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

17 January 2013 10:30 – 17:00 CET
Rue du Duc 100 – 1150 Brussels (BELGIUM)

List of participants

1.	**Katrien Arijs**	ARCHE	*Belgium*
2.	**Bodo Berkner**	Ferro	*Germany*
3.	**Dave Boyd**	Johnson Matthey	*United Kingdom*
4.	**Roland Brasch**	Heraeus	*Germany*
5.	**Edwin Broeckaert**	Umicore	*Belgium*
6.	**Phil Copestake**	BIBRA	*United Kingdom*
7.	**Mari Järvikivi**	Norilsk Nickel	*Finland*
8.	**Dawn Maycock**	WCA	*United Kingdom*
9.	**Adam Peters**	WCA	*United Kingdom*
10.	**Mark Raffray**	Johnson Matthey	*United Kingdom*
11.	**Klaus Rothenbacher**	EPMF	*Belgium*
12.	**Michael Shepherd**	Vale Europe	*United Kingdom*
13.	**Marc Simon**	Traxys	*Luxembourg (part time)*
14.	**Rüdiger Thiele**	Heraeus	*Germany*
15.	**Steven Verberckmoes**	Umicore	*Belgium*
16.	**Carole Wilson**	Vale Europe	*United Kingdom (by conf. call)*

Apologies

Francisco Boo	Metalor	*Switzerland*
Caroline Braibant	EPMF	*Belgium*
Heike Kinz	Umicore	*Germany*
Marie-Laure Ledrich	Traxys	*Luxembourg*
Manfred Probst	Carl Hafner	*Germany*
Hege Stubberud	Xstrata	*Norway*
Carole Wilson	Vale Europe	*United Kingdom*
Roland Winde	Umicore	*Germany*

Draft Minutes

1. Welcome and introduction

The participants were reminded on their obligation to comply with confidentiality and Competition Law. The agenda and minutes of the last meeting were approved.

2. Testing Programme

2.1. Enabling- /phys.-chem. Tests

Summary report enabling tests

A summary report was prepared, which compiles the results from individual enabling tests that had been circulated previously (bio-elution, dustiness, etc.). The report was circulated 10th Jan. 2013. It will form the basis for the ITS finalisation, such as the selection of the second route of exposure for acute toxicity testing and the scope for the repeated dose testing scope (see further discussions under agenda point 2.4).

Irritation/Corrosion testing

Many PGM substances are default classified as 'skin corr. 1A' on the basis of extreme pH and acid/base reserve. If test results (such as pH screening) do not allow discrimination between Skin Corr. 1A/1B/1C, then Skin Corr. 1 must be chosen. Generally, UN Packing group I would apply to substances classified as Skin Corr. 1, while Skin Corr. 1B would trigger UN packing group II and Skin Corr. 1C would trigger UN packing group III. PMC has circulated a list of substances that might require testing.

It was agreed to use the 'In vitro membrane barrier test method' (OECD TG 435) to refine the classification into Cat. 1A, 1B or C. The method is validated to distinguish between Cat 1A, B and C; it has a limited applicability domain (mainly acids/bases) but would be appropriate for our purposes. Other methods, such as modified EPISKIN might also be possible, but it was decided to use OECD 435 since the training set was more relevant for our substances and the method is OECD conformant.
Read across from the respective acids used as solvent (e.g., HNO3, HCl) was not recommended.

Test substances:

- For UVCBs it was agreed that it is the responsibilities of the individual companies to test their respective products. They will also be responsible for their own classifications.
- Mono-constituent substances: PMC will select reference compounds based on substance ID cards

Actions:

- **PMC to collect information via substance ID cards (if not available yet)**
- **Members to confirm interest for testing specific substances by 25th Jan. 2013**
- **PMC to finalise testing scope based on feedback and ID cards**
- **PMC to contact MB Research Labs for a list of labs that use Corrositex kits in Europe**

2.2. Fast-track testing: diamminedichloropalladium – progress update

A short update on the DDP testing programme was given: the PNECs of DDP had to be revised in Nov. 2012, which resulted in potential risks to water, sediment and soil. At the PGM ES meeting on 12th December 2012 it was therefore agreed to conduct 2 additional tests to refine the PNEC:

- Sediment toxicity test (Chironomus, OECD 218)
- Aquatic toxicity test (Chronic Daphnia, OECD 211)

The tests have been commissioned already and will be carried out at the same CRO as for previous tests: Fraunhofer Inst. Schmallenberg, D. The definitive studies should be complete 3rd week of April, with results made available at that time, although draft reports are not expected until May 2013.

