Rhenium Work Group meeting

Brussels, 4th of December 2009

Metals Conference Centre – Gold Room
Rue du Duc 100, B-1150 Brussels

Agenda

1. Introduction
2. Re project progress
3. Communication with pre-SIEFs
4. Budget progress
5. AOB, next meeting & conclusion

1. Introduction

1.2 Participants

Angela Alderman	**Johnson Matthey**	**United Kingdom**
Caroline Braibant	**EPMF**	**Belgium**
Michael Husakiewicz	**Lipmann Walton**	**United Kingdom**
Jean-François Lartigue	**Eramet**	**France**
Gary Van Riper	**Climax Molybdenum**	**United States**
Ewa Zygnerszka	**KGHM Ecoren**	**Poland**

WCA will participate by call to the meeting

Approval of the Agenda

1.3 Pending actions

(Referring back to Minutes 29 September)

Done:

- To perform another literature search and report the outcome in final Phase II report
- To obtain information held by Powmet & others
- To prepare confirmation letter for testing programme and request samples from sample providers
- To provide the samples to WCA upon request by the PMC
- To circulate a request to the Members to formally confirm the nomination of the volunteer Lead Registrants
- To consider IUCLID 5 hosting service proposed by WCA

In progress/today:

- To propose 2010 meeting dates
- To complete uses spreadsheet
- To agree on whether the data owners can be mentioned when stating the bibliographical references in IUCLID 5
- To discuss data-sharing with NFM consortia of metals contained in Nickel Alloy Scrap for dossier preparation
- To validate ID cards before circulation to pre-SIEFs
- To circulate ID cards to relevant pre-SIEFs for substance sameness confirmation
- To share LR nominations with relevant pre-SIEFs

Pending:

- To develop a letter of access template for discussion
- To organise IUCLID 5 training sessions

Objectives of today's meeting

- Discuss progress of Re project (Phase III, IV and V)
- Agree on Re materials ID Cards & launch sameness + LR confirmation
- Confirm 2010 meetings

2. Re project progress

2.1 Phase I

Data collection:

- Other data-holders:
  - Powmet - done
  - BASF – in progress:
    - Confidentiality Agreement (CA) signed by PMC & WCA
    - Overview list received
    - Next steps:
      - BASF to send studies to WCA for evaluation
      - WCA to revert to PMC with evaluation
      - PMC to negotiate potential cost of studies with BASF (WCA to provide estimated value of useful study(ies) for reference purposes)
- Any additional information:
  - WCA?
- Confidentiality/Proprietarity: proposed to refer to data holders' names in IUCLID 5 file (and cross-check with Powmet, BASF & others if this is ok)

2.2 Phase II: Tier 2 (tox)

- Draft ITS report received from WCA
- Background:
  - 1-10 t/a = Annex VII = 5 tox tests
  - 10-100 t/a = Annex VII + Annex VIII = 5 + 8 tox tests

2.2 Phase II: Tier 2 (tox) (cont.)

Re 0 category (Re metal):

- Eye irritation: pending evaluation of existing proprietary data or read-across from APR to Re
- Read-across from APR (using bio-availability data) is proposed for:
  - Skin sensitisation
  - Gene mutation
  - Acute toxicity
- In summary: No test required at this stage

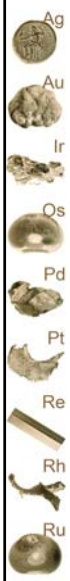
2.2 Phase II: Tier 2 (tox) (cont.)

Re 7 category (all except Re metal and APR):

- If Re WG accepts classification of perrhenic acid as corrosive (suggested by data on dirhenium heptaoxide), no need to test for:
  - Skin irritation
  - Eye irritation
  - Acute oral toxicity
- Read-across from APR (using bio-availibility data) proposed for:
  - Skin sensitisation
  - Gene mutation

Depending on response of Re WG to corrosivity question:
no test required here

2.2 Phase II: Tier 2 (tox) (cont.)



Category Re 7 A (APR):

APR is in higher tonnage band, likely "worst case" from hazard point of view → most data can be read-across from APR to other Re materials

Annex VII:

