DRAFT 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 (12 December 2012) – including status of action items.** 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; the minutes of the last meeting were approved.

2. **Substance identification, sameness and tonnage of Pd substances**
   - 2.1. **ID cards**

     In order to clarify several issues on physical state/properties and to support the substance sameness discussions and other mandatory communication obligations with the SIEF, ID cards have been circulated for PGM substances currently undergoing testing. Based on the feedback received so far, several questions still remain on the physical state and composition of some substances. Therefore, an additional questionnaire was circulated to prepare substance sameness discussions and help decide how to properly register different forms of the same substance. The aggregated information will also be used to further complete the ID cards.

     No comments/ objections regarding the format of the new questionnaire were raised.

     Participants were reminded that the deadline for returning the questionnaire was 19th June 2012. AP1

   - 2.2. **Sameness** *(Cf. slides 10-25 in Annex 2)*
     - **Update nitrates sameness discussion**
       An expert meeting was held 11 December 2012 on the sameness of PGM nitrates. No sameness was concluded between solution and solid for Pt nitrate and for Rh nitrate for the time being. Additional analyses and spectra have been requested and will be discussed at the next expert meeting to finally conclude on this. AP2
     - **Implications for genotoxicity testing**
       The genotoxicity testing/interpretation for Pt and Rh nitrates is on hold until sameness of these substances is clarified. Pd nitrate can be added to genotox scope now. AP3
     - **DDP isomers**
       DDP consists of different isomers: PMC requested feedback of the PGM WG in order to make sure the correct registration route is taken, and that DDP can be used as read-across substance. Not all registrants had provided input on the ratio of isomers.

       The PGM WG meeting concluded that for Pd substances, the reactivity of both cis- and trans-isomers is likely similar. However, the exact isomer ratios should be confirmed based on the IR spectra. Registrants were reminded to provide IR spectra of their DDP products to PMC. AP4
       The final registration strategy for DDP will be based on spectra (e.g., registration as 'monoconstituent substance' or as 'mulitconstituent substance'.
     - **Sameness and skin corrosion testing solids/liquids**
       PMC reminded participants on its position that sameness is the prerequisite for registration. If there is no clarity on sameness between solids and liquids for some substances (e.g., Pt and Rh nitrates, etc.), there is no basis for reading across hazard properties and PMC has therefore recommend that both forms are tested in such cases.

Heraeus did not fully agree and were therefore invited to present their view on the sameness discussions (cf. Annex 4).

- Heraeus received feedback from ECHA indicating that if a registrant can demonstrate that both forms have the same properties, they can be registered in the same dossier.
- The Corrositex test is an *in vitro* test that allows testing both the solid and liquid form of a substance.
- The PGM WG agreed that the species of the solid and the solution are likely to be different for some compounds. Therefore, we have an ethical and moral obligation to test both forms.
- How to cover differences in solvent concentration in the liquid form? As previously agreed, each company will test their own Pt nitrate (so if for instance the concentration of acid is different, this is covered in testing).
- Current test results show that corrosivity between the tested solids and solutions is not significantly different. No explanation for the reason for this can be provided (could be either because of sameness, or because of coincidence)

It was agreed to wait for the results of the PGM sameness expert meeting before deciding on a registration strategy for Pt- and Rh nitrates

2.3. Updated tonnage bands

Earlier this year, the PMC secretariat became aware of an issue in determining the exact tonnage used for DDP. In order to reach the required purity, DDP is sometimes re-dissolved in aqueous ammonia and re-precipitated by the addition of acid. Some Members may have thus counted the tonnage of DDP twice. The PMC secretariat recommended considering the re-dissolution as a purification step and thus counting the DDP tonnage only once. This recommendation has been confirmed with the UK Reach Ready helpdesk and the implications are summarised on slide 26 in Annex 2. As a consequence, DDP now falls into a lower tonnage band and did not require registration by the May 2013 deadline.

3. Final identified uses of Pd and Pd compounds

WCA presented the outcome of the use identification exercise. Cf. Annex 5 and slides 27-34 in Annex 2. Additions/comments:

- The question was raised if the uses are in agreement with the new initiative to align ES titles (EuPhraC) **AP5**
- No comments were made on the final list of uses; the list was approved.

4. PGM testing programme *(Cf. Annex 6 and slides 36-42 in Annex 2)*

4.1. DDP ecotoxicity testing. Tests are ongoing and results are expected in July 2013. The testing is taking longer than expected since extensive preliminary testing was required (stability trial, additional range finder studies). Similar to the mammalian tox testing, DDP is a difficult substance to test.

