PMC – PGM Working Group Meeting

25 MARCH 2015

Welcome and introduction

DAVE BOYD

Welcome and introduction

Confidentiality and Competition Law

Tour de table and apologies

Approval of the Agenda

Approval of the minutes of the last meetings (9 Nov 2014) and status of action points

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.
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 agenda

1. Welcome and introduction
2. Substance identification and sameness of PGMs
3. PGM testing programme
4. Current status of PNEC and DNEL refinement
5. Identified uses
6. Environmental emissions PGMs
7. Occupational exposure PGMs
8. Financial update/ Project Plan
9. AOB, next meetings/calls and closing remarks

Actions 9 October 2014 (1)

Action	Who?	Status
Revise minutes 19 June 2013 PGM WG + ES meeting and put on agenda of the next meeting for approval	PMC Sec	Today, agenda point 5.1
Return outstanding questionnaires on: env., occ., nano	PGM WG	Ongoing
Substance identification and sameness		
Circulate (updated) PGM ID cards to PGM WG	PMC Sec	Ongoing
Review the impact of the diammonium hexachlororuthenate substance identity issue on the PGM testing requirements / testing programme	PMC Sec	Done
Decide on type of registration (mono-constituent substance or UVCB) and sameness between registrants for the substance tetraammonium decachloro-muoxodiruthenate based on additional analysis	PGM Sameness Expert Group	Done
Finalise MoU with the Reconsile Consortium	PMC Sec	Ongoing
Check PMC document on recommended characterisation steps to be performed by each legal entity for each type of nanomaterial (cf. Annex 3)	PGM WG	Done
Recommend laboratory for nanomaterial characterisation and coordinate analysis	PMC Sec	Done
Perform a literature search to compare effect levels of nano-PGMs versus 'bulk' PGMs	PMC Sec/ Consultants	On hold
Send updated substance and tonnage band declarations	Companies	Ongoing
Update PGM indicative list following scope / tonnage band changes once confirmed by companies through updated substance and tonnage band declarations	PMC Sec	Depending on above action
Inform Management Committee / General Assembly / SIEF of PGM scope / tonnage band changes	PMC Sec	Ongoing
Develop a fast track plan for the dipotassium hexachloropalladate registration given the tonnage band / registration deadline change	PMC Sec	On hold; agenda point 2

Actions 9 October 2014 (2)

Action	Who?	Status
Testing programme, PNEC/DNEL		
Derive Pt PNECs	PMC/ WCA	Ongoing
Initiate Ru ecotoxicity testing and additional Rh algae study (if approved)	PMC/ WCA	Done
Derive Ru and Rh PNECs once ecotoxicity testing data are available	PMC/ WCA	Ongoing
Derive DNELs once acute / repeated dose / reprotox testing data are available	PMC/ bibra	Ongoing
Follow up with the corresponding LRs regarding required updates of the CLP notifications	PMC	Ongoing
Identified uses		
Further update the list of Pd/Pt uses following input from the meeting and recirculate	PMC/consu.	Done
Review updated list of Pd/Pt uses and provide further input/comments	PGM WG + Dus	Done
Check Umicore handbook on PGM chemistry and available plating references for information on speciation for surface treated articles	Umicore/ JM	Ongoing
Nominate substances used as bulk catalysts to know how to cover the occupational assessment / if an article service life is needed	JM	Done
Review literature on environmental emissions from automotive catalysts	WCA	
Environmental emissions of Pd and Pd compounds		
Inform the PMC Sec / WCA of wish to participate in the site-specific monitoring programme	PMC WG	Done
Check if companies provided the right tonnage number in the environmental emissions questionnaire (= input tonnage), for all PGMs (including earlier questionnaire on Pd)	PMC	Done
Occupational exposure		
Check which companies will still send the Pt occupational exposure questionnaire	PMC	Done
Clarify outstanding issues with companies regarding the Pt occupational exposure questionnaires	EBRC	On hold
Follow up IPA dataset	EBRC	Done/ Ongoing

Actions 9 October 2014 (3)

Action	Who?	Status
Occupational exposure (ctd.)		
Provide recent IPA publication to EBRC	PMC Sec	Ongoing
Check available dustiness data on DDP / Pt substances	PMC Sec	Done
Other		
Inform Michel Vanderstraeten that we realize the importance of developing RMOs for the chloroplatinates but that due to prioritisation, this work will not be picked up now	PMC Sec	Done

Substance identification and sameness of PGMs

KLAUS ROTHENBACHER

KATRIEN ARIJS

Freezing of substances inventory

- Background:
  - Request PMC Secretariat for predictability in HR and financial resources
  - Registration deadline (2018) approaching
  - Remaining uncertainties in the scope of the PMC:
    - Substances
    - Tonnage bands => data needs
    - Nano forms
- Decision: freezing of the substances inventory in 2015

Freezing of the substances inventory

- Timeline

February 2015
Approval of the concept by Mngt Cttee

March 2015
Final update of Substance Declarations

June 2015
Discuss/ agree approach at Assembly mtg

September 2015
Closure of substance inventory

- Benefits:
  - Ensure better predictability in budget and resources for 2016-2019 workplan
  - Secure on-time registration of good quality dossiers
  - Help with balancing staff workload in the coming years
- Approach approved by management committee 24 Feb. 2015

ID cards

Ongoing:

- ID cards drafted for most PGMs in the testing programme
- ID cards for remaining PGMs will be circulated for input Q3/4 2015
- Existing ID cards will be recirculated for finalisation

Sameness: Update on diammonium hexachlororuthenate vs. 'Tetradoru'

Background

- 'Diammonium hexachlororuthenate' (CAS 18746-63-9, UVCB) is in fact 'Tetraammonium decachloro-mu-oxodiruthenate' (CAS 85392-65-0, mono-const. subst. = 'Tetradoru')
- Confirmed with individual registrants; updated inventory
- 'Diammonium hexachlororuthenate' not supported any longer

Since last meeting

- Reviewed and updated testing strategy
- Revising existing tests on AHCRu to reflect correct substance ID
- Initiated testing programme Ru compounds
- Requested test material

Karstedt concentrate: Update on discussions Reconsile

Agreed with Reconsile on way forward on technical issues

- Spectra required for substance characterisation
- UVCB or multi-const. subst.
- Process definition

Collaboration Reconsile/ MoU

- MoU in preparation, can only be signed once agreement on sameness (June 2015)
- PMC highest tonnage band: 10 – 100 tpa, but Reconsile (LR) only offers to prepare registration 1-10 tpa dossier.

