



MINUTES

Gold Work Group Meeting

Chair: Steven Verberckmoes

19 April 2016, 11:00 – 12:30

Metals Conference Centre
Rue du Duc 100, Brussels (Belgium)



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 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.

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

The minutes of the WG meeting on the October 13, 2015 are approved.

1.4. Status of actions

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

[A28] No TSCA notification needed for TCA at this moment. We are awaiting the final outcome of the OECD 422 study.

[A31] No draft DNELs for TCA could be presented to EBRC due to the problems in the OECD 422 finalisation.

All other actions are completed.

2. Phase I

2.1. Inventory and latest classifications

No changes to the classification were made.

3. Phase II: Data gap analysis & ITS

Testing strategy for the remaining physchem endpoint for TCA hydrate has been drafted and currently the physchem testing is ongoing. Results of the physchem testing is expected in the 2nd half of May.



4. Phase III & IV: Testing programme & Exposure Scenario Data Collection.

4.1. Issues Covance – OECD 474 study TCA

The doses used in the OECD 474 were based on the incorrect doses stated in the MTD. In the MTD no correction for the density of the tetrachloroauric acid (TCA) solution was made. As for additional testing to complete the study a testing proposal needs to be submitted at ECHA, the only way forward for PMC is **a full reimbursement of the complete study. [A32]** The concerns raised by the WG on the completed OECD 474 study is shared by the study monitor O. Green.

In addition, because this is an annex IX test a testing proposal is only required for registration and this doesn't impact the registration time line.

The Au WG approved the proposal to request a full reimbursement of the study [D4].

4.2. Issues Covance – OECD 422 study TCA

The formulation analysis report attached to the OECD 422 study in November, revealed that TCA doses in the MTD and OECD 422 were incorrect as the density of the solution wasn't taken into consideration. After this density correction the variation of the doses in the formulation report were still high (up to 30%) and above the acceptance criteria of Covance ($\pm 15\%$). This leads to an uncertainty of the doses applied in the OECD 422 study and in the end impact DNEL derivation. As was proposed by O. Green and Covance additional formulation stability testing could support the variation in the formulation study. Because of the whole history of the testing, the WG believes that the uncertainty of the doses will remain. Moreover, the proposition of additional stability testing was already proposed end of December 2015 to Covance. And although Covance seems prepared to eventually perform this additional testing, no real progress has been made since end of November when the problem was notified. The study monitor O. Greens confirms that no actual progress with Covance has been made so far and shares the concerns of the WG on the formulation and implications on the DNEL derivation.

A decision by the WG was made on whether to proceed with the current study and uncertainty of to conduct a new study and shift the registration deadline to 2017. Ultimately a new study would not lead to higher DNELs, but should increase the confidence of the study results. **By vote of companies having a vested interest, the Au WG approved that a new OECD 422 study for TCA should be initiated. [D5] [A33]**

Because of the issues that occurred with Covance the design of the study should be reconsidered and test will be performed on the TCA hydrate instead of the solution. **[A34]**

As the WG rejects the results of the OECD 422 of Covance a reimbursement of this study will be pursued. **The Au WG approved the proposal to request a full reimbursement of the study [D6].** The reasoning for reimbursement will be based on the article 10(a) of the contract with Covance, stating that the study is unacceptable for regulatory purposes. A strong justification will be needed to support our doubts of the validity of the test. PMC will communicate directly with Covance on the reimbursements and will coordinate the argumentation. For a strong argumentation the input of both toxicological experts in the WG and the study monitor will be asked. **[A35]**



5. Phase V: Dossier finalisation

Currently the gold (CAS n° 7440-57-5) and Balsams (CAS n° 68990-27-2) are registered by the lead registrant. All necessary document for the co-registrants will be sent out at latest the last week of April. The dossier for Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate (CAS n° 68365-87-7) is in the last phase of the reviewing process and registrant by the lead registrant is foreseen in May.

A new time line for the registration of TCA will be drafted and circulated to the members and consultants.

[A36]

6. Budget

Revisions of the budget of 2016 and 2017 will be needed because of the initiation of a new OECD 422 for TCA. The cost of a new OECD 422 study, according the new OECD guideline, will be around €150.000 excluding the cost of the testing material needed. Moreover, a new study monitoring proposal will be needed for this study. **[A37]**

7. List of actions and decisions

Table 1. Actions agreed on at the Au WG meeting of 19 April '16

[A]	WHAT	WHO	WHEN
32	A full reimbursement of the OECD 474 of TCA with Covance will be pursued	EPMF	Not defined
33	A new OECD 422 study with TCA will be initiated	EPMF/WCA	May '16
34	The study design of the new OECD 422 study with will have to be reconsidered, avoiding similar problems as with Covance	WCA/WG	May '16
35	Drafting of a justification for reimbursement of both the OECD 474 and 422, to be sent to Covance.	EPMF/WG/ WCA	June '16
36	Drafting a new time line for the registration of TCA and circulate to the WG and the consultants.	EPMF	June '16
37	Ask a new study monitoring quotation to WCA for the OECD 422 study.	EPMF	June '16



Table 2. Decisions agreed on at the Au WG meeting of 19 April '16

[D]	WHAT	WHO	WHEN
5	A retest of the OECD 422 will be initiated and a reimbursement pursued from Covance for the OECD 474 and 422	WG	ASAP
4,6	Full reimbursement of OECD 474 and 422 from Covance	WG	ASAP

8. List of Annexes

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