Precious Metals and Rhenium Consortium
Rhenium Work Group Meeting

4th December 2012, 14:00pm-18:00pm CET

1. Welcome and introduction

Angela Alderman & Caroline Braibant

Welcome and introduction

- Confidentiality and Competition Law
- Tour de table & Apologies
- Approval of the agenda
  - Review of actions agreed at and approval of minutes of the last meeting (28 Sep 2012 Re WG conference call) *(All)*

Actions agreed at the 28 Sep 2012 Re WG conference call

What	Who	Status
Prepare WoE argument justifying why Acute Oral Toxicity study does not need to be repeated and why APR does not deserve an oral tox classification	WCA	Done
List reported uses per substance and itermediate and circulate to Re WG for check/completion/approval	WCA	Done
Generate analytical information as per PMC recommendations and pass information to PMC secretariat if wish to be involved in sameness check exercise	Members	Pending, only 1 Member actioned
Inform competitors about administrative burden and risk of registering alone/later (using PMC note)	Members	PMC note pending
Finalise ID Cards and election of LR:		
The Updated ID cards will be circulated for check/approval in Oct 2012	PMC	Done in Nov 2012
Finals versions will be circulated to the respective SIEF to confirm ID, REACH & CLP, and confirm the election of the Lead Registrant in particular in Nov 2012;	PMC	Will be done in Jan 2013
Comments received from the SIEF, if any, will be tabled at next Re WG meeting (cf.item 5 below)	All	Postponed to Feb 2013
Formal notification of the elected LR will be sent to ECHA in Dec 2012	LR	Postponed to Feb 2013
Prepare Agenda for 4 Dec 2012 Re WG meeting	PMC	Done

2. Finalisation of APR testing programme and classification/CSR needs

Paul Whitehead

APR test programme: OECD 422 study

Summary:

- Study complete and draft report is under review
- Effects seen in the high dose group (1000 mg/kg/day)
- Some effects in the intermediate dose group (330 mg/kg/day), above the 300 mg/kg/day threshold for STOT RE 2 classification
- Low dose of 110 mg/kg/day currently considered to be NOAEL

OECD 422 study: histopathology

- Treatment-related effects in pituitary and thyroid glands
- Possible indications of minor thyroid weight changes at low dose (110 mg/kg/day), but mostly within the current control group weight range
- Elevation of thyroid organ weights is an indicator of possible hypertrophy and considered a reversible effect

APR OECD 422: Reproductive effects

- Indication of potential reproductive effects at high dose level, possibly also at intermediate level
- The OECD 422 test is a screening study – if effects are seen these need to be definitive before classification considered
- Reproductive effects at high dose level accompanied by significant general toxicity
- No adverse effects on reproductive organs from histopathology

APR OECD 422: Reproductive effects

- Some evidence of maternal toxicity at intermediate dose level
- Only significant reproductive parameter affected - decreased pup survival – could be due to lack of maternal care due to general toxicity
- Case for non-classification can be made on the basis of the limited nature of the screening study
- ECHA may request that prenatal developmental toxicity study is conducted following dossier evaluation

OECD 422 study : Next steps

- Proposed approach:
  - » Do not classify for general toxicity based on current results, include justifications for non-classification in the REACH dossier
  - » This may be challenged by ECHA when they review the dossier (early registration prior to 2018 likely to lead to Evaluation)
  - » Process the pituitary and thyroid glands from the low and intermediate treatment groups through to slides, but do not have these read by a pathologist. These can be evaluated later if ECHA challenge the NOAEL

OECD 422 study : Next steps

- Include the following justifications for non-classification in the REACH dossier:
  a. Only changes in organ weights with no evidence of organ dysfunction
  b. Adaptive responses that are not considered as toxicologically relevant
- Without specific endocrine function testing, and use of recovery groups, there could be some differences of opinion over application of the above criteria
- However, ECHA would have to successfully argue that a further study is warranted before that could be addressed

OECD 422 study : Next steps

- Delay registration to review reproductive data in depth, and consider whether to submit a testing proposal for further reproductive toxicity studies, eg prenatal developmental toxicity?
- Consider implications for read across from APR to other rhenium substances