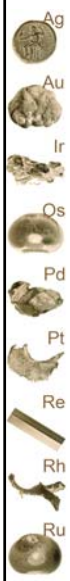
- **Skin irritation:** data available (not irritant)
- **Eye irritation:** data gap (unlikely to be irritant but need to prove it – test proposed, ~ 900 €)
- **Skin sensitisation:** data gap (LLNA proposed: ~ 4000 €)
- **Gene mutation:** data gap (see Annex VIII testing proposed – next slide)
- **Acute oral toxicity:** LD50 > 2 g/kg, no data gap

2.2 Phase II: Tier 2 (tox) (cont.)

Category Re 7 A (APR) (cont.):

Annex VIII:

- **Cytogenicity:** data gap (Micronucleus proposed - ~ 15 000 €)
- **Gene mutation (in mamm cells):** (MLA proposed – cost tbc)
- **Acute inhalation/dermal study:**
  - (Light) possibility to read-across from dirhenium heptaoxide (inhalation)
  - Test needed depends on likely exposure route:
    - Acute oral study (Annex VII) covers one route
    - Need to cover at least two routes - acute inhalation or dermal (~ 1300 €) would be needed – Re WG to indicate most likely exposure to APR:
      - through exposure to aerosols, particles or droplets, or
      - by absorption through skin during production/use



2.2 Phase II: Tier 2 (tox) (cont.)

Category Re 7 A (APR) Annex VIII (cont.):

- **Short-term repeated dose oral/dermal/inhalation toxicity:** 28-day study in rats proposed
  - oral or inhalation depending on most representative route of exposure
  - Can be combined with reprotox test (below) – overall cost tbd
- **Reprotox:** screening test on one species proposed
  - Combined with 28-day study proposed (above)
  - ~ 75 000 €
- **TK:** prepared with data collected through project

2.2 Phase II: Tier 2 (tox) (cont.)

Summary of tier 2 tests:

- Skin sensitisation (~ 4 000 €)
- Eye irritation (~ 900 €)
- Cytogenicity (~ 15 000 €)
- Gene mutation/MLA (~ 15 000 €)
- Acute dermal or inhalation (~ 1300 € for dermal, inhalation cost tbc)
- Sub-acute oral or inhalation combined with reprotox screening (cost tbc)

✓ All above tests performed on APR
✓ Results used to close gaps for other substances/categories through "worst case" read-across

Q1: wait for proprietary data to launch tier 2?
Q2: wait for tier 1 results to launch tier 2?

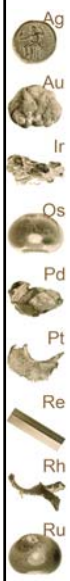
If answer is yes, tier 2 tests may be launched in Spring 2010
Proposed test house: AQura (subcontracting Evonik)

2.3 Phase III: Update on tier 1

- Tier 1 tests agreed at 29 Sep mtg
- Exact number of tests and test items confirmed/commissioned beginning Oct but:
  - Lab queue increased
  - Sample provision delayed
- Start on 2nd Dec instead of 1st wk Oct
- Lab reports date foreseen Mar 2010
- WCA report foreseen Apr 2010

2.4 Phase IV: CSA/CSR & Classification

- CSA required for all materials registered in > 10 t/a - only APR:
  - Identify uses of ammonium perrhenate - done
  - Identify likely emissions and exposure – incomplete
  - If hazardous: produce exposure scenario – in 2010
  - Produce (extended) CSR – in 2010
- All substances require a classification and labelling notification (deadline tbc):
  - Need information on uses + potential emissions and exposure
  - Need test results + available information
  - Proposal from WCA for discussion by WG in Q2 2010 – should contain:
    - Classification proposal
    - Justification for no classification

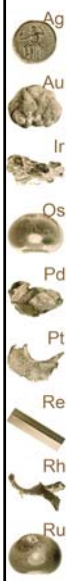


2.4 Phase IV: CSA/CSR & Classification (cont.)

- Collating uses of each material is required as part of IUCLID 5 section 3.5
- In addition, for substances > 10 t/a use information will be used in CSA/CSR (in addition to exposure & emission data)
- PMC Secretariat launched collection of uses on in-scope materials – 5 companies filled in template (result in next slide)

2.4 Phase IV: CSA/CSR & Classification (cont.)

- Re metal:
  - Alloying agent (with Molybdenum)
  - Alloying agent (with Tungsten)
  - Alloying agent (with Nickel)
  - Catalyst agent (with Platinum)
  - Intermediate to produce another substance
  - Medical application (as radio-activated rhenium)
- APR:
  - Alloying agent (with Nickel)
  - Catalyst agent (with Platinum)
  - Intermediate to produce another substance (i.e. Re metal)
- Perrhenic acid:
  - Catalyst agent (with or without Platinum)
  - Intermediate to produce another substance
- Sodium rhenate:
  - Intermediate to produce another substance
- Dirhenium heptasulphide:
  - Catalyst agent (with or without Platinum)
  - Intermediate to produce another substance