4.2. DDP repeated dose testing. The RDT study is being repeated at CiToxLAB but progress is slow. Pre-tests have indicated that dosing formulations are not stable over 7 days, making this procedure unsuitable for dosing. Currently the stability of formulations over 1 day is being evaluated, and in parallel a palatability study is being conducted to evaluate if a dietary study could be conducted (dosing of DDP via food). The feasibility studies will be followed by a range finding study; it is planned to finalise them before end 2013. The full study will follow in early 2014 and is planned to be completed in Q3 2014.

4.3. PGM ecotoxicity testing. There is agreement on scope and testing labs but tests are currently paused due to workload considerations.

4.4. PGM irritation/corrosion testing. The additional Corrositex tests have been completed. The detailed testing scope and a summary of the results have been provided on slide 39. Current results show that corrosivity between solids and solutions is not significantly different. No final

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be

reports are available yet as the respective certificates of analysis for a range of substances were missing. Companies were asked to provide the CoAs to the testing lab if they have not done so yet. **AP6**

4.5. PGM genotoxicity testing. The testing programme has been initiated and the tests are starting now at Covance. The detailed testing scope was presented on slide 40. Substances have been requested already.

4.6. PGM sensitisation testing. A summary of the testing status was presented. Four substances are being tested; 1 test material has not been received yet. The tests are still ongoing as the selection of an appropriate solvent proved challenging and also some stability issues had to be resolved prior to testing.

4.7. PGM acute/repeated dose testing. A range of testing labs was evaluated by PMC and RSA and agreement on labs has been reached with the PGM WG via 'written procedure'. The testing will now be conducted at CiToxLAB (Hungary) and at LPT (Germany). The contracts are being signed and tests are starting now. The detailed testing scope was presented on slide 42. For some substances a decision on whether separate tests (OECD 407/ 421) or a combined OECD 422 test will be conducted cannot be made at that stage. This will be decided once the results of the acute test and the range finding study are available. For the time being, both options are listed in the testing scope.

Overall, the management of the PGM testing programme is time-consuming but under control. RSA is supporting PMC with detailed study monitoring.

5. Current status of PNEC and DNEL refinement for DDP *(Cf. slides 44-48 in Annex 2)*

Due to the revised timing, there is no need anymore to derive tentative PNECs/DNELs/interim RMMs for DDP. Nevertheless it is suggested to keep up the momentum and complete ongoing studies ASAP in order to derive a PNECs and DNELs.

5.1. PNEC derivation

In view of the ongoing discussions on sameness (agenda point 2.2) PMC raised the question if DDP can still be used as read across substance. PMC recommends to continue to use DDP as a lead substance, as we have a robust data set for DDP and it represents a good worst-case. In other words, all other Pd (II) substances are less toxic than DDP and we are thus reading across on a conservative basis. PMC Members agreed to this.

5.2. DNEL derivation

The DNEL derivation for DDP is ongoing. DNELs for other Pd substances are also being derived and currently the following tests have been scheduled:

- *DDP (OECD 422 – ongoing at CiToxLAB)*
- *Palladium dihydroxide* (OECD 422 – CiToxLAB)
- *Tetraamminepalladium(2+) dichloride (OECD 421 – CiToxLAB)*
- *Diammonium hexachloropalladate (OECD 407/421 – CiToxLAB)*

However, Pd dihydroxide is poorly soluble. Although its bioavailability will probably be sufficient for testing the question was raised if not a more soluble Pd(II) substance should be tested in order to increase acceptance by regulators. It was suggested to use Pd sulphate as the most suitable alternative, provided its pH (it is only available as solution) does not impede testing. A fall-back option could be Pd nitrate. **AP7**

6. Environmental emissions Pd and Pd compounds *(Cf. Annex 8 and slides 50-75 in Annex 2)*

6.1. Generic Exposure Scenario (GES) for Pd and Pd substances

- A representative sector-wide GES was developed that is applicable for <u>all</u> Pd compounds based on values calculated from the compiled dataset.
- GES parameters are summarised on slide 55 in Annex 2. Tier 1 GES, based on reasonable worst-case from company data, is calculated with a tonnage of 20 t/a (expressed as Pd based on 90P

of company data). This results in several RCRs >> 1 (= potential risks)

