



Participants

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Minutes

1. Introduction

The objectives of the teleconference were to¹:

- Evaluate the Phase I reports of the PGM and Re projects sent by WCA on 8th of November 2008 in preparation of the upcoming face-to-face meeting with WCA (14 November 2008);
- Evaluate the dustiness and particle size report of Phase IIb of the silver project sent by EBRC on 31st of October 2008;
- Inform the TAP on the outcomes of the OECD 401 algal test performed on silver nitrate at NIVA, and on the progress of the Ag PNEC/EQS discussion with UK authorities;
- Agree on a way forward for the silver project.

2. Phase I of the PGM and Re projects (Annex 1).

The objectives of Phase I were:

- Produce a data matrix which clearly identifies tonnage-relevant IUCLID 5 endpoints for which there are no data, tonnage-relevant endpoints for which valid data potentially exist for PGMs and rhenium, and any other toxicity data on these compounds that could be useful in later phases (e.g., when writing data waivers).
- Provide a preliminary identification of data gaps and endpoints for which grouping and read-across may be possible, and identify any appropriate reference substances on the basis of chemical, physical and biological behaviour in relation to other group members (i.e., any trends across groups).
- Use experience gained through the understanding of previous metals risk assessments, undertaken through the TCNES process, to assess potential read-across conditions.
- Perform a REACH Annex III² assessment to identify substances for which it is predicted that establishing only a physicochemical dataset will be required.

¹ The actions points resulting from each section are provided in **green** (PMC action points (Secretariat, Scientific Manager and Members)) and **orange** (Consultants' action points (WCA/BIBRA or EBRC)).

² According to Article 12(1)b of REACH, the technical dossier shall include as a minimum, the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of 1 tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III. Annex III criteria are:

- substances that they are likely to meet the criteria for category 1 or 2 classification for carcinogenicity, mutagenicity or reproductive toxicity; that are persistent, bio-accumulative and toxic (PBT), or that are very persistent and very bio-accumulative (vPvB);
- substances with dispersive or diffuse use(s) particularly where such substances are used in consumer preparations or incorporated into consumer articles; and
- substances that are likely to meet the classification criteria for any human health or environmental effects endpoints under Directive 67/548/EEC.



Table 1 below summarises the comments/questions raised by the TAP during the teleconference. They have been used as a basis to produce the Agenda for the upcoming meeting (Annex 2).

Table 1. Comments/questions on Phase I reports of PGM & Re projects raised by TAP.

Objective	Item	Observation/Comment	Action point
1: Data matrix	<i>In scope substances</i>	Phase I projects reflect WCA's search for a previous version of the indicative lists, which might have been updated more recently.	Caroline Braibant to provide updated list to WCA.
	<i>Information on out of scope substances</i>	Not reflected in the data matrix. These can be necessary for read-across purposes, or in the event the indicative list is enlarged (following Member's update or arrival of new Members/(Pre-)SIEF joint registrants).	WCA to keep track on information available on out of scope substances.
	<i>Data gathered</i>	<ul style="list-style-type: none"> - Some of the data provided/recommend by Consortium Members is missing from tables. - Moreover, some key sources are not reflected in Phase I reports. - All information available should be included in Phase I's data matrix. Exclusion of any available data should not be done before a quality assessment/ Klimisch evaluation (i.e. Phase II). 	<ul style="list-style-type: none"> - Each contributing Member and Zuzana Hugonin to check inclusion of reference in Phase I reports. - Dave Boyd and Angela Alderman to provide examples of key literature sources that are missing. - WCA to include or justify absence of missing references.
	<i>Solution/solid forms, and hydrate/anhydrous forms</i>	Some of the information missing as per above comment relate to situations where the information which was provided referred to a solution form of a solid listed in the indicative list, or to a hydrated form of an anhydrous form listed in the indicative list.	<p>Zuzana Hugonin to check which substances are examples of these dual situations.</p> <p>WCA to explain how this information will be used (equivalent validity? Read-across?)</p>
	<i>Physicochemical properties (inorganics)</i>	Certain physicochemical properties are not required for inorganics and have therefore been excluded from the data matrix, although the indicative lists may sometimes contain organic forms as well.	WCA to include missing physicochemical properties.
	<i>"Other" properties</i>	Some physicochemical (and other) properties which are not requested by REACH have been included in the data matrix. E.g.: <ul style="list-style-type: none"> - 4,9 Solubility in organic solvents - 4,16 Oxidising reduction potential - 4,18 Storage stability and reactivity to container material - 4,19 Stability: thermal, sunlight, metal - 4,20 pH 	WCA to explain reason for this wider scope of endpoints.



