Precious Metals & Rhenium Consortium

Precious Metals Cyanides Group

24 MARCH 2015 (13:00-14:45 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.	**Francisco Boo**	Metalor	Switzerland
2.	**Roland Brasch**	Heraeus	Germany
3.	**France Capon**	EPMF	Belgium
4.	**Owen Green**	WCA	United Kingdom
5.	**Dirk Hadlich**	Saxonia	Germany
6.	**Becky Marks**	WCA	United Kingdom
7.	**Renaud Nicolay**	EPMF	Belgium
8.	**Erik Teubel**	Saxonia	Germany
9.	**Steven Verberckmoes**	Umicore	Belgium

Apologies

Heike Kinz Umicore 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 PM Cyanides 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	Candidature of SAXONIA HOLDING GmbH as Lead Registrant for Potassium Dicyanoargentate (CAS 506-61-6) and Silver Cyanide (CAS 506-64-9) will be submitted to the SIEF	RN/AR	Not defined	Done
3	Prepare a projection of budgets on the period 2015-2020	RN	Not defined	Done until 2019
4	STOT (thyroid and testicles) under repeated exposure: verify if this classification is notified for PMCN substances	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	Potassium Dicyanoaurate: OECD TG 429 and "enhanced" LLNA (OECD TG 442b) do not allow to clearly determine if substance is skin sensitiser cat. 1A or 1B; S. Verberckmoes, M. Raffray and O. Green would join up efforts to look at the studies more in detail and conclude if one of the category is more relevant	RN	Not defined	
7	A new testing programme should be initiated with PDAg at least for skin and eye studies	RN	Not defined	Done
8	The ITS will be updated to reflect changes in the PDAg testing strategy (and other potential updates to the testing strategy)	WCA	Not defined	Done
9	All PNECs for PDAg and SCn are recommended to be derived from the Ag dossier. WCA prepared a read-across justification to be approved by the WG.	RN		Done
10	"use questionnaire" will be circulated in the next weeks	RN	Not defined	Done
11	exposure and emission questionnaires will be circulated in the next weeks	RN	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	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 Holding GmbH	SAXONIA Holding 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 Irrit. 2 (H315)		
	Eye dam. 1 (H318)		
	Aquatic acute 1 (H400)		
	Aquatic chronic 1 (H410)		
	Met. Corr. 1 (H290)		

Literature search

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

Literature search

- 1 potentially relevant result obtained from the search, full paper not yet reviewed

Search date	Substance	Number of results	Number of potentially relevant results	Number of relevant studies
November 2014	Potassium dicyanoaurate	2	0	0
	Potassium dicyanoargentate	1	1	Not yet reviewed
	Silver cyanide	80	0	0

