Precious Metals Consortium

Precious Metals & Rhenium Consortium

PMCN Work Group

19 April 2016 | Brussels, Belgium
9:30 – 11:00

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

[See participation list and apologies in Annex 1]

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 held on 13 October 2015
- Draft minutes were distributed on 27 October 2015

➔ ***Are the minutes of the WG meeting held on 13/10/2015 approved?***

Status of actions

[A]	WHAT	WHO	STATUS
6	Determine if a more specific classification (skin sensitizer category 1A or 1B) can be assigned to KAu(CN)2 on the basis of the conclusions of the 2 LLNA studies	EPMF/SV/ OG/RB	Oct ‘15, no can’t be subdivided in subcategory 1A or 1B
26	Before starting the KAg(CN)2 testing programme, the corrosivity should be taken into consideration for animal welfare and unwanted toxic effects during genetox tests.	WCA	Done Feb ’16, testing started
27	Review the classification for AgCN and KAu(CN)2 based on the results of the OECD 422 test. Potential STOT classification based on the NOAELs. Also should be crosschecked that substances aren’t double classified.	WCA	Done Apr ‘16
28	A complete list of the non-confidential uses including all the use descriptors will be distributed with the minutes.	EPMF/ ARCHE	Done Oct ‘15
29	A discussion between toxicological experts could aid in the refinement of the DNELs for AgCN and KAu(CN)2. Comments on the draft DNEL report will be gathered by EPMF/ARCHE and a discussion will be set up, if wanted, after this period.	EPMF/SV/ RB	Done Dec ’15, refinements to the assessment factors were made
30	After commenting the draft DNEL report, EBRC will be asked to start the work on exposure scenarios and consider the DNELs as final.	EPMF/ ARCHE	Done Oct ‘15

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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)		

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Phase III
Testing Programme

Test programme – Environment - KAu(CN)2

Test	Laboratory/ Endpoint	Status	Date	Comments
Adsorption/ Desorption (OECD 106)	Fraunhöfer/ Annex VIII	Final	Apr ‘16	Kd = 108.17 – 294.47 cm3/g

Test programme – Mamtox Summary of AgCN and KAuCN2

Test	Substance							
	AgCN				$KAuCN_2$			
	Laboratory	Completion date	Result	Classification	Laboratory	Completion date	Result	Classification
Eye Irritation (in vitro) -BCOP OECD437	Harlan	2014	Negative	Not irritant	Harlan	2014	Positive	Corrosive
Eye Irritation (in vivo) – Rabbit OECD405	Harlan	2014	Positive	Eye damage Category 1 (H318)	Berthold 1992	1992	Positive	Corrosive Eye damage Category 1 (H318)
Skin corrosion test (in vitro) – Episkin OECD431	Harlan	2014	Negative	Non corrosive	Harlan	2014	Negative	Non corrosive
Skin Irritation (in vivo) – Rabbit OECD404	Harlan	2014	Positive	Irritant Category 2 (H315)	Berthold 1992	1992	Positive	Severe irritant Category 2 (H315)
Skin sensitisation – LLNA OECD429	Harlan	2014	Negative	Not sensitising	Harlan	2014	Positive	Sensitising Category 1
					MBRL (adapted protocol)	2015	Positive	

Test programme – Mamtox Summary of AgCN and KAuCN2

Test	Substance							
	AgCN				$KAuCN_2$			
	Laboratory	Completion date	Result	Classification	Laboratory	Completion date	Result	Classification
Acute toxicity – oral OECD423	LPT	2014	LD50 175 mg/kg	Category 3 (H301)	Berthold 1992	1992	LD50 29.2 mg/kg	Category 2 (H300)
Acute toxicity – dermal OECD402	LPT	2014	LD50 >2000 mg/L	Not classified	LPT	2014	LD50 >2000 mg/kg	Not classified
Acute toxicity – inhalation OECD403	Study waived based on dustiness testing results				Study waived based on dustiness testing results			
Repeated oral dose/Reproductive toxicity screen – OECD422	LPT	2015	NOAEL 15 mg/kg/day	Not classified for reproductive effects and STOT RE	LPT	2015	NOAEL 3 mg/kg/day	Not classified for reproductive effects and STOT RE

