PRECIOUS METALS AND RHENIUM CONSORTIUM
TAP & WCA/BIBRA MEETING
14TH NOVEMBER 2008 (10:00 - 14:00)
Chairperson: *Mark Raffray* (Johnson Matthey)
Johnson Matthey Technology Centre
Blounts Court, Sonning Common
Reading RG4 9NH, UNITED KINGDOM

Draft minutes

Action points on WCA/BIBRA have been market in **green**;
Action points on Consortium have been marked in **orange**.

1. Welcome and Introduction.

a. Confidentiality and competition law. All attendees agreed to hold the meeting within the limits of confidentiality and EC competition law rules.

b. Approval of the Agenda. The Agenda (Annex 1) was approved.

c. Tour de table. The list of participants is provided in Annex 1.

2. Clarification on data matrices (Objective 1 of Phase I).

a. Clarification on colour-code and templates used to compile available information per substance. One same template was used for all spreadsheets. This means that, at this stage, there was no difference made between information requirements applying to e.g.: organic and inorganic PGMs, 1-10 tonnes/year and 10-100 tonnes/year substances, or substances and intermediates, etc. These shall be differentiated as part of Phase II, once the available data have been screened for quality/relevance/applicability. WCA will send the Trustee the result of the first ("raw") data selection.[1]

When no references were identified (in Phase I) for a certain endpoint, the endpoint was highlighted in bold red in the substance-specific sheet. When no relevant references were identified for a certain substance, the substance-specific sheet was marked with "*no reference selected as relevant*".

Columns relating to physicochemical properties have been coloured in light blue; those relating to toxicological endpoints have been coloured in pink; those relating to eco-toxicological endpoints have been coloured in green (and environmental fate-related endpoints have been coloured in light purple because they belong to two separate IUCLID 5 sections).

b. Revision of substances covered (update on most recent indicative lists). The indicative list that was sent to WCA in June 2008 has been slightly updated (one additional substance, several ID codes corrected, one substance is clarified as being an intermediate, no-longer confidential entries, and ELINCS entries removed). An updated version is presented as Annex 2.

c. Clarification on how information on "out-of-scope" substances is being identified/tracked/stored by WCA/BIBRA. It was confirmed that information related to "out-of-scope" substances found during literature searches is being kept by WCA in the event the PGM project undergoes a scope enlargement or for gap-filling by read-across. This should include search ouputs from any ELINCS substances. As a reference, it was suggested to WCA/BIBRA to take a look at the PGM and Re substances that have been pre-registered so far and that are not necessarily in scope of the PGM and Re projects, as identified in a list prepared by the Consortium Scientific Manager[2].

[1] **Post-meeting note:** WCA sent all "raw data" to PM & Re Consortium on 15 Nov 2008.
[2] See http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx.

d. Overview of information identified/gathered by WCA/BIBRA:

i. Literature search: It was agreed for the Consortium to send any uncommon "key search words" to WCA/BIBRA to make sure all relevant information is identified in the databases during Phase II of the projects. As regards physicochemical properties, most of them have not yet been identified, but they may be extracted from the general reviews. So far, no specific copyright issues have been encountered by WCA/BIBRA.

ii. PM & Re Consortium Members' contributions: Consortium members have contributed with lists of available in-house studies and recommended references, the latter having usually been identified by WCA/BIBRA in the searched databases. One additional list of studies will be sent to WCA/BIBRA in order to complete the Consortium's contribution[3]. Finally, it was agreed to send WCA/BIBRA any technical specification available to the Consortium for the PGM and Re substances and to request technical specifications to Members in order to complete the submission.

e. Clarification on how information on "solid/liquid", "hydrated/anhydrous" substances was considered by WCA/BIBRA for Phase I work. So far all available information has been compiled for the data-gap analysis and no difference was made between studies reporting on solutions or hydrated forms of PGM or Re, and those reporting on solid or anhydrous forms.

f. Clarification on parameters used as reference to identify relevant endpoints (tonnage band, organic/inorganic, solid/liquid forms, etc.). So as to enable WCA/BIBRA to confirm relevant endpoints per substance: the tonnage bands need to be confirmed (as per upcoming SIEF exchanges); endpoints relevant to organic substances need to be added to the spreadsheets of the organic forms of PGM; the form(s) under which each substance is placed on the market needs to be specified by the Consortium (this information can also be extracted from the technical specifications).
"*Flammability, liquids*" should read "*Flammability*" and Skin irritancy" needs to be extended to "Skin irritancy/Skin corrosion" for the endpoints in the spreadsheets.