Phase II
Data gap analysis & ITS

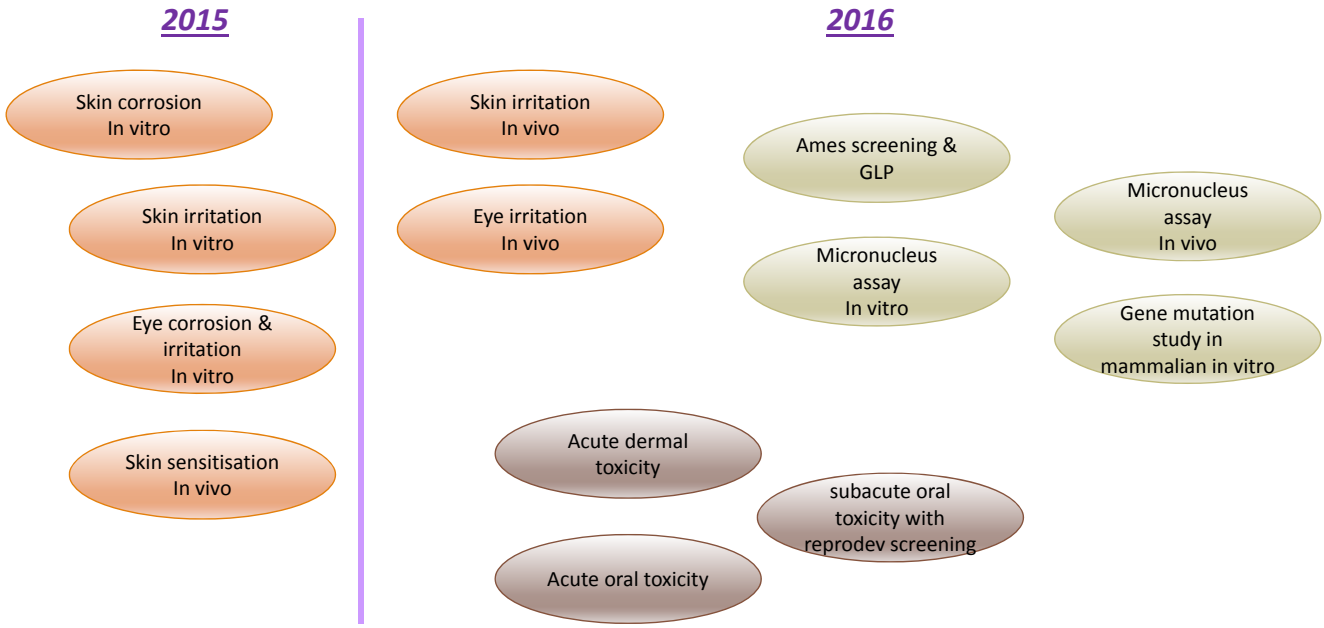
Addendum to the ITS (1/2)

- 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.
  - It has been agreed to conduct a limited OECD 106 adsorption / desorption study with potassium dicyanoaurate. Testing is ongoing at Fraunhofer.
  - Remaining ecotoxicity endpoints have been completed using mixture toxicity modelling and some direct testing for silver cyanide substances, and direct testing only for gold cyanide substances.
  - Dustiness testing and respiratory tract deposition modelling has been conducted with all precious metal cyanide substances. Following this it was concluded that the oral route of administration is appropriate for hazard assessment, and that a route-to-route extrapolation could be performed for assessment of inhalation risk.

Addendum to the ITS (2/2)

- Testing has been conducted for potassium dicyanoaurate and silver cyanide to complete all toxicological endpoints for which existing data was not available, and data waivers could not be used.
- The toxicological testing with potassium dicyanoaurate and silver cyanide showed differences in behaviour between the two substances, particularly with the positive results for potassium dicyanoaurate in the LLNA and *in vitro* micronucleus assay, suggesting that the metal ion contributes to toxicity, in addition to the free cyanide.
- Due to the differences observed in the testing with the other precious metal cyanide substances, read across from free cyanide is no longer considered to be appropriate for potassium dicyanoargentate. Testing has therefore been proposed for this substance, instead of read across.

Potassium Dicyanoargentate mamtox testing approach



Phase III Testing Programme

Test programme - mamtox

- Silver Cyanide: Genetic Toxicology Studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
AMES Screen	Covance UK	Oct 2013	Term	Dose concentrations set for GLP study
AMES GLP (OECD471)	Covance UK/ Annex VII	Jan 2014	Term	-ve result +/-S9
In vitro Micronucleus test (OECD487)	Harlan UK/ Annex VIII	Nov 2014; Awaiting Final	Term	-ve result
In vitro Mammalian mutagenicity test (OECD476)	Annex VIII	May 2015	Ongoing	Two DRF studies required to determine suitable concentrations for main test

Test programme - mamtox

- Silver Cyanide: Eye and Skin irritation studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
In vitro Skin irritation (OECD439)	Harlan UK/ Annex VII	Jan 2014	Term	+ve result (CLP and GHS Category 2 (H315), DSD R38)
In vitro Skin corrosion (OECD431)	Harlan UK/ Annex VII	Jan 2014	Term	-ve result (not corrosive to skin)
BCOP (OECD437)	Harlan UK/ Annex VII	Jan 2014	Term	-ve result (not considered to be ocular irritant (IVIS=5.6))
In vivo Eye irritation (OECD405)	Harlan UK/ Annex VIII	Mar 2014	Term	+ve result in first animal tested. No further testing possible (Eye damage Category 1 (H318))