Karstedt concentrate: Update on discussions Reconsile

Options

- Option 1: Reconsile prepares 1-10 tpa dossier (but: potentially no CSR, ES required)
  - Reconsile proposal
    - Reconsile submits dosser in 2016 and then resigns as LR
    - PMC becomes LR in 2016 and updates dossier
  - Caveat
    - High administrative effort
    - Unpredictable timing
    - Reconsile has no metals experience
- Option 2: PMC assumes LR role now
  - Assure high quality dossier
  - No need to wait with starting testing program

Karstedt concentrate: Update on discussions Reconsile

FOR APPROVAL - The Secretariat recommends:

- Option 2
- Start work program asap
- Assess Impact on 2015 budget

Consideration of PGM nano forms (1)

EC recommendation on nano definition (2011):

≥ 50% of particles 1-100 nm

OR

Surface area > 60 m^2

N.B.:

- Number based = very small mass % of nanoparticles can make a material fall into the nano range!
- Covers also non-intentionally manufactured particles

Consideration of PGM nano forms (2)

Two questionnaires circulated

- Sept. 2014 : Which PGM substances are produced in nano-form (e.g., PGM blacks/others) and at what tonnage?
- Feb.2015: request for information on particle size distribution, surface area, composition (e.g. amounts of oxide), coating + methods used

Limited feedback received

- Some companies did not respond at all, some are late with responses, some currently conducting measurements
- No company provided sufficient information to decide whether or not nano def. is met
  - Some PSD data provided, but no number based PSD
  - Most responses (but not all) reported surface area data (BET)

Consideration of PGM nano forms (3)

Freezing of PMC scope inventory 2015

- Å Data received are not sufficient
- Å Not much time left = need to insure efficient collection of data

Proposed way forward

- Å PMC Secretariat to coordinate collection of data AND producers pay characterisation work individually
- Å Next steps
  - PMC Secretariat to set up (confidential) list of substances/ grades to be tested
  - PMC Secretariat to identify CROs
  - PMC Secretariat to set up framework contract with CROs
  - Producers to send samples directly to lab, reference to contract number
  - Results will go to sponsor (= producers) with cc to PMC Secretariat

FOR APPROVAL

Inventory update – significant changes (1)

Tonnage band increases

- Rh(NO3)3: increase from 1-10t/y to 10-100t/y – this substance has been Annex III exempt so far!
- Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (1:2): : increase from 1-10t/y to 10-100t/y
- Karstedt Concentrate? 10-100 tpa
  - Dipotassium hexachloropalladate: increase from 10-100 tpa to 100-1000 tpa! – new; only confirmed Monday; not considered in ITS yet
  - Ruthenium trichloride: increase from 1-10t/y to 10-100t/y - new; only confirmed Monday; not considered in ITS yet

Tetraammonium decachloro-mu-oxodiruthenate(4-) will replace AHCRu (same tonnage band = 10-100 tpa)

Inventory update – significant changes (2)

No more registrants for

- Dichlorotris(triphenylphosphine)ruthenium (CAS 15529-49-4)
- Diammoniumhexachloro ruthenate
- Iridium dioxide (CAS 12030-49-8Di-µ-chlorobis((1,2,5,6-eta)cycloocta-1,5-diene))diiridium (CAS 12112-67-3)
- Iridium dioxide (CAS 12030-49-8)
- Palladium dioxide (CAS 12036-04-3)

Inventory update – significant changes (3)

FOR APPROVAL: the Secretariat recommends to remove these substances from the scope of the Consortium

Next steps:

- Inform PMC MC
- Inform the PMC Assembly
- Inform the SIEF

N.B.: this is part of the overall process related to the freezing of the scope of PMC

Inventory update – costs implications

Additional time/ cost related to tonnage band increases

Cf. separate spreadsheet

Cost implications tonnage increases

PGM testing program

KLAUS ROTHENBACHER

3.1 Phys-chem tests: results summary

Testing House	Siemens			
Test Item	Results			
	Vapour pressure (p / hPa)			Partition coefficient (log Pow)
	20 °C	25 °C	50 °C	
14221-01-3 Tetrakis(triphenylphosphine)palladium	7.9×10^{-7}	1.3×10^{-6}	1.4×10^{-5}	
13965-03-2 Dichlorobis(triphenylphosphine)palladium	4.6×10^{-7}	8.2×10^{-7}	1.1×10^{-5}	
14024-61-4 Palladium di(4-oxopent-2-en-2-oate)	$< 4.6 \times 10^{-10}$	$< 8.9 \times 10^{-10}$	$< 1.8 \times 10^{-8}$	2.6
14874-82-9 Dicarbonyl(pentane-2,4-dinonato-O,O')rhodium	7.5×10^{-4}	1.3×10^{-3}	1.5×10^{-2}	
17185-29-4 Carbonylhydrotris(triphenylphosphine)rhodium	7.8×10^{-8}	1.4×10^{-7}	2.1×10^{-6}	
14694-95-2 Tris(triphenylphosphine) rhodium (I) chloride	$< 1.6 \times 10^{-8}$	$< 3.0 \times 10^{-8}$	$< 6.0 \times 10^{-7}$	
12092-47-6 Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium (I)	$< 2.2 \times 10^{-9}$	$< 4.2 \times 10^{-9}$	$< 8.4 \times 10^{-8}$	
25470-96-6 Carbonyl(pentane-2,4-dionato-O,O')rhodium	$< 9.8 \times 10^{-10}$	$< 1.9 \times 10^{-9}$	$< 3.8 \times 10^{-8}$	