3. Grouping and read-across possibilities (Objective 2 of Phase I).

a. Clarification from WCA/BIBRA on underlying argument for using, in some cases, the pure (precious) metal as a reference substance for read-across to certain soluble forms. The reason why in some cases the pure metal has been put as a possible reference for read-across is due to the fact that some general reviews for these pure metals may contain information which actually refers to related compounds. It was recognised/understood that this approach does not reflect "grouping" or "read-across" possibilities as per REACH but that it provides instead, a reference to secondary literature sources from which information can be read to fill some of the gaps.

b. Recapitulation on the properties which could justify grouping/read-across possibilities (solubility, bio-accessibility, dustiness and particle size, chemical species, etc.). As per the *Guidance on information requirements - Chapter R.6: (Q)SAR and grouping of chemicals*

[3] **Post-meeting note:** The list was sent by e-mail on 17 November 2008.

(May 2008), the following parameters can be considered when building categories or groups of comparable substances under REACH:

- Ion oxidation state, molecular weight and crystalline (electronic sub-)structure/structural orientation (possibility of using molecular similarity indexes);
- Physical form and particle size/dustiness;
- Purity/impurity, composition and presence of counter-ions or typical chemical groups/species;
- Water solubility, bio-accessibility and bio-availability;
- (Bio-)Chemical reactivity, common precursors and/or breakdown/degradation products;
- Partition coefficient (e.g.: K_{ow}), vapour pressure and viscosity (typically applicable to certain organic forms of PGM).

c. **Evaluation of suitability of preliminary grouping approach for PGM proposed by TAP at 4 June 2008 meeting and identification of equivalent approach for Re substances.** At 4 June 2008 meeting, the TAP had proposed the following groups: zero valency – pure metal; soluble simple salts; complex salts (e.g.: ammine forms); insoluble compounds; halogenated compounds (e.g.: chloroplatinates); and organic forms (e.g.: Pt organic ligands). It was acknowledged at the time, that further grouping divisions might be appropriate based on parameters as indicated in these minutes under item 3b.
In the final version of the PGM and Re projects tender (September 2008, Revision 1.4), WCA suggested that around 16 categories could be identified for PGM and at least 2 for Re substances. WCA/BIBRA will submit a preliminary set of categories as an adjustment to the Phase I report before the end of November 2008 (Annexes 4 and 5). These preliminary categories will be built on the basis of theoretical considerations alone at this stage because the information compiled in Phase I has not yet assessed/screened for quality. The grouping approach will be compliant with REACH Guidance and OECD Guidance recommendations. The categories may undergo further evolution as the project proceeds, but they will be helpful in guiding the path of the project, including the approach to Phase II.

4. Potential for read-across based on previous RA experience (Objective 3 of Phase I).

a. **Identification of WCA's experiences that could be used in PGM and Re projects.** WCA/BIBRA will prepare a short statement including key recommendations on how best to prepare for REACH advocacy considering the new REACH system (Member State Competent Authorities and Advisory Committees) – with a particular focus on a potential substance evaluation (Annexes 4 and 5).

5. REACH Annex III assessment (Objective 4 of Phase I).

a. **Revision of Article 12(1)a, Article 12(1)b, and REACH Annex III criteria.** 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 are likely to meet the criteria for category 1 or 2 classification for carcinogenicity, mutagenicity or reproductive toxicity; or that are persistent, bio-accumulative and toxic (PBT); or that are very persistent and very bio-accumulative (vPvB); or

- substances with dispersive or diffuse use(s) particularly where such substances are used in consumer preparations or incorporated into consumer articles; and
- where these are likely to meet the classification criteria for any human health or environmental effects endpoints under Directive 67/548/EEC.

b. WCA/BIBRA's preliminary evaluation of substances that will not require more than physicochemical properties in their Registration Dossier as per REACH Annex III criteria. WCA/BIBRA will prepare a preliminary assessment of those substances which are unlikely to fulfil Annex III criteria and which may, as such, benefit from "lighter" information requirements (only physicochemical endpoints) (Annexes 4 and 5). This preliminary assessment will be confirmed as part of Phase II.

6. Other comments on Phase I reports.

Additional questions to clarify and improve Phase I reports will be sent to WCA/BIBRA (Annex 3)[4].
WCA currently uses REACHsuite to store information and communicate with customer consortia. WCA and PMC TAP will contact Mike Penman (Penman Consulting, developing REACHsuite) to explore the possibilities/costs involved in using REACHsuite (Annex 6).

