Precious Metals & Rhenium Consortium

Gold Work Group

13 OCTOBER 2015 (11:30-12:30 CET, BRUSSELS)

Welcome and introduction

Competition law and confidentiality

DO	DON'T
Application of competition law	
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.
Consultation in Matters of Competition Law	
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.
Activities in any preliminary phase and at any other stage of operation of the Consortium	
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: - 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
Exchange of Confidential Information	
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 : - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
Documentation on Cooperation	
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.	

Approval of the draft agenda

- Welcome and introduction
- Phase I - Inventory and Literature Search
- Phase II - Data Gap Analysis and Integrated Testing Strategy)
- Phase III - Testing programme
- Phase IV - CSR Generation
- Phase V - IUCLID dossier preparation and submission
- Budget - Projection 2016
- A.O.B., next meeting, closing note

Approval of minutes from previous WG meeting

- The previous Au Work Group meeting was hold on 24 March 2015
- Its draft minutes were distributed on 21 May 2015

➔ ***Are the minutes of the WG meeting held on 24/03/2015 approved?***

Status of actions

[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	Not included in scope for 2018 registration
13	Review and comment the minutes of the 08 Oct 2014 WG meeting	Members	22 Apr '15	Done
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 '15	Done, registration deadline of TCA moved to 2016 Q3
15	Justification paper for the use of neutralized TCA in experiments: submit to members for review	RN	01 Apr '15	Distributed
16	Distribute data matrices to Members. The data matrices show in one look which endpoints are completed and how.	RN	01 Apr '15	Update distributed on 5 Oct '15
17	Submit comments on the ITS addendum.	Members	22 Apr '15	Distributed
18	Issue the nanogold survey to downstream users via the WGC.	RN/FC	01 Apr '15	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 '15	Samples are being sent for Au content analysis

Status of actions

[A]	WHAT	WHO	WHEN	STATUS
20	Propose a preliminary summary proposal of derived DNELs	WCA	31 Mar '15	Done
21	Consider man via environment exposure	ARCHE/RN	24 Apr '15	Doens't need to be performed
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 '15	Done
23	Confirm the physical form of produced TCA and the tonnage if produced as crystal. The WG will then decide if new testing is required	Members	15 Apr '15	TCA will be registered as hydrate. Some additional phys-chem endpoints to be included.
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 '15	Done
25	Add contingency for Phase IV in the 2016 budget	RN	19 Apr '15	Done

Phase I
Inventory & classification

Inventory and latest classifications

IUPAC Name	Gold	Tetrachloroauric acid (in aq. solution)	Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1] heptanethiolate	Balsams, copaiba, sulfurized, mixed with turpentine, gold salts
CAS nr	7440-57-5	16903-35-8	68365-87-7	68990-27-2
EINECS nr	231-165-9	240-948-4	269-858-3	273-589-7
REACH category	Mono-constituent	Mono-constituent	Mono-constituent	UVCB
Dossier prepared	Substance	Substance	Substance	Non-SCC Intermediate
Highest tonnage band	10-100 t/a	10-100 t/a	1-10 t/a	1-10 t/a
Registration deadline	2018	2018	2018	2018
Lead Registrant	C. Hafner	Johnson Matthey	Johnson Matthey	Heraeus
Classification	None	Acute tox. 4 (H302: Harmful if swallowed)	Flam. Solid Cat 1 (H228)	Flam. Solid Cat 1 (H228)
		Skin corr. 1B (H314: Causes severe skin burns and eye damage)		
		Eye dam. 1 (H318: Causes serious eye damage)		
		Aquatic chronic 2 (H411)		
		Met. Corr. 1 (H290: May be corrosive to metals)		

Literature search (Nov '13 – Dec '14)

- 28 potentially relevant papers identified
- 1 article, not related to nanogold, was considered reliable with restrictions (K2).
- Includes EC50 data on bacteria, algae and aquatic invertebrates

Search date	Substance	Number of results	Number of potentially relevant results	Number of relevant studies
December 2014	Gold	5510	28	1
	Tetrachloroauric acid	33	0	0
	Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	0	0	0
	Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	0	0	0

Phase II
Data gap analysis & ITS

Data gap analysis TCA hydrate

- TCA hydrate will be registered and TCA solution will be regarded as a mixture

Endpoint	Comments
Melting/freezing point	To be determinded or waived for solid form
Boiling point	To be determinded or waived for solid form
Water solubility	very soluble in water (> 10,000 mg L^{-1}) (Lide 2008, O'Neil 2006)
Flammability	To be determined or waived for solid form
Self-ignition temperature	To be determined or waived for solid form
Granulometry (particle size distribution)	To be determined or waived for solid form

- In house data on solid TCA collected and will be evaluated by WCA
- Some additional testing might be needed

