



#### 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 (19 June 2013) - 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.

The minutes from the 19 June meeting will be revised following some comments on the scope of the ES work and cannot be approved yet. They will be approved at the next PGM WG + ES meeting. **AP1**

## 2. Substance identification and sameness of PGMs (*Cf. slides 7-12 in Annex 2*)

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

The input received from PMC Members on composition of their substances is variable: some report a range of concentrations (min-max) whereas others report typical concentrations.

For practicality reasons, the PGM WG agrees to report the composition of the reference samples used for testing in the ID cards. This will allow companies to check if the test results apply to their situation (e.g. classification). **AP2**

### 2.2. Diammineplatinum (II) nitrite: UVCB status

Diammineplatinum (II) nitrite, also known as Platinum 'P' salt, is explosive in solid form and hence supplied as a solution, mostly in aqueous ammonia. In water it would convert to a mixture containing the diammine diaquo species and in ammonia to a mixture of tetrammine species. As a solid, it is thus considered a mono-constituent substance but as a solution, it is a UVCB.

The PGM WG agrees to this reasoning. **AP3**

### 2.3. Sameness

#### • Outcome PGM nitrates sameness discussions + UVCB status

A final expert meeting was held 20 August 2013 on the sameness of PGM nitrates. No feedback was received from 3 manufacturers/importers (M/Is) despite several reminders; it will be their own responsibility to prove sameness. PMC received new spectra from 3 other M/Is involved but it was noted that there were technical difficulties in recording good spectra in some instances. Sameness was concluded between solution and solid for both Pt dinitrate and for Rh trinitrate for these M/Is (sameness within solutions/solids of all nitrates and sameness between solution and solid for Pd nitrate was already confirmed previously).

Dave Boyd produced a paper documenting our rationale to declare the PGM nitrates as UVCBs; cf. Annex 3.

#### • Implications for registration strategy

Main impact is on genotoxicity and the way forward will be discussed at the 7 Nov PGM tox expert group meeting. **AP4**

#### • DDP isomers

DDP consists of different isomers but it is difficult to measure the isomer ratio as such. However, the isomers have a different IR fingerprint and based on the IR spectra, it was



concluded that mainly the trans-isomer is present. The PGM WG agrees to the proposal to register DDP as mono-constituent substance (>80% trans-DDP with cis-DDP as impurity).

- **Circulation of proprietary spectra**

The PGM WG has no objections to circulate company spectra by e-mail to the expert group in order to facilitate future sameness discussions.

### 3. PGM testing programme (Cf. slides 13-23 in Annex 2 and Annex 4)

PMC inquired to what extent PGM WG members want to be consulted and if draft study reports should be circulated for comments or only QA'ed final reports. The WG indicated they would be interested in receiving the draft study reports for information. [AP5](#)

#### 3.1. DDP ecotoxicity testing

- Extensive preliminary testing was required as DDP is a difficult test substance.
- The chronic sediment toxicity test (Chironomus, OECD 218) is completed and the study reports an unbounded ('higher than') NOEC, which is not ideal for risk assessment (i.e. we can only conclude that risk is 'lower than'). However, the PMC Secretariat sees no realistic possibility for further refinement of the NOEC and therefore recommends to stop testing at this stage. The PGM WG agrees to this proposal.
- The aquatic toxicity test (Daphnia, OECD 211) is ongoing; more method development is needed before the actual study (planned Q1 2014) can start.

#### 3.2. DDP repeated dose testing (RDT)

- Extensive method development for the oral RDT study (OECD 422) is still ongoing at CiToxLAB:
  - Substance stability has been confirmed if suspensions are prepared on a daily basis.
  - A palatability study has been conducted, indicating that dietary exposure is a viable route for dosing.
  - Work to demonstrate substance stability in the diet over the course of the main study is ongoing.
- Dose selection for the main study and the need to conduct a range-finding study will be discussed at the 7 Nov PGM tox expert group meeting ([AP4](#)).
- Assuming DDP stability is confirmed and the study can start in early 2014, study completion is expected in Q3/Q4 2014. The urgency of the study is stressed, as it is a bottleneck for DNEL derivation/ ES development.
- The exact reason why DDP has proved difficult to test is unclear. Possible explanations are that DDP is very protein reactive and its chemical stability is thus unclear.
- General comment on RDT testing of PGMs: it might be preferable to use oily suspensions instead of aqueous solutions for testing as some PGMs might interact with water or the stabilising agent (e.g., methyl cellulose) The method for selection of the appropriate dosing vehicle will be discussed at the 7 Nov PGM tox expert group meeting ([AP4](#)).

