11 February 2008, 10:30 – 16:00
Metals Conference Centre – Nickel+Zinc Room
100 Rue du Duc, 1150 Brussels

MINUTES 11 FEBRUARY 2008

1. Introduction

1.1. Confidentiality and European Competition Law provisions. The attendees were reminded on their commitment to comply with Confidentiality and Competition Law provisions. *A list of Do's & Don't's is available on request to the Secretariat.*

1.2. Approval of the Agenda, review of the content of the meeting file. The Agenda was approved (cf. Annex 1).

1.3. Tour de table; presentation of new participants (including new PGM's WG chairperson – David Boyd, Johnson Matthey); apologies of non-attendees. The Attendance List is attached (cf. Annex 2). Some representatives attending the meeting are not Consortium Members but are attending because they have an interest in one or more of the substances covered by the Consortium. M. Raffray (Johnson Matthey) introduced D. Boyd, as the new Chair of the PGM's WG.

1.4. Approval of Minutes of last joint meeting (20-21/09/2007). The actions of the last face-to-face meeting were all realised but two: (i) attention should be paid to the situation of alloys and the recommendations available in the EIMAG guidance, in the several opinions on bank products under REACH and the latest guidance on articles, (ii) co-chairs should be identified for the Au WG and the PGM's WG. The Minutes were approved.

1.5. Objective(s) of the meeting. 16 weeks ahead of the start of Pre-registration, the intention was to review the latest development on REACH interpretation and the advancement reached on the several PM Work Programmes. Key action points to ensure an aligned and harmonised Pre-registration of all the substances listed in the indicative lists were clearly signalled during the meeting.

2. Update on REACH generic hot topics.

2.1. Revision of Annex IV & V of REACH. No substantial changes are foreseen in the Annexes. It is unlikely that Precious Metals will benefit from any of the exemptions presented in Annex IV and V, with the exception of those provisions related to (not chemically modified as per Eurométaux factsheet) ores and ore concentrates and which are applicable to the Precious Metals Industry (e.g.: silver ores, concentrates, leached – EC n° 310-058-1, CAS n° 102110-56-5).

2.2. Eurométaux legal interpretation on:

2.2.1. "Any available existing information" – Registration of intermediates.

- According to McDermott Will & Emery Stanbrook, as commissioned by Eurométaux, "any available existing information" should be considered as information which is "*generally available to any identified "data holder"*".
- In RIP 3.1., it is considered as information which the registrant "*holds himself or that he can obtain from other sources […] without any additional testing*".
- This would mean that the information does not necessarily need to be freely accessible to be required as part of a registration of an intermediate. This is an example of where the Letter of the Law and the Spirit of the Law are not in tune: if all available existing information needs to be obtained/purchased, the registration of intermediates could no longer be considered as a "reduced registration".
- The interpretation should consider this lack of tuning and also consider the impact of: (i) the quality of the existing available information (should also non-quality information be integrated into the Registration Dossier? And pay for this?), and (ii) the cut-off date for information to be considered "available" (available by the official registration deadline? Available by the actual registration dates? Another

date?). Clarification on all the above uncertainties should be obtained by the NFM Industry/Eurométaux.

2.2.2. Article 2(7)d – Exemption of recovered substances.

- According to McDermott Will & Emery Stanbrook, as commissioned by Eurométaux, Article 2(7)d does not apply to recovery establishments which are independent and that are not part of a legal entity which has both refining and recovery activities in Europe (the former type of activity leading to the manufacture of substances which will be registered; the latter type leading to the recovery of substances which would be exempted from Registration as per Article 2(7)d). Independent establishments are therefore recommended to pre-register, until the Agency clarifies the registration requirements for recovered substances.
- Based on the above unpersuasive interpretation, it is reasonable to recommend all Members of the Consortium who have recovery activities, to consider both the tonnages of those substances manufactured from refining and recovery activities in their preparation for pre-registration and registration, until additional corroboration is obtained from the EChA.[1]

2.2.3. Loading, unloading and temporary storage of (dangerous) substances and REACH.

- According to McDermott Will & Emery Stanbrook, as commissioned by Eurométaux, loading, unloading and temporary storage of (dangerous) substances are out of the scope of REACH as they are already covered through other legislations.
- A registrant can guarantee strictly controlled conditions during the transport (as part of the entire life-cycle) of an intermediate, if it fulfils all conditions and rules laid down in the applicable regulations for transport (loading, unloading and temporary storage). The rest of the life-cycle should be proved to take place under strictly controlled conditions as specified in REACH.