Test programme - mamtox

- Silver Cyanide: Skin sensitisation studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
LLNA (OECD429) (Thymidine: SI>x3Control)	Harlan UK/ Annex VII	Jan 2014	Term	-ve result; SI of 1.00, 0.88 and 1.09 at 0.5, 1 and 2.5% concentrations (Not sensitising to the skin)

Test programme – mamtox

- Silver Cyanide: General Toxicology Studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
Acute oral (OECD425)	LPT/Annex VII	19 Jun 2014	Term	Oral LD50 175 mg/kg (Category 3 (H301))
Acute dermal (OECD402)	LPT/Annex VII	17 Sep 2014	Term	LD50 >2000 mg/kg (unclassified)
MTD/DRF repeat dose	LPT	Feb 2015	Term	Dose levels of 5, 15, 50 mg/kg/day proposed for main study
Repeat dose tox/Repro tox (OECD422)	LPT/Annex VIII	Draft Apr 2015	Ongoing	HDL reduced to 40 mg/kg/day after 12 days

Test programme - mamtox

- Potassium dicyanoaurate: Genetic Toxicology Studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
AMES Screen	Covance UK	Sep 2013	Term	Dose concentrations set for GLP study
AMES GLP (OECD471)	Covance UK/ Annex VII	Jan 2014	Term	-ve result +/-S9
In vitro Micronucleus test (OECD487)	Harlan UK/ Annex VIII	Nov 2014; Awaiting Final	Term	+ve result
In vitro Mammalian mutagenicity test (OECD476)	Annex VIII			Not required as a result of +ve OECD487 test
In vivo Micronucleus test (OECD474)	Annex IX			Draft testing proposal submitted to WG

Test programme - mamtox

- Potassium dicyanoaurate: Eye and Skin irritation studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
In vitro Skin irritation (OECD439)	Harlan UK/ Annex VII	Jan 2014	Term	+ve result (CLP and GHS Category 2 (H315), DSD R38)
In vitro Skin corrosion (OECD431)	Harlan UK/ Annex VII	Jan 2014	Term	-ve result (not corrosive to skin)
In vivo Skin irritation (OECD404)	ASTA Medica/ Annex VIII	May 1992	Term	This study already existed; severely irritant in 3/3 animals
BCOP (OECD437)	Harlan UK/ Annex VII	Jan 2014	Term	+ve result; occular corrosive or severe irritant (Eye damage Category 1 (H318))
In vivo Eye irritation (OECD405)	ASTA Medica/ Annex VIII	Sep 1992	Term	This study already existed; severe local effect in one animal

Test programme - mamtox

- Potassium dicyanoaurate: Skin sensitisation studies

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
LLNA (OECD429) (Thymidine; SI>3xControl)	Harlan UK/ Annex VII	Jan 2014	Term	+ve result; SI of 7.98, 8.61 and 9.88 at 1, 2.5 and 5% concentrations
Adapted LLNA (BrdU; SI>1.6)	MBR USA/ Annex VII	Feb 2015	Term	+ve result: SI of 3.7, 2.8 and 3.1 at 0.5, 1.75 and 5% concentrations (Skin sensitiser Category 1 (H317))

