Chairman: *Dr Andrew Griffiths* (Umicore)
Co-Chairman: *Dr Mark Raffray* (Johnson Matthey)

18 June 2010, 9h00 – 17h30
Park Hyatt Hamburg Hotel
Bugenhagenstrasse 8, D-20095 Hamburg

# Minutes

## 1. Welcome and introduction

**1.1. Confidentiality and Competition Law.** The participants (Annex 1) were reminded of their commitment to comply with Confidentiality and Competition Law provisions. Attendees were welcomed to the 6th Assembly meeting of the PMC. Traxys was welcomed as the 48th Member of the PMC. 33 Members out of 48 are present or represented at the meeting, therefore reaching a quorum of 69% and validating the meeting decisions.

**1.2. Approval of the Agenda.** The Agenda (Annex 2) was approved. The slides presented at the meeting are available in Annex 3.

**1.3. Actions agreed and approval of the minutes of the last meeting (Brussels, 4 Dec 2009).** All actions have been finalised or were addressed during the meeting. The minutes were approved.

## 2. Status and progress of the PMC Projects

**2.1. Key messages from the Technical Advisory Panel.** *Cf. slides 9-19 of Annex 3.*

- ***Priority projects***. Priority projects of the PMC are the Ag and Refinables ones, under which three substance Registration Dossiers and fourteen UVCB intermediate Registration Dossiers are being prepared for submission before 1 December 2010. Dossiers that will be submitted by the first registration deadline will also include a CLP notification. Members were invited to respond to any request related to these two projects with due diligence. All other projects are continued in a steady manner.
- ***CLP notifications***. For those substances and intermediates which are not subject to the first registration deadline, resources are dedicated to the preparation of CLP notifications before 3 January 2011. Such notifications are required for all substances and intermediates that are placed on the EEA market, no matter the volume, and involve the generation of information on physico-chemical properties (testing programme) and the compilation of available information on toxicological and eco-toxicological effects. The success of the testing programme depends on the availability of Sample Providers. Members were encouraged to respond to any request related to Lead Registrant/Sample providers.[1]
- ***Strictly controlled conditions***. Political pressure on Members States has increased over the last months as regards the interpretation and implementation of REACH requirements towards the strict controlled conditions requirement of intermediates. While the use of personal protective equipment (PPE) was previously not regarded as a lack of strict control for specific tasks such as sampling, loading and unloading, bagging, cleaning, maintenance, etc. authorities are now moving in a direction where the use of PPE in any circumstance would be a clear evidence of absence of strict control. An agreement has been reached with the ECHA to adjust the Guidance on Intermediates after the first registration deadline, in order to allow early registrants to progress with their registration obligations without having to cope with last minute changes. Such early registrants would then be in a position of updating their Registration Dossiers after these are submitted and on the basis of a confirmed guidance. PMC Members were recommended to properly document strictly controlled conditions as per the existing guidance while preparing to

[1] **Post-meeting note:** *Upon request from several Members, the Secretariat offered assisting Members in the preparation of CLP notifications for all precious metals and rhenium substances of interest to PMC Members (in addition to those that are part of the REACH projects). The feed-back received (e.g. not enough resources, difficulty to agree classification proposals in such a short timeframe) did not allow us to go ahead with this project (Annex 4).*

adjust their registration dossiers (e.g. "light" dossiers may need to be updated into "full" dossiers as from 2011).

- ***Monitoring data***. The experience gathered with the Ag project has shown that existing emissions and exposure data is surprisingly limited or non-existent in the sector. Moreover, the generation of data that can be used in the chemical safety assessment (CSA) required for hazardous substances under REACH is subject to quality criteria and requires resources that are not always readily available to PMC Members. Members were encouraged to look at the type and quality of emissions and exposure data that already exists in their companies and/or can be generated and respond to any monitoring data request that may be circulated by the PMC secretariat. Where no monitoring data exists, PMC will request from Members that they generate such data in accordance with very specific qualitative and quantitative requirements.
- ***Substance identification***. In order to provide evidence on the substance identity and confirm the sameness of the materials registered by all co-registrants in one unified Dossier, all registrants are recommended to perform a minimum of analysis on the substances and intermediates they register. Although ECHA guidance exists, Eurométaux has developed recommendations to guide registrants of inorganic materials on the preferred analytical techniques. These recommendations have been taken as a basis to develop PMC guidelines on substance identification (Annex 5). Cf. item 3.2 below.