2.3. Clarification on:

2.3.1. Precious metals ingots and bank products under REACH – Houston Consulting Europe opinion (commissioned by UBS Bank), McDermott Will & Emery Stanbrook (commissioned by PMC), EChA's response to Secretariat.

- The different opinions on the requirements of several bank products of precious metals under REACH have been considered by HCE and McDW & ES, using different arguments. Therefore, the following question was posed to the EChA helpdesk: "*Are precious metals ingots considered as articles or as substances?*". The answer of the EChA was: "*Precious metals ingots are regarded as substances*".
- Following a group discussion, it was noted that the use of words such as "ingot" and "bar" to describe solid forms of precious metals is not harmonised within the Precious Metals Industry. It is hence not certain what the EChA understands as "ingots" either. The EChA will be asked to develop a rationale to support its answer. In order to make sure the formulation of the question does not leave room for interpretation, it will be prepared by the TAP, the MC, with the support of the LBMA.

2.3.2. Tonnage-based waiving in Silver Registration Dossier – Response received from the ECHA. A tonnage/exposure-based waiving argument does not seem to be entirely unfounded according to the answer received by the ECHA. This argument

[1] **Post-meeting note:** The application of the exemption is not clear when the secondary raw material comes from non-EEA origins, for which the tonnages will not have necessarily been covered through a registration before (the idea behind Article 2(7)d seemed to come from the need to avoid registration of double tonnages, i.e. the tonnage of the substance extracted from primary sources + the tonnage of the substance extracted from secondary sources).

is however unlikely to be applicable to the Silver Registration as the higher test requirements are included in both Annex IX (of eventual relevance for powder forms) and X (of relevance for massive forms). However, these tests will not be undertaken before dialogue on testing proposals whereby PM Consortium, via our consultants, should be able to ensure that any new studies are proportionate to actual hazard and exposure circumstances.

2.4. Global Generic ID's for ores and ore concentrates: is it a Precious Metals priority? (deadline: April 2008). Due to the nature of Precious Metals activities, it is likely that precious metals containing-ores and ore concentrates will be covered through other consortia in this exercise anyway. Although it is currently not a priority for the Precious Metals Consortium, after Pre-registration, the Consortium should be involved in the definition of a common method to identify and characterise ores and ore concentrates in order to be given appropriate ID's and classifications following both REACH and GHS requirements.

3. Update on the progress and status of activity of the PM Consortium

3.1. Revision of the Consortium Agreement. The Cost-sharing Work Group is meeting on the morning of the 18th of February to discuss several proposals to include a place-holder for intermediates in the cost-sharing formula. The Legal Work Group is meeting on the afternoon 18th of February to discuss a first draft of the updated Agreement including: (i) an expanded scope and an adjustment of the relevant provisions in this regard; (ii) the improvement of certain accounting and data-collection procedures; (iii) the clarification of certain imprecise provisions. The updated Consortium Agreement should be circulated for approval of the Assembly by mid-March.

3.2. Identification of potential members: new mailing lists. Besides the current 26 members of the Consortium, additional potential members have been identified for precious metals as well as for rhenium. Three mailing lists have been formed: (i) general precious metals parties who might have an interest in the Consortium, (ii) rhenium parties who have recently been informed on the expansion of the Consortium's scope, and (iii) precious metals cyanides parties in order to set up a task force for PM Cyanides.