3. Live demonstration of IUCLID 5 completion (including uses)

Becky Marks

IUCLID completion

- All studies are entered into IUCLID, where possible
- The OECD 422 study will be entered following receipt of the draft report
- Use data will be entered into Section 3.5 following final confirmation of the uses

Summary results for rhenium substances

- Rhenium: Annex III exemptions apply, not classified for the environment or human health
- Perrhenic acid: Annex III exemptions apply, not classified for the environment, Acute Tox. 4 (H302), Skin Corr. 1A (H314), Eye Dam. 1 (H318), Met. Corr. 1 (H290)
- Ammonium perrhenate: 10 – 100 tonne substance, all Annex VII and VIII endpoints fulfilled, not currently classified for the environment or human health

Summary results for rhenium substances

- Sodium rhenate: SCC intermediate, not classified for the environment or human health
- Potassium perrhenate: Annex III exemptions apply, not classified for the environment or human health
- Dirhenium heptasulphide: SCC intermediate, not classified for the environment or human health

4. Finalisation of ID Cards, SIEF communication and sameness check

Caroline Braibant

ID Cards

- Purpose:
  - Centralise reference information on
    - Identity
    - Composition
    - Lead Registrant
    - REACH strategy and classification
    - Scope of the dossier including uses
  - Use as basis for SIEF communication + scope/reference of LoA Agreement
- Schedule
  - Dec 2012 – Approval of ID Cards (especially pending comments + uses)
  - Jan 2013 – Circulation to SIEF for approval & election of LR
  - Feb 2013 – Update of ID Cards and notification of LR to ECHA

Pending comments on ID Cards

- Generic questions:
  - Concentrations to be listed as element (Re content) or compound?
- Compound-specific questions:
  - Ammonium perrhenate: hygroscopic solid?
  - Dirhenium heptasulfide: no input received yet
  - Perrhenic acid: water content?
  - Potassium perrhenate: no input received yet on the appearance/physical state
- Latest version of uses?

Summary of uses

	Use	SU	PROCs	ERCs
Rhenium	Manufacture	3, 14	3, 9, 4, 5, 14, 22, 23, 26, 27a, 27b	1
	Manufacture of alloys	3, 14, 17	4, 22, 23, 24	2, 5
	Formation of fabricated metal products	3, 14, 15	4, 8b, 9, 14, 22, 24, 25	1
	Manufacture of computer, electronic and optical products, electronic equipment	3, 14, 16	3, 4, 8b, 9, 27a	1
Perrhenic acid	Manufacture	3, 9	1, 2, 3, 4, 5, 8b, 9, 22, 23, 26, 27a, 27b	1
	Use as an intermediate	3, 9, 10	3, 4, 7, 8b, 9,	6a
	Use as a catalyst	8	1, 8b	4
Ammonium perrhenate	Manufacture	3, 14	2, 3, 4, 5, 8b, 9, 26	1
	Use as an intermediate	3, 14	1, 3, 4, 7, 8b, 9, 22, 23, 27a	6a
Sodium rhenate (Intermediate under SCC)	Use as an intermediate under SCC	3, 9	1, 3	6a
Potassium perrhenate	Manufacture	3, 9	2, 3, 4, 5, 8b, 9	1
	Use as an intermediate	3	4, 7, 8b	6a
Dirhenium heptasulphide (Intermediate under SCC)	Manufacture	3, 9	1, 2, 3, 8b, 9,	1
	Use as an intermediate under SCC	3, 9	1, 3	6a

Sameness check

- Originally anticipated that Members would send analytical information to WCA for comparison and sameness check across co-registrants
- Only one company has provided analytical information, not possible to do sameness check at this point
- Sameness check can be done either:
  - By each registrant by looking at ID Card and evaluating similarity of registrant's material with material described in ID Card, OR
  - By WCA if all (at least two) registrants provide analytical data to be compared
- In any case, analytical data mandatory in registrant's individual file:
  - Demonstrate identity
  - For powders, demonstrate size range
  - Guidance on recommended techniques available in ID Cards