#### 3.3. PGM ecotoxicity testing

There is agreement on the scope but tests are currently paused due to workload considerations. It is suggested to start testing in Q1 2014. The PGM WG previously agreed on the testing labs (Fraunhofer and Brixham) but as Brixham is closing down, the PMC Secretariat is currently requesting/discussing additional quotes. [AP6](#)

#### 3.4. PGM irritation/corrosion testing

The testing programme at BSL is completed and confirmed Cat 1A classification for H<sub>2</sub>PdCl<sub>4</sub>, whereas classification of all other tested PGMs was refined from Cat 1A to Cat 1B. This will allow refining the transport classification of these substances. Additional testing of proprietary materials was a company responsibility. [AP7](#)



### 3.5. PGM genotoxicity testing

Tests are ongoing at Covance for several PGMs (cf. slides 19-20 in Annex 2). One TSCA 8(e) notification has been submitted as a result of testing (dihydrogen hexahydroxyplatinate notified as a potential mutagen). The genotoxicity testing programme will be reviewed in detail at the 7 Nov PGM tox expert group meeting (AP4).

### 3.6. PGM sensitisation testing

- Four PGMs are being tested for sensitisation potential.
- For one test material the substance identity needs to be confirmed before testing can start as the received material did not match the description in the MSDS.
- Two TSCA 8(e) notifications have been submitted as a result of testing: for diammonium hexachloropalladate (AHCPd) and for Palladium (II) di(4-oxopent-2-en-2-oate) (PdAcAc).
- The LLNA study on AHCPd showed a dermal sensitisation potential but the tested sample contained Pt-impurities, which may have confounded the result. A repeat study was therefore conducted. Results will be reviewed in detail at the 7 Nov PGM tox expert group meeting (AP4).

### 3.7. PGM acute/repeated dose testing.

A range of studies is ongoing at CiToxLAB and LPT (cf. overview on slide 23 in Annex 2). Repeated dose studies can take a long time to complete (ca. 1 year if there are no unforeseen events).

## 4. Current status of PNEC and DNEL refinement (Cf. slides 24-31 in Annex 2)

### 4.1. PNEC derivation DDP and other PGMs

- DDP will be used as read across substance as we have a good data set for DDP and it represents a worst-case (cf. Annex 5). It was agreed at the last PGM WG meeting that there is no need anymore to derive tentative PNECs for DDP but that ongoing studies will be completed ASAP in order to derive a robust PNEC to refine the ES. Data from the aquatic toxicity test are still pending and results are expected Q1 2014. A PNEC will be derived then.
- Ecotox studies for other PGMs are to be started in Q1 2014 (AP6) and results are expected Q3-4 2014. PNECs will be derived once the final data are available.

### 4.2. DNEL derivation DDP and other PGMs

- The RDT study for DDP is ongoing. Study completion is expected Q4 2014 and a DNEL will be derived once the final data are available.
- DNELs for other PGMs are also being derived and the studies are to be conducted at 2 CROs over 2 years (unexpected developments not factored in).

### 4.3. Scope of exposure assessment

Cf. slides 28-31 in Annex 2. ESs are required for hazardous substances that are manufactured and/or imported  $\geq 10$  t/a (hazard assessed for each route/endpoint separately). At this stage it is difficult to assess which ESs are needed as hazard testing is still ongoing. The exact scope will be clear when all test results are available (end 2014). AP8

Cf. further discussion under agenda point 7.2.

It is noted that it is common practice in the metals sector to develop an ES for both human health and environment if a hazard is identified for only one of them. This also seems to be ECHA's recommendation.

## 5. Environmental emissions Pd and Pd compounds

WCA gives a recap of where we currently stand regarding the Generic Exposure Scenario (GES) and the Site-Specific Risk Assessments (SSRAs) for Pd and Pd compounds (cf. slides 34-36 in Annex 2). The RCRs in the SSRAs may improve with the refined PNECs but this might not be sufficient for all sites and for those, monitoring will be needed to demonstrate safe production/use.