Objective	Item	Observation/Comment	Action point
2: Grouping and read across possibilities	<i>Reference substance(s) for read-across</i>	The pure precious metal/rhenium metal has often been considered as the substance from which read-across will be performed. There should be a distinction between (a) Registration dossier "cloning" potential and (b) Grouping/Read-across potential. Further assessment should be performed by WCA in order to include parameters such as solubility, bio-accessibility, dustiness and particle size, and chemical species, etc when identifying the substance(s) with grouping and/or read-across potential.	WCA to adjust Phase I report based on preliminary groupings proposed by PMC at 4th June meeting (item 4.d of Annex 3).
3: Potential for read across based on previous RA experience	<i>WCA's experience</i>	WCA's experience is not detailed or used in any specific manner in Phase I reports.	For Hege Stubberud to provide examples of the form of experience PMC would expect to see in the Phase I reports. For WCA to adjust report accordingly.
4: REACH Annex III assessment	<i>Application of 67/548/EEC criteria</i>	Phase I reports do not reflect any preliminary ³ /advanced evaluation of which PGM and/or Re substances could be prepared for Registration by reporting on physicochemical properties only (e.g.: iridium, rhodium, osmium, etc.).	WCA to provide with a preliminary assessment of those substances for which it is unlikely that they will meet Annex III criteria.
Other	<i>Page numbers</i>	The reports should be page-numbered.	WCA to number pages of reports.
	<i>EINECS numbers references</i>	EINECS numbers have been used solely for each individual excel spreadsheet. It would be highly convenient for the name of the file (and the spreadsheet itself) to also include the name of the substance as per EINECS.	WCA to include name of substance in file and in file's title.
	<i>Data matrix link with individual excel sheets</i>	Would it be possible from an IT point of view, it would be very convenient to be able to access a substance excel spreadsheet by clicking on the name/number of this substance in the overall data matrix.	WCA to check possibility of linking each individual excel file to master data matrix.

3. Dustiness and particle size (silver project) (Annex 1).

TAP recognises the use of the information provided in this report. However, EBRC should be invited to provide PMC with a qualitative assessment of the results, in order to:

- Rank the different powder forms from finest to coarsest, from more to less dusty.
- Compare the results with the CEN/DIN Standards applicable to particulates (check units provided as well).

³ It was acknowledged that any suggestion performed at this stage might require adjustment following a confirmation of the PGM scope (with the identification of (Pre-)SIEF joint registrants).



The above qualitative assessment should enable EBRC to clarify the questions raised by C. Bourda (Metalor) in her e-mail dated 4 November 2008 (Annex 4). **TAP members are invited to read the attached references for more information (Annex 5 and 6) and to send their comments on the report by the 21st of November 2008.**

In the event the translation of the original reports (in German) can be provided by EBRC with no additional cost, **these should be requested by PMC**, as suggested by E. Broekaert (Umicore) (Annex 7).

Post-meeting note: The draft report on bio-accessibility tests performed on silver and silver compounds in synthetic biological media (second report of Phase IIb HH) has been anonymised by EBRC and is attached as Annex 8.

4. Algal study and Ag EQS setting.

4.1. Algal study

A first OECD 401 test was completed with silver nitrate at NIVA on 16 October 2008. The results (Annex 9) were in agreement with what was expected from the screening test⁴ (with nominal concentrations).

The recovery of the compound by chemical analysis was, however, very low (less than 10 %), which is very surprising for a metal. NIVA have therefore analysed the stock solution they had used, and the results of the analysis showed that the recovery was excellent in this case.

Silver ions can show some sensitivity to light, and the algae test is run in light conditions. The exposure to light may have caused the precipitation (silver ions react with oxygen and form an oxide that precipitates). However, there was no precipitation in the stock solution (which is more concentrated), although it was exposed to daylight and room temperature during storage since the completion of the test.

Further, if precipitation had been the cause of the poor recovery, it would have been normal to observe an increased growth following the first hours of toxic action, after the precipitation had occurred, which did not happen (silver ions seem to have been available throughout the entire test duration).

There is a slight reduction in toxicity from 48 to 72 hours, which also occurred in the control. The slightly reduced growth can be explained by the fact that humic acid was used instead of EDTA⁵ in the medium.

NIVA has agreed to re-run the test (within the current contract), which results should be available before the end of November. PMC will find out informally with WCA at 14 November 2008 meeting whether they have encountered similar recovery results and whether they could explain why this happened.

⁴ EC50 values of 6,6 µg/l after 48 h, and of 7,7 µg/l after 72 h for growth rate as endpoint; and 3,6 µg/l after 48 h and 4,0 µg/l after 72 h for yield as endpoint.

⁵ EDTA is used to keep iron available in the test solution. Because of the high density of algae in the control there is a slight deficiency in available iron at the end of the test. At more toxic concentrations, there is less algae and therefore enough available iron. Although this modified medium is suboptimal for the algae, it is the most adapted for metals.