- Msafe GES: the GES was back-calculated to determine at which (lower) tonnage an RCR < 1 is reached, indicating no risk. This results in an Msafe tonnage of 11 t/a DDP (or 5.5 t/a Pd) for DDP manufacture and 1 t/a DDP (0.5 t/a Pd) for electroplating.
- The Msafe should be regarded as tentative as it does not cover the sediment compartment. This has been left out as the current RCR ratios would permit only negligible use of DDP. When submitting in May, we would have omitted the sediment data justifying that sediment testing is ongoing.
- The GES and Msafe will have to be updated once the revised PNECs are available
- The reported RCRs would be lower with local emission factors (EF) but this can only be done site-specifically (see next agenda point)
- We will need to check if DUs are covered by Msafe GES. **AP8**

6.2. Status of site-specific risk assessments (SSRA)

- WCA sent SSRAs to each company in March, which take into account site-specific parameters. Slide 65 in Annex 2 summarises the results of the SSRAs. For the receiving water body, several RCRs are reported higher than 1 (indicating a risk). For receiving water body sediments, all RCRs are > 1.
- It was discussed how to best refined these scenarios:
    - Those RCRs which are close 1 will probably change to no-risk-scenarios once the results of the ongoing tests to refine the PNECs become available; no further refinements were recommended for those cases. The sites with aquatic RCR > 5 (4 sites) and/or sediment RCR > 10 (6 sites), however may still be at risk even after taking into account the new PNECs. It was therefore recommended to initiate a monitoring programme for these sites.

6.3. Proposal for Pd monitoring and sampling

- Where appropriate, WCA had already included monitoring recommendations in the individual SSRAs sent to companies.
- An initial discussion of the scope of the monitoring programme was held:
    - Timing: for companies with RCR> 5/10 as discussed under point 6.2, monitoring can be started now, and does not necessary have to await refined PNECs
    - Unless there are special situations (e.g., batch processes conducted only a few times per year) the sampling period should cover a full calendar year to account for seasonal variations
    - Frequency: water samples should ideally be taken on a weekly/ biweekly basis. Sediment samples integrate emissions more and do not require sampling at this frequency
    - Analytics: the limit of detection (LOD) should be sufficiently low, i.e., lower than the PNECs in order to be able to judge whether or not there is a potential risk
    - Aquatic sampling could be done by trained company personnel. For sediment sampling specific expert knowledge is required. It is recommended to have 1 organisation take the sediment samples for consistency
    - Some companies already have proprietary monitoring programme ongoing, which are approved by regulators so it might be easy to add Pd to it (**AP9** for companies to check + check LOD).
- WCA was asked to draft a discussion paper with recommendations for a sampling programme. This should include a proposal/ quote for the analytical work and for sediment sampling. **AP10**

6.4. Extension of monitoring/sampling to other PGMs

- If indeed a monitoring exercise will be conducted, it was recommended to use the opportunity and also monitor other PGM substances. The incremental costs for additional analyses are negligible. For this reason, it was recommended to carry out the analytical work at one

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be

laboratory.

- The same considerations as for the Pd monitoring work would apply
    - The LODs would need to be sufficiently low
    - Member should check if internal data, or analytical capabilities are already available (and what LOQs can be achieved) **AP9**
- WCA will include the above considerations in their recommendation for sampling/ monitoring of PGMs. **AP10**

It is planned to finalise the ES before the end of the year once we have revised PNECs.

Assessment of waste

- WCA described their approach for the assessment of waste, taking into account the new guidance from ECHA (s. slides 71-75)
- WCA to check if monitoring data are available, which could allow for the emission factors (EF) to be lowered for landfill emissions
- WCA to also check the possibility for SSA where applicable (e.g., internal landfilling with specific EFs). **AP11**

7. Occupational exposure scenarios for DDP *(Cf. Annex 9 and slides 78-94 in Annex 2)*

7.1. Reflection of comments received – open issues

- EBRC presented a summary of progress since the last meeting
- There were no objections to change the title of ES 9.3 to "Industrial use of DDP for surface treatment"
- An update of the ES for DDP is required since it has been reported that DDP may also be dried during the process, resulting in a lower moisture content (see further discussion next agenda point). This was agreed **AP12**