### 5.1. Proposal for Pd monitoring and sampling (Cf. Annex 6 and slides 37-47 in Annex 2)

WCA presents their monitoring proposal:

- Suggested monitoring points are the wastewater effluent discharge from the site (site effluent), the influent and effluent of the municipal STP, the receiving water/sediment upstream of the discharge and the receiving water/sediment downstream of the discharge. Water/sediment downstream of the discharge was flagged as the essential monitoring point.
- Some site emissions have been estimated based on limit of detection (LoD) measurement. Where the LoD is relatively high, emission estimates could be improved by having effluent samples analysed at laboratories that can achieve a lower LoD. It is noted that if concentrations in the site effluent are then demonstrated to be low, it might not be necessary to monitor the other points as you can make assumptions for the receiving water based on the site effluent.
- If monitored levels are below the LoD, 50% of the LoD will be used.
- It is noted that if PNECs are lower after PNEC refinement, this might be obviously problematic for the monitoring programme.
- The monitoring of STP influent and effluent to define the Pd removal rate in STP should be a sector initiative (possibly looking at 3 STP sites), whereas monitoring of the site effluent and receiving water/sediment should be done at the individual sites.

Monitoring Pd removal in STPs:

- It is suggested to have this done by an expert consultant.
- Two sampling regimes are suggested at 3 STPs. The average removal rate will be used in the exposure assessment.
- The municipal STP in the Hanau industrial park, which receives wastewater from several PGM processing companies, is suggested as one of the STPs for this study. [AP9-11](#)
- Results will be used to verify the existing, estimated removal rate (80%) or to calculate a new one.

Site-specific monitoring:

- Will only be needed for sites with a risk. This may also be affected by the outcome of the STP removal study. Currently 80% removal is assumed but this may be lower.
- Receiving water body:
  - Sampling for minimum 6 months is proposed. However, this will not be sufficient to cover seasonal variations, and should preferably be one year.
  - 1 week of daily sampling is proposed at least twice during the sampling programme at each site.
  - Sample collection can be undertaken by site operatives and handling should be fully recorded. It is suggested to have an SOP. [AP12](#)
  - Results for total/dissolved and sedimentary Pd (and for other PGMs) will be used to assess the validity of the partition coefficients used in the exposure assessment.
- Sediment:
  - Sample collection should be undertaken by an expert consultant. ExCal consultancy is suggested, whose expertise is acknowledged by the PGM WG.
- For the analysis of the samples, Environmental Sciences Group (ESG) is recommended. [AP13](#)

If RCRs are still higher than 1 after monitoring, we will need to proceed to other options, such as a bioavailability correction.

The PGM WG agrees monitoring will be needed and suggests to start in Q2 2014.

It is noted that there is no indication of a problem with stack emissions based on conservative estimates.



## 5.2. Extension monitoring/sampling to other PGMs (Cf. Annex 6 and slides 48-50 in Annex 2)

A robust conclusion on the potential need for monitoring of other PGMs can only be made once PNECs are available and an initial ES has been conducted. This is not the case yet. However, as a pragmatic approach, it is proposed to include other PGMs in the monitoring programme. For these pragmatic reasons and in the interest of time, the PGM WG agrees to include other PGMs in the Pd monitoring programme. The analysis of additional PGMs (and other PMs, e.g. Ag, Au) in the samples already taken will imply only minimal additional costs so there is little downside to this approach. [AP14-16](#)

## 5.3. Assessment of waste

Cf. slides 51-54 in Annex 2.

## 6. Occupational exposure Pd and Pd compounds

### 6.1. DDP dustiness tests and impact on occupational exposure scenarios for DDP

The refinement of the occupational ES for DDP is on hold until further information is available:

- Two additional dustiness tests: draft report of 1 dustiness test received, 2<sup>nd</sup> test should be finalised soon.
- Clarification on drying of DDP: a site visit was conducted during which this question was clarified among others.
- Final DNEL report: relevant study on-going

### 6.2. Additional data needs and timing for occupational exposure scenarios other Pd compounds

An occupational exposure questionnaire and a submission form for inhalation monitoring data were circulated in 2012 for 12 Pd substances manufactured/ imported  $\geq 10$  t/a:

- Quality check of these data was done over summer.
- E-mails were sent for further clarification: awaiting response from 1 company.
- Manufacturers were asked to provide short process overviews for manufacturing processes to indicate chronological order of activities: awaiting responses from multiple companies.
- Since the information above and on hazard profiles is not yet complete and to avoid duplication of work, it is suggested to wait for finalisation of DNELs and conclusive hazard assessment (i.e. end 2014) to develop occupational exposure scenarios for other Pd compounds. The PGM WG agrees to this proposal.

