Chairman: *Guy Ethier* (Umicore)
Co-Chairman: *Mark Raffray* (Johnson Matthey)

14 June 2013, 10:00 – 16:30
Högberga Gård (Fåhreus meeting room)
Grindstigen 5-6, 181 62 Lidingö, Sweden

Minutes

AP refers to Action Points listed at the end of this document
This version has been updated to reflect the comments made by a PMC Member following circulation of the draft minutes by e-mail

1. **Welcome and introduction** *(Cf. Slides 2-6 of Annex 3)*

   1.1. **Reminder on Confidentiality and Competition Law.** Participants were reminded on their obligation to comply with confidentiality and Competition Law rules.

   1.2. **Tour de table and apologies.** The list of participants is available in Annex 1. The minimum quorum was reached and the meeting is hence valid.

   1.3. **Approval of the Agenda.** The Agenda (Annex 2) was approved; item 4.1 was moved upwards after item 1.4 in order to allow F. Le Curieux to meet other obligations and leave the meeting before 11:30 am. The slides presented at the meeting are available in Annex 3.

   1.4. **Status of actions agreed at and approval of minutes of last meeting (5 Dec 2012).** All actions are done or on-going. Members' feed-back on their (dis)satisfaction with the PMC Secretariat's work is summarised in slides 5-6 of Annex 3. Overall PMC Members are very satisfied with the exception of the speed at which minutes are circulated (sometimes too late after the meeting has taken place) and the added-value of PMC membership versus LoA purchase. Though PMC Secretariat can ensure minutes are circulated earlier, it may need further clarification from those PMC Members having indicated that the added-value of joining the Consortium (versus LoA purchase) is not evident (**AP1**). The minutes were approved.

2. **Membership information** *(Cf. Slides 7-12 of Annex 3)*

   - Following the submission of a complete and valid membership request, the PMC Assembly welcomed BASF as a new Member (**AP2**).
   - An updated list of Members was presented to the Assembly. The list is likely to be further updated following the merger of the PMC memberships of 1) Glencore and Xstrata ***(Post-meeting note:)***, and 2) Sempsa and Heimerle und Meule (**AP3**).
   - The PMC Assembly approved the replacement of J. Schafnitt by T. Wenger as the representative of Metalor in the PMC Management Committee. Members will be invited to nominate representatives for the 2014-2016 Mgmt Cttee and elect the new composition at the Dec 2013 Assembly meeting (**AP4**).
   - The PMC Assembly was updated on the LoA sold over 2010-2013 (up to 1 June 2013); the amounts collected in 2013 will be deducted from the 2014 invoices, if and as decided by the Assembly at the Dec 2013 Assembly meeting (**AP5**).

3. **CLP inventory & CLP platform** *(Cf. Slides 13-14 of Annex 3)*

   PMC Members agreed for the PMC Secretariat not to actively lead the CLP platform discussions/C&L harmonisation while it remains in its current (inefficient) form and to use the Registration Dossiers to report the recommended classification (and supporting evidence) instead.

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4. Registration

4.1. Presentation from ECHA on Substance Identification, Read-across justification, and other Dossier Compliance recommendations *(Cf. Annex 4)*

F. Le Curieux (frank.lecurieux@echa.europa.eu), Senior Scientific Officer and Team Leader in the Evaluation Unit of ECHA reminded PMC Members on the dossier and substance evaluation procedure principles and features, and presented key recommendations from ECHA to registrants to improve the overall quality of existing and future dossiers and as such, maximise the chances for industry to succeed both the dossier and substance evaluation exercises. These recommendations include:

- Identify registered substance (forms) as clearly as possible;
- Demonstrate representativity of reference (test/read-across) material;
- Provide detailed and data-supported documented justification to deviate from information requirements (e.g. waiving or read-across) or from recommended assessment approaches (including assumptions of assessment factors and models); and
- Pro-actively update registration dossiers rather than waiting for ECHA to request such updates following random or targeted compliance checks.

As regards nanomaterials, ECHA recommendations can be summarised as follows:

- The scope of any dossier should be clarified so as to indicate clearly whether nanoforms are included or excluded from the risk assessment performed under REACH;
- Detailed characterisation data (on particle size, aggregation/agglomeration, dustiness, surface area, and surface treatment using more than one method) should be provided to demonstrate the (non-)nanomaterial status of the substance and the individual nanoforms of a given substance which are covered by the risk assessment submitted under REACH;
- Appropriate sample preparation, characterisation, and dosimetry should be ensured/reported as a condition to validate test data;
- Provide detailed read-across justification (if read-across is applied across 'forms' of a substance); the read-across should be based on more than just composition and should ideally consider fate and behaviour and/or toxicokinetics of each form;
- Report IUCLID endpoint study records separately for each form or surface treatment; and
- Pro-actively update dossiers with developing recommendations tailored to address nano-specific requirements which were not available at previous registration deadlines in order to demonstrate that REACH is the proper framework to 'tackle' nanomaterials.