**2.2.** **Ag.** *Cf. slides 20-41 of Annex 3.* Three out of the eight substances and intermediates in scope of the Ag project will be registered before 1 December 2010: Ag, Ag2O and AgNO3. Three areas remain to be finalised:

- ***Effects data***. Since there is no chronic soil data available on silver, this data is being generated through an *ad hoc* testing programme. Draft results should become available in September, which will then be fed in the CSA exercise (see below).[2]
- ***Chemical Safety Assessment (CSA)***. This constitutes Phase IV of the Ag project. It involves many steps, including the generation and assessment/evaluation of effects, emissions and exposure data, the derivation of several acute and chronic PNEC and DNEL as well as the drafting of ES which will reflect the risk management measures that are recommended to ensure a safe manufacture and use of the substance. PMC Members were recommended to participate in the upcoming ES Workshop and to respond promptly and with due diligence to any request circulated by the secretariat.
- ***Classification***. The finalisation of a classification proposal for all Ag compounds awaits the results of the soil testing programme, the results of the Transformation/Dissolution (T/D) tests, a refinement of the oxidising properties test on silver nitrate and the outcome of the literature search/evaluation made by EBRC on published and proprietary data on argyria.[3]
- ***Nanosilver***. PMC's position regarding a separate registration of silver and nanosilver remains unchanged. **AP1** Participation in RIP-oN1 continues, especially now that discussions taking place in this group are no longer nano-specific in the view of industry (e.g.: surface treatment or size proposed as potential identifiers). Although Member States and NGO's have the opinion that nanomaterials and bulk materials are different materials because they exhibit different properties, industry is trying to bring back the discussion around identification rather than on information requirements (RIP-oN2) or risk assessment needs (RIP-oN3). The Nanotechnology Industries Association (NIA) has been contacted in order to exchange experience on risk assessment as one of NIA's members is leading the nanosilver risk assessment case study in RIP-oN3; it would be beneficial to

[2] **Post-meeting note:** *As the availability of the soil data is now delayed, it is proposed to use modelled soil data instead and update the concerned dossiers when the test data become available.*
[3] **Post-meeting note:** *Classifications were finalised by end September 2010. For silver metal, an environmental classification is proposed for powders; for massive forms no environmental classification is proposed but some parallel work is required to interpret some of the results that were obtained. Notifications will be submitted in early November.*

apply a compatible approach to both the nano and the conventional silver cases.[4]

- ***Remaining registration files***. After Ag, Ag2O and AgNO3, five Ag substances still require registration before 2018. However, in order to progress with these registrations as closely as the first ones (read-across was applied throughout entire Ag scope), the secretariat aims at finalising these Dossiers and submitting them in 2011.

**2.3. Au and PM CN-.** *Cf. slides 42-50 of Annex 3.* This project is now fully placed with WCA, who has evaluated the work done by Dr Knoell Consult (Germany) and completed it where required. Full literature search reports were received and testing recommendations are being refined in light of immediate CLP data needs (T/D test on gold powder and determination of physico-chemical properties).[5]
Phase III (REACH testing programme, i.e. toxicological and eco-toxicological tests) will not be launched before 2011. Once the effects data set is complete, the need to perform a CSA in these projects will be considered. This may require the need to generate monitoring data where it does not exist (cf. item 2.1 above).

**2.4. PGM.** *Cf. slides 51-59 of Annex 3.* Due to the number of substances and intermediates to be prepared for registration as part of this project, this is the PMC's most complex project. Focus is currently placed on the identification of Sample Providers/Lead Registrants for each in scope material and in the refinement of the scope of the CLP testing programme. The proposed Lead Registrants were approved by the Assembly. Transformation/Dissolution tests have been launched on all PGM and sparingly soluble PGM compound powders at CANMET (Canada) in order to avoid a default environmental classification (results are expected in August).[6]
Phase III (REACH testing programme, i.e. toxicological and eco-toxicological tests) will not be launched before 2011. Once the effects data set is complete, the need to perform a CSA in these projects will be considered. This may require the need to generate monitoring data where it does not exist (cf. item 2.1 above).[7]

**2.5. Re.** *Cf. slides 60-65 of Annex 3.* Full literature search reports were received and a read-across strategy was defined based on available information and REACH requirements (ammonium perrhenate is considered to be a conservative worst case and potassium rhenate a realistic worst case). This strategy is confirmed by performing UV visible spectroscopy on all in scope Re materials in order to confirm whether or not the rhenate ion is the dominant species in solution in all cases (tests originally performed at AQura are being repeated at Johnson Matthey Technology Centre). The testing programme has commenced with a series of physico-chemical and environmental tests (preliminary results show no environmental toxicity).[8]
In order to allow focusing on the preparation of the CLP notifications, the remainder of Phase III (REACH toxicological testing programme) will not be launched before 2011. Once the

