Precious Metals Consortium

Precious Metals & Rhenium Consortium

PMCN Work Group

6 October 2016 | Brussels, Belgium
10:45 – 11:15

Precious Metals Consortium

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 & Apologies

Approval of the draft agenda

1. Welcome and Introduction
2. Phase I: Inventory & Classification
3. Phase III: Testing programme
4. ~~Phase IV: Exposure scenario data collection~~
5. Phase V: Dossier finalisation
6. Budget
7. AOB, next meetings/calls and closing remarks

Approval of minutes from previous WG meeting

- The previous PMCN Work Group meeting was hold on 16 April 2016
- Draft minutes were distributed on 2 May 2016

➔ ***Are the minutes of the WG meeting held on 16/04/2016 approved?***

Status of actions

[A]	WHAT	WHO	STATUS
31	Updated data gap matrix will be distributed as annex of the minutes	EPMF	May ‘16
32	Authorize the in vitro mammalian cell mutation test (OECD 476)	EPMF	Apr ‘16
33	The Occ ES draft will be sent around, highlighting the most critical PROCs.	EBRC/ EPMF	May ‘16
34	It is suggested that each member checks that all their PROCs are covered in the draft Occ ES document and which of relevance to you. Also give your consent on PROCs that meets your requirements.	WG	May ‘16
35	Updated data gap matrix will be distributed as annex of the minutes	EPMF	May ‘16

Precious Metals Consortium

Phase I
Inventory & Classification

Inventory and latest classifications

IUPAC Name	Potassium dicyanoargentate	Silver cyanide	Potassium dicyanoaurate
CAS nr	506-61-6	506-64-9	13967-50-5
EINECS nr	208-047-0	208-048-6	237-748-4
REACH category	Mono-constituent	Mono-constituent	Mono-constituent
Dossier prepared	Substance	Substance	Substance
Highest tonnage band	10-100 t/a	10-100 t/a	10-100 t/a
Registration deadline	2018	2018	2018
Lead Registrant	Saxonia Edelmetalle GmbH	Saxonia Edelmetalle GmbH	Umicore
Classification	Acute tox. 2 (H330: Fatal if inhaled)		
	Acute tox. 1 (H310: Fatal in contact with skin)		Skin sens. 1
	Acute tox. 2 (H300: Fatal if swallowed)	Acute tox. 3 (H301)	Acute tox. 2 (H300: Fatal if swallowed)
	EUH032: contact with acids liberates very toxic gas		
	Skin corr. 1A (H314)	Skin irrit. 2 (H315)	
	Eye dam. 1 (H318)		

Precious Metals Consortium

Phase III
Testing Programme

Test programme – Mamtox Summary of KAgCN2

Test	Laboratory	Completion date	Result	Comments	Classification
Eye Irritation (in vitro) - BCOP OECD437	WIL Research/CRL, The Netherlands	July 2015	Positive	In vitro irritancy score ≥55 – induces serious eye damage Final report issued July 2015	Eye irritant Category 1 (H318)
Eye Irritation (in vivo) – Rabbit OECD405	Study waived based on positive in vitro skin/eye corrosion/irritation result				
Skin corrosion test (in vitro) – Episkin OECD431	WIL Research/CRL, The Netherlands	June 2015	Positive	Mean relative tissue viability <50% after 3 mins and <15% after 1 hour Final report issued June 2015	Corrosive Category 1A (H314)
Skin Irritation (in vivo) – Rabbit OECD404	Study waived based on positive in vitro skin/eye corrosion/irritation result				
Skin sensitisation – LLNA OECD429	Study waived based on positive in vitro skin corrosion result				

Test programme – Mamtox Summary of KAgCN2

Test	Laboratory	Completion date	Result	Comments	Classification
Acute toxicity – oral OECD423	Study waived based on positive in vitro skin/eye corrosion/irritation result				No data
Acute toxicity – dermal OECD402	Study waived based on positive in vitro skin/eye corrosion/irritation result				No data
Acute toxicity – inhalation OECD403	Study waived based on dustiness testing results				No data
Repeated oral dose/Reproductive toxicity screen – OECD422	WIL Research/CRL, The Netherlands	Main study starts April 2016	MTD: 10 mg/kg/day induced slight adverse effect on bodyweight gain and food intake initially; 30 mg/kg/day was lethal to all animals; unconfirmed rat oral LD50 quoted at 21 mg/kg	Selected dose levels for the main study were 1, 3 and 10 mg/kg/day. Only minimal toxicity shown at 10 mg/kg/day, not considered to be adverse. Final report in review (see next slide). Copy sent to consortium on 6th September 2016	Unclassified (STOT-RE)
Formulation analysis method development	WIL Research/CRL, The Netherlands	April 2016	All data acceptable	Final report issued April 2016	

Test programme – Mamtox Summary of KAgCN2

- **OECD 422 study**
  - Study plan Amendment No. 7 referred to the omission of formulation stability analysis
    - It is considered that this study plan Amendment No. 7 does not adequately cover all the details surrounding this omission. However, under GLP, Amendment No. 7 has to remain and be signed off, however….
  - WIL Research/CRL have been requested to issue a **draft** study plan Amendment No. 8 which should detail the circumstances of this omission and a view of the impact on the study from a Regulatory acceptance point of view.
  - This draft study plan Amendment No. 8 will be unsigned and will allow us to review its contents and make any necessary amendments before it is issued for approval

