




Rhenium Work Group Meeting

Brussels, 4th of December 2008

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Phase I introduction

By: **WCA** – Physico-chemical data & Eco-toxicology
Bibra – Toxicological part

• **Objectives:**

1. Data matrix identifying tonnage-relevant IUCLID 5 endpoints.
2. Identification of data gaps and endpoints for which grouping and read-across may be possible. Identify any appropriate substances in relation to other group members (chemical, physical and biological behaviour).
3. Assess potential read-across conditions.
4. REACH Annex III assessment.

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Ag

Au

Ir

Os

Pd

Pt

Re

Rh

Ru

Indicative list

Consortium vs. Consultant

	Consortium	Consultant
Rhenium & Rhenium containing compounds	7	9

- At this stage it is not important whether it is “substance” or “intermediate” - necessary to gather as much information as possible.
- The indicative lists need to be synchronized (e.g. rhenium-containing scrap, ion-exchanger polymer).

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What was delivered in Phase I?

- 7 Excel spread sheets named by CAS number.** References grouped by REACH endpoint, ordered by REACH Annex.

Difficult to manage the data & keep the track of actions.

- Data analysis matrix**
Collating all the information requirements and potential read-across.

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What was delivered in Phase I?

- **Draft report...**
 - describing the search methodology.
 - listing the number of references identified for each substance.
 - highlighting the “data analysis matrix” results in short description.

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- **TAP Teleconference 12 November 2008**
- **face-to-face meeting 14 November 2008, Johnson Matthey, Reading, UK**

COMMENTS

- 1. Relevancy of some endpoints:**
 - concerning inorganics (e.g. flammability)
 - choice of the endpoints for the “data analysis matrix”
- 2. Objectives 1 & 2 were fulfilled, but!**
 - definition of categories was missing, together with the rationale behind it
 - objective 3 (assessment of the potential read-across conditions) and objective 4 (REACH Annex III assessment) were not addressed

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What was delivered in Phase I?

- **Revised report/Final report**
- **delivered within short time period (2 weeks) from face-to-face meeting**
- **all 4 objectives were addressed**

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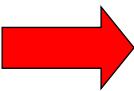



Defining categories

- Annex XI – allows for the evaluation under REACH by grouping chemicals.

Advantages: interpolation & extrapolation of the data from one or more chemicals to other category members.

- reduces the testing
- reduces the cost
- helps the evaluation of the "difficult compounds"
- may save the time
- can increase the confidence in risk assessment

 Crucial to gather all available in-house studies!!!

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Defining categories

Theory: Hazard and risk assessment is established technique for metals – properties are likely to be the same, or follow a trend, as a result of a common metal.

Bioavailability – in most cases determines effects seen. Information to assess bioavailability can range from water solubility measure to *in vivo* uptake and toxicokinetics.

Other factors: chemical speciation
valency/oxidation state

For consideration:

- Does the metal itself belongs to the same category as the compound of that metal?
- Is the toxic potential of the substance determined only by the nature of the metal ion?

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Defining categories

Complication: **None** of the compounds included in the project have been **identified as category members** under existing risk assessment programmes (e.g. USEPA, OECD or EU).

Preliminary approach:

- oxidation state – reasonable starting point at this stage of project in respect to the speciation in environmental waters and biological fluids.
- possible toxicity of the counter ion – may increase the number of categories, but if the counter ion is found not to be toxic substance can join the general category for the oxidation state.

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Defining categories

Category	Name of the substance
Re0	Rhenium
Re7	Perrhenic acid
	Dirhenium heptaoxide
	Sodium rhenate
	Calcium perrhenate
	Dirhenium heptasulphide
Re7A !!!	Ammonium perrhenate
ReX ???	Rhenium-containing scrap
	Ion-exchanger polymer

Short coming:
Categorising based on oxidation state and
(eco)toxicity of the counter ion is not sufficient!

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Annex III

- concerns the substances registered in quantities between 1 and 10 tonnes.
- regarding also Article 12, only the physico-chemical data are required for the registration for these substances.

Conditions to be met:

1. The substance is unlikely to meet the criteria for category 1 or 2 classification for carcinogenicity, mutagenicity or reproductive toxicity or the criteria in REACH Annex VIII (PBT, vPvB)
2. The substance does not have dispersive or diffuse uses, particularly where such substances are used in consumer preparations and
3. The substance is unlikely to meet the classification criteria for any human health or environmental effects endpoints under Directive 67/548/EEC.

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Annex III

- Substances which may meet the criteria

Rhenium
Perrhenic acid
Dirhenium heptaoxide
Sodium rhenate
Calcium perrhenate
Dirhenium heptasulphide

- Requires a revision of Consultant's indicative list.
- Article 12 – all available physico-chemical and (eco)toxicological information must be included.
- Demonstrate non-dispersive use of each substance.

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Outputs of Phase I - summary

- The results of literature searches have been combined with non-proprietary and proprietary data. The references have been reviewed and those considered relevant to a REACH endpoint have been reported on a per substance basis.
- Preliminary categories have been identified on the basis of oxidation state and the potential toxicity of the counter ion.
- A data matrix has been constructed to identify data gaps. Where possible we have given an indication of the potential for read-across or derogation.
- An initial assessment has been made to identify substances that may fulfil the criteria for an Annex III exemption.

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Further actions

Consultants:

- *regarding Phase I*
 - Final review of reference lists following comments on Phase I outputs.
- *regarding Phase II*
 - Review each reference, assign a Klimisch code and complete a robust summary where appropriate.
 - Finalise substance categories and justifications and agree these with the PMC.
 - Create category data matrices to identify data gaps.
 - For data gaps, either justify data waiving (including Annex III exemptions), justify read across, or identify as a 'true' data gap.

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Further actions

Consortium:

- **provide all existing in-house studies!!!**
- **create substance profile: technical specification and physico-chemical endpoints.**
(starting with hexachloroplatinic acid and palladium, high and low hazard profile, data rich and poor substance to refine Phase II costing).
- **decide on IT tool to manage the data and to keep track of actions.**

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Any question?
Any recommendation?