



Precious Metals
Consortium

Precious Metals & Rhenium Consortium

Gold Work Group

21 March 2017 | Teleconference
10:00 – 10:30



Precious Metals
Consortium

Welcome and introduction



Competition law and confidentiality

DO	DON'T
<u>Application of competition law</u>	
Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
<u>Consultation in Matters of Competition Law</u>	
Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.	Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.
<u>Activities in any preliminary phase and at any other stage of operation of the Consortium</u>	
Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.	Pursuant to Art. 101 and 102 TFEU, activities which have the object of the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: <ul style="list-style-type: none"> - Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU); - Joint boycotting of other companies; - The unjustified unequal treatment of trade partners; - The abusive exploitation of a dominating market position.

DO	DON'T
<u>Exchange of Confidential Information</u>	
Involve a Trustee for the exchange of Confidential Information.	The exchange of Information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to : <ul style="list-style-type: none"> - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
<u>Documentation on Cooperation</u>	
Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	



Tour de Table & Apologies

[See participants list in supplementary documents]

Approval of the draft agenda

1. Welcome and Introduction
2. Phase III: Testing programme
3. Phase V: Dossier finalisation
4. Budget
5. AOB, next meetings/calls and closing remarks

Approval of minutes from previous WG meeting

- The previous Au Work Group meeting was hold on 16 October 2016
- Draft minutes were distributed on 15 March 2017

→ *Are the minutes of the WG meeting held on 16/10/2016 approved?*

Status of actions

[A]	WHAT	WHO	STATUS
38	Waiver statement, expert judgement on flammability of TCA based on the oxidation state of the compound	EPMF/WCA	Dec '16
39	Completion of the gene mutation endpoint by a weight of evidence approach	EPMF/WCA	June '17



Precious Metals
Consortium

Phase III Testing Programme



Test programme – Physicochemical Analyses, TCA

Test	Laboratory/ Endpoint	Status	Date	Comments
Flammability	Annex V		June '17	

1. **Waiving:** different predefined waivers present in IUCLID, no column II waivers for our substance.
2. **Testing:** Perform a (preliminary) flammability test on TCA.
3. **Weight-of-evidence:**
 - Use the paper of Otto et al. (2014) to state that no flammable products are formed during decomposition.
 - Oxidation state Au in TCA.
 - Attach several MSDS that state TCA is not combustible.
 - Other information?

Otto, K., Oja Acik, I., Krunk, M., Tõnsuaadu, K. & Mere, A. Thermal decomposition study of H₂AuCl₄·3H₂O and AgNO₃ as precursors for plasmonic metal nanoparticles. *J. Therm. Anal. Calorim.* **118**, 1065–1072 (2014).

Repeated Test programme – Mamtox TCA Repeat dose toxicity and associated studies

Test	Laboratory	Start Date	Completion Date	Comments
Dose Range-Finding study	LPT (Study No. 33737)	4 th October 2016	November 2016 (In-life phase)	Dose levels selected for this study 0, 30, 100 and 300 mg/kg/day TCA Draft report has been reviewed by OPG and MH in January 2017. Awaiting second draft from LPT
Repeated oral dose/Reproductive toxicity screen – OECD422	LPT (Study No. 33738)	8 th November 2016 – start of pre-mating period/oestrus cycle monitoring 23 rd November 2016 – Start of dosing	January 2017 (In-life phase)	Draft data originally estimated for review in April 2017. A formal draft report of all data is estimated for mid-May 2017. This draft report will contain formulation analysis results which are due at end-April 2017
Formulation analysis method development	LPT	w/b 19 th September 2016	Draft report available 28 th October 2016	Method validation and results from DRF study samples are appended to the DRF study report (33737) Results of samples from the main study will be appended to the main study report (33738)

Test programme – Mamtox TCA Repeat dose toxicity

Test	Laboratory	Completion date	Result	Comments	Classification
OECD474 – in vivo micronucleus assay	Covance	Final report issued February 2015	Negative	<p>Formulation prepared by weight therefore dose levels (25, 50 and 100 mg/kg/day) based on unadjusted MTD of 100 mg/kg/day</p> <p>Formulation analysis revealed assays for all groups to be within -11% of nominal</p> <p>All dose levels therefore were below the adjusted MTD of 210 mg/kg/day</p> <p>Analysis of bone marrow smears for gold (Umicore-unreported data) did not detect gold in the target tissue at any dose level</p> <p>Plasma samples from rats on the MTD study (dosed at 168 or 210 mg/kg/day – adjusted for density) were despatched to Umicore for analysis of gold content in an attempt to demonstrate exposure.</p>	<p>Not classified on this study, however, study to be repeated as an Annex IX study.</p> <p>Weight-of-Evidence to be drafted</p>

