Chairman: *Steven Verberckmoes (Umicore, Belgium)*
Secretariat: *Renaud Nicolay (EPMF, Belgium)*

24 March 2015 (10:30-12 :15 CET)
Metals Conference Centre, Rue du Duc 100, B-1000 Brussels

MINUTES

[A] refers to an *Action* agreed during the meeting and is enumerated at the end of this document.
[D] refers to a *Decision* approved during the meeting.

1. Welcome and introduction

1.1. Reminder on Confidentiality and Competition Law

Participants are reminded on their obligation to comply with confidentiality and competition laws. All participants to the meeting are acting as moderators in this respect.

1.2. Tour de table and apologies

The list of participants is available in Annex 1.

1.3. Objectives, previous WG meeting minutes approval, agenda approval

The objectives of the meeting are to update Members of the Gold ("Au") Work Group ("the WG") on the current status of the different phases of the project, to exchange critical information on the elements necessary to timely progress in the making of the registration dossier, and to agree on the next steps for its finalisation. The slides presented during the meeting are available in Annex 2.

More time is left to Members to submit comments on the minutes of the last WG meeting [A13]

The draft agenda is approved as distributed and is available in Annex 1.

1.4. Status of actions

The status of actions that were agreed at the last Au meeting(s) is presented on slide 7 of the meeting's slidedeck (Annex 2). Updates can be summarised as follows:

Action 1: the timing of phases IV and V of the project's work plan has been reviewed and modified by the consultants, WCA and EBRC. The consultants have underlined that a range could be estimated for the duration of the critical tasks, but not a precise timing as dependent of too many factors. This update, with average duration will now be impacted in the Microsoft Project plan and submitted to the WG for information [A14].

Action 6: WCA prepared a justification paper for the use of neutralized TCA in experiments. This paper will be submitted to members for review [A15].

Action 9: the collection of input from experts to discuss the similarity of nanogold with massive gold is on hold until a decision has been made on the registration of nanogold [A9].

Action 12: the detailed strategy for completing the endpoints is well visible in the data matrix produced on a regular basis by WCA. The matrix is showing a clear status on the completion of the required endpoints and will be distributed to the members for information [A16].

All other actions are completed.

2. Phase I

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2.1. Inventory and latest classifications

No changes to the inventory and classification.

2.2. Outcome of literature searches

The newly suggested databases have been included in the sources for literature search. WCA presents the result of the 2014 literature search. So far no relevant studies were noticed but the review of gold studies is still ongoing (28 potentially relevant papers, incl. nanogold).

3. Phase II: Data gap analysis and Integrated Testing Strategy

3.1. Addendum to the ITS

The addendum to the ITS has been prepared and submitted to the WG for review together with the meeting material. No questions were raised by the WG during the meeting but an extra review period is granted to Members for submitting their comments on the ITS addendum [A17].

3.2. Nanogold surveys

The first and second nanogold surveys with members have not given significant positive results. This is not completely unexpected as the production and use of nanogold may be the fact of downstream users. The World Gold Council (WGC) previously agreed that nanogold matching the definition recommended by the European Union is on the market. The nanogold survey will be forwarded to downstream users via the WGC [A18]. PMC will reserve its right to include nanogold in or out of its registration dossier, considering the potential consequences on the preparation of the dossier.

It's underlined that the REACH annexes may soon be modified to officially include nano-substances' requirements by the end of this year.
On the top, CARACAL has been discussing some changes in the requirements for 1-10 T registration dossiers. This could be a way to partially tackle the nanos and include more requirements for smaller tonnage bands.

4. Phase III: Testing Programme

4.1. Update on the progress of the testing programme

The testing programme is reaching an end.

For mamtox assessment, only reports are still expected. The validity of the negative result of the OECD TG 474, *in* vivo micronucleus assay, will be discussed offline re the demonstration of exposure of target tissues to the test item [A19]. The first conclusions on the OECD TG 422, following the end of the histopathology assessment, will give the direction on the NOAEL.

For environment, the adsorption/desorption test with TCA should soon be completed; it was delayed due to the need to repeat the preliminary test (issue with the blank sample). Its result will impact the PNECs of which the value could be derived in June.

4.2. Proposed classification for registration

The results of the ongoing OECD TG 422 and of the possible additional testing that may be conducted to refine PNECs may still influence the classification. It's therefore too soon to

conclude on the classification that will be submitted with the registration dossier. It is noted that when full results of the OECD TG 422 will be available, STOT will need to be checked.

5. Phase IV: Exposure scenario data collection

5.1. Theoretical approach to characterization of risk

WCA is presenting the high-level process for risk assessment in the REACH registration dossier.

This presentation is putting in perspective the importance of completing the questionnaires on the collection of exposure/emission information and the asset to benefit of existing monitoring data if any.

5.2. Status of PNECs and DNELs derivation

Only TCA requires the derivation of these values.

Aquatic PNECs have been derived. Soil and sediment PNECs will be derived based on the result of the adsorption/desorption test (month of May). A refinement of the PNECs may be required with new chronic ecotoxicity testing.

The derivation of DNELs should be completed in May. A summary proposal should already be available in March [A20]. Furthermore, the man via environment exposure will be considered by PMC as the consultant who will be in charge. It is advised to contact ARCHE since they developed MvE strategy for several other metals [A21].