Test programme – mamtox

- Potassium dicyanoaurate: General Toxicology Studies

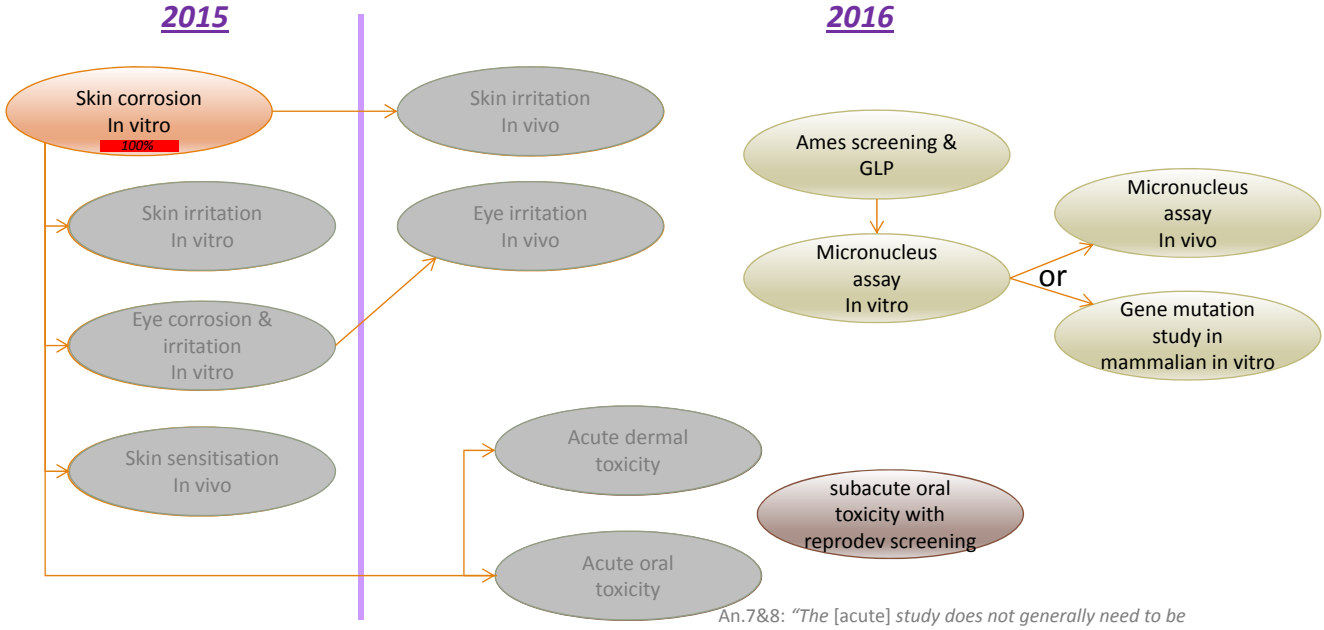
Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
Acute oral (OECD425)	?/Annex VII	n/a	n/a	Study already existed (Category 2 (H300))
Acute dermal (OECD402)	LPT/Annex VII	17 Sep 2014	Term	LD50 >2000 mg/kg (unclassified)
MTD/DRF repeat dose	LPT	22 Sep 2014	Term	Dose levels of 1, 3, 10 mg/kg/day proposed for main study
Repeat dose tox/Repro tox (OECD422)	LPT/Annex VIII	Draft Apr 2015	Ongoing	Updated pathology report received 13 Mar 2015

Test programme – mamtox

- Skin and Eye toxicology studies – Potassium dicyanoargentate

Test	Laboratory/ Endpoint	Draft/Final Report	Status	Comments
In vitro skin irritation (OECD439)	WIL Res (Annex VII)			Not required due to +ve OECD431
In vitro skin corrosion (OECD431)	WIL Res (Annex VII)	24 Feb 2015	Term	+ve result; cell viability 12% at 3mins and 3% at 1hr
BCOP In vitro eye (OECD437)	WIL Res (Annex VII)		On hold	Pending decision from WG
In vitro eye (HET-CAM)	WIL Res (Annex VII)		On hold	Pending decision from WG
In vivo eye (OECD405)	WIL Res (Annex VIII)		On hold	Pending decision from WG
LLNA (OECD429)	WIL Res (Annex VII)		On hold	Pending decision from WG

Potassium Dicyanoargentate mamtox testing approach



An.7&8: *"The* [acute] *study does not generally need to be conducted if the substance is classified as corrosive to the skin"*

Test programme - environment

- Adsorption / desorption test (OECD 106) with Potassium dicyanoaurate
- Ongoing at Fraunhofer
  - Some difficulties with analysis have delayed the study
  - Preliminary tests complete
  - Main test started – duration ~2 weeks
  - 2 additional soils will follow
  - Tests due to be completed end April
  - Draft report due May