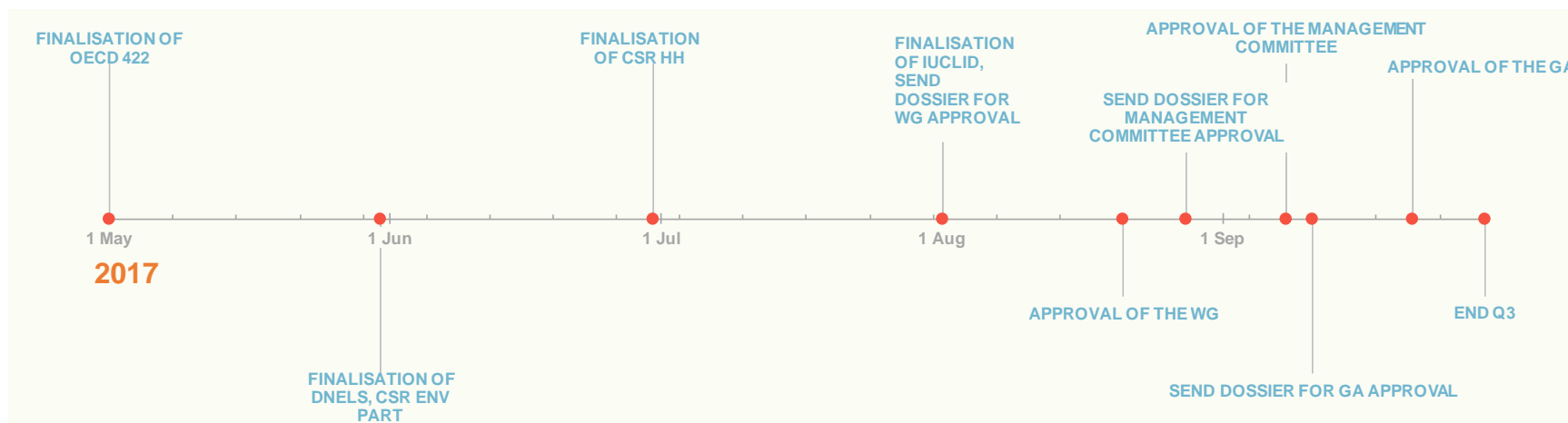


Precious Metals
Consortium

Phase V Dossier finalisation



Timeline TCA





Precious Metals
Consortium

Budget



Accounts 2016

	Budget to be spent	Budget to be invoiced	Real expenses
2.3 Au-specific costs	122.700 €	79.550 €	7.110 €
2.3.1 Au REACH registration	87.500 €	57.350 €	-18.940 €
2.3.1.1 Phase 1: Literature search, data gap analysis and recommendations	0 €	0 €	110 €
2.3.1.2 Phase 2: In-depth data gap analysis and integrated testing strategy	1.000 €	1.000 €	19.505 €
2.3.1.3 Phase 3: Experimental studies (testing programme including cost of samples)	32.350 €	29.550 €	-51.261 €
2.3.1.4 Phase 4: Generation of Chemical Safety Reports	48.500 €	21.150 €	7.588 €
2.3.1.5a Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers	650 €	650 €	3.584 €
2.3.1.5b Phase 5b: IUCLID 5 Hosting System	5.000 €	5.000 €	1.534 €
2.3.2 Au REACH dossier maintenance	0 €	0 €	
2.3.3 Au REACH evaluation	0 €	0 €	
2.3.4 Au REACH classification & labelling (not relevant)	0 €	0 €	
2.3.5 Au REACH authorisation (not relevant)	0 €	0 €	
2.3.6 Au internal and external fixed Scientific Manager	35.200 €	22.200 €	26.051 €
2.3.7 Au Building reserves	0 €	0 €	0 €

Including Covance reimbursement of 167 354 euros under phase 3!

Draft Budget 2018

	PMC 2018	PMC 2018
	Budget <i>to be invoiced</i>	HR
2.3 Au-specific costs	81.266 €	0,1
2.3.1 Au REACH dossier maintenance	63.500 €	
2.3.1.1 Au Rolling maintenance	18.500 €	
2.3.1.2 Au Further improvement	45.000 €	
2.3.2 Au REACH evaluation	0 €	
2.3.3 Au REACH classification & labelling (not relevant)	0 €	
2.3.4 Au REACH authorisation (not relevant)	0 €	
2.3.5 Au internal and external fixed Scientific Manager	17.766 €	
2.3.6 Au Building reserves	0 €	



Precious Metals
Consortium

Final Remarks



Final Remarks

- A.O.B. : PMC approval process of dossiers > new practice (next slide)
 - Actions summary
 - Conclusions
 - Next meeting/conf call:
 - PMC General Assembly meeting: **31/05-01/06 2017, Pforzheim**
 - Next Au Work Group conference call: **17 October 2017 (AM)**
- + Ad-hoc meetings/conf call

PMC approval process of dossiers with more than two registrants: new practice recommended by Mgt Cttee



N.B.: In the consortium agreement, no decision has to be taken at unanimity, but only at qualified majority (2/3). The reason was to avoid that one company could block the entire system.



THANK YOU

www.epmf.be | info@epmf.be

Avenue de Broqueville 12, B-1150 Brussels
+32 (0)2 775 63 86