5.3. Data collection: uses + ENV/HH/Waste exposure

The TCA questionnaires have been circulated in December 2014. The collection of responses has been extended already a first time and will be extended one last time until mid-April 2015 in order to try and receive more relevant monitoring data.

The request for completing use questionnaire for the 3 other substances in the PMC gold inventory will be launched in the next days with a reply period of 1,5 month [A22] now that the confidentiality questions with the PMC Secretariat on collection of Members' data has been clarified.

EBRC is enquiring if there is further information on physical form of TCA. Until now it was always agreed that TCA is produced in solution. However it appears to have cases where the substance is produced as crystal. New form of TCA may trigger additional testing. And this would influence the occupational and environmental risk assessment. Members will be invited to confirm by 15 April the physical form of their produced TCA and the tonnage if produced as crystal, and the dustiness tests will be forwarded to EBRC. The WG will then decide if new testing is required [A23].

5.4. Implications of a monitoring programme

The addition of Au to the PGM monitoring programme can be done at minimal cost, probably around 6 euros per analysis. [D] The Au WG is recommending that Members of the Au sub-assembly already conducting a PGM monitoring programme add the analysis of Gold. The duration of a monitoring programme is typically between 6 months and 1 year. The Secretariat will review and facilitate the process: communicate to the Sub-Assembly the advice to add Au to the PGM monitoring programme and coordinate with WCA the update of the PGM monitoring programme [A24].

6. Phase V: Dossier finalization

6.1. Status of IUCLID dossier completion

WCA is presenting the status of dossier completion for the 4 Au substances. Available studies have been entered in the dossiers for gold, Aurio[…], Balsams[…] and TCA. Some waivers have to be completed for Gold and some more studies will still be added to the TCA dossier. DNELs and PNECs should also be entered in TCA.

As mentioned under item 1.4, the data matrices of dossier completion will be distributed to Members for information.

6.2. Updated project plan and registration target

As mentioned under item 1.4, the project plan will be updated taken into consideration the latest review of phases IV and V by the consultants, and distributed to the Members.

7. Budget 2015 and projections on 2016-2019

The budget 2015 is presented in parallel with the current (end Feb 2015) expenses. The budget is on track with no identified risk of exceeding it.

It's underlined that a contingency should be foreseen for Phase IV. The 2015 budget has been proposed on the strict basis of the consultants' proposals, without additional contingency. Contingency could be added in the 2016 budget [A25].

The first estimate of this 2016 budget is presented. It may change in the next months and its final vote will occur in the December 2015 General Assembly.

8. Next steps and AOB

The Chairman, Steven Verberckmoes (UMICORE), summarizes the main discussions, actions and decisions taken during the meeting. SVE also reminds the importance for companies to provide the maximum of input to the use/emission/occupational questionnaires.

The list of actions agreed over the conference call is listed at the end of the document.

The next conference call or meeting will be setup on an ad hoc basis. POST-MEETING NOTE: the next WG meeting is scheduled on Tuesday 13 October 2015. Ad hoc meetings/calls may occur in between.

Renaud Nicolay announced that he will leave EPMF end of April 2015. The Chair thanked him for his support to PMC.

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List of Actions

Table 1. Actions agreed at the Au WG Meeting on 24 March 2015

[A]	WHAT	WHO	WHEN	STATUS
9	*On hold until decision on inclusion of nanogold*: collect input from experts (chemists from PMC Members, consultants) to decide if nanogold can be considered similar to massive/bulk gold	RN	Not defined	On hold
13	Review and comment the minutes of the 08 Oct 2014 WG meeting	Members	22 Apr 2015	Ongoing
14	Update work plan with review of the consultants for timing of phases IV & 5 and distribute to the WG for information.	RN	01 Apr 2015	Ongoing
15	Justification paper for the use of neutralized TCA in experiments: submit to members for review	RN	01 Apr 2015	Distributed
16	Distribute data matrices to Members. The data matrices show in one look which endpoints are completed and how.	RN	01 Apr 2015	Distribute w/ minutes
17	Submit comments on the ITS addendum.	Members	22 Apr 2015	Distributed
18	Issue the nanogold survey to downstream users via the WGC.	RN/FC	01 Apr 2015	Done
19	The validity of the negative result of the OECD TG 474, *in* vivo micronucleus assay, will be discussed offline re the demonstration of exposure of target tissues to the test item	SVE/MRA/ WCA/RN	24 Apr 2015	RN to initiate
20	Propose a preliminary summary proposal of derived DNELs	WCA	31 Mar 2015	Ongoing
21	Consider man via environment exposure	ARCHE/RN	24 Apr 2015	Not started
22	Distribute to members the use questionnaire for the 3 last substances in the PMC gold inventory with a reply period of 1,5 month	RN	01 Apr 2015	Done
23	Confirm the physical form of produced TCA and the tonnage if produced as crystal, and forward dustiness test to EBRC if available. The WG will then decide if new testing is required	Members	15 Apr 2015	Not started
24	Communicate to the Sub-Assembly the advice to add Au to the PGM monitoring programme and coordinate with WCA the update of the PGM monitoring programme	RN	15 Apr 2015	Ongoing
25	Add contingency for Phase IV in the 2016 budget	RN	19 Apr 2015	Done

List of Annexes

1. Approved Agenda and List of participants
2. Slides presented during the meeting

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