[4] **Post-meeting note:** *RIP-oN3 takes place in the context of detailed Non-Disclosure Agreements which prevents NIA's member from openly sharing any experience gained in RIP-oN3. A draft report circulated for comment to several industry representatives show that the no effects levels derived for nanosilver under RIP-oN3 are very conservative, mainly due to very high assessment factors that are applied on the dataset because of its small size. The approach taken for nanosilver in RIP-oN3 is however in line with the one taken by PMC to risk assess bulk silver.*

[5] **Post-meeting note:** *Physico-chemical and a T/D tests have been launched at Harlan UK and ECTX; first results are expected by mid and end October 2010, respectively. Also, WCA is preparing classification proposals for each substance in order to be circulated in late November and discussed/agreed at an* ad hoc *WG meeting on 30 November.*

[6] **Post-meeting note:** *Physico-chemical tests have been launched at Harlan UK; first results are expected by mid October 2010. Also, WCA is preparing classification proposals for each substance in order to be circulated in late November and discussed/agreed at an* ad hoc *WG meeting on 1-2 December.*

[7] **Post-meeting note:** *Although most of the intermediates of this project are not due for registration before 2013 or later, registration dossier preparation will start as soon as practical in 2011. Whether these dossiers will be prepared as "light" or "full" dossiers will depend on the implementation of the adjusted interpretation around strict control (see item 2.1 above).*

[8] **Post-meeting note:** *Physico-chemical and T/D tests have been launched at Harlan UK and ECTX, respectively. The T/D test confirmed the absence of an environmental classification for Re (Ecotoxicological Reference Value (ERV) above release). Also, WCA is preparing classification proposals for each substance in order to be circulated in late November and discussed/agreed at an* ad hoc *WG meeting on 3 December.*

effects data set is complete, the need to perform a CSA in these projects will be considered. This may require the need to generate monitoring data where it does not exist (cf. item 2.1 above).[9]

**2.6. Refinables.** *Cf. slides 67-73 of Annex 3.* Fourteen UVCB intermediates resulting from precious metals refining streams are subject to registration by 1 December 2010. This project is not organised into the usual five phases that characterise the other PMC projects but focuses rather on the proper identification and characterisation and associated classification of each so-called "complex refinable".
The classification applicable to each refinable is derived in a tiered approach starting with default assumptions that are refined with information on species, Transformation/Dissolution, and particle size and/or surface area data (tool developed by Arche and Eurométaux known as MeClas).
Most of the Non-Ferrous Metals consortia having to prepare registration dossiers for complex UVCB intermediates have developed an approach whereby an adequate characterisation and classification of their intermediates on the basis of their composition would make additional Annex VII (eco-)tox tests irrelevant.
This has been shared informally with the ECHA who fully supports the use of T/D test results to derive environmental classification instead of proceeding to unnecessary testing. On the toxicological endpoints however, ECHA has more reservations that need to be addressed by the Industry.

**2.6.1.** The **evolving interpretation around strict control** (see item 2.1 above) may significantly influence this project in particular. Indeed, although other intermediates are not due for registration before 2013 or later (thereby allowing guidance to evolve in the meantime), these intermediate dossiers that will be submitted to the ECHA before 1 December 2010 may have to be updated already in early 2011. This update may require the generation of "full" dossiers in addition to the foreseen GHS/CLP update.

## 3. Preparing for Registration and CLP notifications

**3.1. PMC plan for June-December 2010 period.** *Cf. slides 75-78 of Annex 3.* PMC's current priorities are defined by two deadlines: the first REACH Registration deadline of 1 December 2010 and the first CLP Notification deadline of 3 January 2011. The submission of the 17 Registration Dossiers (3 Substance and fourteen UVCB Intermediate ones) coupled with the preparation of more than 100 CLP notifications (involving the set-up, monitoring and follow-up of a physico-chemical testing programme as well as gathering and evaluation of all available (eco-)toxicological data) involves many steps for which the time and expertise of Consultants, Members and Secretariat officers are essential to success.

- **Duties of Lead Registrants.** *Cf. slides 79 and 81 of Annex 3*
- **Duties of co-registrants.** *Cf. slides 80 and 81 of Annex 3*
- **Other duties, e.g.: progress-tracking by the Management Committee.** *Cf. slide 82 of Annex 3.* The Management Committee shall actively follow, support and steer the progress of the actions listed in slides 75-78 of Annex 3.