3.1 Phys-chem tests: results summary

Testing House	BAM	
Test Item	Results	
	Readily combustable solids	Self-heating substances
13820-53-6 Disodium tetrachloropalladate	Not flammable solid	Not self-heating substance
16919-73-6 Dipotassium hexachloropalladate	Not flammable solid	Not self-heating substance
10025-99-7 Dipotassium tetrachloroplatinate	Not flammable solid	Not self-heating substance
10025-97-5 Iridium terachloride	Not flammable solid	
10025-83-9 Iridium trichloride (and hydrate)	Not flammable solid	

PGM ecotox.: 2015 testing Recommendation PGM experts meeting

Substance	Test				Comment
Diammonium Sodium Hexakis (nitrito-N) Rhodate	acute algae		ASRIT		Algae agreed at Oct 2014 PGM expert mtg
HHPA - compound with 2-AE	acute algae	acute daphnia	ASRIT	act. fish	ASRIT approved at Oct. 2014 mtg.
CPA			ASRIT		Data gap, can read across to AHCPt then
Ru dimer	acute algae	acute daphnia	ASRIT	acute fish	Tests already agreed for AHCRu
Rh(NO3)3			ASRIT		

Colour code	*already approved*	*recommend to approve*

- Additional cost: Algae (ca 7000 Euros) + ASRIT (3* 8000 Euros) + daphnia (5000 Euros) + acute fish (10000) = 46 000 Euros
- Remaining ecotox budget 2015: 117 000 Euros
- Last minute changes: RuCl3: tests on algae+daphnia+fish+ASRIT = 35 000 Euros

Any Objections?

PGM genotixicity testing

- Updated ECHA guidance genotox testing: need TP for all Annex IX/ X tests, irrespective of tonnage
- No impact on our testing strategy

PGM genotoxicity testing – summary from PGM tox experts group

Status

- All scheduled tests completed or in reporting phase

Next steps

- Dihydrogen hexahydroxyplatinate compound with 2-aminoethanol
  - Testing proposal for in vivo micronucleus study, combined with RDT OECD 422 (**150 000 Euros** – need to confirm cost)
  - Read across results to HHPA as worst case = no new tests required for HHPA
- Rh(III) genotoxicity
  - Confirm if both Ames tests on Rhodium nitrate were on solids (done) (ca **4000 Euros**)
  - If yes, conduct Ames test on Rhodium nitrate solution
- RuCl3
  - Last minute tonnage change
  - Need Ames test + MLA + hprt test = ca **40 000 Euros**

PGM acute/ RDT testing – Results summary

		NOAEL in mg/kg bw/d	
OECD	**422**	**407**	**421**
Diammonium Sodium Hexakis (nitrito-N) Rhodate	1000 (systemic, dev., reprotox)	-	-
Palladium dihydroxide	1000 (systemic) 1000 (reprotox)	-	-
Diammonium Hexachloropalladate **Alert: classification change; STOT RE1!**	-	30 (local effects) 100 (systemic)	100
Tetraamminepalladium(2+)dichloride	4 (systemic) 100 (reprotox)	-	-
Diamminedichloropalladium	> 300 (systemic, dev., reprotox)	-	-
AHCPt	-	10	30 (general tox.) 30 (reprotox) 100 (pups)
HHPA	1000 (general tox.) 1000 (reprotox/ pups)	-	-
TPtNO3	-	-	250 (general tox.) 1000 (reprotox/ pups)

PGM acute/ RDT testing – summary from PGM tox experts group

All scheduled tests completed or in reporting phase

Rh(NO3)3 in 10 -100 tpa band now

- RDT - Read-across from OECD 422 on Diammonium sodium hexakis(nitrito-N)rhodate not possible
- Need separate OECD 422 study = **120 000 Euros**

HHPA- compound with 2-AE in 10 – 100 tpa band now

- Skin/ eye irritation + Sensitisation (EpiSkin + LLNA) = **20 000Euros**
- RDT : need OECD 407 study, combined with in vivo MN test = **150 000 Euros**? (need to confirm)

Karstedt concentrate

- High uncertainty, testing/ data on hydrolysis critical for decision (ca **50 000 Euros**)

KHCPd (last minute change)

- Testing proposal required for most tests, no immediate need for testing (TP ca **250 000 Euros**)
- Need toxicokinetics study first = **50 000Euros**

RuCl3 (last minute change)

- Need RDT test OECD 422 = **120 000 Euros**

Current status of PNEC and DNEL refinement

KLAUS ROTHENBACHER

PNEC derivation – summary from PGM tox expert group mtg

Status

- Palladium
  - PNECs finalised
- Platinum
  - Preliminary PNECs derived based on available data
  - Some ecotox testing ongoing, PNECs to be finalised once results received
- Rhodium and ruthenium
  - Testing ongoing, PNECs to be derived once results received
- Iridium
  - No PNECs required

Next steps

- Complete scheduled testing in 2015 (if approved)
- Derive Pt PNECs in Q2 2015, derive other PNECs once data available

DNEL derivation – summary from PGM tox expert group mtg

Status

- On schedule, except for Ru-compound
- Need to update schedule with newly agreed tests

Next steps

- Derive DNELs once above hazard assessment completed
- Planned for 2015-2016

CLP update – CLP notifications

Previous meeting

- Discussed classification changes
- Recommended to lead notifiers to update classifications accordingly

ITS Matrices

- Were updated in March 2015 with all new test results
- Classifications also updated in line with new data

Next Steps

- Recommend to update classifications only once all data are ready
- Exception: classifications that require action 'without undue delay'

Any Objections?

