From: KNIGHT Derek [mailto:Derek.KNIGHT@echa.europa.eu] **Sent:** Friday 7 March 2014 10:33 **To:** Violaine Verougstraete **Cc:** Hugo Waeterschoot; VERSONNEN Bram; RASENBERG Mike; NICOLAS Ronan; DE COEN Wim; DE SEZE Guilhem; MUSSET Christel; YLA-MONONEN Leena; VIRTA Tarja; FIGIEL Pawel **Subject:** Registration of metal UVCBs: follow up to discussions on 4 March

Dear Violaine,

Many thanks for the useful meeting on Tuesday, which brought together the previous discussions into a clear way forward. I can summarise the outcome as follows as ECHA's understanding of the situation (to avoid possible misunderstanding, this text has been agreed with our management as informal feedback, not official advice):

Metal UVCBs upgrade of intermediates dossiers to full registration

The priority is for the registrations to be upgraded by the agreed deadline of 30/4/14.

As a consequence the dossiers can only be of a certain standard & will have to be improved.

The 4 interlinked issues for these metal UVCBs are: (a) SID, i.e. splitting/combining substances as currently registered, (b) combining information on the metal constituents to assess the properties of the UVCBs for classification & risk assessment & (c) compiling the dossiers (IUCLIDs & CSRs) (d) legitimate access to information on the UVCB constituents.

(a) SID issues

ECHA invites Eurometaux (EM) to submit a SID plan describing the current status of the dossiers concerning the SID part in March, as far as possible with indications which registrations will be kept, merged or split with the corresponding supporting rationale. Based on the interaction with ECHA, EM is now aware that there are issues with the SID strategy taken that will require revision of the scope of the substance registrations.

ECHA has already communicated clearly general advice to EM on satisfactory SID for these metal UVCBs, so that they can have an adequate understanding of what to aim for. In view of the complexity of how these substances are produced, the guidance foresees a degree of flexibility in defining the key identifiers for the source and the process description:

- Due to source and process variability, there is considerable variability in composition (a) between grades manufactured/imported by individual registrants & (b) between different member registrants in one joint submission. This is both within member dossiers and across member dossiers in the joint submission. Due to the 'generic' descriptions used within the SIEFs for the joint submissions, e.g. multiple sources are merged there is a large % ranges for many metals constituents reported for the registered substance (e.g. 0.1-99 % Pb); although the representative compositions registered at individual registrant dossier level is in general considerably less broad (e.g. 90-95 % Pb).

- In terms of defining the scope of the descriptor & name for identifying what is considered as one substance (i.e. the 'source' & 'process'), it is important to consider the effect on the composition i.e. it may be that some feed stocks generate a comparable composition in the resulting UVCB, similarly some processes combined with source also generate comparable compositions. Note that extremely broad ranges would normally indicate that the source and process may be overly generically defined.

- The situation is made more complicated because for some of the substances, EINECS names and numerical identifiers have been used to identify the registered substance, although

the scope of the entry has been extended and the EINECS entry does not identify the registered substance. Consequently the identity of the registered substance needs clarification for transparency in terms of scope. The priority now is to get a transparent SID for the registered substances, irrespective of the old EINECS descriptors (as this would be pertinent to establishing the 'phase-in' status of the substances, which is not the matter of concern for these registration upgrades). The registrants cannot change the EC entries assigned in their registrations. ECHA may, under specific circumstances, provide the service of making such changes. However, ECHA cannot exclude that certain registrants will need to submit new registrations instead of updating their current dossiers by the agreed deadline of 30/4/14. Technical instructions can be provided later.

Taking into account the abovementioned issues, the SID plan will need to include as a minimum the following information for each substance concerned:

- Substance identity profile as originally agreed by all registrants (name, numerical identifiers, description, scope etc.) and the rationale for choice of an EC entry.

- An indication as to whether the (joint or individual) submission for the substance originally registered will be subject to a merging, a splitting, a refinement of the substance identity profile and/or a change of an EC identifier.

- The updated SID specifications (name, numerical identifiers (EC entries or 600, 700 or 900 list entries, CAS entries…), description(*), scope etc.) of each substance used to fall under the substance identity profile originally agreed and that will be subject to the planned registration update(s) or new registration(s)

  (*) The description should include the list of sources and processes covered (also links between sources and processes e.g. schematic representation of the industrial processes per metal and per technology, indicating at which step the different substances are 'created').

- Regarding the composition: clarification on how the concentration ranges were determined for the registered substance and how they reflect the actual variability in the composition (i.e. typical variation for a specific registrant vs among different registrants, 'outliers' etc.).

