



Chairman: D. Boyd (Johnson Matthey, United Kingdom)  
Secretariat: K. Rothenbacher & C. Braibant (EPMF, Belgium)

Metals Conference Centre - Room Nickel/Zinc  
Rue du Duc 100 - 1150 Brussels (BELGIUM)

## 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 (27 June 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. PdCl<sub>2</sub> in aqueous HCl vs. H<sub>2</sub>PdCl<sub>4</sub>) 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

The deadline for response was 4 October 2012, but so far only limited feedback was received. PMC Members are reminded of the importance of this exercise; the Exposure Scenarios can only be as good as the input data. Data are needed by 15 October. **AP1**

### 3. Reminder on background and current status of the PGM CSA/CSR + ES work (Cf. slides 10-14 in Annex 2)

7 Pt and 9 Pd substances are currently > 10 t/a and classified for environment / human health endpoints in the PMC inventory (dd 10 April 2012), hence requiring a CSR. From these substances, only DDP requires full registration in 2013. Therefore, data collection and assessment are prioritized for DDP and/or the Pd family (effects from and exposure to Pd ion). In addition to the 9 Pd substances in scope, a CSR will be produced for Pd metal and Pd dioxide, resulting in a total of 11 Pd substances in scope. Depending on the outcome of the on-going testing programme, additional PGM > 10 t/a may require a CSR.

The ES for each compound will include various exposure pathways:

- Environment: emissions to environment versus PNEC for all environmental compartments;
- Man via the environment: exposure via environment / food versus DNEL;
- Workplace: occupational exposure versus DNEL for each relevant route of exposure;
- Consumer: emissions from consumer goods versus DNEL (It will need to be discussed how exactly to handle jewellery exposure);
- Exposure via food: presence in food versus DNEL;
- Combined exposure: all in one scenario;
- Waste: emissions from waste streams versus PNEC and DNEL? A multi-metallic methodology is currently being developed by ARCHE under the umbrella of Eurométaux.

WCA will be responsible for the environmental exposure assessment, exposure of man via the environment and waste exposure. EBRC will be responsible for the occupational exposure scenarios and - if relevant - for the consumer, food and combined exposure work.



To collect all necessary information for the CSRs and ESs for the Pd substances, 4 excel-based questionnaires / collection forms were circulated:

1. **Use questionnaire** (for manufacturers and/or importers, and DUs) to collect information on all identified uses of registrants and their DUs to be added to the Registration dossier (for all tonnage bands), for the entire life cycle of all Pd substances. Non-reported uses will not be covered in the Registration dossier and may be considered as non-authorized uses in the EU;
  2. **Environmental emissions questionnaire** (for manufacturers - and DUs if refinement/tailoring needed) to collect information on tonnage, potential emissions to air & water, RMMS & treatment efficiencies, monitoring data and confounding factors. Compiled data will be used to develop ES;
  3. **Workplace exposure questionnaire** (for manufacturers - and DUs if refinement/tailoring needed) to collect information on workplaces, OCs and RMMs implemented on sites. Compiled data will be used to develop ES;
  4. **Workplace exposure data collection form** (for manufacturers - and DUs if refinement/tailoring needed) to collect measured workplace exposure data. Compiled data will be used to develop ES.
4. **Draft PNECs / DNEL for diamminedichloropalladium (DDP)** (Cf. slides 16-17 in Annex 2)  
All scheduled ecotoxicity tests have been successfully completed. Only acute tests were performed, resulting in the application of high assessment factors (AF) and thus low PNECs for DDP. Refinement will depend on ES needs.

For the DNEL derivation for DDP, the repeated dose toxicity (RDT) study had to be terminated. The study will have to be repeated but will not be completed in time for the 2013 registration. Thus, a tentative DNEL will have to be derived. Available studies on Pd compounds were examined and there is only one available and valid RDT study: an oral study on tetraamminepalladium hydrogencarbonate (out of scope substance). The derivation of a tentative DNEL will offer a provisional solution and will be further discussed with WCA and at the PGM WG meeting. [AP2-3](#)

5. **Identified uses of Pd and Pd compounds** (Cf. slides 19-27 in Annex 2)  
WCA received 89 completed questionnaires for 20 substances from 43 companies (including 21 total downstream users): cf. slides 21-23 in Annex 2. There are a number of outstanding issues to be clarified: cf. slides 25-26. [AP4-5](#)

Comments PMC Members:

- Manufacturers doubt that all downstream users have responded and that they realise they cannot trade if their use is not reported. When the list of uses is finalised, it is suggested to send it to all downstream users stating that uses not on the list may not be authorised. [AP6](#)
- If new uses are identified later on, they can be added if necessary.
- For future questionnaires, the aim of the questionnaire should be very clearly communicated.