Phase III
Testing Programme

Test programme - mamtox

- Genetic Toxicology Studies - TCA

Test	Laboratory/ Endpoint	Status	Date	Comments
In vivo Micronucleus test (OECD 474)	Covance UK/ Annex VIII	Final	Mar 2015	Dose levels set at 25, 50 and 100 mg/kg/day; Clear –ve has been indicated. Exposure of the bone marrow to be confirmed by determining the presence of Au (analysis on raw data from OECD 422)

Test programme – mamtox

- General Toxicology Studies - TCA

Test	Laboratory/ Endpoint	Status	Date	Comments
Repeat-dose/Repro screen Rat study (OECD 422)	Covance UK/ Annex VIII	Draft	Sep 2015	General toxicity: NOAEL: 30 mg kg^{-1} bw day^{-1} Reproductive toxicity: NOAEL: 100 mg kg^{-1} bw day^{-1} (reproduction) NOAEL: 10 mg kg^{-1} bw day^{-1} (development)
Formulation analysis	Covance UK	Draft	Sep 2015	ICP-MS methodology; Within GLP accepted limits.

Test programme - environment

- Adsorption / desorption test (OECD 106)
- Ongoing at Fraunhöfer for TCA
  - Difficulties with analysis have delayed the study
  - Tests complete
  - Still some unresolved issues concerning the mass balance
  - Draft report expected coming days (excluding mass balance)

Proposed classification for registration

Substance	Classification
Gold	None
Tetrachloroauric acid	Acute tox. 4 (H302) Skin corr. 1B (H314) Eye dam. 1 (H318) Aq. Chronic 2 (H411) Met corr. 1 (H298)
Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	Flam solid Cat 1 (H228)
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	Flam solid Cat 1 (H228)

Ongoing desorption/adsorption test.

Phase IV
CSR Generation

Life cycle tree

- Life cycle trees drafted for all the Gold substances
- CHESAR was used to facilitate the consistency between the exposure scenarios and section 3.5 of IULCID
- Glossary:
  - **Manufacture: M**
  - **Formulation: F**
  - **Industrial end use at site: IW**
  - **Professional end use: PW**
  - **Consumer end use: C**
  - **Service life (by workers in industrial site): SL-IW**
  - **Service life (by professional workers): SL-PW**
  - **Service life (by consumers): SL-C**

Life cycle tree (simplified without use descriptors)

Table 1. Overview of exposure scenarios of aurio

Identifiers	Titles of exposure scenarios and the related contributing scenarios
ES1 - M1	Manufacture - Manufacture of the substance (as such)
ES2 - IW1	Use at industrial site - Use as an intermediate

Life cycle tree (simplified without use descriptors)

Table 1. Overview of exposure scenarios of balsams

Identifiers	Titles of exposure scenarios and the related contributing scenarios
ES1 - M1	Manufacture - Manufacture of the substance (as such)
ES2 - F1	Formulation - Formulation
ES3 - IW1	Use at industrial site - Production of gold-containing articles ‣ *Related subsequent service life:* ES7; ES8; ES6
ES4 - PW1	Use by professional worker - Production of gold-containing articles ‣ *Related subsequent service life:* ES7; ES8
ES5 - C1	Consumer Use - Production of gold-containing articles ‣ *Related subsequent service life:* ES8
ES6 - SL-IW1	Service life (worker at industrial site) - Handling of gold-containing articles in industrial settings
ES7 - SL-PW1	Service life (professional worker) - Handling of gold-containing articles in professional settings
ES8 - SL-C1	Service life (consumers) - Handling of gold-containing articles by consumers

Life cycle tree (simplified without use descriptors)

Table 1. Overview of exposure scenarios of gold

Identifiers	Titles of exposure scenarios and the related contributing scenarios
ES1 - M1	Manufacture - Manufacture of the substance (as such)
ES2 - IW1	Use at industrial site - Use as an intermediate
ES3 - IW2	Use at industrial site - Use as chemical in health services and in laboratories
ES4 - PW1	Use by professional worker - Use as chemical in health services and in laboratories
ES5 - F1	Formulation - Formulation
ES6 - IW3	Use at industrial site - Reforming/Reshaping of gold metal ‣ *Related subsequent service life:* ES21; ES20; ES17; ES16; ES19; ES18
ES7 - PW2	Use by professional worker - Reforming/Reshaping of gold metal ‣ *Related subsequent service life:* ES21; ES20; ES19; ES18
ES8 - IW4	Use at industrial site - Production of gold alloys ‣ *Related subsequent service life:* ES21; ES20; ES17; ES16; ES19; ES18; ES10; ES11
ES9 - PW3	Use by professional worker - Use of dental alloys ‣ *Related subsequent service life:* ES10; ES11
ES10 - SL-PW1	Service life (professional worker) - Service life of dental alloys in professional settings
ES11 - SL-C1	Service life (consumers) - Service life of dental alloys by consumers
ES12 - IW5	Use at industrial site - Use in surface treatment ‣ *Related subsequent service life:* ES21; ES20; ES17; ES16; ES19; ES18