Identified uses

BECKY MARKS

DANIEL VETTER

JUTTA SCHADE

Overview responses on questionnaires

Questionnaire collecting information on	Number of questionnaires completed	Number of outstanding questionnaires/responses	Deadline
Uses Pt substances	59 (from 24 manufacturers/DUs)	- (questionnaires received for all Pt substances, all to check if their uses are covered)	15 Aug 2014
Env emissions Pt, Rh and Ru substances	13	2	29 Aug 2014
Occ exposure Pt substances	14	2	19 Sep 2014
Production of nano-forms	9	6	30 Sep 2014
Characterisation of nano forms	8	7	10 Mar 2015

Pd and Pd substances

- Use list nearly finalised
- Some outstanding gaps – uses indicated but use descriptors not provided
  - » Use descriptors suggested where possible
  - » Please confirm / add additional descriptors if these uses should be retained
- Some PROCs may change during follow up of occ. Exposure questionnaire

Pt and Pt substances

- Compilation of uses and use descriptors near-complete
- Some follow up questions still ongoing
- Main changes since last version of table:
  - » Additional uses added
  - » Incompatible use descriptors removed – where agreed with companies
  - » Some uses declared confidential – not included in summary table
    - *Follow up sent to some companies - agree to the generic use titles and descriptors being included in the non-confidential table? (no confidential process information will be shared)*

Chloroplatinates and PROC 4

SCC of chloroplatinates

- Some companies reported PROC4 for chloroplatinates = not handled under SCC
- PROC4 included in list of collated uses (and thus in the IUCLID file)
- Companies to remove this (or other PROC) in their company-specific file if not applicable to them
- Assess level of containment: RiCoG - http://www.ebrc.de/ricog.html

Article service life

Comments EBRC on minutes 19 June 2013 PGM WG mtg

Suggest to replace

"In earlier meetings, it was agreed to perform an exposure assessment for Pd metal, although no hazard was identified for this substance. During the meeting, it was indicated that only a qualitative assessment could be performed for Pd metal in the absence of a toxicological reference value. It was indicated by EBRC that an exposure assessment would only be meaningful if a DNEL would be derived to which exposure estimates could be compared with."

By

"Although it was agreed in earlier meetings for the exposure assessment of DDP to include the service life of surface treated objects (as a reflection of the need to cover the entire life-cycle of a substance), it was indicated by EBRC that an exposure assessment for palladium metal would only be meaningful if a hazard for human health would be identified for palladium metal."

Article service life - Catalysts

- Service life of automotive catalysts
  - » Literature search conducted to obtain environmental exposure information
  - » Results screened and some papers obtained for review
- Separate service life required for other types of catalysts?
  - » Environmental catalysts
  - » Process catalysts

Article service life: Catalysts

Substance	Use	Type of catalyst use	ASL required?
Dichlorobistriphenylphosphine Palladium	Production and use of catalysts - Industrial		
Palladium (II) diacetate	Production and use of catalysts - Industrial		
Palladium	Production and use of Pd metal containing catalysts - Industrial	Automotive	Article service life of automotive catalysts
Palladium (II) di(4-oxopent-2-en-2oate)	Production and use of catalysts - Industrial		
Palladium chloride	Production and use of catalysts - Industrial		
Palladium dinitrate	Production and use of catalysts - Industrial		Article service life of automotive catalysts - consumer
Palladium Oxide	Manufacture of Pd oxide containing catalysts - Industrial	Automotive	Article service life of automotive catalysts - consumer
Tetrakis(triphenylphosphine) palladium	Production and use of catalysts - Industrial		

Article service life: Catalysts

Substance	Use	Type of catalyst use	ASL required?
Dihydrogen hexahydroxyplatinate with 2-aminoethanol	Formulation of catalysts – Industrial Downstream use of catalysts – Industrial		
Hexachloroplatinic acid	Manufacture of Catalyst – industrial		
Platinum dioxide	Formulation of catalysts – Industrial Downstream use of catalysts – Industrial	Automotive	Article Service Life – Use in automotive catalysts
Platinum	Formulation of catalysts – Industrial Downstream use of catalysts - Industrial		Article Service Life - Use in environmental catalysts Article service life - Use as a catalyst in contact lens solutions - Consumer
Karstedt Concentrate	Use of catalysts – industrial Use of catalysts – professional		Article Service Life – Professional handling of silicones Article service life – Handling of silicones by consumers
Tetraammineplatinum dichloride	Downstream se of catalysts – industrial		
Tetraammineplatinum dinitrate	Downstream use of catalysts - industrial		
Dipotassium tetrachloroplatinate	Production of catalysts – industrial Downstream use of catalysts - industrial		

Article service life

Substance	Use	ASL required?
Dihydrogen tetrachloropalladate	Use in metal surface treatment – Industrial	Article service life of surface treated products
Palladium diammine dichloride	Use in electroplating or metal surface treatment- Industrial	Article service life of surface treated products
Palladium	Use in metal Surface treatment – Industrial Reforming and reshaping of Pd metal – Industrial Reforming and reshaping of Pd metal - Professional	Article service life of surface treated products–Professional and Consumer Article service life of Pd metal and Pd alloy containing products –Professional and Consumer
Palladium chloride	Use in metal Surface Treatment – Industrial Use in non-metal surface treatment – Industrial Production of Inks and paints - Industrial	Article service life of surface treated products–Professional and Consumer Article service life of dried paints
Palladium sulphate	Used in galvanation or metal surface treatment – Industrial	Article service life of surface treated products– Professional and Consumer
Tetraammine Palladium dichloride	Use in metal surface treatment - Industrial	Article service life of surface treated products–Professional and Consumer