We assume that this information is readily available for each of the registered substances (in some cases it is published on the SIEF page), as without this information, registration the joint submission obligations would have not been fulfilled. As such, the above information cannot be considered as new information being requested – it is simply a request to make this information available.

(b)Determining the (eco)toxicological properties

There is extensive information on the metal contained in the UVCBs (EM have collected this information into a tool called 'MMD' for most but not all of the metals). The challenge is to combine this into a 'good enough' prediction of each UVCB to (a) fulfil the REACH information requirements (for a high tonnage substance), (b) for classification (EM have a 'MECLAS' tool for this) & (c) for hazard assessment, (d) for use in risk assessment for the CSR. There are

several key interrelated scientific challenges: (a) how to take account of different release, (rate & extent) of metals from the UVCB (i.e. bioavailability both regarding environmental effects & for the toxicological properties), (b) how to deal with chemical speciation (& transformation) of the released metals & (c) somehow to combine the information on the separate components for classification & hazard/risk assessment & (d) to address uncertainties & incomplete knowledge**.**

There is a knowledge gap in this field of regulatory science & therefore it has to be accepted that the April registrations will have 'first-attempt' properties predictions using the simplified methodology that EM have developed & discussed with ECHA (together with its unsolved limitations & problems).

ECHA suggests EM develops & publishes (in a peer reviewed scientific journal) a short description of their overall 'initial' approach, specifically addressing the assumptions made with the associated uncertainties & 'strengths & weaknesses' in these scientific arguments; it would be important to give an overall consideration of the consequences the 'weak links' (uncertainties & incomplete knowledge) in order to be reassured of the 'robustness' of the overall 'WoE' predictions from this methodology. A key aspect of such a methodology is the rational justification of the approach used to assess the combined effects of the released metals from UVCB substances. For chemicals with different modes of action (independently acting), there is no robust evidence that exposure to a mixture is of health or environmental concern if the individual chemicals are present at or below their individual zero-effect levels. Although there is limited information on modes of action of substances in general, prior knowledge of the chemical & biological properties of the constituent metals (or metals in general) might be useful in justifying an 'independent action' approach for this 'initial' approach for the registrations.

ECHA suggests EM could as an interim 'working solution' assess the (eco)toxicological properties of the UVCBs for the April registrations by:

- Using this 'initial' (published) methodology to combine information from the constituent metals to assess the properties of the UVCBs & to derive PNECs & DNELs

- Using information on the constituent metals from the MMD; or for constituents not in the MMD using information from published reviews/summaries, including as a 'last resort' the disseminated registration 'processed information' on classification &/or PNECs & DNELs.

- Using MECLAS for classification

Dossiers & administration

Information on the metals contained in the UVCBs must somehow be put into the dossiers. The property predictions should be presented so that the methodology is transparent & adequately documented so that a reviewer or other interested party can understand how the predictions are derived.

ECHA suggests EM submits dossiers with information on the properties of the UVCBs presented in IUCLID:

- The Endpoint Summary could be a suitable place to summarise the property prediction by means of cited references to:
    - The published methodology &
    - The information on the constituent metals used for the WoE from the MMD or

published reviews/summaries (or the disseminated including registration 'processed information' on classification &/or PNECs & DNELs)

- The MECLAS tool for classification

In addition there should be a short narrative of how the property is estimated using these referenced information & tools.

- The Summary of (Eco)Toxicological Information is a suitable place to summarise how the DNELs or PNECs are from the constituent metals are used in risk assessment, i.e. either to estimate a DNEL or PNEC for the UVCB or by examining the RCRs of the constituent metals together.

(c) Legitimate access

The registrant is responsible for ensuring they have the necessary legitimate access to information on the registered substance & should take legal advice if necessary. However, it is to be noted that (a) apparently EM have 'bought' the rights use the data on the constituent metals in their MMD & (b) only high-level 'processed information' on classification &/or PNECs & DNELs is used from published sources (reviews/summaries or as a last resort disseminated registration information) for the WoE for constituents not in the MMD.

Dr Derek J Knight Senior Scientific Advisor Executive Director's Office European Chemicals Agency Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland Tel. + 358 9 6861 8215 derek.knight@echa.europa.eu echa.europa.eu
The above represents the opinion of the author and is not an official position of the European Chemicals Agency. This e-mail, including any files attached to it, is intended for the use of the individual to whom it is addressed. If you have received this message in error, please notify the author as soon as possible and delete the message.