7.2. Dustiness tests and impact on occupational exposure scenarios

- A variable moisture content is expected due to varying times between digging off filters and further processing (drying, packaging).
- So far, dustiness data for 2 DDP samples are available, one dried sample and one sample with a moisture content of ca 20%. It was agreed to cover the whole range of moisture contents and determine the dustiness of two more samples: a) a material at the lower range of moisture content and b) a material at the higher range of moisture content.
- Practically, selecting samples for testing will be a challenge as most companies do not measure the moisture content of DDP at various stages of the process on a regular basis. It will therefore be difficult to source representative samples. The following steps were suggested:
    - Low moisture content sample: ask the company that reported the lowest moisture content sample to take a sample just before packaging it **AP13**
    - High moisture content sample: ask the company reporting the highest moisture content to take a sample right after the filtration **AP13**
    - The two additional samples will be tested at DMT. Only dustiness testing is needed, i.e., no cascade impactor assessment. **AP13**

8. Next steps and timeline for dossier submission

Cf. slides 97-100 in Annex 2. PMC presented an updated time line for the dossier submissions of PGMs. The timing for DDP has been delayed due to the need for extensive method development of the repeated dose study at CiToxLAB (s. discussion agenda point 4.2) and a DNEL is now planned to be available in Q3/ Q4 2014.

Similarly, for the other PGMs, the time-critical pathway are the repeated dose tests, followed by DNEL derivation and finalisation of occ. ESs. This will be PMC's highest priority for the coming quarters.

8.1. Occupational exposure scenarios for other Pd substances

Data on all relevant Pd compounds (> 10 tpa + hazardous) has been collected in 2012, checked for completeness and included in the database. (DDP had been prioritised due to the 2013 Reach deadline at the time). A final quality check will now be initiated.

Although it was agreed in earlier meetings for the exposure assessment of DDP to include the service life of surface treated objects (as a reflection of the need to cover the entire life-cycle of a substance), it was indicated by EBRC that an exposure assessment for palladium metal would only be meaningful if a hazard for human health would be identified for palladium metal.

The latest guidance from ECHA (Guidance on information requirements and chemical safety assessment Part B: Hazard Assessment Reference: ECHA-11-G-16-EN) indicates that occupational ES are only required if a hazard to human health has been identified. **AP14**

The timing will depend on the availability of required information, for instance the DNELs for other Pd substances. PMC advised that the DNELs will be the bottle-necks: studies are ongoing but it will take until end 2014 for them to be finalised and definitive DNELs to be derived. It was agreed to in the meantime proceed with the ES work as far as possible, e.g., with data collection and derivation of tentative ES – similar to what we did for DDP. EBRC will do the preparatory work over summer and will start developing the occ. ES as from October. **AP15, AP16**

Use of CHESAR for 2018 registration

EBRC indicated that considerable improvements have been made to the CHESAR tool by ECHA and that it is now more suitable for metals. EBRC recommended to use CHESAR, at least for section 3.7 of IUCLID.

PMC indicated that they would like to better understand the pros/ cons of CHESAR before making a decision. Currently, there is not much experience on the metals side with using CHESAR. For 2018 some metal consortia will use it, but no metals dossiers have been submitted yet using CHESAR.

It was suggested for EBRC to give presentation on CHESAR at an internal meeting with PMC first. PMC will then take the issue back to the PGM WG with a recommendation. **AP17**

In the meantime, the ES can be developed without CHESAR (it would anyway only be used as a reporting tool), so no time is lost.

8.2. Launch of exposure and emission data collection for Pt substances and intermediates

See slide 90 in Annex 2. Data on the relevant Pt compounds have not yet been collected and will be collected in the same way as for the Pd substances. Data collection will start after summer when further information on measured data is also available. DUs have not been identified yet.

It was noted that workplace exposure data on are also available from the International PGM Association (IPA). PMC indicated that a data sharing agreement with IPA has been signed; the data are currently being aggregated. The final data will be available before 2nd October 2013. **AP18**

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

It is proposed to hold the next PGM Exposure Scenario meeting on 6th November 2013 in Brussels.

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

It was discussed whether standard phrases could be used in our ESs. Standard phrases would allow for easier translation of eSDS as well as for better interpretation at the downstream user level. ES without standard phrases are very impractical for companies.

However, standard phrases are currently focussing on organic substances and other metal commodities are not using standard phrases right now. In the meantime, some standard phrases for metals have been developed by individual companies. They have already been shared with EM. However, it is currently not clear if they can be freely shared with all commodities and further discussion is needed to clarify access to these standard phrases **AP19, AP20**

In case standard phrases are to be used, EBRC recommends using CHESAR for the development of ES to avoid duplication of work (ES for CSR and ES for eSDS).