Test programme – Mamtox Summary of AgCN and KAuCN2

Test	Substance							
	AgCN				$KAuCN_2$			
	Laboratory	Completion date	Result	Classification	Laboratory	Completion date	Result	Classification
Ames test – Bacterial cell mutation OECD471	Covance	2013	Negative	Not classifiable	Covance	2013	Negative	Not classifiable
In vitro mammalian cell gene mutation test – OECD476	Covance	2015	Negative	Not classifiable	Study not required as a result of positive OECD487 test			
In vitro cytogenicity test in mammalian cells – OECD487	Harlan	2014	Negative	Not classifiable	Harlan	2015	Positive (no FISH analysis)	Potentially aneugenic or clastogenic
In vivo micronucleus test – OECD474	Study not required				Testing proposal to be submitted			

Test programme – Mamtox Summary of KAgCN2

Test	Laboratory	Completion date	Result	Comments	Classification
Eye Irritation (in vitro) - BCOP OECD437	WIL Research	July 2015	Positive	In vitro irritancy score ≥55 – induces serious eye damage	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	June 2015	Positive	Mean relative tissue viability <50% after 3 mins and <15% after 1 hour	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	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	MTD phase completed – proposed dose levels for the main study are 1, 3 and 10 mg/kg/day	tbd
Formulation analysis method development	WIL Research	April 2016	All data acceptable	Final report approved	

Test programme – Mamtox Summary of KAgCN2

Test	Laboratory	Completion date	Result	Comments	Classification
Ames test – Bacterial cell mutation OECD471	WIL Research	April 2016	Negative	First draft report in review	Not classifiable
In vitro mammalian cell gene mutation test – OECD476	WIL Research	tbd			
In vitro cytogenicity test in mammalian cells – OECD487	WIL Research	May 2016	Negative	Preliminary results only are available and we are awaiting the first draft report	Not classifiable

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Phase IV
Exposure Scenario Data Collection

PNEC derivations - $KAu(CN)_2$

PNEC	Value
Freshwater	2,0E-04 mg L^{-1}
Freshwater sediment	7,25E-02 mg kg^{-1} wwt 3,29E-01 mg kg^{-1} dwt
Marine water	2,0E-05 mg L^{-1}
Marine sediment	7,25E-03 mg kg^{-1} wwt 3,3E-02 mg kg^{-1} dwt
Intermittent releases	2,0E-03 mg L^{-1}
Soil	5,87E-02 mg kg^{-1} wwt 6,67E-02 mg kg^{-1} dwt
STP	6,0 mg L^{-1}

PNEC derivations – AgCN & $KAg(CN)_2$

PNEC	Value
Freshwater	4,0E-05 mg dissolved Ag L^{-1}
Freshwater sediment	96,4 mg kg^{-1} wwt 438 mg kg^{-1} dwt
Marine water	8,6E-04 mg dissolved Ag L^{-1}
Marine sediment	96,4 mg kg^{-1} wwt 438 mg kg^{-1} dwt
Agriculture Soil	1,24 mg kg^{-1} wwt 1,41 mg kg^{-1} dwt
STP	0,025 mg dissolved Ag L^{-1}

Draft Environmental Exposure Scenarios

	Status	Comments
AgCN	Draft	Reviewed by WG
$KAg(CN)_2$	Draft	Reviewed by WG
$KAu(CN)_2$	Draft	In review by WG

What if you use or produce more than the Msafe amount?

- Msafe is calculated for a RCR of ~0,8
- For significant higher tonnages scaling can be performed or a site specific risk assessment conducted

Draft DNEL derivations AgCN and KAuCN2

- The DNEL calculations have been conducted only for worker exposure (not consumer). Whilst consumers would be exposed to articles plated with silver or gold as a consequence of using silver cyanide or potassium dicyanoaurate during the plating process, the consumer would not actually be exposed to either of these substances. Also as oral intake is not considered relevant for workers, only the values for dermal and inhalation have been presented using route to route extrapolation.

