a conclusive classification for palladium metal is available.
- Additional information on measured data may influence the exposure assessment due to assignment of measured data to activity classes/workplaces.
- The results of the additional dustiness testing (cf. agenda point 6.1) will be reflected and may influence exposure assessment. **AP14-15**
- For DDP, no additional uses should be included.
- Thus far, EBRC received two comments on the draft ES:
  - It was suggested to use standard phrases in the ES, as these can then also be used for the eSDS. EBRC does not advise this since regulators are to understand the ES for the CSR. However, the ES could be translated in an ES for eSDS if PMC Members so wish (consortium decision).
  - The used activity classes (AC1-10) might be confusing. It is therefore suggested to use more descriptive titles. **AP16**

6. PNEC and DNEL refinement for diamminedichloropalladium (DDP) *(Cf. slides 67-69 in Annex 2)*

PNEC refinement: cf. agenda point 4.4.

For the DNEL derivation for DDP, the repeated dose toxicity (RDT) study is being repeated but will not be completed in time for the 2013 registration (**AP17**). Thus, tentative DNELs were derived using the only available and valid RDT study on tetraamminepalladium hydrogencarbonate (out of scope

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substance). The tentative DNELs are presented on slide 69 in Annex 2. WCA will issue a revised DNEL document (AP18). EBRC will check the inhalation exposure data to see if peak exposures are relevant. If not, there will be no need for an acute inhalation DNEL (AP19).

6.1. Need for additional dustiness tests on damp materials

Dustiness testing for DDP resulted in high dustiness. However, the results of the exposure questionnaire indicated low dustiness/aqueous solution for DDP. As dustiness tests were previously performed on dry material, three DDP samples with different known water content will be selected for new dustiness testing and then the one with the highest dustiness (worst-case) will be used for the ES. AP14-15

For the other Pd compounds, it is suggested to check the literature for the water content of damp materials and check if we can read-across from DDP.

7. Next steps and timeline for data refinement/generation and ES refinement

Cf. slides 71-72 in Annex 2. The final draft ESs for DDP will be presented at the next meeting on 13 March.

8. AOB, next meetings/calls, and closing remarks.

It is proposed to have the next PGM Exposure Scenario meeting 13 March 2013.

Annexes

1. Agenda & list of participants
2. Slides presented at the meeting
3. Occupational exposure scenarios DDP – First draft (EBRC, 7 Dec 2012)

Actions

Table 1. Actions agreed at the 12 December PGM Exposure Scenario meeting in Brussels

	What?	Who?	When?
Substance identification and sameness Pd substances			
1.	Circulate updated versions of the ID cards of: • Diamminedichloropalladium (DDP) • Diammonium hexachloropalladate • Dihydrogen tetrachloropalladate • Palladium dichloride • Palladium dinitrate	KA	Jan-Feb 2013
2.	Clarify outstanding issues on sameness of PGM nitrates	KA/KR with input from experts & PMC Members	Jan-Feb 2013
Identified uses of Pd and Pd compounds			
3.	Clarify remaining issues on uses with PMC Members (with focus on DDP first): • Provide PMC Members with a definition of intermediate - industrial use versus intermediate - professional use. • Dichlorobistriphenylphosphine Pd, Pd(II) diacetate, tetrakis(triphenyl-phosphine) Pd and Pd(II) di(4-oxopent-2-en-2oate): catalysts instead of processing aids? • Pd dinitrate: 'intermediate - professional use' referring to use in small-scale chemistry research? • Pd oxide: declared uses cover catalyst use? • Follow up intermediate/SCC incompatible PROCs.	WCA	Jan 2013
4.	Send input / comments on uses to WCA • Pd chloride not reported under dihydrogen tetrachloropalladate and vice versa?	PMC Members	By end Jan 2013

	• Pd: use descriptors for handling and use of Pd containing materials?		
5.	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	1 Feb 2013
6.	Send input / comments on uses to PMC Sec	Downstream users through PMC Members	By 15 Feb 2013
Environmental emissions of Pd and Pd compounds			
7.	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 (as Pd metal equivalent) for Pd processing starting materials, intermediates and final products.	PMC Members	ASAP but no later than 11 Jan
8.	Refine Generic Exposure Scenario (GES) and site-specific risk assessment (SSA) for Pd and Pd substances based on extra data provided	WCA	Jan-Feb 2013
9.	Based on results of the GES and SSA, decide whether or not there is a need for substance-specific refinement	WCA	Feb 2013
10.	Based on results of the SSA, follow up need for monitoring programme with individual sites	WCA	Feb 2013
11.	Conduct additional testing for DDP to refine the PNECs: • Sediment toxicity test (Chironomus, OECD 218) • Aquatic toxicity test (Daphnia, OECD 211)	CRO through PMC Sec	Jan-May 2013
12.	PNEC refinement	WCA	Jun 2013
Occupational exposure of Pd and Pd compounds			
13.	Clarify remaining issues on occupational exposure and on monitoring data with PMC Members and further refine/update GES for DDP	EBRC	Jan-Mar 2013
14.	Select 3 damp DDP solids with different known water content and perform dustiness testing	PMC Sec	Jan 2013
15.	Reflect results of the additional dustiness testing in the ES for DDP	EBRC	Feb-Mar 2013
16.	For each activity class, add a description of the involved tasks and a short name in the ES	EBRC	Feb 2013
PNECs / DNEL for diamminedichloropalladium (DDP)			
17.	Repeat RDT study (OECD TG422 combined toxicity/reproductive screen study) for DDP for final DNEL derivation	PMC Sec/ CiToxLAB	Oct 2012 – End 2013
18.	Issue a revised DNEL document	WCA	Jan-Feb 2013
19.	Check inhalation exposure data to see if peak exposures are relevant	EBRC	Jan-Feb 2013
DDP dossier submission			
20.	Submit DDP registration dossier with tentative RMMs	PMC Sec/WCA	By 31 May 2013
21.	Update DDP registration dossier following PNEC refinement	PMC Sec/WCA	Summer 2013