5. Next steps including:

- Timeline for Dossiers submission
- 2013 budget/membership fees

Becky Marks and Caroline Braibant

Proposed timeline

	What?	Who?	When?
1	SIEF communication	PMC Secretariat	Dec 2012-Feb 2013
2	Generate analytical data for sameness check and individual registration file completion	Registrants	Dec 2012 →
3	Sameness check and update of ID Cards	Re WG	Feb-Mar 2013
4	Notification of elected Lead Registrant to ECHA	LR	Feb 2013
5	Ensure installation of latest IUCLID 5 version	Registrants	Dec 2012 →
6	Completion of joint IUCLID 5 file	WCA	Dec 2012-Feb 2013
7	Preparation and review of CSR	Re WG	Feb-Mar 2013
8	Review of dossier before creation	Re WG	Mar 2013
9	Finalise IUCLID 5 file, pass TCC and send it to LR	WCA	Mar 2013
10	Generate joint submission object and token security number on REACH-IT	LR	Mar 2013 →
11	Complete joint IUCLID 5 file with company-specific data, pass TCC, create dossier, submit joint dossier to ECHA and inform PMC of progress of submission	LR	Mar 2013
12	Join joint registration object via REACH-IT	Co-registrants	Mar 2013
13	Prepare co-registrant company-specific file and provide to co-registrants	WCA	Mar 2013
14	When joint dossier successfully submitted, complete company-specific IUCLID 5 file, pass TCC, create dossier and submit to ECHA	Co-registrants	Mar/Apr 2013
15	Review LoA price and announce availability of LoA Agreement	PMC Secretariat	Apr-Jun 2013
16	Follow-up LoA requests	PMC Secretariat	May 2013 →
17	Determine PMC membership/maintenance fee for Re dossiers applicable as from 2014	PMC Secretariat + Assembly	Jun 2013

2013 budget/membership fees

Budget item	Budget
Generic costs	601.278 €
Ag-specific costs	444.641 €
Au-specific costs	148.950 €
PM CN- -specific costs	361.105 €
PGM-specific costs	1.636.208 €
Re-specific costs	50.950 €
Refinables-specific costs	612.150 €
Hydrazine-specific costs	38.220 €
TOTAL	**3.893.502 €**

- Dossier finalisation and submission

Re budget – 50% of Re reserves
50.950 € – 65.999 €
=
no Re invoice in 2013, living on reserves

Re WG meeting - Brussels, 4 Dec 2012

2014 budget/membership fees

Re metal-specific costs

Permanent budget items of low tonnage, low profile project

Budget Re project assuming no questions from ECHA, no Registration updates, no Evaluation, and no Authorisation obligations:

- One literature search/y = 3.000 €
- Review of C&L (if 3rd ATP to CLP) = 3.000 €
- IUCLID 5 Hosting = 3.000 €

= ~ 10.000 € to be shared by 8 Re Members as per cost-sharing formula

i.e. ~ 1.250 €/year per Member

Option to retain Re-specific reserves & possible LoA incomes

- Amount calculated after dossier finalisation and submission (~ 50.000 €?)
- Until fully exhausted and need to invoice "maintenance" costs again
  - 50.000 € / 10.000 € = ~ 5 years without Re-specific invoice?
  - Transparent report of status of expenses, LoA incomes, and reserves at occasion of Assembly meetings (which would be quorated even without Re only members participating)
- Applicable as from 2014, for decision at Jun 2013 Plenary Meeting

2014 budget/membership fees

Generic costs

- Cost-sharing foresees equal sharing
- Human resources increasing due to increasing general workload
- Annual contribution to generic costs around 13.000 €/Member
  - excluding reserves and LoA incomes credited from PMC Members

What would be a Re WG member's acceptable contribution to generic costs?

6. AOB, next meetings and closing remarks

Angela Alderman

- AOB?
- Next meetings and calls
  - End Mar 2013
    - Sameness check
    - Finalisation of dossiers
  - Jun 2013 (Plenary Meeting)
    - Review Re expenses 2008-2013
    - Calculate available reserves
    - Agree on maintenance + contribution to generic costs for low tonnage, low profile project members
- Closing remarks

THANK YOU!