2.4 Phase IV: CSA/CSR & Classification (cont.)

- From original list of uses, the following were not reported/may not appear in CSA/CSR of Re materials dossiers:
  - Electrical contact – covered by alloying applications
  - Medical application/radio-activated Re

Option 1: Re WG to re-check with customers to make sure there is no need to include these uses in our CSA/CSR work

Option 2: WCA invited to progress on IUCLID 5 compilation and Exposure & Emission questionnaire based on uses reported so far

Re WG invited to select most appropriate option

2.4 Phase IV: CSA/CSR & Classification (cont.)

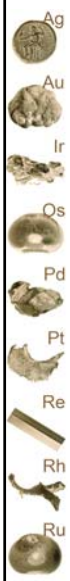
How to classify our rhenium materials?

REACH-specific guidance applicable to this discussion are:

- Substance identification guidance – not useful
- Data-sharing guidance

GHS/CLP-specific guidance applicable is:

- Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of substances and mixtures



2.4 Phase IV: CSA/CSR & Classification (cont.)

Articles 10(1) and 11(1) of CLP Regulation:

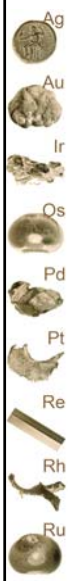
- If a **substance A** is classified as per Annex VI to the CLP Regulation, and that **substance A** is present in another **substance B** as an impurity or individual constituent in concentrations at or above the concentration limit or cutt-off value, this other **substance B** should be classified as hazardous accordingly.
- It does not mean that a proposal for harmonised classification shall be submitted for the **substance B** in which the classified **substance A** is present if this **substance B** in itself does not fulfil the criteria for classification.
- If a **substance B** is subject to classification only due to the presence of an **impurity or other constituent A** that is classified, the **substance B** should not be listed as a classified substance under CLP.

2.4 Phase IV: CSA/CSR & Classification (cont.)

Guidance on data-sharing:

- There may be instances in which the parties to a SIEF agree that different classification and labelling may apply with regard with the same substance, for instance if the difference is attributed to an impurity, for which the relevant hazardous properties are known.
- Members of the SIEF can also disagree as to the classification and labelling of the substance. In this context, REACH allows opting out from the classification and labelling in the context of the joint submission.

Q: Are Re WG in favour of one classification (based on 80% rule) or a more flexible approach using the opt-out approach?



2.4 Phase IV: CSA/CSR & Classification (cont.)

How to classify our Rhenium materials?

- Need to agree on typical rhenium material profile (ID Card – purity threshold/impurity levels)
- Need to agree on classification for each material:
  - proposed by WCA
  - discussed/challenged by Re WG
  - adjusted by WCA
  - approved by Re WG
  - proposed to SIEF
  - included in IUCLID 5 section 2

2.5 Phase V: IUCLID 5 compilation

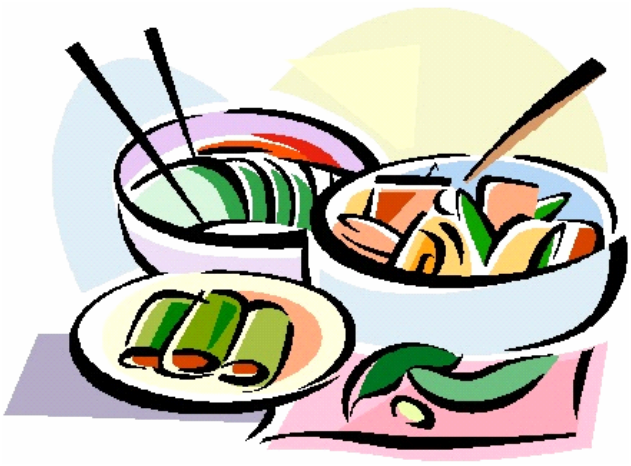
Information on uses needed here!