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

### 7.1. Usability IPA data

The PMC Secretariat received a first set of occupational exposure monitoring data from IPA, which was shared with EBRC (on a confidential basis):

- A first evaluation of the dataset has been done by EBRC and evaluation/clarification is ongoing. [AP17](#)
- Currently, only a subset may be suitable for use in REACH ES. (Note: this will likely still leave sufficient data for our REACH purposes.)

A questionnaire on identified uses is to be launched for all substances (for inclusion in IUCLID Section 3.5 and for potential development of ES for hazardous substances manufactured/imported  $\geq 10$  t/a). The development of an occupational exposure questionnaire and submission form for additional inhalation monitoring data will be based on initial information (e.g. results from dustiness tests, information on identified uses, site visits/process overviews provided by industry experts). [AP18-19](#)

### 7.2. Timing and practicalities

A pragmatic approach to proceed with the ES work is proposed:

- Strictly speaking (as discussed above) ES can only be developed once the hazard assessment has



been completed and all hazards have been identified

- However, all our PGMs that are manufactured/imported  $\geq 10$  t/a, except metals and PdO, are already classified (cf. slides 61-63 in Annex 2), so it is reasonable to assume that we need to prepare an exposure assessment for all of these.
- Start collecting existing information in Q1 2014 (uses, environmental/occupational emissions, OCs, RMMs, etc.).
- It is noted that DUs are often the same for different PGMs, so it is suggested to collect all use data together for different PGMs.
- Start with environmental/occupational monitoring Q2/Q3 2014. All PGMs will be monitored in parallel.
- Conduct testing programme/hazard assessment in parallel with use and exposure data collection/generation.
- Launch the exposure assessment after completion of the hazard assessment (by Q2/Q3 2015).

The ideal workflow is summarised on slides 66-67 in Annex 2, and shows finalisation of the exposure assessment by end 2016. This should be well in time for the 2018 registration deadline but we have to take into account a contingency for 'unexpected' events, so we will have to make sure to keep the momentum (AP20).

The PGM WG agrees to the proposed approach/timing.

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

The PGM WG agrees that there is no need to meet until springtime 2014/after we start the data collection. We can decide on the monitoring programme by e-mail. AP21

##### 8.1. Use of standard phrases

Cf. slide 69 in Annex 2.

##### 8.2. Use of CHESAR (Cf. Annex 7 and slides 70-71 in Annex 2)

EBRC recommends using CHESAR for the development of ES to avoid duplication of work (ES for CSR and ES for SDS). The use of CHESAR for the inorganic sector is currently under evaluation by the Eurométaux ES working group in a dedicated project that is supposed to start next year. Klaus Rothenbacher and Roland Winde are attending the meetings of this working group. AP22

##### 8.3. EuPhraC initiative and compatibility with uses Pd and Pd compounds

Cf. slide 69 in Annex 2.

##### 8.4. TSCA 8(e) notifications (Cf. slide 72 in Annex 2)

TSCA 8(e) notifications are required if "significant new information" is generated. Notifications are submitted by the PMC on behalf of its members. Recent notifications have been done for:

- Dihydrogen hexahydroxyplatinate (mutagenicity)
- Diammonium hexachloropalladate (sensitisation)
- Palladium di(4-oxopent-2-en-2-oate) (sensitisation)

## Annexes

1. Agenda & list of participants
2. Slides presented at the meeting
3. The chemistry of palladium, platinum and rhodium 'nitrates' (Dave Boyd, 10 Sep 2013)
4. PGM testing programme update for October 2013
5. Summary of ecotox read across approach Pd (WCA, 1 Oct 2013)
6. Proposal for site-specific environmental monitoring programme for Pd (WCA, 30 Oct 2013)
7. Position paper on the use of CHESAR (EBRC, 1 Nov 2013)