An intermediate dossier for diammonium hexachloropalladate will be submitted in 2013. The use questionnaire details PROCs 3, 9, 22 & 27A for this substance. However, the recent ECHA annotation letters focusing on the compatibility of PROCs with the intermediates/SCC definition state that PROCs 22 and 27A are not compatible with the requirement on SCC. Eurométaux is currently discussing the challenged PROCs with ECHA, as they feel that the assessment of SCC should rely not only on the PROCs but also on the justification that will be provided in Appendix 3. Depending on the outcome of this discussion, the PROCs in the intermediate dossiers might have to be reviewed/updated. [AP7](#)



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The PMC secretariat suggests organising an interactive 1-day workshop on REACH and intermediates, if there is enough interest from PMC members. The objective of the workshop is to get more clarity on the definition of intermediate/SCC/waste through presentation of theoretical background and practical examples. Specific (anonymised) case studies provided by PMC Members would be presented and potentially evaluated by experts/MSCA representatives (e.g. from Germany/UK) (caveat is that different MS may have different interpretation). It is stressed that examples at the workshop should not be viewed as final and applicable to all companies. The final decision on intermediate status is still company specific. (**Post-meeting note:** *The intermediate workshop will be organised as part of the next PM Refinables meeting on 13 December 2012.*) **AP8**

The status of a substance as an intermediate is not specific to its chemical nature but to how it is used. This means that for the same substance, you can have intermediate use and substance use. In IUCLID 5.4, tonnages can be split according to use but total tonnage has to be used to define registration deadline.

Substances used in surface treatment cannot be intermediates.

## 6. Environmental emissions Pd and Pd compounds (Cf. slides 29-46 in Annex 2)

### 6.1. 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 close to 1), additional data may be required for higher tier modelling.

### 6.2. Results of the environmental emissions questionnaire

WCA has received 10 questionnaires from 8 companies with a variable level of detail. Most datasets were insufficient to enable site-specific assessments or to make a meaningful contribution to the derivation of a GES. Follow-up questions have been sent out.

The minimum information required for the GES is:

- 1) Total tonnage Pd/Pd compounds used at the site per year;
- 2) Total emissions of Pd to air per year and removal efficiencies of treatment;
- 3) Total emissions of Pd to water and number of emission days per year;
- 4) Waste water treatment (on site, off site, none), removal efficiencies and flow rates for on-site WWTP, STP and ultimate receiving water body. Flow rates are key information for achieving a lower RCR for emissions to water, and can be easily collected by e.g. calling your local STP or looking up online;
- 5) Dilution factors due to STP/ultimate receiving water body;
- 6) Limits of detection.

Those PMC Members that have not sent an environmental emissions questionnaire yet, will receive a reminder highlighting the minimum information required and stressing that if they do not provide data, they will not receive a site-specific ES and will need to be able to prove their site fits the conditions used in the developed GES. **AP9-11**

It is stressed that the more data provided by companies through the questionnaires, the more statistically robust the emission factors (important parameter for GES) will be. Therefore, PMC Members are encouraged to provide as much data as possible.



### 6.3. Draft Generic Exposure Scenario (GES) for Pd and Pd substances: what information is currently missing?

The preliminary parameter values for the environmental GES are summarized on slide 40 in Annex 2. The emission factor for water is currently 62,5 g/t (per ton of Pd not per ton of waste) based on the questionnaire responses. PMC Members commented that this is very high. This number will be revised based on further clarifications by companies/extra measurements. There are currently insufficient data for an emission factor to air, so more data will be needed. If there are no (measurable) Pd emissions to air, 50% of the detection limit (LoD) can be used to estimate stack emissions, or the SpERC for emissions to air proposed by ARCHE for manufacture of metals and metal compounds (0.03% or 300 g/T) can be used in the GES for Pd compounds.