Proposed classification for registration

Substance	Proposed Classification	Changes to currently notified clasification
Potassium dicyanoaurate	Acute In tox. 2 (H330) Acute oral tox. 2 (H300) Skin Irrit. 2 (H315) Eye dam. 1 (H318) Skin Sens. 1 (H317) Aquatic acute 1 (H400) Aquatic chronic 1 (H410) Metal corr. 1 (H290) EUH032: contact with acids liberates very toxic gas	Dermal classification removed based on acute dermal test result

Ongoing desorption/adsorption test and OECD 422 study

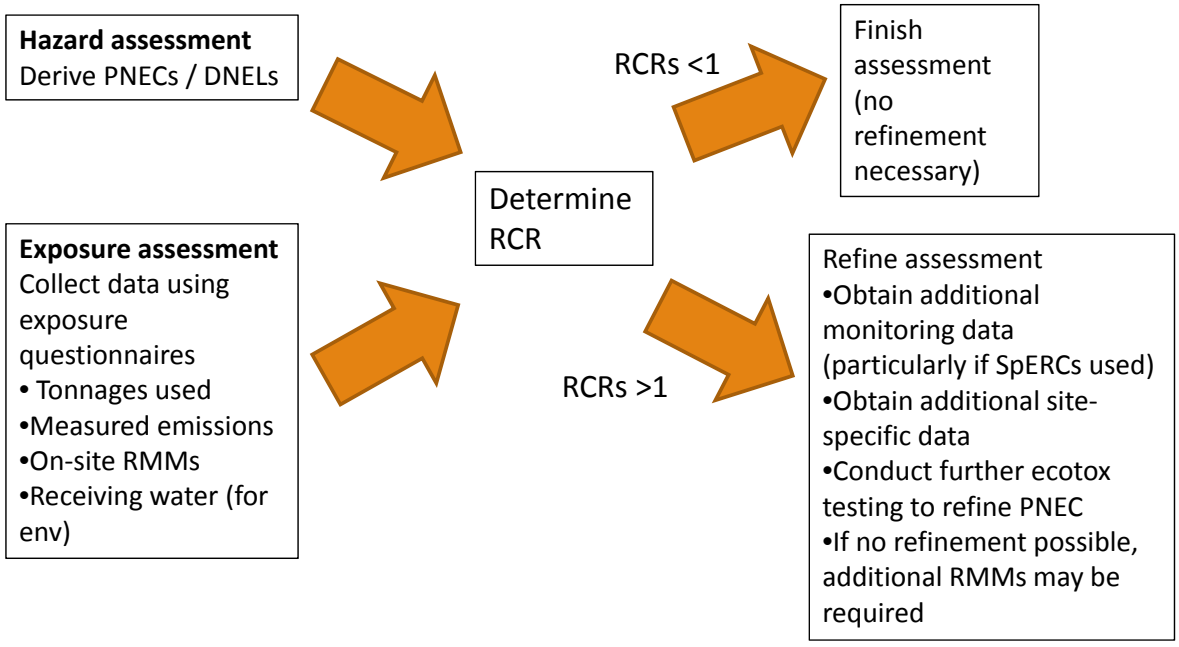
Proposed classification for registration

Substance	Proposed Classification	Changes to currently notified clasification
Potassium dicyanoargentate	Aquatic acute 1 (H400) Aquatic chronic 1 (H410) Metal corr. 1 (H290) Human health classifications to be confirmed following test programme	
Silver cyanide	Acute In tox. 2 (H330) Acute oral tox. 3 (H301) Skin Irrit. 2 (H315) Eye dam. 1 (H318) Aquatic acute 1 (H400) Aquatic chronic 1 (H410) Metal corr. 1 (H290) EUH032: contact with acids liberates very toxic gas	Dermal classification removed based on acute dermal test result Oral classification changed from Cat 2 to Cat 3 based on acute oral result (LD50 >50<300mg/Kg)