## Actions

**Table 1.** Actions agreed at the 6 November PGM Working Group + Exposure Scenario meeting in Brussels

|                                                             | What?                                                                                                                                                                 | Who?                    | When?                    |
|-------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------|
| 1.                                                          | Revise minutes 19 June PGM WG + ES meeting and put on agenda of the next meeting for approval                                                                         | PMC Sec                 | ASAP                     |
| <b>Substance identification and sameness</b>                |                                                                                                                                                                       |                         |                          |
| 2.                                                          | Report the composition of the reference samples used for testing in the ID cards                                                                                      | PMC Sec                 | As needed                |
| 3.                                                          | Check if registrants handle the solid form of Diammineplatinum (II) nitrite                                                                                           | PMC Sec                 | Dec 2013                 |
| <b>Testing programme</b>                                    |                                                                                                                                                                       |                         |                          |
| 4.                                                          | Inform PGM WG members on outcome of 7 Nov PGM tox expert group meeting                                                                                                | PMC Sec                 | After approval minutes   |
| 5.                                                          | Circulate the DDP sediment toxicity report to the PGM WG for information                                                                                              | PMC Sec                 | ASAP                     |
| 6.                                                          | Circulate updated quotes and final recommendation for PGM ecotoxicity testing for approval                                                                            | PMC Sec                 | Done (cf. e-mail 29 Nov) |
| 7.                                                          | Inform PMC Sec if additional irritation/corrosion tests are available on PGMs                                                                                         | PGM WG members          | ASAP                     |
| <b>Scope of exposure assessment</b>                         |                                                                                                                                                                       |                         |                          |
| 8.                                                          | Follow up scope of exposure assessment with EBRC                                                                                                                      | PMC Sec                 | As needed                |
| <b>Environmental emissions of Pd and Pd compounds</b>       |                                                                                                                                                                       |                         |                          |
| 9.                                                          | Make separate monitoring paper for STP study with more details on transport costs etc.                                                                                | WCA                     | Dec 2013                 |
| 10.                                                         | Check if it will be possible to perform the STP study at the municipal STP in the Hanau industrial park                                                               | WCA/PMC Sec             | Dec 2013 - Jan 2014      |
| 11.                                                         | If STP study can be done in Hanau, perform a brief study of the known PGM processing companies there (in parallel with STP study) to check if all PGMs come from them | WCA                     | Q1/Q2 2014               |
| 12.                                                         | Write SOP for site-specific sample collection                                                                                                                         | WCA                     | Q1 2014                  |
| 13.                                                         | Do background check on Environmental Sciences Group (ESG)                                                                                                             | PMC Sec                 | Q1 2014                  |
| 14.                                                         | Update the costs in the monitoring paper to include the costs of analysing other precious metals and include estimated costs for transport of samples to laboratory   | WCA                     | Dec 2013 - Jan 2014      |
| 15.                                                         | Make overview of sites where monitoring of other PGMs will likely be needed based on existing data                                                                    | WCA                     | Q1 2014                  |
| 16.                                                         | Initiate STP removal study and site monitoring for all PGMs in parallel                                                                                               | WCA with PGM WG members | Q2 2014                  |
| <b>Occupational exposure of Pd and Pd compounds</b>         |                                                                                                                                                                       |                         |                          |
| 17.                                                         | Follow up evaluation of usability IPA data                                                                                                                            | EBRC                    | Q1 2014                  |
| <b>Use and exposure/emission data collection other PGMs</b> |                                                                                                                                                                       |                         |                          |
| 18.                                                         | Develop questionnaire for the collection of use information of other PGMs                                                                                             | WCA/EBRC                | Q1 2014                  |
| 19.                                                         | Develop questionnaire for the collection of exposure/emission data of other PGMs                                                                                      | WCA/EBRC                | Q2 2014                  |
| <b>Other</b>                                                |                                                                                                                                                                       |                         |                          |
| 20.                                                         | Sit together with EBRC to set priorities and to prepare all necessary PGM registrations in time for the 2018 deadline                                                 | PMC Sec                 | Q1 2014                  |
| 21.                                                         | Decide on monitoring programme by e-mail                                                                                                                              | PGM WG                  | Q1 2014                  |
| 22.                                                         | Track outcome of Eurométaux CHESAR evaluation project                                                                                                                 | PMC Sec                 | As needed                |