Article service life

Substance	Use	ASL required?
Platinum	Reshaping and reforming of Pt metal and alloys– Industrial Reshaping and reforming of Pt metal and alloys– Professional Uses resulting in inclusion into matrix – Industrial Industrial use of dental alloy – Industrial Use of dental alloy - Professional	Article service life of Pt metal and alloys in jewellery and investment products – consumers Article service life of Pt metal and alloys in devices used by consumers Article service life – use by workers Article Service Life of consumer dental alloy
Diammineplatinum nitrite	Use in surface treatment - industrial	Article Service Life of surface treated products

PGM: pilot case DU exposure assessment

Background

Exposure programme:

- Focus on manufacturing process
- Only few relevant monitoring data gathered to develop exposure scenarios
- Modelling is very often used at DUs level

Issue:

- For hazardous substances, monitoring data are critical for
  - Registration and the development of realistic GES
  - Evaluation: to avoid that substance is prioritized based on potential Regional Risk or on potential occupational risk
  - Authorisation: during the RMO process, the prioritization and in case if an Authorisation is required

Develop and implement an exposure programme at DUs level is time and resource consuming but critical

Proposal

Short term:

- Focus in 2015 on a pilot case for DU exposure assessment: to be selected on PGMs based on the following criteria:
  - Most hazardous substances
  - Mapping of uses finalized
  - DUs sectors where associations exist and are active
  - Other?

  N.B.: the pilot case must be conducted under the current budget!
- In 2015, develop in 2016-2018 PMC workplan an exposure programme based on priorities (classification, tonnage, critical uses…)
- In 2015, develop a strong Dus communication programme to implement the PMC exposure programme

Mid-term:

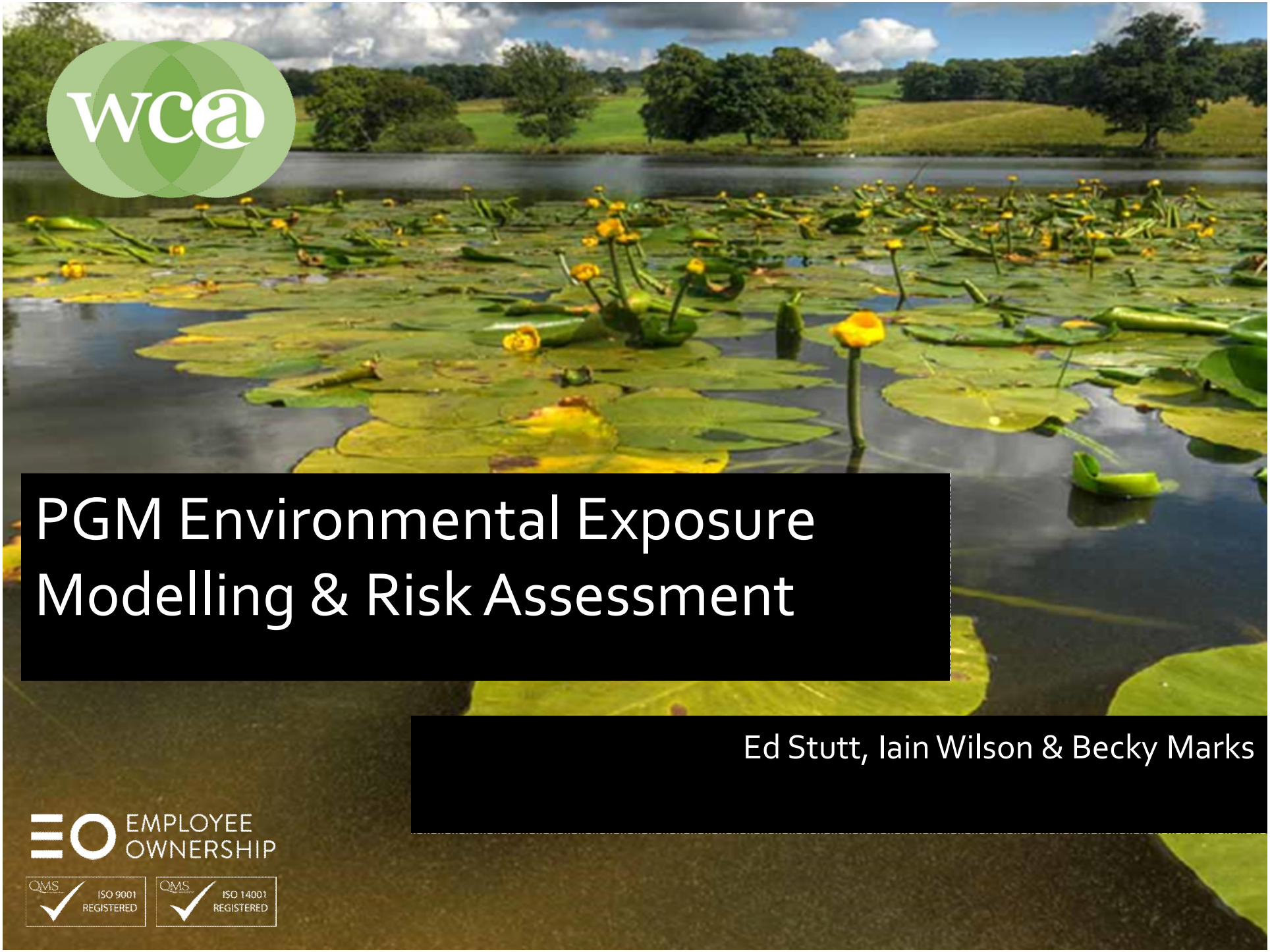
- 2016 – 2018: implement the exposure programme in a tiered approach

- Long-term: full integration of the exposure programme in the dossiers updates

Pilot case DU exposure assessment

- *In 2015, launch a pilot case DU exposure assessment with PGM*
- *2016-2018: develop an exposure programme in PMC workplan*
- *Beyond 2018: fully integrate exposure programme in the dossiers updates*