Ongoing OECD422 study with Silver cyanide

Phase IV
CSR Generation

Uses and exposure
Risk assessment process



Use and exposure
PNEC and DNEL derivation

- Exposure work required for all PM cyanide substances
- Aquatic PNECs have been derived for potassium dicyanoaurate based on results from acute ecotox studies
  - PNEC freshwater: 0.0002 mg KAuCN /L
  - PNEC marine water: 0.00002 mg KAuCN/L
  - PNEC intermittent releases: 0.002 mg KAuCN/L
  - PNEC STP: 6.0 mg KAuCN/L

  Soil and sediment PNECs will be derived using equilibrium partitioning when adsorption / desorption results received
  - Results expected end April
- Further (chronic) ecotoxicity testing may be required to refine PNECs following initial screening risk assessment
- WG agreement to read across PNECs from silver for silver cyanide substances

Use and exposure PNEC and DNEL derivation

- DNELs
  - Worker Dermal and Inhalation DNELs for long-term exposures for potassium dicyanoaurate and silver cyanide will be derived using route to route extrapolation from NOAEL or LOAEL established in the Repeat-dose oral toxicity studies (OECD422).
    - Completed study data expected May/June 2015
    - DNELs derived by end of June/July 2015
    - A summary proposal, in advance of final data, and based on LDL and IDL used in the OECD422 studies, 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
- Measured data required to avoid use of conservative default values
- If other gold or silver substances are used on-site this should be indicated in the questionnaires
- If metal SpERCs are used, these need to be justified based on measured data for the sector
- 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 2 companies (status 17 March 2015)
- Monitoring data are currently not available
- Is further information on physical form (e.g. dustiness tests) available?
- Depending on additional feedback / availability of monitoring data and level of DNELs → potential initiation of monitoring campaign required

Use and exposure Waste release to environement

- Questionnaire on release to environment from waste sent to manufacturers and representative DU (deadline on 13 March 2015)
- Members/manufacturers: responses received from 2 companies (status 17 March 2015)
- DU: response received from 1 company (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

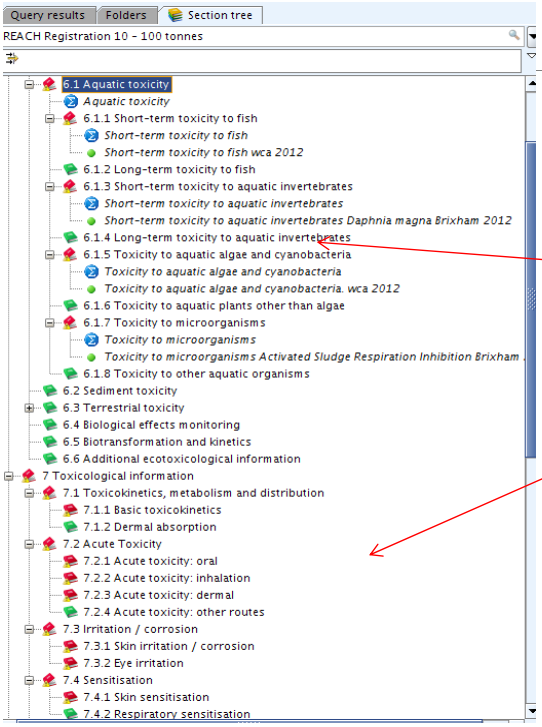
Potential costs: <€10k, even for one year monitoring of continuously operating site

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
- ***Last deadline for questionnaires: 15/04/2015***