	$KAuCN_2$	AgCN	Comments
Point of Departure	3 mg/kg/day	15 mg/kg/day	Lowest NOAEL from OECD422 studies
Workers			
Inhalation			
Systemic effects			[a]Acute DNELs not derived. Potential for acute effects are protected by long-term DNEL [b]No route-specific data. Skin and eye irritant. Potential for local effects protected by long-term DNEL and CLP
Long-term exposure	0.071 mg/m^3	0.352 mg/m^3	
Acute/Short-term exposure	Not derived[a]	Not derived[a]	
Local effects			
Long-term exposure	Not derived[b]	Not derived[b]	
Acute short-term exposure	Not derived[b]	Not derived[b]	
Dermal			
Systemic effects			[c]Assuming 10% dermal absorption [d]Unclassified in acute dermal exposure but positive skin irritant. This DNEL is protected by long-term DNEL and CLP
Long-term exposure	0.1 mg/kg/day[c]	0.5 mg/kg/day[c]	
Acute/Short-term exposure	Not derived[a]	Not derived[a]	
Local effects			
Long-term exposure	Not derived[d]	Not derived[d]	
Acute short-term exposure	Not derived[d]	Not derived[d]	

Occupational exposure scenarios for potassium dicyanoaurate and silver cyanide

PMCN WG Meeting

Brussels

April 2016

Daniel Vetter
EBRC Consulting
Hannover, Germany

19/04/16

Available information for occ. ES

- Responses to occupational exposure questionnaire from manufacturers
- Use nominations
- IUCLID files with hazard conclusions for workers
- Few data points from inhalation monitoring available (occ. ES will be predominantly based on modelling)
- Telephone interviews held for clarification on uses
- Dustiness tests available:
  - Potassium dicyanoaurate: high dusty (moisture content <0.01)
  - Silver cyanide: medium dusty (moisture content 0.05)

Scope: potassium dicyanoaurate (occ.)

Route	Type of effect	Type of risk characterisation	Hazard conclusion
Inhalation	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 0.071 mg/m³ (0.0118)
	Systemic, acute	Qualitative	Hazard unknown (no further information necessary)
	Local, long-term	Qualitative	Medium hazard (no threshold derived)
	Local, acute	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 0.1 mg/kg bw/day (0.0033)
	Systemic, acute	Not needed	No hazard identified
	Local, long-term	Qualitative	High hazard (no threshold derived)
	Local, acute	Qualitative	High hazard (no threshold derived)
Eye	Local	Qualitative	High hazard (no threshold derived)

Scope: silver cyanide (occ.)

Route	Type of effect	Type of risk characterisation	Hazard conclusion
Inhalation	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 0.352 mg/m³ (0.0588)
	Systemic, acute	Qualitative	Hazard unknown (no further information necessary)
	Local, long-term	Qualitative	Medium hazard (no threshold derived)
	Local, acute	Qualitative	Medium hazard (no threshold derived)
Dermal	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 0.5 mg/kg bw/day (0.0167)
	Systemic, acute	Not needed	No hazard identified
	Local, long-term	Qualitative	Low hazard (no threshold derived)
	Local, acute	Qualitative	Low hazard (no threshold derived)
Eye	Local	Qualitative	High hazard (no threshold derived)

Further information

- Feedback on “Preliminary risk assessment for workers” issued by EBRC in November 2015
- Chesar to be used for generation of occ. ES
- Use description and exposure assessment to stop after transformation of substances, this affects:
  - Manufacture
  - Downstream uses such as surface treatment
  - Corresponding life cycle trees

Exposure modelling (MEASE)