**3.2. Substance identification.** *Cf. slides 83-87 of Annex* 3 and item 2.1 above. Annex 5 contains the recommended analysis to properly identify and prepare each substance and intermediate for a sameness check. Members are invited to launch these analyses as soon as possible, starting with those materials requiring registration by 1 December 2010. Due to resource constraints PMC Officers can unfortunately not assist with this task.

[9] **Post-meeting note:** *To be discussed in more detail at 3 Dec 2010 Re WG meeting.*

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**3.3. SIEF communication.** *Cf. slides 88-89 of Annex* 3. PMC has been focused on finalising the seventeen Registration dossiers subject to submission before 1 December 2010 and has hence had no communication with pre-registrants outside PMC in the meantime. With the arrival of Audrey Rondepierre, Office Assistant to the PMC and in charge of administrative and communication tasks, communication with pre-SIEFs via REACHsuite will be re-launched, starting with the circulation of a Sameness and Lead Registrant survey in summer, followed by the circulation of a CLP notification proposal in autumn. Members are invited to make sure they receive all e-mails coming through their REACH-IT address through REACHsuite.[10]

**3.4. Registration check-list and guidance.** *Cf. slides 90-92 of Annex* 3. Although most of the work required to compile the IUCLID 5 files that will constitute the REACH Registration Dossiers files is done by the consultants, a small portion remains to be completed by the entity responsible for submitting these files, e.g.: the Lead Registrants (with the support of the PMC Officers) and co-registrants under REACH must also submit their legal entity-specific file. Under CLP, a joint submission by one volunteer company is sufficient and does not necessarily need to be completed by individual submissions. Guidance should be finalised before Registration submission. **AP2**

**4. Review of the Consortium Agreement**. *Cf. slides 93-101 of Annex* 3. The revised Consortium Agreement was approved by unanimity (Annex 6).

**4.1. Approved addendum, clarifications, etc.** It had been previously agreed that several addenda and clarifications, which were prepared in response to inquiries from Members and non-Members of the Consortium, would be integrated into the Consortium Agreement on the occasion of the next necessary update. The updated Consortium Agreement therefore includes these changes where relevant (indicated in the text by an orange colour and a comment in each case). These changes to the Consortium Agreement did not require any vote as they had already been approved at previous meetings.

**4.2. Adjusted agreement – 2010-2020 PMC activity (cf. budget predictions below).** PMC activity has evolved since its set-up, therefore requiring an adjustment of the Agreement in order to address those events which were unknown at the time of the first drafting and first update of the Consortium Agreement. Three key changes made to the Agreement relate to:

- **Purpose/Scope:** the purpose and scope were adjusted to allow Members to continue their joint efforts to address CLP as well as post-Registration obligations. Moreover, the Consortium cannot be dissolved before the purpose has been achieved.
- **Changes to the Agreement:** although changes to the Consortium Agreement originally required a unanimous vote, the 2 ½ years of experience of the Consortium has shown that participation of some Members is not as regular and active as expected; therefore rendering minimum quorum requirements or votes by unanimity difficult to implement. The updated Consortium Agreement has been adjusted so that a 2/3 majority is sufficient to approve changes to the Consortium Agreement.
- **Members's commitments:** considering the fact that the projects run by the Consortium evolve at different speeds and may progress earlier than others (different Registration deadlines), and that the Generic costs of the Consortium are shared equally among all Members, the commitment of all Members had to be reinforced in order to avoid early withdrawals from the Consortium membership. Indeed, although the main focus of the

[10] **Post-meeting note:** *Sameness and Lead Registrants surveys have been circulated to the SIEF for all seventeen 2010 Registrations. No objections have been received from pre-registrants. Next step will be to propose Letters of Access (LoA) for non-PMC Members wishing to be legitimate joint registrants of the dossiers prepared by the PMC and to circulate the classification proposals prepared by the Consortium.*

Consortium so far has been on the Ag and Refinables projects, some Members who joined for Au, PM CN-, PGM or Re have contributed equally to the Generic costs since the set-up of the Consortium.
The Consortium therefore has been strengthened where relevant to clarify the obligations of Members towards the Consortium as well as the risk early registrants may have of losing their right to the Registration Dossier if they withdraw from the Consortium. The Consortium activity must be considered as a 2007-2020 commitment for all Members.
On the other hand, the Consortium secretariat is committed to minimising secretariat costs to the absolute minimum that is required to maintain and update the dossiers, including communication with later registrants, authorities and the ECHA.