The repeated dose testing at CiToxLAB is progressing; the CRO is currently working on the formulation development/validation. Results from the definitive study are not expected until the end of the year.

2.3. Full PGM testing programme – ecotoxicity testing Palladium family

WCA presented a proposal to reduce the amount of testing required by employing a read across approach based on a worst-case substance. The PNECs derived for that substance could then be read across to all Pd compounds. So far, it had been agreed to read across only within defined categories (e.g., between Pd(II) or Pd(IV) compounds).

The PGM WG agreed that a broader read across strategy is in general a valid and pragmatic approach, however care has to be taken when selecting an appropriate worst-case substance.

Limited acute testing of dipotassium- or diammonium hexachloropalladate was originally proposed in order to identify the most appropriate substance for read across.. The PGM WG felt that hexachloropalladates are likely to be complex substances for the purposes of ecotoxicity testing, due to the following reasons:

- They are strong oxidizers. Toxicity would be expected to be markedly higher than for Pd(II) substances
- Stability: if put into water/biological systems Pd(IV) is likely to convert rapidly to Pd(II), so the environmentally relevant species would be Pd(II)
- Potential emissions of hexachloropalladates are therefore likely to reach the environment as Pd(II), certainly if they have to pass through an STP.

It was therefore decided that a Pd(II) substance would be a better choice for a worst-case substance. Based on the existing data, the best available current prediction is that DDP would be the worst case. It was therefore agreed to use DDP as basis for read across. The testing currently carried out on DDP will thus be directly relevant also for the other Pd dossiers.
For the sake of the Hexachloropalladate dossiers, we will produce an expert statement regarding the stability of the hexachloropalladates, and the likelihood of these species existing in environmental systems. This paper will conclude on the most appropriate means for deriving environmental PNEC values for the hexachloropalladates (which may be based on the reduced forms, i.e. Pd(II) complexes).

Action: Dave Boyd to prepare short discussion paper on the stability of Hexachloropalladates in aqueous solutions/biological media.

Decisions on further testing on Pd(IV) substances will be taken once the discussion paper is available. Alternatively, the discussion paper can form the basis for the justification in the Reach dossiers for the selection of read-across substance.

Emissions from automotive catalysts

WCA raised the point that emissions from automotive catalysts will have to be considered when deriving the PECregional for Pd substances. It was acknowledged that this is a point that needs consideration. However, it was clarified that DDP is not used in automotive catalysts and this aspect will therefore not be relevant for the DDP dossier. In the DDP dossier, the PECregional can be calculated as normal by EUSES.
The International Platinum Group Metals Association has many data on this, and is currently generating additional data. It was suggested to share some of the relevant data, e.g. the original literature survey by Zereini and other relevant HSRG data or literature searches. After WCA has had a chance to digest the data, a follow-up meeting between IPA/PMC and WCA could be arranged.

Action: PMC to liaise with IPA and release first set of relevant data to WCA
Action: PMC to organise meeting with IPA/WCA to discuss data and next steps

2.4. Full PGM testing programme – mammalian toxicity testing

2.4.1. Acute toxicity – second route of exposure

Overall, no additional testing for a second acute route of exposure will be required.

