Precious Metals & Rhenium Consortium

Gold Work Group

24 MARCH 2015 (10:30-12:15 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.	

Tour de table and apologies

List of Participants

1.	**Angela Alderman**	Johnson Matthey	United Kingdom	
2.	**Roland Brasch**	Heraeus	Germany	
3.	**France Capon**	EPMF	Belgium	
4.	**Owen Green**	WCA	United Kingdom	
5.	**Mark Hosford**	Johnson Matthey	United Kingdom	
6.	**Alexandra Levesque**	PX Group	Switzerland	
7.	**Becky Marks**	WCA	United Kingdom	
8.	**Renaud Nicolay**	EPMF	Belgium	
9.	**Agnieszka Piechota**	KGHM	Poland	
10.	**Mark Raffray**	Johnson Matthey	United Kingdom	
11.	**Nissanka Rajapakse**	Johnson Matthey	United Kingdom	
12.	**Mike Shepherd**	Vale	United Kingdom	*By teleconference*
13.	**Mika Toivola**	Boliden	Finland	
14.	**Steven Verberckmoes**	Umicore	Belgium	
15.	**Carole Wilson**	Vale	United Kingdom	*By teleconference*
16.	**TBC**	Aurubis	Germany	

Apologies

Massimo Blattner	Valcambi	Switzerland
Heike Kinz	Umicore	Germany
Christoph Roehlich	Heraeus	Germany

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 (2015 & 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 08 Oct 2014
- Its draft minutes were distributed on 18 Mar 2015

➔ ***Are the minutes of the WG meeting hold on 08/10/2014 approved?***

Status of actions from previous WG meeting

[A]	WHAT	WHO	WHEN	STATUS
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	ongoing
2	The initial PMC nanogold survey will close by 10 Oct 2014 and its outcomes communicated by the Secretariat	RN	Not defined	Done
3	Prepare a projection of budgets on the period 2015-2020	RN	Not defined	Done until 2019
4	OECD 474 with TCA: further clarify the position paper with the chronological order of events including the timing of the updated guidance	RN	Not defined	Done
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	Done
6	Prepare a justification why the use of neutralised TCA was chosen for testing purposes	WCA	Not defined	Done - submit to WG
7	The “use questionnaire” will be circulated in the next weeks	RN	Not defined	Done
8	The nanogold survey will be re-issued and include new considerations on characterization of nanomaterials	RN	Not defined	Done – results under analysis
9	Collect input from experts (chemists from PMC Members, consultants) to establish if nanogold should be considered similar to massive/bulk gold	RN	Not defined	On hold (is nanogold in scope?)
10	Exposure and emission questionnaires will be circulated in the next weeks	RN	Not defined	Done
11	The Au and PGM PMC project managers will coordinate to check if/how the merge of the PGMs and Au monitoring programme could be done	RN+KR	Not defined	Done
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	Done – data matrices

Phase I
Inventory & classification

Inventory and latest classifications

- The inventory and classifications have not been modified since the previous Work Group Meeting and no modifications are expected.

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)		

⚠ Correction of presentation shown during the meeting

Literature search

- Searches conducted individually for each substance name and CAS number. Search strings were used for gold.
- Databases searched:
  - Toxline
  - Thomson Innovation
  - US-EPA ECOTOX Database
  - National Toxicology Program (NTP)
  - InChem

Literature search

- 28 potentially relevant papers identified
- 26 relate to gold nanoparticles (some may also contain comparative data)

Search date	Substance	Number of results	Number of potentially relevant results	Number of relevant studies
November 2014	Gold	5510	28	Not yet reviewed
	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

Addendum to the ITS (1/2)

- ITS addendum prepared
  - Covering test results and decisions made since the original ITS report (2012)
- The main updates for the project have been:
  - Remaining physico-chemical tests have been conducted at Harlan Laboratories. All physico-chemical endpoints are now complete.
  - Balsams, copaiba, mixed with turpentine, gold salts confirmed as having Annex III exemptions.
  - It has been agreed to conduct a limited OECD 106 adsorption / desorption study with tetrachloroauric acid. Testing is ongoing at Fraunhofer.
  - Remaining ecotoxicological testing has been completed at Brixham Environmental Laboratory.
    - All ecotoxicological endpoints are now complete for tetrachloroauric acid.
    - Further testing may be required for PNEC refinement following the first screen of the exposure assessment.