4.2. Update on PMC (post-)Registration work

- **Registration** *(Cf. Slides 20-26 of Annex 3)*
  - **Au:** work in progress, with mammalian toxicity testing to be launched soon. Need to consider whether dossier will cover nanoAu (**AP6**).
  - **PM CN-:** work in progress, with mammalian toxicity testing to be launched soon. Need to identify remaining Lead Registrants (**AP7**).
  - **PGM:** work in progress, tackled in tiers, starting with DDP and Pd family as DDP was originally anticipated for registration in 2013 (now postponed to 2018 following the review of the tonnage calculation by PMC Members). In addition to the testing programme (which includes some repeated tests due to formulation preparation and stability issues among others), exposure scenarios are being prepared and may require monitoring data to be generated to demonstrate the low exposure/emissions to Pd and PGM in general. It is essential to quickly conclude the WG sameness discussions in order to ensure the correct materials are being registered and to validate the

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robustness of the read-across strategy which is so important to achieve an efficient registration of all in-scope PGM. It was agreed that the Management Committee would receive a progress report as to whether the sameness issue was resolved in a timely manner (**AP8**). Registration dossiers will be submitted as soon as they are ready in the 2014-2018 window with the possible exception of those PGM for which a RMO-aligned strategy may need to be deployed.

- **Re:** Six of the seven dossiers will be submitted in June 2013, thanks to the efficient contribution and management of the Lead Registrants and K. Arijs (Project Facilitator). Consequently, the price of a LoA for Re and Re compounds will be calculate on the basis of the registration dossier preparation cost incurred by Members over the 2008-2013 period.

- **Registration updates** *(Cf. Slides 27-29 of Annex 3)*

  - **Ag:** following the successful submission of the Ag, Ag2O and AgNO3 dossiers in 2010, these have been updated in 2012 and the submission scope has been completed with three additional submissions efficiently prepared with the photographic industry. The next update of the Ag and Ag compounds' dossiers is foreseen by end 2013 when the on-going research is finalised and before the Evaluation by the Dutch Competent Authorities begins. The outcome of the recent literature search (performed twice per year to capture new publications on all forms of silver) has revealed the weak nature of the existing aquatic PNEC and the Ag WG is developing recommendations for additional risk assessment research to strengthen these.
  - **Refinables:** after several meetings with ECHA, the approach to register complex UVCB substances under Article 10 of REACH (full registration or dossier 'upgrade') is not fully finalised and 'validated'. The September EM-ECHA meeting should allow finalising the approach and the submission of the dossier upgrades before the end of the year, unless ECHA requests more information than the one that is being prepared (e.g. 28d validation toxicity study). An additional Re containing Refinable may be added to the scope of work (to be discussed by the Ref WG at its 18 June 2013 meeting).

5. **Evaluation** *(Cf. Slides 30-37 of Annex 3)*

The Ag dossier has been/is subject to two types of evaluation procedures:

- **Dossier Ev:** a technical conference call with ECHA and a written response to MS questions allowed resolving open questions on the testing proposals included in the Ag dossiers. PMC is however still awaiting the final and formal decision from ECHA confirming that the test can be performed as proposed.

- **Substance Ev:** will commence in March 2014 after the next version of the CoRAP list is published, but requires a number of administrative and technical preparatory steps which are summarised in slides 35 and 36 of Annex 3 to be performed ASAP. The Substance Evaluation of the Ag Dossier should be regarded as an opportunity for PMC to check/further complete the assessment done as well as to gather learning lessons and best practice that should be implemented in all PMC registration dossiers. Though the Ag WG and Nano TF have normally met separately in the past, joint conference calls and meetings will be organised from now on in order to maximise the efficiency of the review of the dossier content before the update is submitted. PMC Members were also reminded on the importance of both the joint dossier and the individual dossiers to be updated in preparation of the Evaluation as we should collectively demonstrate that all forms of Ag reported by the individual manufacturers/importers are

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properly covered by the risk assessment submitted in the dossier of the Lead Registrant (**AP**).

6. **Authorisation** *(Cf. Slides 38-68 of Annex 3)*

PMC Members were reminded/informed on:

- Risk management options (RMO) available in the EU to ensure or condition the use of SVHC: authorisation, restriction, harmonised classification and labelling, OEL setting, substance or sector-specific regulation, etc.;
- Each option applies more or less to specific situations where they can achieve the desired impact of improved safety; if they are applied without considering the specific situation they may trigger useless bureaucracy, challenge the competitiveness of a given sector, or even jeopardise a number of applications which are dependent on a given SVHC but crucial to society (e.g. without refractory ceramic fibres, there are no heavy duty engine exhaust catalysts, and no exhaust gas emission prevention and control possible, with all the environmental and health impacts this would cause);
- It is hence very important to perform a RMO analysis before deciding on the risk management option to be implemented. Unfortunately the registration dossiers do not necessarily contain RMO analysis-information and in many cases the RMO analysis is done by MS without the participation of industry;
- Knowing that respiratory sensitisers are probably the next category of substances which may be "mined" by MS for inclusion on the Candidate List (via Art. 57f), there is a need to prevent respiratory sensitisers relevant for the PM sector being put through Authorisation if other routes are more likely to address the safe use of these in a more efficient manner (e.g. OEL setting). This can be done pro-actively via RMO initiatives, or in response to the Registry of Intentions (ROI) announcements;
- If Authorisation is required on a given substance it means all (manufacturers and) users of this substance need to prepare, submit and regularly update an Authorisation Application which triggers a significant administrative and financial burden on companies, with a risk that the Application may be refused by the authorities if deemed incomplete in e.g. demonstrating the non-substitutability of the substance; and
- It is important for the PM sector to monitor both substances (potentially) listed on the SVHC as well as the identification of new listing criteria (e.g. STOT RE, endocrine disruptors, respiratory sensitisers, etc.). RMO analysis preparation, advocacy (i.e. specific advocacy specialists), and Hydrazine TF-type of initiatives may be necessary in future if Authorisation impacts the sector more significantly (**AP9**).
- As regards the Hydrazine project, it has taken longer than anticipated to deliver on the initial tasks mainly because the input to the scoping study and defining the boundaries of the Analysis of Alternatives (AoA) requires multi-disciplinary input from within the various companies and there is no Authorisation challenge confirmed ahead yet. Another learning lesson is that although Members agreed to work collectively and prepare a joint Authorisation Application (AA) when the time comes, the preparation of this AA requires company-specific information to be collected which cannot be easily aggregated into a joint AA. Members recognise and agree that steps beyond the AoA may need to do separately by each companies.

7. **PMC organogramme and associated budget for 2013 (II) and 2014** *(Cf. Slides 69-85 of Annex 3)*

- PMC organogramme: Following a presentation of the risks and challenges faced by PMC with its currently limited staffing resources, the PMC Assembly approved the Management Committee's recommendation to hire a Consortium Manager as well as the associated budget decisions related to this hiring: using 2012 reserves to cover the cost of this Manager hired as from Sep 2013 (which was not included in the 2013 budget invoiced in Apr 2013), and increasing the 2014 budget to cope with this additional human resource (and the decrease of C. Braibant's time

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from 4 to 3 days/week dedicated to PMC work).

- 2014 budget proposal: was approved with the clarification that the Ag and Refinables project budget lines will be refined in time for the Dec 2013 Assembly meeting. The 2014 invoices do not yet reflect the amounts credited from the generic and project specific costs after the 2013 accounts are closed and before invoicing.
- A member of the Re WG raised an objection with regards to the amount of generic costs to be charged by the consortium to Re WG members only registering Re substances after registration has been submitted and no additional work beyond dossier maintenance is anticipated. It was indicated that decreasing the generic costs paid by such Members would require adjusting the cost-sharing formula and be unfair to other PMC Members having equally shared generic costs since 2007 when joining the Consortium though their registrations are not due before 2018.
- The Chairman of PMC informed PMC Members that the Board and Management Committee intended to develop a more formalised remuneration scheme to ensure in line with proper human resource practices, and to aid a transparent preparation of each year's budget proposals.

8. AOB[1], next meetings and closing remarks *(Cf. Slides 86-88 of Annex 3)*

- No other business was proposed.
- The next meetings will take place in/on:
  - Brussels, Belgium, 4 Dec 2013
  - Bern, Switzerland, 12 Jun 2014
- Sincere thanks were expressed to the hosts (Boliden) and the PMC Secretariat officers for the very well organised meeting.

Annexes:

1. List of participants
2. Agenda
3. Slides presented at the meeting (including slides on Authorisation)
4. Slides from ECHA

Table 1. Actions agreed at 14 June 2013 PMC Assembly Meeting

	What?	Who?	When?
1.	Clarify reasons for insufficient evidence of added-value of PMC membership versus LoA purchase	Members	Dec 2013
2.	Join relevant WG of PMC	BASF	ASAP
3.	Update Substance and tonnage band declarations following PMC membership mergers Present updated list of PMC Members to Assembly	Glencore+Xstrata SEMPSA+Heimerle Secretariat	ASAP Dec 2013
4.	Nominate representatives for the 2014-2016 PMC Management Committee	Members	Dec 2013
5.	Present refined 2014 invoices and invite PMC to decide upon use of reserves (including LoA incomes)	Secretariat	Dec 2013
6.	Agree on scope of Au dossier (with or without nanoAu)	Au WG	ASAP
7.	Identify LR for PM CN-	PM CN-	ASAP
8.	Progress/Finalise PGM sameness discussions and report to Mgmt Cttee	PGM WG	ASAP
9.	Consider need for Hydrazine TF-type of initiatives for other PM or non-PM substances added to the SVHC and/or Priority List(s)	PMC	On-going

[1] Only items which do not require decision are allowed under AOB

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