The exposure modelling is done by calculation of a Predicted Environmental Concentration (PEC) for various compartments, which are then compared to the PNEC to give an RCR. At least two exposure scenarios will be needed (mostly with discharge to municipal STP but not all). A number of parameter values are required to undertake modelling of PECs like partition coefficients, removal efficiency from STP and effect levels (PNECs and DNEL for MvE).

The first RCR calculations using the preliminary GES for DDP using defaults (total Pd emissions compared to PNEC DDP) were presented by WCA. Extra data will be needed to refine these calculations. [AP12](#)

The RCR for sediment was particularly high. It was noted that sediment testing may be needed to refine the PNEC. [AP13](#)

### 6.4. 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). Exemptions from the qualitative exposure assessment are summarized on slide 45 in Annex 2 and include recycling processes.

9 respondents included estimates for the amount of solid waste produced (tonnes metal/yr): 7 respondents recycle their waste for re-use, 2 respondents send waste to landfill. The waste is generally in the form of sludges or filter cakes, or press cakes.

The potential requirement for several exposure scenarios 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;
- 3) Estimation of released amounts from relevant recycling processes.

ECHA Guidance R18 details default release fractions for landfill.

## 7. Occupational exposure Pd and Pd compounds (Cf. slides 49-71 in Annex 2)

### 7.1. Occupational ES building approach

The core information requirements for the occupational ES are summarized on slide 50 in Annex 2. To facilitate the development of ESs, the exposure assessment is based on activity classes (AC), grouping processes/workplaces for Pd. Several processes (with similar OCs and RMMs) were grouped in 1 activity class to decrease the confidentiality issue and the number of questionnaires. 10 ACs were developed and are being used for the assignment of measured data and for read-across concepts (with regard to measured data and downstream uses).



## 7.2. Results of the occupational exposure questionnaire

The aim of the occupational exposure questionnaire was to gather OCs and RMMs related to individual data points. Questionnaires were received for 11 of the 12 Pd substances. In total, EBRC received more than 27 completed questionnaires. 27 are currently included in the EBRC database, further information is required on additional questionnaires. In general, ACs seem to be appropriate for most companies. Follow-up questions have been sent out to solve inconsistencies in the received questionnaires (cf. slides 55-58 in Annex 2). Those PMC Members that have not sent an occupational exposure questionnaire yet, will receive a reminder. [AP14-16](#)

The extent of the current dataset of inhalation monitoring data is not sufficient for some ACs. At least 12 data points are needed per exposure setting. Use of modelled data may be possible for some ACs. Use of analogous data from similar substances may be another solution (but will not be needed if modelled data can be used). Read-across from Pt will however not be possible, as Pt has a different hazard profile.

## 7.3. Draft occupational exposure assessment for Pd and Pd substances

A first exposure assessment was performed for DDP (2013 registration). As only 6 measured DDP exposure values were available, the preliminary assessment was based on modelling data (MEASE estimates). The exposure assessment was exclusively performed for nominated physical forms. Additional physical forms (e.g. from dustiness testing and use questionnaire) were not yet considered. Furthermore, the ratio process temperature (PT)/melting point (MP) was not yet considered, which might have an influence on emission potential during processes at (substantially) elevated temperatures. MEASE exposure estimates varied from < 0,001 to 7 mg/m<sup>3</sup> (with consideration of least efficient LEV) whereas measured data ranged from 0,1 µg/m<sup>3</sup> to 364 µg/m<sup>3</sup>. 2 or 3 ACs are of potential concern. Further use of additional RMMs is recommended.

The exposure assessment will be refined with extra data. [AP17-18](#)

## 7.4. Need for additional dustiness tests on damp materials

Dustiness testing for DDP resulted in high dustiness. However, most PMC Members indicated low dustiness/aqueous solution for DDP in the exposure questionnaire. Dustiness tests were performed on dry material, however, for damp material like DDP, they should be done on the damp material as we need evidence on low dustiness. If dustiness tests show low dustiness for damp materials, this could be used in MEASE.

It is suggested to select 3 DDP samples with different known water content for the dustiness test and then select the one with the highest dustiness (worst case) for the ES. [AP19](#)

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.