Addendum to the ITS (2/2)

- It was agreed that no further ecotoxicity testing will be conducted for gold metal. Instead, waivers based on lack of solubility will be included, based on the results from the T/D test.
- A bio-elution study in artificial gastric fluid was conducted with gold metal, at CIMM. Based on the lack of dissolution shown in this study, studies with administration via the oral route will be waived.
- The genetoxicity test programme with tetrachloroauric acid has been conducted, including an *in vivo* micronucleaus assay conducted using neutralised tetrachloroauric acid, required following a positive result in the *in vitro* micronucleus assay. The *in vivo* micronucleus assay was negative, therefore no further testing or classification is required for this substance.
- It was agreed to conduct a combined repeat dose / reproductive screening (OECD 422) study using neutralised tetrachloroauric acid, and this test has been commissioned and is nearing completion at Covance Laboratories UK.

Nanogold surveys

- Survey #1:
  - Based on the nanomaterial definition recommended by the EU Commission
  - Outcome: 1 member reported the production of nanogold in small quantities
  - Difference with the expected answers (use of nanogold in medecine, cosmetics, electronics …)
  - No measured data provided demonstrating that grades do not meet the nano definition
- Survey #2:
  - With proposed protocol for characterization of nanomaterials
  - Focus on producing data from BET and number-based particle size distribution
  - Deadline: 10 April 2015
  - Current trend: similar to survey #1

➔ ***Today, nanogold would not be covered by a PMC registration dossier.***

Phase III
Testing Programme

Test programme - mamtox

- Genetic Toxicology Studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
AMES Screen	Covance UK	Oct 2012	Term	Toxic to Salmonella strains (not pH related)
AMES GLP (OECD471)	Covance UK/ Annex VII	Oct 2012	Term	-ve result upto toxic concentrations (not pH related)
In vitro Micronucleus test (OECD487)	Covance UK/ Annex VIII	Jan 2013	Term	+ve response (-S9) and equivocal response (+S9)
In vivo Micronucleus test (OECD474)	Covance UK/ Annex VIII	Mar 2015	Term	Dose levels set at 25, 50 and 100 mg/kg/day; Clear –ve has been indicated

Test programme – mamtox

- General Toxicology Studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
MTD/DRF Rat study	Covance UK	Feb 2015	Term	MTD for repeat dosing set at 100 mg/kg/day
Repeat-dose/Repro screen Rat study (OECD422)	Covance UK/ Annex VIII	Mar 2015	Term Track down path	Dose levels set at 10, 30 and 100 mg/kg/day; neutralised formulation; path on stomach and kidney
Formulation analysis	Covance UK	Mar 2015	Term	ICP-MS methodology; initial problems with positive analytical bias

Test programme - environment

- Adsorption / desorption test (OECD 106)
- Ongoing at Fraunhofer for TCA
  - Some difficulties with analysis have delayed the study
  - Preliminary tests complete
  - Main tests due to start in ~2 weeks time (3 soils)
  - Tests due to be completed in May
  - Draft report due in June

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

Uses and exposure
Risk assessment process

Hazard assessment
Derive PNECs / DNELs

Exposure assessment
Collect data using exposure questionnaires
- Tonnages used
- Measured emissions
- On-site RMMs
- Receiving water (for env)

Determine RCR

RCRs <1

Finish assessment (no refinement necessary)

RCRs >1

Refine assessment
- Obtain additional monitoring data (particularly if SpERCs used)
- Obtain additional site-specific data
- Conduct further ecotox testing to refine PNEC
- If no refinement possible, additional RMMs may be required

Use and exposure PNEC and DNEL derivation

- Exposure work is only required for TCA
- Aquatic PNECs have been derived based on results from acute ecotox studies
  - PNEC freshwater: 0.0048 mg TCA/L
  - PNEC marine water: 0.00048 mg TCA/L
  - PNEC intermittent releases: 0.048 mg TCA/L
  - PNEC STP: 0.2 mg TCA/L
- Soil and sediment PNECs will be derived using equilibrium partitioning when adsorption / desorption results received
  - Results expected in May
- Further (chronic) ecotoxicity testing may be required to refine PNECs following initial screening risk assessment