Life cycle tree (simplified without use descriptors)

ES13 - IW6	Use at industrial site - Production of gold-containing articles ‣ *Related subsequent service life:* ES21; ES20; ES17; ES16; ES19; ES18
ES14 - PW4	Use by professional worker - Production of gold-containing articles ‣ *Related subsequent service life:* ES21; ES20; ES19; ES18
ES15 - C1	Consumer Use - Production of gold-containing articles ‣ *Related subsequent service life:* ES21; ES20
ES16 - SL-IW1	Service life (worker at industrial site) - Service life of articles with high contact potential (gold-containing surfaces) in industrial settings
ES17 - SL-IW2	Service life (worker at industrial site) - Service life of articles with low contact potential (gold included as internal part of the article) in industrial settings
ES18 - SL-PW2	Service life (professional worker) - Service life of articles with high contact potential (gold-containing surfaces) in professional settings
ES19 - SL-PW3	Service life (professional worker) - Service life of articles with low contact potential (gold included as internal part of the article) in professional settings
ES20 - SL-C2	Service life (consumers) - Service life of articles with high contact potential (gold-containing surfaces) by consumers
ES21 - SL-C3	Service life (consumers) - Service life of articles with low contact potential (gold included as internal part of the article) by consumers
ES22 - F2	Formulation - Formulation of cosmetic products
ES23 - C2	Consumer Use - Consumer cosmetic use

Life cycle tree (simplified without use descriptors)

Table 1. Overview of exposure scenarios of TCA

Identifiers	Titles of exposure scenarios and the related contributing scenarios
ES1 - M1	Manufacture - Manufacture of the substance (as such)
ES2 - F1	Formulation - Formulation
ES3 - IW1	Use at industrial site - Use as an intermediate
ES4 - F2	Formulation - Formulation
ES5 - IW2	Use at industrial site - Production of imaging and printing articles ‣ *Related subsequent service life:* ES9
ES6 - IW3	Use at industrial site - Production of printing plates ‣ *Related subsequent service life:* ES9
ES7 - IW4	Use at industrial site - Application of imaging and printing chemicals ‣ *Related subsequent service life:* ES10; ES9; ES11
ES8 - PW1	Use by professional worker - Use in photographic applications ‣ *Related subsequent service life:* ES10; ES11

Life cycle tree (simplified without use descriptors)

ES9 - SL-IW1	Service life (worker at industrial site) - Handling of photographic articles in industrial settings
ES10 - SL-PW1	Service life (professional worker) - Handling of photographic articles in professional settings
ES11 - SL-C1	Service life (consumers) - Handling of photographic articles by consumers
ES12 - IW5	Use at industrial site - Use in electrochemical and galvanic plating ‣ *Related subsequent service life:* ES15; ES16; ES14
ES13 - PW2	Use by professional worker - Use in electrochemical and galvanic plating ‣ *Related subsequent service life:* ES15; ES16
ES14 - SL-IW2	Service life (worker at industrial site) - Handling of coated articles in industrial settings
ES15 - SL-PW2	Service life (professional worker) - Handling of coated articles in professional settings
ES16 - SL-C2	Service life (consumers) - Handling of coated articles by consumers

Draft DNEL calculation

- Tetrachloroauric acid (hydrate)
  - Worker, long-term inhalation route-systemic:

    DNEL = 0.028mg/m^3
  - Worker, long-term dermal route-systemic:

    DNEL = 0.008 mg/kg/day (0.56 mg/day) [100% absorption]

Phase V
Dossier finalisation

Project Timeline

Budget

Budget 2016

	Budget to be spent	Budget to be invoiced
Au-specific costs	***87.200 €***	***57.350 €***
Au REACH registration	**87.200 €**	**57.350 €**
Phase 1: Literature search, data gap analysis and recommendations	0 €	0 €
Phase 2: In-depth data gap analysis and integrated testing strategy	1.000 €	1.000 €
Phase 3: Experimental studies (testing programme including cost of samples)	32.350 €	29.550 €
Phase 4: Generation of Chemical Safety Reports	48.200 €	21.150 €
Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers	650 €	650 €
Phase 5b: IUCLID 5 Hosting System	5.000 €	5.000 €
Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)	0 €	0 €
Au REACH dossier maintenance	**0 €**	**0 €**
Au REACH evaluation	**0 €**	**0 €**
Au REACH classification & labelling	**0 €**	**0 €**
Au REACH authorisation (not relevant)	**0 €**	**0 €**

Final Remarks

Final remarks

- A.O.B.
- Actions summary
- Conclusions
- Next meeting/conf call:
  - PMC General Assembly meeting: **1-2 December 2015**, Brussels
  - Next Au Work Group meetings: **19-21 April 2016** and **4-6 October 2016**
  - + Ad-hoc meetings/conf call