Phase V
Dossier finalisation

KAg(CN)2



Potassium dicyanoargentate

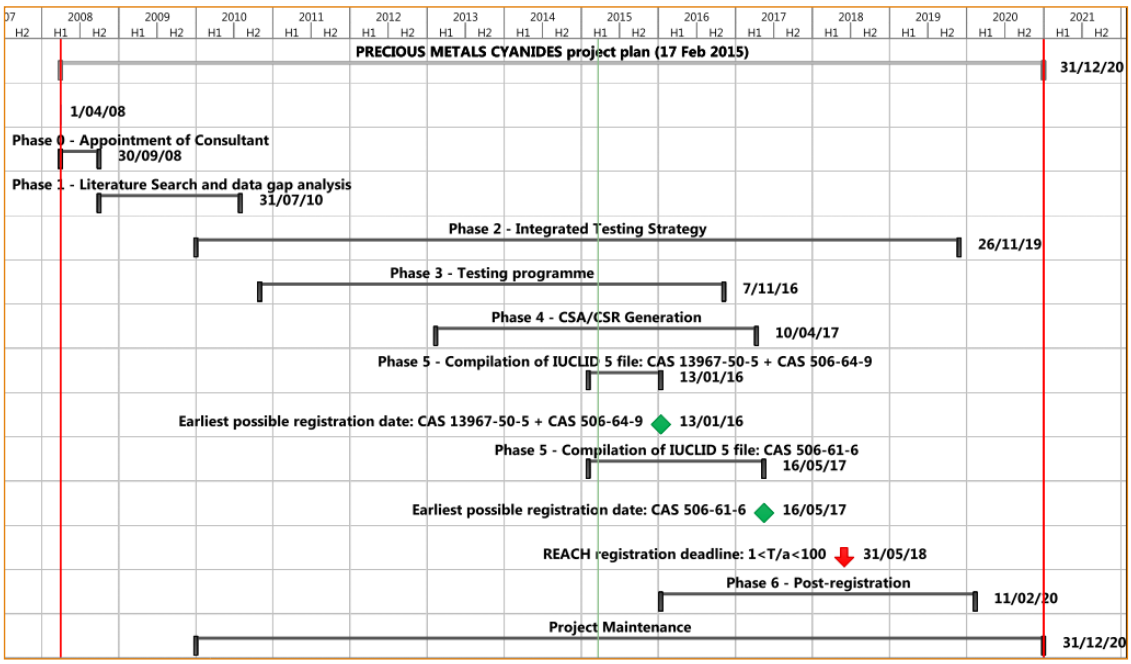
- Studies entered as received
- Ecotox endpoints completed
- Mamtox endpoints still to complete – testing ongoing

KAu(CN)2 AgCN

Potassium dicyanoaurate and silver cyanide

- Phys-chem and ecotox studies entered
- Some mamtox studies outstanding
- PNECs and DNELs 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.	€ 5.250	ITS addendum for additional KAgCN2 testing programme	€ 0
III.	€ 90.000	Finalise study programme KAu(CN)2 & AgCN + continue KAg(CN)2	€ 45.960
IV.	€ 80.000	based on actual proposals (70% invoiced)	€ 0
V.	€ 8.150	based on proposal (33% invoiced) (incl. hosting system)	€ 0
TOTAL	**€ 193.900**	Budget increased of 132.550 € compared to June assumptions. Uncertainty of +180k eur	**€ 45.960**

Budget 2016

2.4PM CN- -specific costs		***295.000 €***
2.4.1PM CN- REACH registration		**295.000 €**
2.4.1.1	*Phase 1: Literature search, data gap analysis and recommendations*	10.000 €
2.4.1.2	*Phase 2: In-depth data gap analysis and integrated testing strategy*	5.000 €
2.4.1.3	*Phase 3: Experimental studies (testing programme including cost of samples)*	250.000 €
2.4.1.4	*Phase 4: Generation of Chemical Safety Reports*	20.000 €
2.4.1.5	*Phase 5: Generation of IUCLID 5 Files and Registration Dossiers*	5.000 €
	IUCLID 5 Hosting System	5.000 €
2.4.1.6	*Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)*	0 €
2.4.2PM CN- REACH dossier maintenance		**0 €**
2.4.3PM CN- REACH evaluation *(not applicable)*		**0 €**
2.4.4PM CN- REACH classification & labelling		**0 €**
2.4.5PM CN- 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 PM Cyanides Work Group meeting: w/c 12 October 2015
  - + Ad-hoc meetings/conf call