3.3. Preparation of the 2008 Plenary Meeting (Toledo, 20/06/2008): deliverables. The deliverables to be presented at the meeting in Toledo should centre on giving the best key recommendations to ensure an aligned, harmonised and on-time pre-registration.

4. Silver Work Programme.

4.1. Finalisation and approval of Silver profiles (current status; available data and key data gaps) before they are circulated to members. Eight (8) companies have updated their silver technical specifications and three (3) others have only submitted them for the first time, meaning that a total of twenty out of twenty-two (20/22) Members have submitted their technical specifications to date. The substance profiles will be updated accordingly and they will be distributed to allow each Member to compare the profile of its silver substances to those which have been established at Consortium level and make sure they fit the description before the profiles are considered as reference substance descriptors for the Consortium and the third parties (e.g.: consultants) working with the Consortium.

4.2. Commitment point for reference substance selection for Silver Work Programme (inclusing EBRC & Euras Phase IIb); related decision-making. The Minutes of the last TAP + Ag WG teleconference, including a table listing and describing granulometry and particle size distribution data on silver, silver nitrate and disilver oxide powder and crystal forms, were used as a basis to select the most representative samples for Phase IIb

of the Silver Project[2]. First and second selection samples were identified; some clarifications will be requested to the Companies having provided these sample descriptions in order to make sure the samples do fulfil the needs of the Consortium as well as the needs of the tests to be performed.

Table 1. Selected silver samples for Phase IIb of the Silver Project.

Substance	First selection	Second selection	Pending information
Silver[3]	Inhalable: Sample Y2 Respirable: Sample N3	Inhalable: Sample K Respirable: Sample D	- Company D should confirm the particle size data more accurately (avoid "<" symbol). - Company K should expand the particle size data to D10, D50 and D90. - Company Y should define the shape and confirm the particle size data more accurately (avoid ranges and "<" symbol).
Silver nitrate	None	None	Silver nitrate is only produced in crystal form and does not need to undergo dustiness and transformation/dissolution tests
Disilver oxide	Inhalable: Sample C1 Respirable: Sample N	Inhalable: Sample C2 Respirable: Sample N	- Company C should confirm the particle size data more accurately (avoid ranges).

Companies C, N and Y will be asked to prepare their silver and disilver oxide samples. Should they not be able to provide them, the Trustee will turn to the companies manufacturing/importing the second selection samples. As quantities vary from test to test, EBRC and Euras will be asked to confirm how much of each material is required per test. Based on this answer, a full request will be addressed to each relevant company, including the description of the powder sample(s) which has(have) been selected and the list of compulsory information as requested by EBRC and Euras.
For internal use only, the Trustee shall keep a coded/confidential record of the batch numbers of each sample which has been sent to EBRC and Euras for Phase IIb in order to ensure traceability throughout the entire battery of enabling and experimental tests enclosed in the Silver Project.

4.3. Other data sources (SIEF data holders, Biocidal Products Directive, etc.) and consultant project updates (Phase IIa). Although EBRC appears on the "List of participants and of applicants having submitted a dossier in accordance with Article 5(3) of Regulation (EC) N° 2032/2003", Maren Bode (EBRC) confirmed that this is erroneous as

[2] Mr András Szép (SEKOM) recommended the Trustee to find out how the Molybdenum and Tungsten consortia were identifying their most representative powder samples. **Post-meeting note:** The question was raised to Mrs Sandra Carey (International Molybdenum Association) on the 14th of February, who confirmed that Molybdenum powder samples were also selected among those forms being currently placed on the EU market. Other consortia representatives (e.g. Mrs Nadia Vinck (Euroalliages)) have indicated that the use of composite samples is not recommended.