As this is a generic metals issue, it was recommended to bring this up for discussion at the EM Exposure Working Group. **AP21**

9.2. Water solubility paper

A manuscript has been prepared for publication of the results of our recent water solubility measurements in the peer-reviewed literature. PMC is currently awaiting some feedback (e.g., on how to acknowledge the sample providers in the paper) and will then circulate the draft final manuscript. PMC Members were reminded to come back with comments asap. (Post meeting note: feedback has been received and the manuscript has been circulated for comments on 28th June). **AP22, AP23**

Annexes

1. Agenda & list of participants
2. Slides presented at the meeting
3. Update document PGM Exposure Scenarios (PMC Sec, 14 Mar 2013)
4. Extract mail Heraeus regarding sameness solids/liquids
5. List of declared uses (WCA, 13 Mar 2013)
6. PGM testing programme update (mail & excel file)
7. Pd PNECs - read-across approach (mail & WCA paper)
8. Draft environmental exposure scenarios DDP (WCA, 6 Mar 2013)
9. Occupational exposure scenarios DDP:
   9.1. Final draft (EBRC, 26 Feb 2013)
   9.2. Comments received on first draft and responses (EBRC, 26 Feb 2013)
10. Timeline DDP ES

Actions

Table 1. Actions agreed at the 19 June PGM Exposure Scenario meeting in Brussels

	What?	Who?	When?
Substance identification and sameness Pd substances			
1.	Complete and return questionnaire on physical forms	PMC Members	ASAP
2.	Organise expert meeting to clarify outstanding issues on sameness of PGM nitrates	PMC Sec	End Jun 2013
3.	Add Pd nitrate to genotox scope	PMC Sec	ASAP
4.	Measure and report the ratio of DDP isomers; send IR spectrum of DDP	DDP registrants	31 July 2013
Final identified uses of Pd and Pd compounds			
5.	Confirm if uses are in line with EuPhraC initiative	PMC/EBRC/WCA	31 Aug 2013
PGM testing programme			
6.	Provide outstanding CoAs to BSL	Sample providers	30 June 2013
PNECs / DNEL for diamminedichloropalladium (DDP)			
7.	Consult with TAP on choice of Pd sulphate / Pd nitrate as alternative for Pd	KR	30 June 2013

	dihydroxide RDT testing / read across source for other Pd(II) substances		
Environmental emissions of Pd and Pd compounds			
8.	Companies to confirm if DUs are covered by Msafe calculations	PMC members	31 August 2013
9.	Members to advise on existing company specific monitoring programmes, incl. which PGMs are covered and LODs for respective metals	PMC members	15 July 2013
10.	Draft outline for site-specific monitoring programme	WCA	31 July 2013
11.	Check possibility for site-specific assessment of waste ES (int. landfills)	WCA	31 July 2013
Occupational exposure of Pd and Pd compounds			
12.	EBRC to update DDP ES to reflect drying of product	EBRC	Dependent on AP13
13.	Request DDP samples (high and low moisture content) and initiate testing at DMT	PMC	31 July 2013
14.	Exchange latest classifications for PGMs and confirm required scope of occ. ES.	PMC/ EBRC	31 Aug 2013
15.	Final quality check of questionnaire data for other Pd compounds, and advise on potential additional data needs	EBRC	31 Aug 2013
16.	Advise on tentative DNELs to be used	PMC/ BIBRA	31 Aug 2013
17.	Hold meeting PMC/ EBRC to discuss pros/cons of CHESAR. PMC to report back to PGM WG	EBRC/ WCA / PMC	30 Sept 2013
18.	PMC to share aggregated occ. exp. data for Pt with EBRC	PMC	2 Oct 2013
Standard phrases			
19.	Send list of metal standard phrases to EPMF to share with EBRC	R Winde	31 July 2013
20.	Check if metal standard phrases can be used for the ES of PGM	EBRC	Dependent on AP19
21.	Consult with EM ES task force to check if there is an agreement between Umicore and EM to share metal standard phrases, and if this can be handled as a generic metals project	KR	23 Sept 2013
Water solubility paper			
22.	Finalise water solubility paper following permission to publish data from external data holders. Acknowledge sample providers in paper.	PMC	done
23.	Circulate updated manuscript to PGM WG for commenting	PMC Sec	done