- Initial exposure estimates for handling of high dusty substances at ambient temperature, PROC 26 ($KAu(CN)_2$):
  - Inhalation: 10 mg/m³ → RCR $KAu(CN)_2$: 141
  - Dermal: 1.41 mg/kg bw/d → RCR $KAu(CN)_2$: 14.1
  - Combined RCR $KAu(CN)_2$: 155
- Refinement: non-dispersive use, intermittent direct handling, **generic LEV**, gloves and RPE with **APF of 40** ($KAu(CN)_2$):
  - Inhalation: 0.055 mg/m³ → RCR $KAu(CN)_2$: 0.77
  - Dermal: 0.014 mg/kg bw/d → RCR $KAu(CN)_2$: 0.14
  - Combined RCR $KAu(CN)_2$: **0.92**
- Higher estimates for prof. uses (factor 1-10; lower efficiency)

Draft occ. ES and commenting

- Draft occ. ES are currently under development (end April)
- PROCs have been revised based on additional information
- Separate “Methodology document” will be provided
- Commenting form to be developed
- Comments are highly appreciated, amongst others, on
  - Relevance or non-relevance of physical forms (solution/solid, dustiness) for process steps
  - Concentration of substances in mixtures
  - Relevance or non-relevance of professional uses
  - Presence of localised controls and availability of PPE
  - Reduced exposure duration, where relevant

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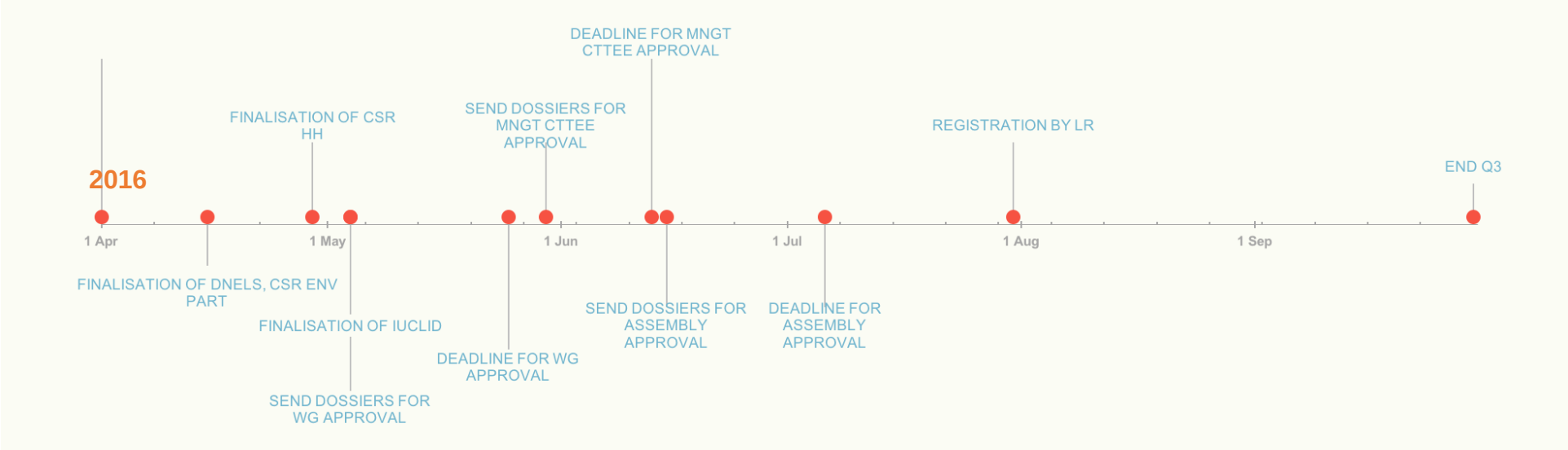
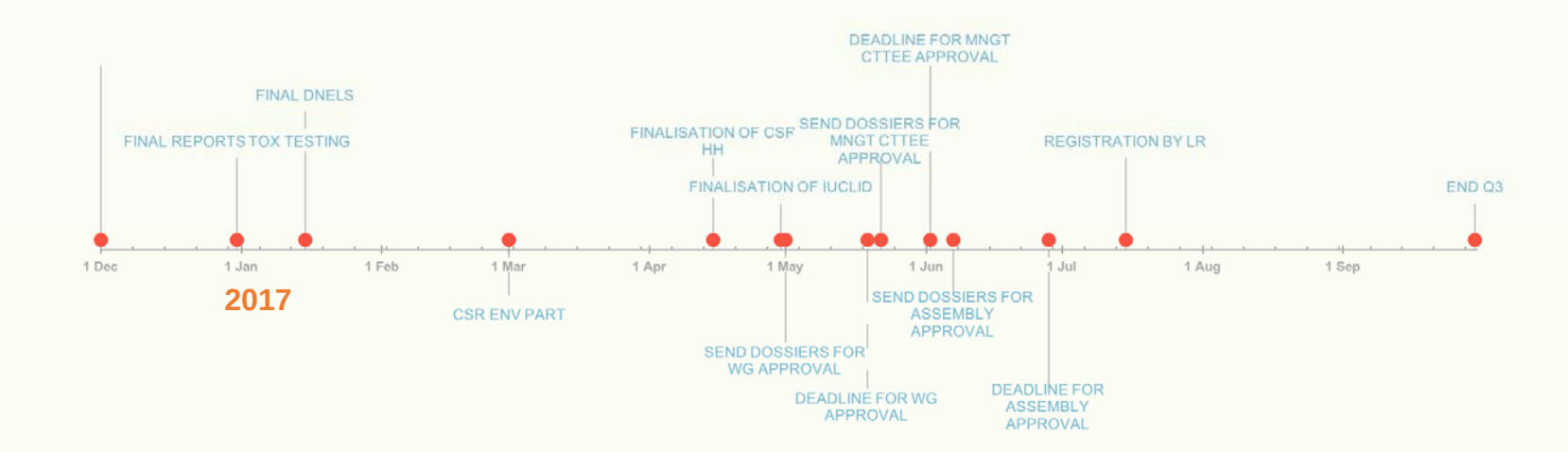
Phase V
Dossier finalisation

