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

08 October 2014 (10:30-12:00 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 and agenda approval

The objectives of the meeting are to update Members of the Precious Metals Cyanides ("PMCN-") Working Group ("the WG") on the progress made in the different phases of the project since the previous WG meeting. Furthermore this meeting aims at making decisions on critical elements necessary to land the registration project on schedule. The slides presented during the meeting are available in Annex 2.

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 5 of the meeting's slidedeck (Annex 2). Updates can be summarised as follows:

The project's work plan has been updated to reflect a realistic estimate of the earliest possible registration date according to the REACH Precious Metals & Rhenium Consortium ("PMC") Secretariat. However, the proposed timing for Phases IV and V of the project, i.e. generating the CSR, ES and the IUCLID dossier, will need to be confirmed by the consultants [A1].

The WG approved the candidature of SAXONIA HOLDING GmbH as Lead Registrant for Potassium Dicyanoargentate (CAS 506-61-6) and Silver Cyanide (CAS 506-64-9). The candidature will now be submitted to the SIEF [A2].

In its June 2014 General Assembly, PMC asked each project to prepare a projection of budgets on the period 2015-2020 [A3]. This action is currently not started for PMCN-.

All other actions are completed.

2. Phase I

2.1. Inventory and latest classifications

The PMCN- inventory is not modified: 3 substances, all with a Lead Registrant approved by the WG. SAXONIA Holding GmbH is thanked for volunteering as new Lead Registrant for Silver Cyanide (SCn) and Potassium Dicyanoargentate (PDAg).

There is a major classification change: the second LLNA test (OECD TG 442b - BrdU Elisa) with Potassium Dicyanoaurate (PDAu) confirmed the skin sensitisation potential of the substance. Classifications and the follow-up that should be given are discussed with more details below under item 4.1.

METALOR indicates to have received an updated classification from its supplier for KCN, classifying the substance as STOT (thyroid and testicles) under repeated exposure. Is there a risk of read-across of this classification to our substances (KAu(CN)2 and KAg(CN)2)? The Secretariat will verify if this classification is notified for PMCN substances [A4].

2.2. Outcome of literature searches

The literature search is organised once every year, around November. WCA presents the result of the 2013 literature search. It's agreed that the databases explored should be widened to sources such as NTP, OECD, EPA, etc. [A5].

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

No updates or modifications to the data gap approach and ITS. It's reminded that PDAg has a read-across strategy from soluble cyanides whilst PDAu and SCn are supported by their own results.

4. Phase III: Testing Programme

4.1. Current status, bottlenecks and next steps

WCA reminds the testing status as it was at the previous WG meeting and updates on the progress of studies in between the 2 meetings (genotox, eye and skin, acute and OECD 422 (repeated dose toxicity/reproductive toxicology screening), ecotox). To be stressed:

4.1.1. PDAu:

i. The LLNA (OECD TG 429) and then the "enhanced" LLNA (OECD TG 442b) concluded on a positive skin sensitisation risk (see item 2.1) and the substance will be classified as skin sensitizer category 1 without specifying A or B as the studies do not allow a clear decision in this respect (EC3 value not derived); S. Verberckmoes, M. Raffray and O. Green would join up efforts to look at the study more in detail and conclude if a category is more relevant [A6]. MBResearch, CRO where the OECD 442b test was made, asked for the authorisation to submit a poster on this test to the organisers of the next SOT: S. Verberckmoes (UMICORE, PMCN- Chairman) and M. Raffray (JOHNSON MATTHEY, PMC TAP Chairman) agreed on the principle, and PMC will first review the abstract before any release is allowed to SOT organisers.

ii. The BCOP test (*in vitro* eye irritation/corrosion) was conducted retrospectively as the *in vivo* test existed; both concluded in a +ve effect.

iii. The acute dermal study returned a negative result which means that the substance will not be classified as Acute tox. 1 (H310: Fatal in contact with skin) as initially expected.

iv. An adsorption/desorption test (ecotoxicity) is started has no literature data is available to derive soil/sediment PNECs.

4.1.2. SCn:

i. The BCOP test returned a surprising negative result, triggering an *in vivo* eye irritation test which was unequivocally positive; the outcome of the BCOP was false.

ii. The acute oral study, OECD TG 425, concluded to a LD50 of 175 mg/kg: A single oral administration of 55 mg/kg b.w. resulted in no premature deaths and clinical observations resolved within 24 hours of dosing. After a single oral administration of 175 mg/kg b.w. 2 of the 4 animals died and clinical observations in the surviving

animals resolved within 24 hours of dosing. A single oral administration of 550 mg/kg b.w. resulted in the death of both animals. All surviving animals gained the expected body weight. The classification is proposed to be changed to Acute Oral Cat 3 instead of Acute Oral Cat 2 (H300: Fatal if swallowed)

iii. The acute dermal study returned a negative result which means that the substance will not be classified as Acute tox. 1 (H310: Fatal in contact with skin) as initially expected.