7. Next steps, AOB and Conclusion.

a. Phase II. In order to improve the accuracy of the cost predictions of Phase II, WCA/BIBRA will work on one pilot Phase II project. This will allow determining the time requirements involved in performing a full quality-assessment and data-gap analysis of the information available on one or two representative substance(s)/category(ies). Hexachloroplatinic acid (CPA), and either Palladium or Palladium oxide[5] have been proposed as suitable (worst case/lowest hazard profile) representatives. The identification of substance categories should be quickly followed by the identification of reference/source substances which will undergo "enabling tests" (transformation/dissolution, bio-accessibility, etc.) so as to confirm similarities and trends in categories, and subsequent read-across possibilities to target substances. Intelligent Testing Strategy should include grouping into categories, and exploring/exploiting read-across and exposure/threshold of toxicological concern (TTC)[6] based-waiving potential.

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[4] **Post-meeting note:** these were sent to WCA on 17 November 2008. The adjusted reports are available as Annex 4 and 4 to the minutes.

[5] **Post-meeting note:** As palladium oxide is only an intermediate, Palladium was considered to be a better case for the pilot project.

[6] "*The threshold of toxicological concern (TTC) is a pragmatic risk assessment tool that is based on the principle of establishing a human exposure threshold value for all chemicals, below which there [only] is a very low probability of an appreciable risk to human health. The concept that there are levels of exposure that do not cause adverse effects is inherent in setting acceptable daily intakes (ADIs) for chemicals with known toxicological profiles. The TTC principle extends this concept by proposing that a de minimis value can be identified for many chemicals, in the absence of a full toxicity database, based on their chemical structures and the known toxicity of chemicals which share similar structural characteristics. By avoiding unnecessary toxicity testing and safety evaluations when human intakes are below such a threshold, application of the TTC approach would focus limited resources of time, cost, animal use and expertise on the testing and evaluation of substances with the greatest potential to pose risks to human health and thereby contribute to a reduction in the use of animals. An Expert Group of the European branch of the International Life Sciences Institute-ILSI Europe-has examined the TTC principle for its wider applicability in food safety evaluation. The Expert Group examined metabolism and accumulation, structural alerts, endocrine disrupting chemicals and specific endpoints, such as neurotoxicity, teratogenicity, developmental toxicity, allergenicity and immunotoxicity, and determined whether such properties or endpoints had to be taken into consideration specifically in a step-wise approach. The Expert Group concluded that the TTC principle can be applied for low concentrations in food of chemicals that lack toxicity data, provided that there is a sound intake estimate.*" Downloaded from: http://cat.inist.fr/?aModele=afficheN&cpsidt=15475386.

b. Phase III and IV: Exposure data collection. As indicated above, data on uses and exposure becomes necessary so as to confirm the testing strategy (Phase III) and prepare the Chemical Safety Reports (Phase IV) of those substances which require so (> 10 tonnes per year). The format under which these data can be collected was discussed; the questionnaire should be user-friendly and allow collecting the information that is required for PGM and Re (considering their low tonnages and their general low hazard profile). WCA will further refine their in-house questionnaire and the Consortium will make available to WCA, in December 2008, the sections of Eurométaux' multi-metallic questionnaire (Annex 7) that seem to be of interest to PGM and Re (as per an evaluation of J. Levison) so these can be incorporated into the final format as required. The Consortium will inform its Members on the need for such data at the upcoming Assembly meeting (Brussels, 3 December 2008).

c. Phase V. It was proposed to upload confirmed information onto IUCLID 5 so as to complete the Registration Dossiers throughout Phases II → V. Although this may be convenient for some data which can be considered to be definitive, it may not be applicable for all substances and endpoints. It was agreed that Dossier compilation should be done in the most cost-efficient and pragmatic manner so as to ensure an on-time Registration.

8. Courtesy visit of Johnson Matthey Technology Centre. The attendees participated to a courtesy visit of Johnson Matthey Technology Centre. The Consortium and WCA/BIBRA thanked Johnson Matthey for its kind hospitality.

Annexes

1- Agenda and list of attendees
2- Updated version of PGM and Re indicative lists
3- Additional questions/clarifications requests on Phase I reports
4- Phase I report of PGM project
5- Phase I report of Re project
6- Presentation of REACHsuite (Baytouch)
7- Multi-metallic questionnaire