[3] **Post-meeting note:** The inclusion of a nanoscale Silver powder reference in the Phase IIb testing, to take into account future technology and expected regulatory scrutiny, has been reviewed with EBRC. . They have advised that this would be a prudent action and testing will proceed accordingly.

they only notified silver but never submitted a dossier for any of their clients under the Biocides Products Directive. M. Bode recommended the Consortium to contact the Silver Task Force for Biocides to identify eventual silver data-holders in advance of the SIEF exchanges. Members of the Consortium are encouraged to keep the Secretariat updated on any other sources of silver data and information which should be considered for Phase IIa of the Silver Project[4]. R. Garrett (Ames Goldsmith) offered to try and contact the Silver Task Force for Biocides. P. Godfrey (Cambridge Environmental Assessments) offered to try and contact the OECD Committee.

4.4. Review timeline projections for consultant project based on progress to date.[5]

4.5. Particular recommendations for Pre-registration preparation.

- It is proposed to attendees to produce reference sheets per substance, containing only those parameters which will be requested for pre-registration. In order to make sure all Consortium Members "fall" immediately in the same SIEF list, it was agreed to agree on a reference name and ID code per substance and intermediate, which would be used by all Consortium Members when pre-registering. Before (a) mentioning other names (synonyms) and ID codes for the substances to be pre-registered, or (b) indicating the name and ID codes for substances which could be useful for read-across and (Q)SAR, an agreement should be reached at Consortium level on: (i) which other names and ID codes should be mentioned, if any; and (ii) what advantages and disadvantages the indication of read-across and (Q)SAR-relevant substances would imply for the organisation of both the SIEF and the Consortium. To make sure all pre-registrants are immediately assigned to the same SIEF per substance, and preparation of Registration can start immediately, it is currently recommended not to indicate synonyms or (Q)SAR/read-across-related substances when Pre-registering.
- As it is still unclear how the pre-registration IT system will work, it is recommended to use an excel sheet to fill the different pre-registration information requirements so it can eventually be uploaded as an .xml file in case of IT problems.
- It is highly recommended to Consortium Members to pre-register early in the pre-registration window instead of waiting for the latest period in that window.

5. Gold Work programme.

5.1. Latest version of the Gold indicative list. The updated Gold indicative list was presented to the attendees. Three substances and five intermediates are listed to date.

5.2. Finalisation and approval of substance profiles before they are circulated to Members. Two (2) companies have updated their gold technical specifications and three (3) others have only submitted them for the first time, meaning that a total of nineteen out of twenty-two (19/22) Members have submitted their technical specifications to date. The substance profiles will be updated accordingly and they will be distributed to allow each Member to compare the profile of its gold substances to those which have been established at Consortium level and make sure they fit the description before the profiles are considered as reference substance descriptors for the Consortium and the third parties (e.g.: consultants) working with the Consortium.

5.3. Proposed timeline and particular recommendations for Pre-registration preparation. Cf. section 4.5 above.

[4] **Post-meeting note:** Ames Goldsmith has collected additional studies on silver which have not yet been listed on any of the reference lists used for the Silver Project to date. A CD is being prepared and will be sent to the Secretariat in order to be forwarded to EBRC & Euras and used in Phase IIa.

[5] **Post-meeting note:** Maren Bode (EBRC) and Koen Oorts (Euras) have confirmed on the 22 and 20 Feb 2008, respectively, to be on-schedule and to be reporting on Phase IIa in May 2008. Confirmation letters for Phase IIb HH and IIb Env were sent to EBRC and Euras, respectively, on the 4th of March 2008.

6. PGM's Work Programme.

6.1. Latest version of the PGM's indicative list and status of the related technical specifications. The latest version of the PGM's indicative list provided by the Trustee was reviewed. Though it is thought to be largely complete for manufactured and imported substances, it is predicted that additional entries will be added running up to June 2008 for PGM intermediates and refinables related inputs. Two (2) companies have updated their PGM's technical specifications and two (2) others have only submitted them for the first time, meaning that a total of eleven out of fourteen (11/14) Members have submitted their technical specifications to date – these have slightly extended the available dataset (see also later comments in relation to item 6.3).