Use and exposure PNEC and DNEL derivation

- DNELs
  - Worker Dermal and Inhalation DNELs for long-term exposures for tetrachloroauric acid will be derived using route to route extrapolation from NOAEL or LOAEL established in the Repeat-dose oral toxicity study (OECD422).
    - Completed study data expected March/April 2015
    - DNELs derived by end of April/May 2015
    - A summary proposal, in advance of final data, and based on LDL and IDL used in the OECD422 study, will be produced end March 2015
  - General Population DNELs – need for these to be determined from use information

Use and exposure Collation of uses

- Collect use information from registrants
  - Registrants should obtain use information from their downstream users
- Use questionnaires circulated – please complete if this has not been done:
- In latest version of IUCLID (5.6) some use descriptors are considered obsolete for particular types of uses (eg only ERC 1 applicable for Manufacture)
- Once completed use questionnaires are returned, uses will be collated under generic use titles
  - Use descriptors will be checked for compatibility
- Follow up questions may be sent out to individual companies for clarification
- Use information required for all substances, regardless of classification

Use and exposure Environmental exposure data

- Questionnaires circulated to collect environmental exposure data
- Low level of responses currently received
  - Few questionnaires and very limited data received on stack emissions to air
- Measured data required to avoid use of conservative default values
- If metal SpERCs are used, these need to be justified based on measured data for the sector
- Some site-specific data, e.g. on receiving water body can be taken from PGMs questionnaires if same site covered
- Current data insufficient to produce robust GES – please provide data if you have it available

Use and exposure
Occupational exposure data

- Occupational exposure questionnaire sent to manufacturers
- Responses received from 5 companies (status 17 March 2015)
- None of the companies has indicated availability of monitoring data
- Is further information on physical form (e.g. dustiness tests) available (in case TCA is not exclusively handled in solution)?
- Depending on additional feedback / availability of monitoring data and level of DNELs → potential initiation of monitoring campaign required

Use and exposure Waste release to environment

- Questionnaire on release to environment from waste sent to manufacturers and representative DU (deadline on 13 March 2015)
- Members/manufacturers of TCA and Gold: responses received from 3 companies (status 17 March 2015)
- DU of TCA and Gold: responses received from 5 companies (status 17 March 2015)
- Questionnaires currently being processed
- Overall, quality is good
- More responses expected to be representative of sector
- Reminder with deadline on 15/04 for EU manufacturers with a produced volume > 1kg/year

Implications of a monitoring programme

- If data provided is not sufficient to demonstrate RCR <1 for a site, site monitoring may be required
- Aquatic and sediment monitoring programme being conducted for PGMs. If involved in this programme, gold analysis can be added for the same samples (at minimal cost)
- Aquatic monitoring programme – minimum 6 months
  - Sampling recommendations tailored to processes operating on site (e.g. batch or continuous)
  - Accounting for variation in time and conditions (i.e. over multiple seasons with daily sampling over a week on two occasions)
  - Sample collection undertaken by site operatives and fully recorded
- Sediment monitoring programme
  - Lower sampling frequency (only 2 sets of samples)
  - Samples collected by consultant

Potential costs: <€10k, even for one year monitoring of continuously operating site

Conclusions on questionnaires

- More questionnaires could have been expected
- No monitoring data was received
- Questionnaires are used to
  - Identify uses that will be registered
  - Report the good practice for operational conditions and risk management measures
  - Calculate a sector-representative risk vs. a too conservative risk
    - Avoid unnecessary and costly implementation of new risk management measures
    - Possibly avoid a long monitoring programme that would postpone registration of up to 1 year
- ***TCA last deadline for questionnaires: 15/04/2015***
- Other Gold substances: questionnaire circulated this week with a 1,5 month reply period

Phase V
Dossier finalisation

Status of the IUCLID dossier

- Gold: All available studies entered in IUCLID. Waivers to be completed.
- Balsams, copaiba, sulfurized, mixed with turpentine, gold salts: All available studies entered in IUCLID.
- Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate: All available studies entered in IUCLID.