**4.3. Cost-sharing formula (for simple and complex intermediates).** The original cost-sharing formula did not consider intermediates as the interpretation at that time was that registering an intermediate would only require "any existing available information"; hence only literature search and IUCLID 5 preparation. The PM Refinables project demonstrated that the Registration of an intermediate can require more than these two simple tasks, such as proper identification/characterisation and testing (for classification purposes); these often involve the participation of external consultants and experts, and therefore requires financial support. In light of this evolving experience, the cost-sharing formula was re-visited in order to allocate intermediates in the formula. It was proposed to give a weight of 1 to intermediates requiring no REACH Annex VII data and a weight of 5 to intermediates requiring REACH Annex VII data (equivalent to substances in the lowest tonnage band). In the event no REACH Annex VII data is conducted (e.g.: the classification is done on the basis of calculations such as with MeClas), the intermediate would carry a weight of 1 too.[11]

**5.** **2007-2020 PMC Budget & Letter of Access** *Cf. slides 102-106 of Annex* 3. The proposed budget projection and associated Letter of Access (LoA) cost was approved by all Members. As a contingency, it was agreed to propose each LoA at a cost equivalent of the highest end of the cost range. As regards the LoA Agreement, it was suggested to provide the same amount information to LoA as given to PMC Members to proceed with Registration. This is justified by the fact that LoA purchasers are paying an equivalent amount to the one paid by PMC Members and also in the interest of PMC Members, who wish to avoid incorrect/incomplete submissions considered as "opt-out" cases or similar cases leading to confusion and administrative burdens. It was clarified that LoA are required for non-Members only (Members have a legitimate right to refer to the dossier they submit if they have declared the concerned substance to the secretariat when joining the Consortium or otherwise updated).[12]

**6.** **2010 budget revision, 2011 budget proposal** *Cf. slides 107-114 of Annex* 3. Although a tentative 2010 budget had been approved in December 2009, this budget had to be reviewed in light of the CLP project needs, the addition of Metal-specific costs slot for the PM Refinables project, amongst others. The CLP project indeed involves testing costs as well as sample reimbursement costs (which are far from negligible for the PGM project, for instance); this causes a significant increase in some of the Metal-specific costs. As regards the PM Refinables-specific costs, these did not exist in 2009 and did inflate the overall revised 2010 budget. Other increases and decreases are justified in the attached slides and were discussed in detail during the meeting. The revised budget was approved by

[11] **Post-meeting note:** The cost-sharing formula may need to be re-visited again in 2011 depending on the changing interpretation of the concept of intermediates and strict control in ECHA Guidance.
[12] **Post-meeting note:** *LoA have been proposed to Ag, Ag2O and AgNO3 as well as to the fourteen Refinables SIEFs. These LoA can be signed online on each applicable REACHsuite SIEF page and the steps following this signature are processed by Audrey Rondepierre, Office Assistant to the PMC and in charge of administrative and communication tasks. By end of October four LoA had been sold (all for Ag substances).*

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unanimity and it was agreed to invoice this budget in two parts: 50% in July 2010 and 50% in December 2010. A 2011 budget was provided for information but is subject to revision at the next Assembly meeting. **AP3**

## 7. AOB, next meeting and closing remarks

**7.1. OECD programme:** *Cf. slides 116-119 of Annex* 3. Answers were provided to all questions raised by the Assembly on the OECD programme. However, it was proposed to make a vote on whether or not to participate to this initiative at the next Assembly meeting (**AP4**).

**7.2. Next PMC Assembly Meeting:** The next PMC Assembly meeting was re-scheduled from 2 December 2010 to 12 January 2011 in order to allow all REACH 2010 registrations and all CLP notifications to be submitted before the end of 2010.

**7.3. Next PMC Plenary Meeting:** Cambridge, 17 June 2011, hosted by Johnson Matthey. Invitations will be sent in early 2011.

**Annexes**

1. List of participants
2. Agenda
3. Slides presented at the meeting
4. CLP notification *ad hoc* project
5. PMC substance identification recommendations
6. PM Consortium Agreement as approved at 18 June 2010 PMC Plenary Meeting

**Table 1.** Actions agreed at 18 June 2010 PMC Plenary Meeting

| | What? | Who? | When? |
|---|---|---|---|
| **1.** | Find out whether any Member manufactures or imports other nanoforms of precious metals (e.g.: nanogold or so-called "colloidal gold" | CB | ASAP |
| **2.** | Finalise REACH and CLP guidance | CB | End Jul |
| **3.** | Add budget tracking columns to project plans | TH + AR | ASAP |
| **4.** | Vote on participation of PMC to OECD-HPVC programme | Members | 12 Jan 2010 |
| **5.** | Proceed to nominations and election of Mgmt Cttee 2011-2013 | CB | ASAP |