6.2. Particular considerations for PGM's[6]:

It will be necessary to determine substance sameness (according to RIP 3.10 principles) for all substances for which at least two companies have reported interest. In such situations it was agreed that spectroscopic analysis together with adjunctive techniques (metal and other elemental analysis) would be the chosen approach. Cases where sameness confirmation should be straightforward were identified as: (i) metal (zero valency state) where PGM's metal content and purity would be sufficient for characterisation; and (ii) tetrammine compounds, and substances with organic ligands, where no significant divergence in spectra are expected. Participants agreed on initiating the sameness evaluation programme according to the following principles:

(a) For solid (all but metallic sponges) PGM's:
- A request can be sent to all the Members of the PGM's Consortium (deadline for submission 21st of April 2008);
- The standard technique is: infra-red spectroscopy (IR) using nujol mulls between caesium iodide plates from 4000 cm^{-1} to 250 cm^{-1} and setting the resolution to 4 cm^{-1} + determination of PGM's content (full elemental analysis not required);
- Full method (e.g.: instruments related parameters) must be properly documented and reported in order to enable a reasonable comparison;
- Electronic versions of the method and spectra shall be sent to the Trustee, who shall be responsible for anonymising them. Spectra (even anonymised) shall not be circulated by e-mail to anyone. Sameness shall be assessed during *ad hoc* face-to-face meetings held between the concerned Members only.

(b) For solutions it was considered feasible to initially attempt to simplify sameness assessment by evaporating them to dryness (as RIP 3.10 allows for exclusion of the solvent/vehicle components where these may be separated without radically affecting the stability of the substance or changing its composition). A few substances may not be amenable to this approach, e.g. Karstedt catalyst solution. Four substances were identified for a pilot project: Chloroplatinic Acid (4 companies), Platinum nitrate (3 companies), Palladium nitrate (3 companies), and Ruthenium trichloride (2 companies). It was proposed that.
- The technique would first be tested on Chloroplatinic Acid (CPA) by the four concerned companies. ;
- Each one of these companies should be required to produce the following information for CPA: (1) ultra-violet visible spectroscopy (UV) and (2) infra-red spectroscopy (IR) using nujol mulls between caesium iodide plates from 4000 cm^{-1} to

[6] **Post-meeting note:** This section adjusts initial discussions which took place on 11 February, based on outcomes of a further dialogue between representatives of Johnson Matthey, Umicore, Vale Inco and Heraeus notably, during an *ad hoc* teleconference held on the 4th of March 2008 at 15h00 CET.

250 cm^{-1} and setting the resolution to 4 cm^{-1} + determination of PGM's content (full elemental analysis not required). Step (2) shall be performed on the dried solution[7];
- Full method (including time up to evaporation and instrument related parameters) must be properly documented and reported in order to enable a reasonable comparison;
- Electronic versions of the method and spectra need to be sent to Trustee, who shall be responsible for anonymising them. Spectra (even anonymised) shall not be circulated by e-mail to anyone. Sameness shall be assessed during *ad hoc* face-to-face meetings held between the concerned Members only.

No significant confidentiality issues were raised during the discussions, but sharing of reference samples will have to be assessed on a case-by-case basis as the programme proceeds. A formal letter from the Trustee is to be sent out to the concerned companies to request IR spectra and PGM's content. It was estimated that the pilot programme detailed above could be completed in approximately 4 weeks. Existing official guidance document references related to spectral analysis were briefly reviewed, including RIP 3.10 and the previous guidance (67/548/EC Manual of Decisions).

6.3. Preparation of substance profiles: how to achieve this in time for the pre-registration window? Certain participants considered that assembling full substance profiles for all PGM substances ahead of the Pre-Registration window (i.e. by June 2008) may now be a too aggressive target. A pragmatic alternative was discussed which could be sufficient to allow Members to progress Pre-Registration in an aligned manner. This would essentially rely on augmenting the existing PGM's technical specifications in a selective manner (three steps approach). The PGM's WG would coordinate the extension of these datasets as necessary, e.g. to support sameness evaluations, by requesting Members to gap fill on key parameters, or otherwise find other ways to obtain this data. Where data requests are made to Members, these should be as specific as possible, and indicate any associated requirements, e.g. timing for the information provision. In order to be on-time for pre-registration, D. Boyd (Johnson Matthey), chair of the PGM's WG, will prepare a project plan for the group (Annex 3).