TCA

Query results | Folders | Section tree

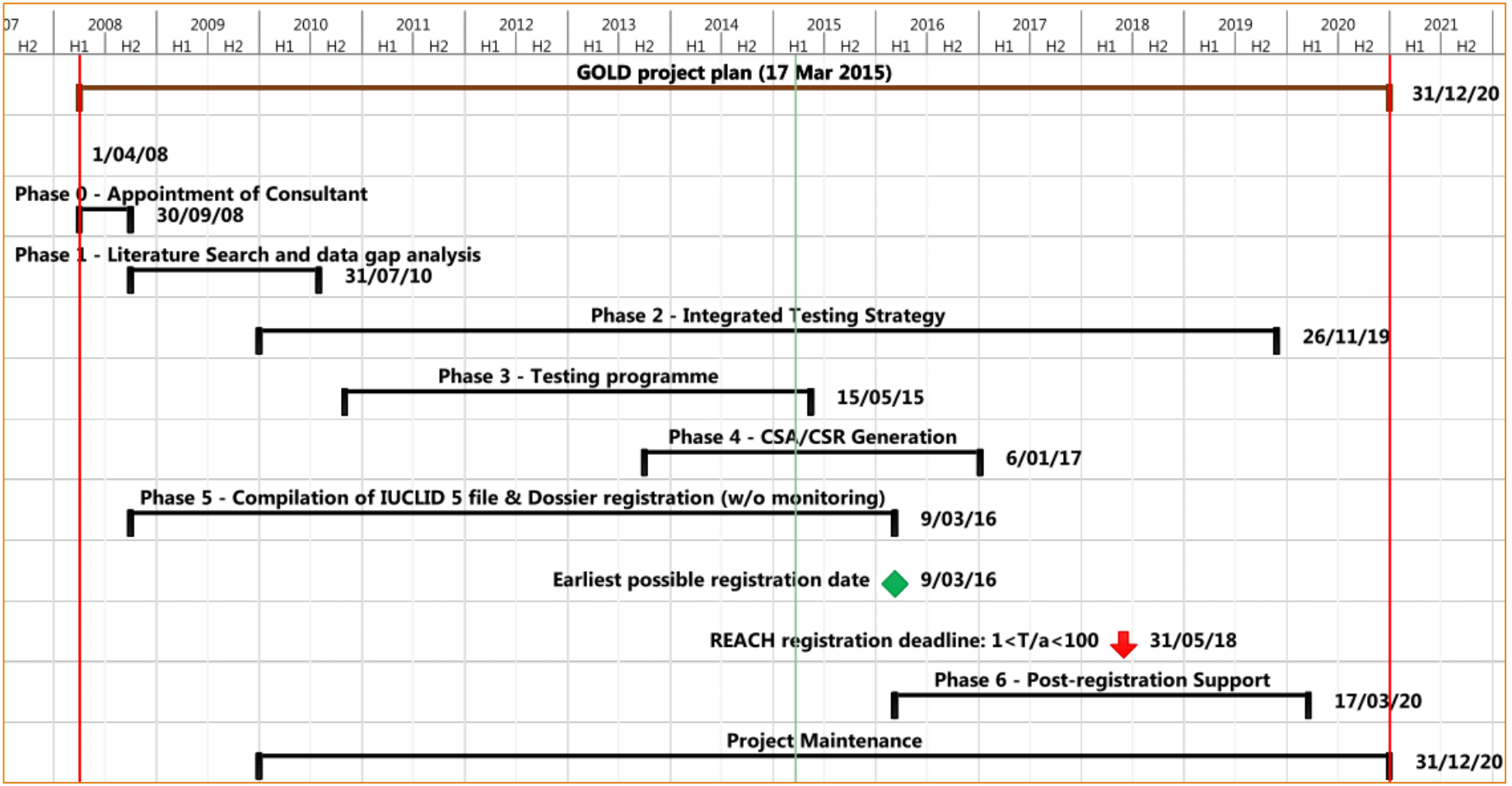
REACH Registration 10 - 100 tonnes

- 7 Toxicological information
  - 7.1 Toxicokinetics, metabolism and distribution
    - 7.1.1 Basic toxicokinetics
    - 7.1.2 Dermal absorption
  - 7.2 Acute Toxicity
    - *Acute Toxicity*
    - 7.2.1 Acute toxicity: oral
      - *Acute toxicity: oral - Key Study - Berthold (2010)*
      - *Acute toxicity: oral. Adaptation*
    - 7.2.2 Acute toxicity: inhalation
      - *Acute toxicity: inhalation - Waiver*
    - 7.2.3 Acute toxicity: dermal
      - *Acute toxicity: dermal - Waiver*
    - 7.2.4 Acute toxicity: other routes
  - 7.3 Irritation / corrosion
    - *Irritation / corrosion*
    - 7.3.1 Skin irritation / corrosion
      - *Skin irritation / corrosion. Key Study - Berthold (1993)*
      - *Skin irritation / corrosion. Supporting Study - Lehmeier (2013)*
    - 7.3.2 Eye irritation
      - *Eye irritation - Waiver*
  - 7.4 Sensitisation
    - 7.4.1 Skin sensitisation
      - *Skin sensitisation - Waiver*
    - 7.4.2 Respiratory sensitisation
  - 7.5 Repeated dose toxicity
    - 7.5.1 Repeated dose toxicity: oral
    - 7.5.2 Repeated dose toxicity: inhalation
    - 7.5.3 Repeated dose toxicity: dermal
    - 7.5.4 Repeated dose toxicity: other routes
  - 7.6 Genetic toxicity
    - 7.6.1 Genetic toxicity in vitro
      - *Genetic toxicity in vitro. Supporting Study - Kanematsu (1980)*
      - *Genetic toxicity in vitro (Ames screening). Supporting study - McGarry (2012)*
      - *Genetic toxicity in vitro (Ames full). Key study - McGarry (2012)*
      - *Genetic toxicity in vitro (HLM). Key study - Watters (2013)*
    - 7.6.2 Genetic toxicity in vivo