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



Overview Registration Progress – $KAg(CN)_2$



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Budget

Final Budget 2015

	Budget	Real	Delta
PMCN REACH registration	**193.900 €**	**213.883 €**	***-19.983 €***
Phase 1: Literature search, data gap analysis and recommendations	10.500 €	1.844 €	*8.656 €*
Phase 2: In-depth data gap analysis and integrated testing strategy	5.250 €	2.999 €	*2.251 €*
Phase 3: Experimental studies (testing programme including cost of samples)	90.000 €	159.510 €	*-69.510 €*
Phase 4: Generation of Chemical Safety Reports	80.000 €	44.691 €	*35.309 €*
Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers	5.000 €	2.169 €	*2.831 €*
Phase 5b: IUCLID 5 Hosting System	3.150 €	2.671 €	*479 €*

Budget 2017

	Budget to be spent	Budget to be invoiced
PMCN-specific costs	**74.200 €**	**68.200 €**
PMCN REACH registration	**25.500 €**	**19.500 €**
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	18.000 €	14.500 €
Phase 5a: Generation of IUCLID 5 Files and Registration Dossiers	2.500 €	0 €
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 €
PMCN REACH dossier maintenance	**13.500 €**	**13.500 €**
Phase 4: Generation of Chemical Safety Reports	10.000 €	10.000 €
Phase 5b: IUCLID 5 Hosting System	3.500 €	3.500 €
PMCN REACH evaluation	0 €	0 €
PMCN REACH classification & labelling	0 €	0 €
PMCN internal and external fixed Scientific Manager	**35.200**	**32.200**

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Final Remarks

Final Remarks

- A.O.B.
- Actions summary
- Conclusions
- Next meeting/conf call:
  - PMC Plenary meeting: **1-2 June 2016**, **Wroclaw**
  - Next Au Work Group meeting: **4-6 Octobre 2016, Brussels**
  - + Ad-hoc meetings/conf call

THANK YOU

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