Inhalation exposure was considered to be not relevant for all PGM substances due to low dustiness/lung deposition coupled with low bio-elution values. Two exceptions: platinum black has a lung (pulmonary compartment) deposition rate of ca 6% but has a very low bioavailability. Dihydrogen hexahydroxyplatinate has a lung (pulmonary) deposition rate of 2.4% but a high bioavailability. However, dermal/ inhal. toxicity will likely be in same range as via the oral route for both substances, so it was considered there would be no benefit from testing a second route and WoE/read across from the oral route was recommended. For Dipotassium and Diammonium hexachloroplatinates, although not definitively SCC [although see action below], it was agreed that waivers could be drafted on the basis of very low exposure under industrial handling.
PMC was unable to source palladium monoxide for the bio-elution tests. There is a need to confirm with registrants if the substance is still supported.
Acute oral tests need to be conducted for Diammonium hexachlororuthenate, Diammonium sodium hexakis(nitrito-N)rhodate, and Palladium di(4-oxopent-2-en-2-oate). The need for testing a second exposure route of these substances will be revisited after the acute oral tests are completed.

Actions:

- **Diammonium hexachlororuthenate: PMC to confirm with registrants if handled under SCC**
- **Diammonium hexachloroplatinate: PMC to confirm with registrants if handled under SCC at 100 – 1000 tpa**
- **Diammonium hexachloropalladate: PMC to confirm with registrants if handled under SCC at 100 – 1000 tpa**
- **Palladium monoxide: PMC to confirm if still supported by registrants**
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2.4.2. Genetic toxicity

The testing scope is largely completed and it was agreed to commence testing per the summary test plan proposed by wca. The CRO of choice is Covance, but it was agreed to request at least two competing quotes. Due to the relatively large program scope, a cost discount should be negotiated with the CRO.
PGM nitrates: once the sameness discussions are completed, the PGM genotoxicity expert group will be re-convened to discuss how to best proceed for those substances.

Action: WCA to request at least 2 competing quotes for planned tests
Action: WCA to try to negotiate appropriate discount
Action: PMC to schedule PGM genotoxicity expert group meeting once sameness discussion of PGM nitrates is completed (expected in Q1 2013)

2.4.3. Repeated dose testing

Overall, six substances were recommended for RDT/ reprotox. screening. One Rhodium- and one Ruthenium (unless SCC) salt, and 2 Palladium- and 2 Platinum salts (see table overpage).

Read-across data on repeated dose toxicity is available for Tetraammineplatinum(2+) dinitrate and Tetraamminepalladium(2+) dichloride, but data on reprotox. (OECD 421) will have to be generated for these two compounds.

It was decided not to test the metals but to make robust arguments based on enabling study results, TK considerations, and any available read across from an appropriate soluble metal salt. The proposed testing scope is summarized in the below table.

It was discussed whether it would be preferable to carry out a combined RDT/repro screen (OECD 422) or separate tests (OECD 421 and 407): for most cases a combined test will be sufficient. It has the advantage that it is animal sparing, and saves time and cost. It was decided to use this test design for compounds predicted to have lower toxicity. Where significant toxicities occur these can interfere with the reproductive parameter aspects of the OECD 422 conduct, and potentially result in a need for repeat tests. It was therefore decided to conduct separate tests for more 'complicated' substances. Since the separate test design will produce more robust results, it will be less likely that a test needs to be repeated or that further clarifications will be necessary, and this approach is thus considered scientifically justifiable.

Summary PGM RDT Testing Scope							
Substance	**Acute oral**	**Acute inhal**	**Acute dermal**	**Repeated dose tox. OECD 422**	**Reprotox OECD 421**	**Separate OECD 407 and 421**	**Comment**
Diammonium sodium hexakis(nitrito-N)rhodate	+	-	-? Assess after acute oral	Assess after acute oral	-	Assess after acute oral	
Diammonium hexachlororuthenate	+	-	-? Assess after acute oral	Assess after acute oral	-	Assess after acute oral	confirm if still SCC
Palladium dihydroxide	-	-	-	+	-	-	
Palladium di(4-oxopent-2-en-2-oate	+	-	-? Assess after acute oral	-	-	-	
Tetraamminepalladium dichloride	-	-	-	-	+	Read-across for TG407	
Diammonium hexachloropalladate	-	-	-	-	-	+	confirm if still SCC at 100-1000 tpa
Tetraammineplatinum dinitrate	-	-	-	-	+	Read-across for TG407	
Diammonium hexachloroplatinate	-	-	-	-	-	+	confirm if still SCC at 100-1000 tpa
Dihydrogen hexahydroxyplatinate	-	-	-	+	-	-	
Total	**3**	**0**	**0**	**2 (+2?)**	**2**	**2 (+2?)**	