Test programme – Mamtox Summary of KAgCN2

Test	Laboratory	Completion date	Result	Comments	Classification
Ames test – Bacterial cell mutation OECD471	WIL Research/CRL, The Netherlands	April 2016	Negative	First report issued May 2016	Not classifiable
In vitro mammalian cell gene mutation test – OECD490	WIL Research/CRL, The Netherlands	August 2016	Positive	Study conducted in accordance with the most recent guideline, No. 490: "Genetic Toxicology: In vitro Mammalian Cell Gene Mutation Test using the Thymidine Kinase Gene" (adopted 28 July 2015) Final draft report reviewed by OPG and sent to WG 22nd September 2016	Dependent on result of in vivo test
In vitro cytogenicity test in mammalian cells – OECD487	WIL Research/CRL, The Netherlands	May 2016	Negative	Final report issued June 2016	Not classifiable
In vivo somatic cell genotoxicity study in mammalian cells – OECD474	To be selected	-	-	Testing proposal to be submitted	-

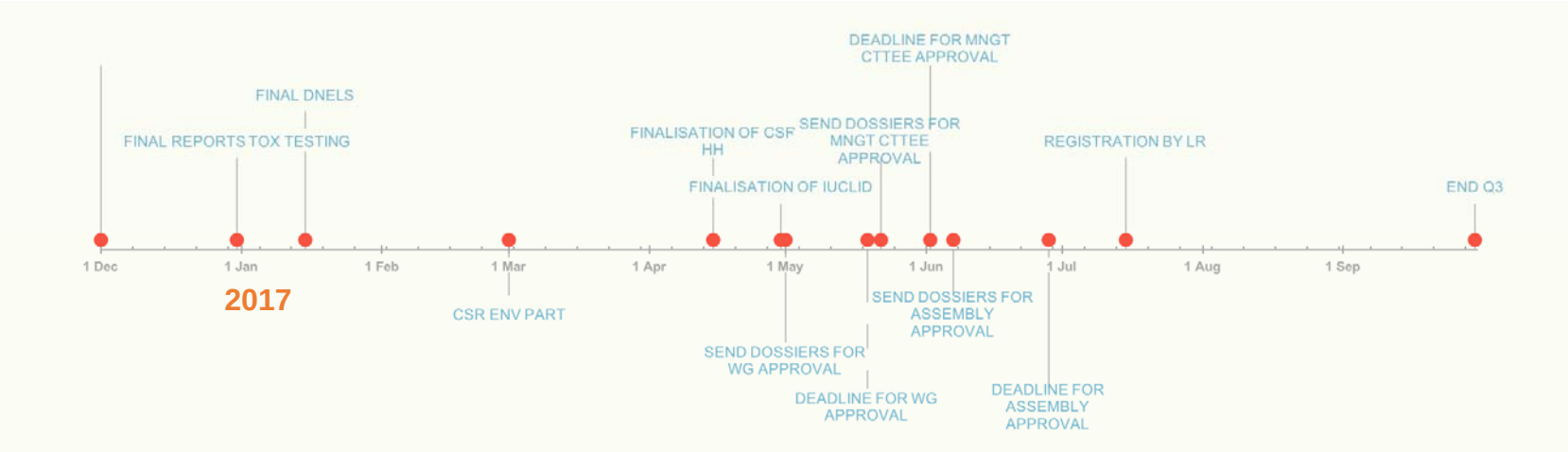
Precious Metals Consortium

Phase V
Dossier finalisation

Overview Registration Progress – AgCN & $KAu(CN)_2$

Dossier	Status
AgCN	Dossier finalised, registration ongoing by LR
$KAu(CN)_2$	Dossier finalised, registration ongoing by LR
$KAg(CN)_2$	Registration foreseen for Q3 2017

Overview Registration Progress – $KAg(CN)_2$



Precious Metals Consortium

Budget

Budget 2017

	Budget to be spent	Budget to be invoiced
PMCN-specific costs	**72.700 €**	**64.200 €**
PMCN REACH registration	**16.500 €**	**8.000 €**
Phase 1: Literature search, data gap analysis and recommendations	0 €	0 €
Phase 2: In-depth data gap analysis and integrated testing strategy	0 €	0 €
Phase 3: Experimental studies (testing programme including cost of samples)	0 €	0 €
Phase 4: Generation of Chemical Safety Reports	13.000 €	7.000 €
Phase 5a: Generation of IUCLID 6 Files and Registration Dossiers	2.500 €	0 €
Phase 5b: IUCLID 5 Hosting System	1.000 €	1.000 €
PMCN REACH dossier maintenance	**5.000 €**	**5.000 €**
Phase 5a: Generation of IUCLID 6 Files and Registration Dossiers	5.000 €	5.000 €
PMCN REACH evaluation	**2.000 €**	**2.000 €**
PMCN REACH classification & labelling	**0 €**	**0 €**
PMCN internal and external fixed Scientific Manager	**14.200 €**	**14.200 €**
PMCN building reserves	**35.000 €**	**35.000 €**

Precious Metals Consortium

Final Remarks

Final Remarks

- A.O.B.
- Actions summary
- Conclusions
- Next meeting/conf call:
  - PMC General Assembly meeting: **6-7 December 2016**, **Brussels**
  - Next Au Work Group meeting: **21-23 March 2017, Brussels**
  - + Ad-hoc meetings/conf call

THANK YOU

www.epmf.be | info@epmf.be

Avenue de Broqueville 12, B-1150 Brussels
+32 (0)2 761 01 00