7. Consultants selection for Au and PGM's project.

7.1. Progress to date and next steps. A meeting with WCA/BIBRA was held in Sutton (United Kingdom) on the 17th of January. Following the outcomes of this meeting, the consultants were invited to tender (tender received on 10th of February 2008). A meeting with RCC/Safepharm will be held in Brussels on the 12th of February 2008 and a third meeting with Dr Knoell Consult will take place in Hanau (Germany) on the 5th of March 2008. The option of working with two consultancies (one for Gold + PM CN^- and one for PGM's + Rhenium) instead of only one is being considered by the TAP (as a kind of safety net).

8. Rhenium Work Programme (Annex 4).

7 **Post-meeting note:** the best way to dry PGM-containing solutions, such as CPA, without affecting the identity of the substance has proven to be less straightforward than expected. Once the method is refined, the same technique could then be used for Palladium nitrate solution, Platinum nitrate solution and Ruthenium trichloride solution.

9. Precious Metals Cyanides Programme.

9.1. Formation of a PM CN- task force: participants and chairpersonship. It was agreed to invite the seven (7) companies involved in PM CN^- to form a specific task force for PM CN^-.

9.2. Presentation of the current PM CN^- inventory. The current inventory was presented. Two Silver CN^- substances and two Gold CN^- substances are currently listed. None of these are intermediates. Although it is likely that CN^- will be the key anion/influencing actor when assessing the toxicological and eco-toxicological profile of these substances, the potential for read-across among each couple of substances should however not be taken for granted as the behaviour of each one of them varies depending on the dissociation constant of the complex ion, the dilution and the pH (e.g: at low pH, more cyanide dissociates and the toxicity increases).

9.3. Data gathering: ECETOC document + Members' contributions. According to Mr Antonio Domínguez-Pérez (CyPlus), the ECETOC report (cf. Annex 8) assembles 95% of the available information on CN- and should therefore be a generous source of information to prepare PM CN^- for (pre-)registration. Members are however further invited to share any data they might have available on PM CN^- or CN^-.

9.4. Substance profiles and buddy system: task distribution. It was agreed to form a task force in 9.1 and eventually agree on a way forward in line with the organisation of the other work groups.

9.5. Consultancy: manage as satellite project of the Gold Work Programme? All the attendees supported the idea to include the PM CN^- REACH work as a satellite project of the Gold project. Whether the costing of the PM CN^- budget should be separate from or included in the overall Gold project needs to be explored further on[8].

10. AOB and next meeting.

10.1. Eurométaux multi-metallic questionnaire for the preparation of exposure scenario. Eurométaux has built a generic questionnaire to collect exposure and emissions data to prepare the Chemical Safety Report (Annex 5). The current multi-metallic questionnaire is mainly driven by parameters which are typical to base metals. It was therefore agreed to use the multi-metallic questionnaire as a basis to build a questionnaire for PM only, whose Industry is different from the base metals industry. It can also be envisaged to use the questionnaire as an annex to PM's own questionnaire or proposed exposure scenario.

10.2. Pre-registration IT. A presentation on the Pre-registration IT is available in Annex 6.

10.3. Next meetings.

(a) 18th March 2008: PGM's WG *ad hoc* teleconference (to be confirmed);

(b) 18th April 2008: TAP + PM WG + Re WG face-to-face meeting in Brussels (to be confirmed).

11. Conclusion.

[8] **Post-meeting note:** Four out of the seven (4/7) Members registering PM CN^- also register Gold and/or Gold compounds. Fifteen out of the nineteen (15/19) Members do not register PM CN-. However, it is likely that the data and information existing on CN^- will suffice to predict/calculate the toxicity of the PM CN^- at any value of concentration or pH and that no additional tests (and subsequent costs) are required.