Environmental emissions



PGM Environmental Exposure Modelling & Risk Assessment

Ed Stutt, Iain Wilson & Becky Marks

EMPLOYEE OWNERSHIP

QMS ISO 9001 REGISTERED

QMS ISO 14001 REGISTERED

Content

- Site-specific monitoring programme
  - » Background and update
- STP monitoring programme
- PGM Environmental exposure questionnaires
  - » Summary of responses and data requirements for Pt, Rh & Ru substances

Site Specific PGM Monitoring Programme

- Site specific risk assessments recommended where RCR>0.5 and essential where RCR>1 indicates an unacceptable risk to the environment
- Where emission data (i.e. WWTP or stack discharge) + modelling indicate that RCRs >1 there is a requirement to undertake monitoring to demonstrate safe production/use
- Monitoring also recommended for RCR = 0.5 – 1,
  - » e.g. to remove doubt from uncertainties in exposure assessment and likely requirement to undertake assessment of mixtures

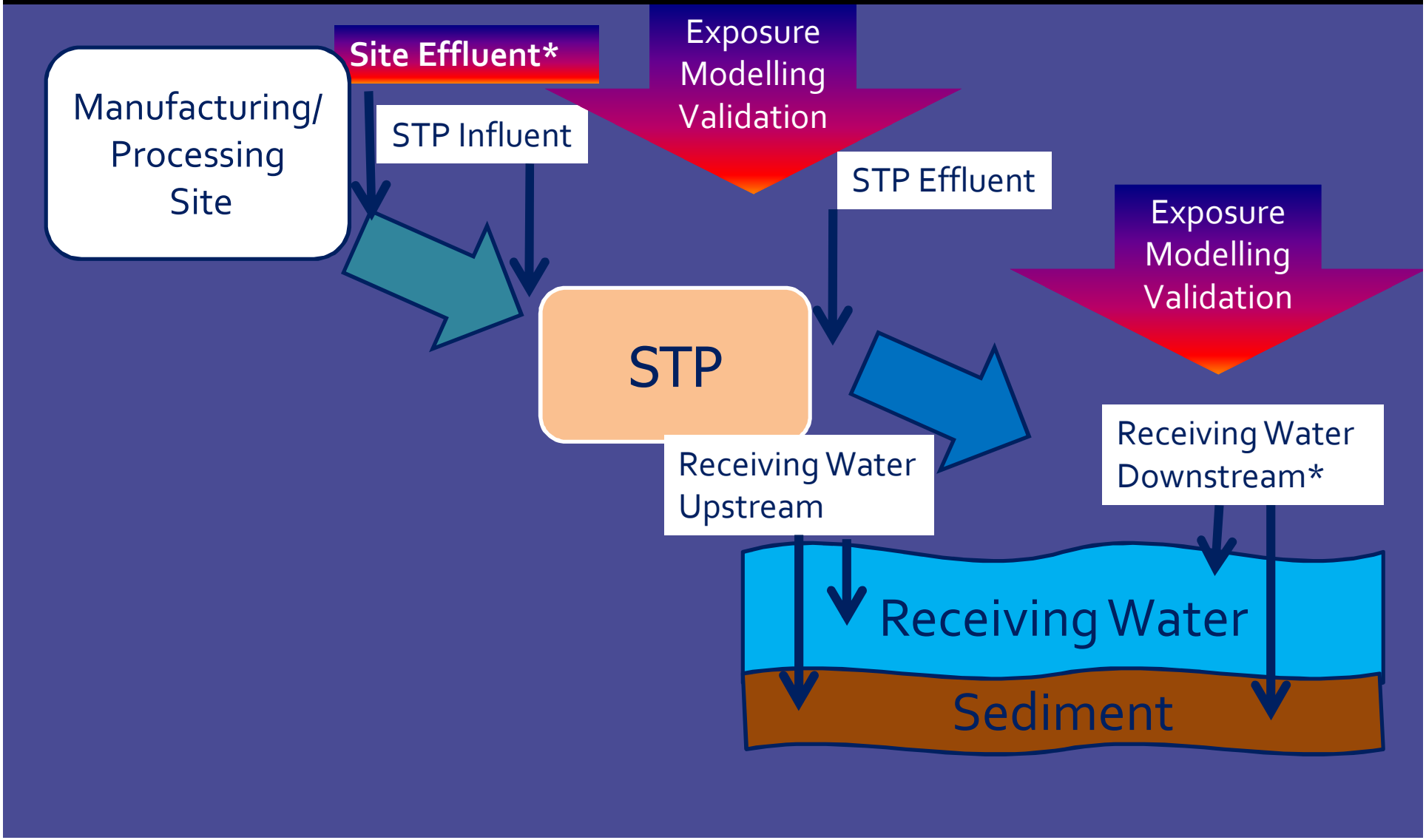
Site Specific PGM Monitoring Programme

- Pd aquatic exposure estimates are based on:
  - » the quantities of Pd substances produced and emissions data from the site (known)..... +
  - » Numerous **assumptions** on environmental fate and behaviour of Pd (and for some sites, dilution in receiving water body)
- Exposure can be refined on the basis of monitoring for:
  - » Removal rate for Pd and other PGMs in STP [sector initiative]
  - » Effluent discharge level (e.g. using lower LoD), concentrations in receiving water body and sediment downstream of discharge [site specific]

