



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 PM Cyanides ("PMCN") 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 PMCN 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 4: A provider of METALOR sent a safety data sheet for KCN mentioning the classification of this substance as STOT for testicles and thyroid. PMC is wondering if there is a risk of read-across to its PMCN substances. After verification on the ECHA website, it appears that this classification has already been indicated by some pre-registrants for PMCN substances. The ongoing OECD 422 studies will confirm if this is applicable.

Action 6: The Secretariat will facilitate discussions between *SVE, MRA and OGR to discuss if a more specific classification (skin sensitizer category 1A or AB) can be assigned to potassium dicyanoaurate (PDAu) on the basis of the conclusions of the 2 LLNA studies [A6].*

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 [A15].*



All other actions are completed.

2. Phase I

2.1. Inventory and latest classifications

The acute dermal study showed that Acute tox. 1 (H310 Fatal in contact with skin) is not applicable to Silver Cyanide (SCn) and PDAu. **The presented meeting slidedeck will be corrected accordingly and distributed with the minutes [A16].** The ongoing test with potassium dicyanoargentate (PDAg) will say if it's applicable to this substance, but the current result indicates a skin corrosive 1A classification.

The lower acute toxicity by the oral route for SCn is making sense considering the lower bioavailability of the CN and Ag in this less soluble compound.

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 PDAg studies is still ongoing (1 potentially relevant paper).

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. Zoom on the ITS for Potassium Dicyanoargentate

The details of the new testing programme on PDAg is presented for 2015 and 2016.

4. Phase III: Testing Programme

4.1. Update on the progress of the testing programme

The PDAu and SCn testing programmes are reaching their conclusion as far as testing is allowed without prior approval of a testing proposal by ECHA for *in vivo* studies.

For mamtox assessment with SCn, the OECD 476 (*in vitro* mammalian mutagenicity test) and OECD 422 (repeat dose toxicity combined with screening of reproductive and developmental toxicity) are ongoing.

For mamtox assessment with PDAu, the OECD 422 is ongoing and the **testing proposal for the OECD 474 (*in vivo* micronucleus test) has been prepared by WCA and will be submitted to the WG for review [A18].**

For mamtox assessment with PDAg, the *in vitro* skin corrosion returned an unexpected very positive result, which should normally end the testing programme per REACH Annex VII. This would also mean that the substance would be considered a skin sensitiser per the game of equivalent concern. There is however a possibility that the test identified a positive toxicity rather than actual skin corrosion property. The known pH of the test item cannot explain this



result. Therefore, the WG decided to further assess properties of the substance by **conducting the BCOP (*in vitro* eye irritation/corrosion) study [A19]**. The latest study has been budgeted in 2015. The BCOP would be confirmed with a 2nd equivalent test.

For environment, the adsorption/desorption test with PDAu should soon be completed; it was delayed due to the need to repeat the preliminary test (issue with the blank sample). Its results will impact the PNECs derivation which will be done in June when the results will be available.

4.2. Proposed classification for registration

The still unknown results in the different testing programmes and the possible need to perform additional testing to refine PNECs may still influence the classifications. It's therefore too soon to conclude on the classifications that will be submitted with the registration dossiers.

A question was raised regarding the justifications related to CMR endpoints. It is important to ensure consistency across the different PMC dossiers on the data waivers used when relevant.

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 are known for PDAu, SCn and PDAg. Soil and sediment PNECs of PDAu will be derived based on the result of the adsorption/desorption test (month of April). A refinement of the PNECs may be required with new chronic ecotoxicity testing.

The derivation of DNELs should be completed in July. 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

All 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 (measured) data.

EBRC is enquiring if there is further information on physical form of the substances. **The dustiness tests will be forwarded to EBRC [A22]**.

5.4. Implications of a monitoring programme

A monitoring programme was already made on pure silver and WCA will check the silver dossier if this is applicable to the PMCN needs [A23]. If not, the addition of Ag to the PGM monitoring programme can be done at minimal cost, probably around 6 euros per analysis. [D] **The PMCN WG is recommending that Members of the PMCN sub-assembly already conducting a PGM monitoring**



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

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Metals Conference Centre, Rue du Duc 100, B-1000 Brussels

programme add the analysis of Ag. The Secretariat will review and facilitate the process: communicate to the Sub-Assembly the advice to add Ag to the PGM monitoring programme and coordinate with WCA the update of the PGM monitoring programme [A24]. The duration of a monitoring programme is typically between 6 months and 1 year.

6. Phase V: Dossier finalization

6.1. Status of IUCLID dossier completion

WCA is presenting the status of dossier completion for the 3 PMCN substances. Mainly the mamtox information still needs to be entered. DNELs and PNECs should also be entered for PDAu and SCn.

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. It is worth to note that the PDAg registration dossier may be ready by mid-2017.

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.



List of Actions

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

[A]	WHAT	WHO	WHEN	STATUS
6	Determine if a more specific classification (skin sensitizer category 1A or AB) can be assigned to potassium dicyanoaurate on the basis of the conclusions of the 2 LLNA studies	SVE/MRA/OGR/ RN	22 Apr 2015	RN to initiate
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	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
16	Members will submit comments on the ITS addendum.	Members	22 Apr 2015	Distributed
17	The acute dermal study showed that Acute tox. 1 (H310 Fatal in contact with skin) is not applicable to Silver Cyanide (SCn) and PDAu. The presented meeting slidedeck will be corrected accordingly and distributed with the minutes	RN	01 Apr 2015	Done. Distribute w/ minutes
18	Review the testing proposal for the OECD 474 (<i>in vivo</i> micronucleus test) with PDAu	Members	22 Apr 2015	Distributed
19	Initiate the BCOP study with PDAg	WCA	25 Mar 2015	Done
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	Forward dustiness tests to EBRC for analyzing the forms of the substances	WCA	01 Apr 2015	Done
23	Check the silver dossier if the monitoring programme made on pure silver is applicable to the PMCN needs	WCA	22 Apr 2015	Not started
24	Depending on result of action 23, if the Ag monitoring made previously is not applicable to PMCN, communicate to the Sub-Assembly the advice to add Ag to the PGM monitoring programme and coordinate with WCA the update of the PGM monitoring programme	RN	Linked to action 23	On hold until conclusion of action 23
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 (with correction of classification on slide 09 - [A16])