  - 7.7 Carcinogenicity
  - 7.8 Toxicity to reproduction

Tetrachloroauric acid

- Studies entered as received
- Some toxicological studies still to be entered
- DNELs still to be entered

Updated Project Plan



Budgets

Budget & Expenses 2015

Phase	Expenses budgeted	Assumptions	Expenses (Feb 2015)
I.	€ 10.500	Average based on experience (minimum cost is 2.000eur)	€ 0
II.	€ 0	If not reported from 2014	€ 0
III.	€ 0	study programme should be completed in 2014	€ 266,95
IV.	€ 38.000	based on actual proposals (70% invoiced)	€ 0
V.	€ 8.150	based on proposal (33% invoiced) (incl. hosting system)	€ 0
TOTAL	**€ 56.650**	**Budget is stable (+4%) compared to June assumptions**	**€ 266,95**

Budget 2016

2.3Au-specific costs	***23.000 €***
2.3.1Au REACH registration	**23.000 €**
2.3.1.1Phase 1: Literature search, data gap analysis and recommendations	10.000 €
2.3.1.2Phase 2: In-depth data gap analysis and integrated testing strategy	0 €
2.3.1.3Phase 3: Experimental studies (testing programme including cost of samples)	0 €
2.3.1.4Phase 4: Generation of Chemical Safety Reports	5.000 €
2.3.1.5Phase 5: Generation of IUCLID 5 Files and Registration Dossiers	3.000 €
IUCLID 5 Hosting System	5.000 €
2.3.1.6Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)	0 €
2.3.2Au REACH dossier maintenance	**0 €**
2.3.3Au REACH evaluation *(not applicable)*	**0 €**
2.3.4Au REACH classification & labelling	**0 €**
2.3.5Au REACH authorisation *(not applicable)*	**0 €**

Conclusions

Conclusions

- A.O.B.
- Actions summary
- Conclusions
- Next meeting/conf call:
  - PMC General Assembly meeting: 04 June 2015, Milano
  - Next Au Work Group meeting: w/c 12 October 2015
  - + Ad-hoc meetings/conf call