Site-specific risk assessments for Pd

Site Ref	Receiving water body	Release factor to water	RCR STP	RCR Receiving water body	RCR Receiving water body sediment	Release factor to air	RCR Local Air	RCR Local soil (no sludge)
		g/T				g/T		
Site A	Freshwater via STP	5.8	3.00×10^{-7}	0.026	0.36	1.1	1.1×10^{-5}	0.08
Site B	Freshwater via STP	109.5	4.41×10^{-4}	**22**	**109**	300	1.5×10^{-2}	0.08
Site C	Freshwater via STP	0.9	2.03×10^{-7}	0.026	0.36	300	4.6×10^{-3}	0.08
Site D	Freshwater via STP	62.5	2.71×10^{-5}	0.16	**1.0**	300	7.3×10^{-3}	0.08
Site E	Freshwater	25.3	NR	0.042	0.44	61.0	1.7×10^{-3}	0.08
Site F	Freshwater via STP	0.2	5.17×10^{-9}	0.025	0.35	158	1.4×10^{-4}	0.08
Site G	Marine water	68.2	NR	**10**	**163**	300	4.1×10^{-3}	0.08
Site H	Freshwater via STP	68.2	3.39×10^{-7}	0.026	0.36	300	5.6×10^{-3}	0.08
Site I	**No emissions**							
Site J	Freshwater via STP	357.1	1.13×10^{-4}	0.60	**3.1**	300	9.7×10^{-3}	0.08
Site K	Freshwater via STP	833.3	9.04×10^{-4}	**4.6**	**23**	300	3.3×10^{-3}	0.08
Site L	Freshwater via STP	78.0	1.63×10^{-6}	0.033	0.39	300	5.6×10^{-4}	0.08
Site M	Freshwater via STP	68.2	9.25×10^{-5}	0.50	**2.6**	300	5.6×10^{-4}	0.08
Site N	Marine water via STP	180.0	5.55×10^{-4}	**2.5**	**39**	300	5.6×10^{-3}	0.08
Site O	Freshwater via STP	459	1.9×10^{-5}	0.055	0.499	300	5.0×10^{-4}	0.08

Required Monitoring Points*



Current Status of PGM Monitoring Programme (Water)

- Sampling & analysis of effluent and receiving water samples ongoing for several sites
- Samples analysed for total and dissolved PGMs (as relevant) and phys-chem properties
- Monitoring programmes at individual sites anticipated to continue for 6 to 12 months based on review of site-specific results and SSRA
  - » About to finish for one site
- Companies currently not taking part in the monitoring programme can still be included

Current Status of PGM Monitoring Programme (Sediment)

- Sediment monitoring programme discussed several times and endorsed at the last meeting
  - » Recommended for all sites (where practical)
- Undertaken on 1 occasion at 2 sites in UK
- Only 2 sites in mainland Europe have so far indicated a willingness to take part
  - » Not practical to organise a sampling trip using UK-based consultants for a very small number of sites
  - » Option to use local consultants for sampling (send samples to ESG for analysis)

Sewage Treatment Plant (STP) Monitoring Programme

- No quantification for removal rate of any PGMs in sewage treatment plants (STPs)
- STP removal rate in current Pd exposure assessment estimated from information on partitioning to suspended particulate matter
  - » controlled by partitioning to organic carbon
- Significant uncertainty regarding this assumption
- Removal rate can only be quantified by measuring PGMs in sewage influent and effluent

Monitoring PGM Removal in STPs

- A monitoring programme has been established at STPs that are receiving discharges from plants processing effluent containing PGMs
- Conditions (and removal rates) can vary between STPs and over time
  - » Sampling at 3 STPs in two different countries
  - » Sampling to address seasonal variation (specifically, high and low flow conditions)
  - » Average removal rate taken forward to use in exposure assessment

Monitoring PGM Removal in STPs

- First round of monitoring took place in November-December 2014
  - » Provisional results indicate removal rate for Pd very similar to that predicted from partitioning
  - » But lower removal rates for other PGMs
- Second round of monitoring arranged for next month
  - » High flow conditions
- Third round of monitoring to take place in late August/early September
  - » Low flow conditions

Environmental exposure questionnaire for PGMs

- Questionnaires being returned up until January 2015
- Follow up questions sent to individual sites

➢ Aim is to facilitate compilation of sector-wide data for preparation of Generic Exposure Scenario(s) (GES)

➢ Provision of initial dataset for site-specific risk assessment (SSA)

» If initial assessments indicate a pass (i.e. RCR <<1) then this will be all that is required….or additional data or monitoring required

Response to the questionnaire

PGM	Questionnaires (sites)	Emissions to water (sites)	Emissions to air(sites)
Pt	13	8	3
Rh	7	4	2
Ru	4	3	1

- Majority provided estimates of emissions to water although little data on emissions to air
  - » Potential to generate sector EF for water or justify Kd-based SpERC approach
  - » Insufficient data for emissions to air

Response to the questionnaire

- Similarly to process for Pd, questionnaire responses will be compiled and representative values (90P or 50P) taken to inform GES for joint submission
- Risk characterisation not possible until we have test data to derive PNECs
- Draft GES and SSRAs on receipt of PNECs
  - » Flagging any issues as soon as possible

Follow-up to the questionnaire

- Still waiting on initial dataset from 1 or 2 sites
- Follow-up questions sent to most sites
  - » Requests for further data ('filling in the blanks')
  - » Clarification (e.g. presentation of tonnage data)
- Thanks for a number of very quick responses
- Key requests in follow up:
  - » Clarification on overall tonnage ('net input' for each PGM)
  - » RMM type & removal efficiency (%)
  - » Receiving water characteristics, e.g. flow rate (esp. 'new' sites)
  - » Measured emissions to air!!!

Environmental exposure assessment for PGMs

- Thank you for data and responses to date……..

  …but we still need more

- The larger the dataset the more representative it is of the sector (…..and more likely to satisfy ECHA!)