For the palladium (II) group, it was decided to test Palladium dihydroxide in an OECD 422 test. It has a low water solubility but >70% bio-elution in gastric fluid, so would thus be suitable for RDT. The results will be read across to all Pd(II) substances, including anionic tetrachloropalladates and also to Palladium di(4-oxopent-2-en-2-oate). Testing of dihydrogen tetrachloropalladate would also have been a possibility but the substance might have caused local issues due to its low pH. Both compounds (and other Pd-compounds) will likely form the same $PdCl_4^{2-}$ species in the stomach, so read across was considered appropriate.
Diammonium hexachloropalladate will also have to be tested; it was recommended to conduct two separate tests for this substance rather than the combined OECD 422 test, i.e., OECD 421 and 407.
In the platinum family, read-across RDT data is available for Tetraammineplatinum dinitrate but an OECD 421 test is required. Tetraammineplatinum dinitrate is explosive when dry, so care should be taken when handling the material. The moist material or an aqueous solution are not explosive, though, and therefore the conduct of an OECD 421 test (typically, aqueous solutions are dosed) was considered possible, using the necessary precautions. Since it is difficult to ship the substance internationally, it was proposed to test the substance in a UK lab (where the sample provider is located) if at all possible.

Dihydrogen hexahydroxyplatinate is an acid but its pH is moderate at 2.9. It is thus not corrosive and can be used in animal testing. An OECD 422 test was recommended for Dihydrogen hexahydroxyplatinate; the results can then be read across to Platinum dinitrate. Platinum dinitrate is corrosive (based on extreme pH = -0.7) and cannot be tested itself.

Diammonium hexachloroplatinate was recommended to be tested in separate OECD 407/421 tests. The results can then be read across to Hexachloroplatinic acid and to Dipotassium hexachloroplatinate.

3. PGM project planning

3.1. Selection of CROs

As discussed under agenda point 3.2, we will need at least 2 CROs to carry out the tests. PMC indicated that in view of the expensive nature of these tests, quotations from at least 4 CROs should be requested.
The merits of several CROs were discussed:

- Some CROs were excluded due existing PMC precendent (HLS)
- Some labs were considered not to have their prime experience in running OECD 422 tests on chemicals (e.g., Covance are more pharma-oriented, no experience on WIL/NL is available)
- LPT (D) might be a potential candidate but no experience with RDT studies was available with that CRO
- PMC's recent experience with CRL has proved disappointing
- The following CROs were considered to be potential candidates: CiToxLAB, Harlan/CH (formerly known as RCC), Sequani (UK) and BASF (D)

Action: WCA/RSA to request quotes for agreed tests from agreed labs.

3.2. Scheduling of tests

WCA recommended carrying out the RDT tests in parallel at 2 different CROs to provide flexibility with timing. Tests could be started in 3/4 month intervals, i.e., 3/4 tests/year/CRO. As with previous RDT, RSA will be contracted to handle the study monitoring. RSA indicated that they can assign a dedicated study manager for each CRO.**Action: WCA/RSA to update testing plan in view of agreed scope**

4. AOB, next meeting and closing remarks

A short update from the expert meeting on PGM nitrates' sameness from 12th December 2012 was given. The results of the sameness discussion were summarized as follows:

	Sameness solutions	Sameness solids	Sameness solids and solutions	Comment
Pd-nitrate	+	+	+	
Pt-nitrate	+	+	-	More data requested
Rh-nitrate	+	-	-	More data requested