4.1.3. PDAg: based on the Integrated Testing Strategy, the mammalian toxicity classification of PDAu would read-across to PDAg, which means that PDAg would be classified as skin sensitizer (see item 2.1) though there is no suspicion of skin sensitisation effect so far. Though the CN- ion is the dominant factor in this toxicity of PDAu, an effect of the metallic ion is suspected as the toxic behaviour is not typical of CN- toxicity only but would be influenced by the presence of gold. No read-across can be scientifically justified between different metallic ions (Au and Ag) and it's therefore agreed that a new testing programme should be initiated with PDAg at least for skin and eye studies [A7] (proposed CROs: LPT, Harlan, Wil Research) and the read-across from PDAu to PDAg is not invalidated [D]. The ITS will be updated to reflect this change (and other potential updates to the testing strategy) [A8].

4.2. Status and timing of PNECs and DNELs derivation

Water PNECs for PDAu have been derived based on ecotoxicity data but not the soil/sediment PNECs that will be derived following completion of the adsorption/desorption test.

All PNECs for PDAg and SCn are recommended to be derived from the Ag dossier. WCA prepared a read-across justification to be approved by the WG [A9].

There is currently no sufficient data to derive DNELs. Missing data is expected by end Q2 2015. If the derivation of final DNELs may only be possible pretty late in the process, the derivation of intermediate DNELs could be considered.

5. Phase IV: Use, exposure and emission data collection

5.1. Use data collection

The "use questionnaire" will be circulated in the next weeks [A10].

5.2. Exposure and emission data collection

The approach to the collection of occupational exposure and environmental emission data, and the purpose of this exercise is presented. One of the important aspects in providing as many and accurate data as possible in this data collection exercise is to show compliance with the Generic Exposure Scenario (GES) via a site-specific assessment for manufacturers.

The exposure and emission questionnaires will be circulated in the next weeks [A11].

The active participation of Members to respond to these questionnaires is important to progress in the dossier completion as quickly as possible. Experience with other PMC substances already showed that this requires a close follow-up from all parties. Failure to provide sufficient and representative data may result in conservative inputs and RCR > 1. This would trigger a monitoring programme.

5.3. Potential monitoring needs

A monitoring programme is recommended by WCA for manufacturing sites with RCR > 0,5.

A monitoring programme would trigger extra-costs and significantly extend the time needed to complete the dossier.

6. Phase V: Dossier finalization

6.1. IUCLID dossier constitution

WCA is presenting the status of dossier completion for the 3 PMCN- substances.
- PDAu: studies entered when completed
- SCn: studies entered when completed, need to agree on PNEC approach
- PDAg: cancellation of read-across from soluble cyanides for mammalian tox, a testing programme will be initiated (see item 4.1.3)

The overview of dossier completion should ideally point out to the strategy for completing the endpoints, e.g. which ones are completed via read-across [A12]

6.2. Registration target and project full overview

The current work plan is presented, ending with an earliest registration date around mid-2016. It's mainly based on an estimate made by the PMC Secretariat of the duration for completing phases IV and V. This timing will be discussed with the consultants with in mind to analyze if/how phases IV and V can be concluded more quickly [see A1].

7. Next steps and AOB

The Chairman, Steven Verberckmoes (UMICORE), summarizes the main discussions, actions and decisions taken during the meeting.

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.

No other business was raised.

List of Actions

Table 1. Actions agreed at the Au WG Meeting on 08 Oct 2014

[A]	WHAT	WHO	WHEN
1	Planning for Phases IV and V of the project, i.e. generating the CSR, ES and the IUCLID dossier, will be discussed with the consultants with in mind to analyze if/how they can be concluded more quickly	RN	Not defined
2	Candidature of SAXONIA HOLDING GmbH as Lead Registrant for Potassium Dicyanoargentate (CAS 506-61-6) and Silver Cyanide (CAS 506-64-9) will be submitted to the SIEF	RN/AR	Not defined
3	Prepare a projection of budgets on the period 2015-2020	RN	Not defined
4	STOT (thyroid and testicles) under repeated exposure: verify if this classification is notified for PMCN substances	RN	Not defined
5	Databases explored in the literature search should be widened to sources such as NTP, OECD, EPA, etc. and still include searches on nanogold	WCA	Not defined
6	Skin sensitisation: OECD TG 429 and “enhanced” LLNA (OECD TG 442b) do not allow a clear decision if the substance is a skin sensitiser category 1A or 1B; S. Verberckmoes, M. Raffray and O. Green would join up efforts to look at the studies more in detail and conclude if one of the category is more relevant	RN	Not defined
7	A new testing programme should be initiated with PDAg at least for skin and eye studies	RN	Not defined
8	The ITS will be updated to reflect changes in the PDAg testing strategy (and other potential updates to the testing strategy)	WCA	Not defined
9	All PNECs for PDAg and SCn are recommended to be derived from the Ag dossier. WCA prepared a read-across justification to be approved by the WG.	RN	Not defined
10	“use questionnaire” will be circulated in the next weeks	RN	Not defined
11	exposure and emission questionnaires will be circulated in the next weeks	RN	Not defined
12	WCA’s report on dossier completion should point out to the strategy for completing the endpoints, e.g. which ones are completed via read-across	WCA	Not defined

List of Annexes

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

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