Occupational exposure

Occupational exposure
Status and way forward

Platinum Group Metals Meeting

Brussels

25 March 2015

Jutta Schade
EBRC Consulting
Hannover, Germany

Outline

- Chesar life cycle tree (LCT)
- Status of occupational exposure assessment
- Approach for occupational ES

Chesar life cycle tree (LCT)

- Finalisation of use lists required (living document)
- Information on plating not yet received
- Information on (bulk) catalysts not yet received
- Potentially reflecting data structure of IPA exposure data
- Approach followed for occ. exposure assessment to be reflected in LCT
- Outstanding questions to be sent to manufacturers by EBRC

→ Development of LCT will start once above information is available

Status of occupational ES

- Identified uses → Chesar LCT → Scope of exposure scenarios
- Hazard conclusions in IUCLID → Scope of exposure assessment
- Occ. exp. questionnaires checked for completeness
- Bilateral communication will be initiated with manufacturers
  - Waiting for decision on approach
  - Clarification or data gaps to be addressed
  - Submission form for monitoring data to be sent
  - (survey on handled substances in a workplace)

Inhalation exposure assessment

- Model estimates may only demonstrate safe use for close systems (rigorous containment)
- Monitoring data
  - assumed being essential in anticipation of rather low DNELs
  - not yet surveyed
  - also available from IPA, however:
    - Information requirements under REACH not always met (discussed in last WG meeting)
    - Data set not complete, additional data announced for this year (communication ongoing)
    - Publication not yet made available to EBRC
  - generation of additional data may be required

Approach for occupational ES

- Comment received during last WG meeting:
  - ñ*Exposure in the workplace can be to poorly soluble or soluble Pt compounds, to chloroplatinates or any combination of these: how to develop relevant exposure scenarios adequately addressing the varying hazard potential?*ò
- ñSubstance-specific standard REACH approachòvs. ñAdvanced workplace-specific approachò
  - Particularly relevant at manufacturing stage
  - Use of the substance(s) in the manufacture of other substances
  - Relevance for other uses?

Comparison of approaches - Example

Substance-specific ESs

Use of ĂSubstance Añ for the manufacture of ĂSubstance Cñ

Use of ĂSubstance Bñ for the manufacture of ĂSubstance Cñ

Handling of ĂSubstance Añ (Pt metal)

Handling of ĂSubstance Bñ (sol. platinum but no chloroplatinate)

LEV not required

PPE not required

LEV required

PPE required

Workplace-specific ESs

Manufacture of ĂSubstance Cñ

Manufacture of ñSubstance Cò (no exposure to chloroplatinates / sol. platinum)

Manufacture of ĂSubstance Cñ (exposure to chloroplatinates)

LEV not required

PPE not required

LEV required

PPE required

Comparison of approaches - Details

	Substance-specific approach	Workplace-specific approach
Fulfilling REACH requirements	yes	yes
Reflection of actual work practice	not consistently	yes
Nature of exposure considered	no	yes
Realistic assessment of workersórisk	not consistently	yes
Demonstration of diligence/responsibility	not consistently	yes
Clarification on questionnaire required	yes	yes
Monitoring form to be developed	yes	yes
Survey on nature of exposure required	no	yes

Comparison of approaches - Details

	Substance-specific approach	Workplace-specific approach
Fulfilling REACH requirements	yes	yes
Reflection of actual work practice	not consistently	yes
Nature of exposure considered	no	yes
Realistic assessment of workersórisk	not consistently	yes
Demonstration of diligence/responsibility	not consistently	yes
Clarification on questionnaire required	yes	yes
Monitoring form to be developed	yes	yes
Survey on nature of exposure required	no	yes

Financial update – project planning

First DRAFT budget 2016

	PMC 2016
	Budget
PGM-specific costs	***719.000 ú***
PGM REACH registration	**719.000 ú**
Phase 1: Literature search, data gap analysis and recommendations	16.000 ú
Phase 2: In-depth data gap analysis and integrated testing strategy	3.000 ú
Phase 3: Experimental studies (testing programme including cost of samples)	365.000 ú
Phase 4: Generation of Chemical Safety Reports	250.000 ú
Phase 5: Generation of IUCLID 5 Files and Registration Dossiers	80.000 ú
IUCLID 5 Hosting System	5.000 ú
Phase 6: Administration/others (secretariat work for project management, organisation & participation in meetings, communication)	0 ú
PGM REACH dossier maintenance	**0 ú**
PGM REACH evaluation	**0 ú**
PGM REACH classification & labelling	**0 ú**
PGM REACH authorisation	**0 ú**

Project planning

Programme on schedule

- Scheduled tests will be completed in 2015
- Deriving PNECs/ DNELs as soon as data available
- Ru is delayed due to substance (non-) availability
- Need to assess impact of last minute tonnage band changes + Karstedt

Next Steps

- Derive PNECs and DNELs in 2015
- Work on ES in 2015/2016
- Prioritising registration batches (we have 63 substances currently)
  - More details will be presented at next meeting

A.O.B.
Next meeting
Closing remarks

ECHA CMR review

ECHA is prioritising CMR substances for risk management

- Cross checks if registrants/ notifiers have used correct harmonised classifications
- Review of other registered/ notified CMR substances
  - with class. > harmonised class., Or
  - with no harmonised class
- More than 1000 CMR substances flagged

Hexachloroiridic acid and Rhodium trichloride: one notifier has reported classification as Carc. Cat. 2

- PMC not aware of any data supporting these classifications
- Currently trying to identify underlying data via SIEF/ CLP platform

RMO on Chloroplatinates (1)

Background:

- Chloroplatinates – respiratory sensitizer
- Respiratory sensitizer is considered as an « equivalent concern » under REACH to be identified as relevant SVHC and included into the Candidate List
- In 2014: RMO project on chloroplatinates has been approved

Conduct the RMO exercise on chloroplatinates in 2015

- Eurometaux RMO mock up is available
- Case studies are needed on other substances than CMR
- ECHA proposed to discuss and review the proposed methodology at the RiME – excellent opportunity to streamline and harmonize the RMO methodology used by authorities!

RMO on Chloroplatinates (1)

Consultant: Michel Vander Straeten

Timing: April-September 2015

Aims:

- the development/refinement of an RMO identification concept that is adapted to the needs of the PMC taking into consideration current state of knowledge and available data
- the application of the concept in an actual RMO identification exercise.

Project structure:

- Scoping and organisation
- RMO identification
- Refinement of justifications

Thank you!