## 8. Next steps and timeline for data refinement/generation and ES refinement

Cf. slides 74-75 in Annex 2. The first draft ESs for DDP will be presented at the next meeting on 12 December, and will be circulated 7 December. Refinement of the ESs will be done January-February and final ESs should be ready by end of February.

## 9. AOB, next meetings/calls, and closing remarks.

It is proposed to have the next PGM Exposure Scenario meeting 12 December 2012.



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## Annexes

1. Agenda & list of participants
2. Slides presented at the meeting

## Actions

Table 1. Actions agreed at the 9 October PGM Exposure Scenario meeting in Brussels

	What?	Who?	When?
<b>Substance identification and sameness Pd substances</b>			
1.	Send input / comments to KA on the ID cards of: <ul style="list-style-type: none"> <li>• Diamminedichloropalladium (DDP)</li> <li>• Diammonium hexachloropalladate</li> <li>• Dihydrogen tetrachloropalladate</li> <li>• Palladium dichloride</li> <li>• Palladium dinitrate</li> </ul>	PMC Members	By 15 Oct 2012
<b>PNECs / DNEL for diamminedichloropalladium (DDP)</b>			
2.	Derive tentative DNEL for DDP, based on RDT study tetra-amminepalladium hydrogencarbonate, to enable conducting the Exposure Scenario calculations	PMC Sec / WCA	Oct 2012
3.	Repeat RDT study (OECD TG422 combined toxicity/reproductive screen study) for DDP for final DNEL derivation	PMC Sec / CiToxLAB	Oct 2012 - End 2013
<b>Identified uses of Pd and Pd compounds</b>			
4.	Send input / comments on the compiled list of uses to WCA	PMC Members	By 15 Oct 2012
5.	Assess which use descriptors can be combined and clarify remaining issues on uses with PMC Members (with focus on DDP first)	WCA	Oct-Nov 2012
6.	Once finalised, send list of DDP uses to downstream users clearly stating that uses not on the list may not be authorised	PMC Sec through PMC Members	Dec 2012
7.	Depending on the outcome of the PROCs discussion at the January 2013 Eurométaux/ECHA workshop, review and/or justify PROCs of intermediate Dossiers	WCA	Jan 2013
8.	Prepare and circulate one-pager on proposed intermediate workshop (addressing waste/non-waste, intermediate, UVCB status of PM Refinables) to check interest from PMC Members	KA	Nov 2012
<b>Environmental emissions of Pd and Pd compounds</b>			
9.	Send personalised reminder to PMC Members not having sent an environmental emissions questionnaire yet, highlighting the minimum information required for the GES	KA	ASAP
10.	If not done yet, complete environmental emissions questionnaire for each site producing Pd and/or Pd substances (1 per site) and return to project coordinator	PMC Members	ASAP but no later than 26 Oct
11.	Clarify remaining issues on environmental emissions of Pd compounds with PMC Members	WCA	Oct 2012
12.	Refine Generic Exposure Scenario (GES) for Pd and Pd substances based on extra data provided	WCA	Oct-Nov 2012
13.	Based on results of the GES, decide whether or not there is a need to refine the PNECs and perform further effect studies	All	Dec 2012
<b>Occupational exposure of Pd and Pd compounds</b>			



PRECIOUS METALS AND RHENIUM CONSORTIUM  
PGM Project - Exposure Scenario Meeting  
9 October 2012, 10:00-15:30 CET

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14	Send personalised reminder to PMC Members not having sent an occupational exposure questionnaire yet	KA	ASAP
15	If not done yet, complete occupational exposure questionnaire (1 per site) and data collection form for each site producing Pd and/or Pd substances and return to project coordinator.	PMC Members	ASAP but no later than 26 Oct
16	Clarify remaining issues on occupational exposure and on monitoring data with PMC Members	EBRC	Oct 2012
17	Refine Generic Exposure Scenario (GES) for DDP based on extra data provided	EBRC	Oct-Nov 2012
18	List possible next steps for occupational exposure assessment EBRC will be looking at	EBRC	Oct-Nov 2012
19	Select 3 damp DDP solids with different known water content for dustiness testing	PMC Sec	Oct-Dec 2012