4.2. Ag EQS setting

M. Raffray held a one-to-one phone call with M. Crane (WCA) on 10 November 2008 in order to discuss the draft Hazard Assessment for silver⁶ to derive an Environmental Quality Standard (EQS)⁷ prepared for the UK Environment Agency (EA) by WCA. The outcome of this exchange is summarised in Annex 10.

Current standards for dissolved silver in fresh and saltwater were derived from the ecotoxicological dataset available in early 2008, and following the EU Technical Guidance Document (EU TGD) assessment factor (AF) approach (see <http://ecb.jrc.ec.europa.eu/TGD/>); they take no account of ambient physico-chemistry and its potential impact on silver bio-availability in the environment.

At that time, Species Sensitivity Distributions (SSD) were not used because the available ecotoxicological dataset did not contain the minimum number of taxonomic groups required by the EU TGD. There are two possibilities to remedy to this:

- a. Filling (some of) the gaps by:
 - i. Re-evaluating previously existing but excluded by the time of the first PNEC derivation;
 - ii. Evaluating recent publications; and/or
 - iii. Performing reliable long-term toxicity tests on species belonging to the missing taxonomic orders (for freshwater and saltwater), and/or
- b. Determine the bio-available fraction of (nano-forms and other forms of) silver in the environment by developing a chronic Biotic Ligand Model (BLM), addressing both nanoforms and other forms of silver.

The algal study discussed above contributes to option a.iii above (freshwater only; saltwater SSD remains difficult to establish in the absence of data⁸). Meanwhile the results of this study become available, WCA derived a preliminary long-term freshwater PNEC for silver by:

- means of an SSD using all data that is available and which meets the minimum standards required for such an assessment (not a full Klimisch *et al.* evaluation); and
- applying an AF of 5.

It showed that algae does not constitute the most sensitive indicator species (preceded by Salmonid fish, and followed by insect) and allowed to derive a tentative long-term freshwater PNEC of 10,8 ng/l. This value is only slightly higher than the current PNEC (of 8 ng/l) and quite below the most sensitive eco-toxicological data in the dataset.

WCA, EA and EA's expert peer reviewers will meet on 4 December 2008 in order to discuss the Species Sensitivity Distribution (SSD) approach and in particular, the possibility of (table 2):

⁶ Silver nano-particles are addressed in the document; there is recognition that they require separate assessment.

⁷ The draft document was included as Appendix 1 of WCA's tender for silver REACH registration continuation project (dated October 2008).

⁸ A comparison between the distributions of freshwater and saltwater eco-toxicity data for silver shows that freshwater species could be more sensitive than marine species. The application of the PNEC for freshwaters to saltwaters could be protective of these eco-systems, but probably unnecessarily stringent as well.



Table 2. Routes to be explored by WCA and UK EA when setting EQS for silver, and related potential contribution/action point for silver industry.

Possible route	To be clarified	Potential action point of silver industry
Reducing the AF of 5	This is possible only if additional data becomes available. Which data would be required as a priority?	Share (draft) results of algal study with WCA in advance of the meeting. To produce information to complete priority dataset.
Deriving the silver PNEC with reference to background concentrations and existing monitoring data	Does this refer to "natural" background concentrations? What monitoring data exactly would be required? Monitoring data obtained at manufacturing sites? How detailed should this data be? What format should the data collection follow?	Check applicability of results of GEMAS project (mapping of natural concentrations of metals in soil). Collect monitoring data following an agreed approach/format - to be announced at 3 December PMC Assembly meeting.
Taking silver's bio-availability into account, by: - developing a chronic BLM, or - using ion-selective electrodes to monitor the concentrations of silver ions in environmental samples.	BLM requires a lot of time and financial resources. Ion-selective electrodes may not adequately measure nano-forms of silver.	Explore possibility of contributing to silver bio-availability project. Need to verify how nano-forms of silver intend to be addressed in risk assessment, as compared to other forms of silver.

Annexes

1. E-mail containing Phase I report of PGM project, Phase I report of Re project, and e-mail with silver project Phase IIb dustiness and particle size report and related documents.
2. Agenda 14 November 2008 meeting with WCA/BIBRA.
3. Minutes of 4 June 2008 meeting with WCA/BIBRA.
4. C. Bourda e-mail dated 4 November 2008.
5. Brouwer, D. H. *et al.* article on "Size selective dustiness and exposure: Simulated workplace conditions" (2006).
6. Lidén, G. article on "Dustiness testing of materials handled at workplaces" (2006).
7. E. Broekaert e-mail dated 5 November 2008.
8. H. Stubberud e-mail containing results of first OECD 401 test performed by NIVA on silver nitrate.
9. Draft phase IIb HH report on bio-accessibility of silver and silver compounds in synthetic biological media.
10. Key points of phone call between M. Crane (WCA) and M. Raffray on Ag EQS.