IUCLID 5 sections	Completed by
Section 1 General Information	PMC
Section 2 Classification Notification	WCA
Section 3 Manufacture, Use & Exposure	PMC
Section 3.5 Identified Uses	WCA
Section 4 Physical & Chemical Properties	WCA
Section 5 Environmental Fate & Pathways	WCA
Section 6 Ecotoxicological Information	WCA
Section 7 Toxicological Information	WCA
Section 8 Analytical Methods	WCA + PMC
Generate final CSR	WCA

PMC = PMC staff, LR and/or other Members with support of WG and TAP

2.6 Project timeline towards Registration

See handouts



3. Communication with pre-SIEF

3.1 Change in LR

- Change in LR for Ammonium perrhenate:
  - Before: KGHM Ecoren
  - Now: Heraeus
- Now ready to go to pre-SIEF
  - Through ID Cards

3.2 Proposed ID cards

- As agreed at last mtg, template was produced using Ni Alloy scrap example + refinable example
- ID Cards in preparation with WCA – two types:
  - Mono-constituent: As per Ag example
  - Multi-constituent/UVCB: As per Refinable example – for nickel alloy scrap
- Group to review each ID Card and approve next week

3.2 Proposed ID cards (cont.)

Ni alloy scrap:

- Transported intermediate < 1000 t/a
  - → "Any existing available information"
  - → No testing but analytical information
- Classified because of Ni content (at least)
  - → Registration by 2010
- < 5 Pre-registrants
- One pre-registration as multi-constituent substance
- Proposed: move to Refinables project
- Remaining: Registration strategy

Precious Metals and Rhenium Consortium,
Rhenium Work Group

Registration of Ni alloy scrap

Case study / Proposal
(for internal use only)
5 November 2009

Content

1. Confirm intermediate status (chemical modification and strict control)
2. Confirm tonnage band
3. Confirm name
4. Registration approach
   i. Multi-constituent approach 1
   ii. Multi-constituent approach 2
   iii. UVCB approach
   iv. Summary of approaches
5. Recommendation

1. Confirm intermediate status

- Need to proof that the material undergoes a chemical change and that it is handled under strictly controlled throughout its entire life cycle
- Need to describe processes it undergoes to prove the “chemical nature” of these (see next slide)
- Each registrant to document handling and processing conditions to make sure strict control is implemented = minimised exposure and emissions

1. Eurométaux guidance

(ECHA guidance does not exist)

Chemical modification may be induced by:

- Optical/Mechanised Sorting
- Magnetic/Electrostatic Separation
- Gravity or Dense Medium Separation
- Preferential Crushing, Grinding or Milling
- Screening, Hydrocycloning or Classification
- Agglomeration or Froth Flotation
- Thickening & Filtration
- Drying (or calcination that results in removal of water & impurities only)
- Pelletising by granulation only
- Leaching/Washing Processes to remove impurities

Chemical modification may be induced by:

- Leaching Processes to extract the value-mineral
- Pelletising with sintering (*subject to ongoing review)
- Ion-Exchange, Solvent Extraction or Electro-winning
- Pressure Digestion in aqueous NaOH
- Sintering, Roasting & Smelting
- Calcination involving changes in the chemical structure (e.g., CO_2 release)
- Precipitation and gas precipitation

2. Confirm tonnage band

- Transported isolated intermediate < 1000 t/a:
  - Available information
  - Classification
- Transported isolated intermediate > 1000 t/a:
  - Available information
  - Annex VII information requirements (physico-chemical, ecotox and environmental fate and behaviour)
  - Classification

3. Confirm name

- Avoid “Alloy” → associated to “special preparation” which requires the individual registration of each component
- Avoid “Scrap” → associated to waste which is outside the scope of REACH but under the Waste Directive

4. Registration approach

- Multi-constituent substance – two possibilities:
  1. Submit one dossier referring to the dossiers of the individual constituents, or
  2. Submit one dossier including all the available information on the reaction mass

- UVCB – one possibility:
  - Submit one dossier including all available information on the substance (focussing on “main constituents”

Option 1 constitutes a natural continuation as the material was originally pre-registered as a multi-constituent substance (reaction mass) and not as a UVCB (because no EINECS number existed)

4.i. Multi-Constituent Approach 1:

One dossier referring to individual constituents

- Need right to refer to individual dossiers:
  - Need letter of access = need to pay for this right
  - Consortium will most probably not be able to pay once for all its Members
  - Each legal entity will have to pay for the letter of access separately (~ 3000 € / intermediate dossier based on Ni example)
- Need to make sure all individual constituents are registered by 2010
  - Ni, Al, Co, Fe, Mo, Re → consortium exists, likely to be registered (by 2010? Not sure. ECHA may grant time for these dossiers to become available)
  - Cr, Hf, Ta, Ti, W → not sure whether registration will occur (at all or by 2010. ECHA may grant time for these dossiers to become available)

4.ii. Multi-Constituent Approach 2:

One dossier including information on reaction mass as such

- Use classification that will become freely available from all consortia (multi-lateral agreement to share classification for free
- Use any information that is available on the reaction mass as a whole
- Make sure you list all the constituents (up to 100 %)

4.iii. UVCB Approach

- Use classification that will become freely available from all consortia (multi-lateral agreement to share classification for free)
- Use any information that is available on the reaction mass as a whole
- List only the main constituents (those that are intrinsic to the manufacturing process (substance identity) and/or that trigger classification)

4.iv. Summary of approaches

	MCS 1	MCS 2	UVCB
Principle	Refer to individual dossiers + classification shared for free by metals consortia	Include available information on reaction mass + free classification	
Advantage	Strongest/Most responsible approach Gives you the right to manufacture or import individual constituents separately (as intermediates only)	Follows REACH guidance, simple, faster, cheaper	
Disadvantage	Need to make sure all constituents are registered (on-time)	Can be considered as being less "responsible" because using a smaller/weaker dataset (from a safety point of view). No right to register any of the constituents separately/individually	
Cost (per legal entity)	~ 3000 € x 10 (for 10 letters of access) + ~ 1500 € to prepare IUCLID 5 file (assuming 5000 €/ 4 registrants assumed) + preparatory work by consultant (literature search, classification & labelling, etc.) - tbd = ~ 31500 €/registrant	1500 € to prepare IUCLID 5 file (assuming 5000 € and 4 registrants) + preparatory work by consultant (literature search, classification and labelling, etc.) - tbd	

5. Recommendation

- Naming (as per Guidance):
  - If MCS route followed: reaction mass of [list of all constituents]
  - If UVCB route followed: source and process it originates from + main constituents
- Thinking of the "robustness" of the arguments and future activities, preferred order would be: MCS1 > MCS2 > UVCB

3.3 Proposed timeline

Dec 2009	Circulate registration + joint submission intentions survey Circulate ID cards (sameness + LR confirmation)
Jan 2010	Collect responses from above surveys Notify ECHA about SIEF formation (no longer "pre-SIEF") and confirmed LR
Feb/Mar 2010	Develop Letter of Access, have it approved by Assembly, and propose to SIEF
Apr/May 2010	Confirm LoA (first invoices to joint registrants) Provide guidance & training for joint submission
Jun/Dec 2010	Continue promoting LoA
2011	Finalise dossier and prepare for joint submission

4. Budget progress

4.1 2010 Re-specific budget

Budget item	2010 budget	2010 Light budget
Generic	**584.780,35 €**	**453.142,95 €**
Re-specific	**192.500,00 €**	**60.000,00 €**
Phase I	*0,00 €*	*0,00 €*
Phase II	*2.500,00 €*	*0,00 €*
Phase III	*150.000,00 €*	*50.000,00 €*
Phase IV	*10.000,00 €*	*10.000,00 €*
Phase V	*32.980,00 €*	*0,00 €*
TOTAL	777.280,35 €	513.142,95 €

Approved at 3 Dec Assembly meeting

4.2 2010 Re-specific costs

Costs	Invoiced in 2007-2009 (€)	Spent over 2007-2009 (€)*	Reserve left (€)**
Generic	831.516,67	683.588,49	147.928,18
Re-specific	238.000,00	24.054,15	213.945,85

Agreed at 3 Dec Assembly meeting to invoice Light 2010 budget in two invoices (50% each) and to use reserve for ongoing/upcoming work

5. AOB

5.1 2010 Re WG meetings

Brussels, 23 April 2010

&

Brussels, 23 September 2010

5.2 2010 PMC Assembly meetings

Hamburg, 18 June 2010

&

Brussels, 2 December 2010

5.3 Training

- Proposed: back-to-back with Re WG's 23 April mtg
- Content:
  - IUCLID 5 file finalisation (with company-specific information)
  - IUCLID 5 file submission to ECHA (through REACH IT)

Thanks for your participation!

Have a safe journey back home
and enjoy your winter holidays!