

Intermediates Task Force Meeting

Thursday, 24 October 2013

10h30 – 16h00

Metals Conference Centre
100 rue du Duc – 5th Floor
1150 Bruxelles

Chair: Katia Lacasse (ECI)

MAIN MESSAGES & ACTION POINTS

The attendance list, draft agenda and slides are attached as Annexes 1, 2 and 3.

1.	Introduction and approval of draft agenda The chair opened the meeting and welcomed the participants. The purpose of today's meeting was to: - provide information on on-going communication with ECHA, report on last meeting and anticipate next meeting - discuss and finalise approaches on issues identified during the development of the UVCB pilot cases
2.	Feedback on on-going communication with ECHA Timing issue Violaine explained that EM had received an informal question from Mike Rasenberg further to the annotation letters sent out by ECHA last year, to which several companies had replied explaining that Article 10 dossiers were under preparation; these were submitted Q3 2013. ECHA noted that companies under the EM umbrella had not sent in any dossiers, and requested an informal chat with EM before proceeding. Violaine had replied to ECHA summarising activities since last year and interactions with ECHA (on SID, classification, formatting issues). In parallel, Hugo met Christel Musset (ECHA), who gave the following answer to our status report: EM and ECHA will have a final meeting to discuss inorganic UVCB assessment in early 2014, after which companies will have exactly 3 months in which to submit their registration dossiers. The priority now is to fine-tune the remaining issues within our approaches and to finalise the dossiers for submission. Further updates might still be necessary, but it is important to recall that dossiers need to be submitted by the deadline set by ECHA. Overview of exchanges with ECHA Federica gave a concise overview of our meetings with ECHA on the inorganic UVCBs assessment and follow-up actions (Slide 4): • After the SID meeting in January 2013, EM provided ECHA with a note aimed at facilitating regulators' understanding of inquiries relating to inorganic UVCBs. ECHA's response was to request additional clarifications and examples, and EM provided further input. We are now waiting for feedback from the ECHA experts; • After our IUCLID/Chesar-formatting issues meeting in June 2013, ECHA informed EM that it

	was interested in cooperating with inorganic pilot cases for the further development of IUCLID and Chesar. The details/modalities of this collaboration still need to be defined; • After the October 3 meeting on the classification of inorganic complex materials and the presentation of the MeClas tool, ECHA requested a last meeting to discuss the overall approach on inorganic UVCBs chemical safety assessment. A more detailed report was provided on the meeting held on the classification of inorganic complex materials and MeClas (October 3). The meeting was attended by ECHA experts from the classification, substance identification and evaluation Unit. ECHA reacted positively to the tool, including in respect of its scientific assumptions and calculations. It did, however, express some concern about the way in which registrants might use (or have used) the tool: some key questions debated during the meeting related, in fact, to how to prevent misuse of the tool. A number of key issues were discussed in greater depth; these require further actions to ensure the transparency of the tool (Slides 7-10). Some actions are characteristically relevant for the MeClas Steering Committee (who held a confcall on October 23), while others are important for the activities of the task force and recommendations to registrants. In particular, the following issues need to be directly considered by the Intermediates task force: • In our internal Guidance on inorganic UVCBs -under development- it will be important to clearly explain that the classification is based on a tiered approach, where worst-case assumptions are taken initially (i.e. worst-case speciation) and then refined, according to available information. • MeClas output does not at present include so-called “in-between calculations”: in order to enhance the transparency of the results, MeClas could enable such information be included in the output sheet, and it is recommended that registrants include such overviews in the registration files. • Composition variability and how this is handled in MeClas was extensively debated during the meeting, in order to align on a possible ‘harmonised’ approach to assess typical concentrations. Details of this are reported further in the minutes under item 3: <i>Practical UVCBs assessment issues</i>, and will also be included in the Internal Guidance on inorganic UVCBs. The following topics were also discussed: • Multi-Metallic Database (MMD): ECHA inquired whether authorities could obtain access to the database. This raises the need to further reflect on access to MMD with the REACH Forum: there is a need to remain constructive and consider that MMD shows that we have access to data • Unit World Model (UWM): launch publications on UWM (UWM task force) to work on its regulatory acceptance • Combined toxicity: it was noted that additivity would most probably put all scenarios at risk. It was suggested to include a placeholder in the cases developed /dossiers submitted and refer to the approaches/research as currently developed, exploring e.g. what is happening at NOECs, PNECs level, etc. The common placeholder could take the form of a joint industry statement on on-going work research. Action: EM to draw up and circulate a draft (Katrien will help) During the meeting, ECHA pointed out several times the need to make the link between MeClas input/output information requirements and the overall CSA process. In practice, it now wants to
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	see the entire CSA reasoning, with all the issues that we have been explaining up to now being put together. It recommended that a meeting be requested in writing, and we are now in the process of finalizing a date. In principle, the meeting will take place in the second half of January 2013, and will represent the conclusive meeting of the inorganic UVCBs assessment exercise. Pilot cases are expected. More details regarding the structure of the meeting will be communicated to the task force as soon as the date and the agenda have been fixed. Agreed actions: • Update the Guidance based on MeClas meeting input • Follow up MeClas updates with the MeClas Steering Committee (on-going) • Draft a joint industry statement on on-going work/research on combined toxicity to be included as placeholder in dossiers. (EM with Katrien D. support)
3.	Technical work The technical work currently on-going was discussed during the meeting, keeping in mind the new deadline for submission of the Article 10 dossiers and the remaining issues to be resolved before the next meeting with ECHA. The following aspects were discussed: • <u>Status of the pilot cases</u> Three main pilot cases are under development by ECI, ILA and EPMF. Daniel Vetter presented a scheme that summarises the overall assessment approach as debated in the previous meetings (Slide 16). The scheme aims to illustrate the main steps to be followed when assessing an inorganic UVCB substance: substance identification and composition information are the initial steps that further lead to the hazard / exposure assessment and risk characterisation. The main message is that assessing an inorganic UVCB actually requires combining <i>n</i> risk assessments in the same registration dossier, for the <i>n</i> UVCB constituents. The scheme was extensively debated, and a couple of amendments were suggested to ensure that it will best reflect the several assessment steps. The following suggestions were taken up to update the scheme (see Annex 4) The process/source information circle is linked directly to the Substance ID step: ○ Composition information circle is then linked to the specific composition (Me + Me speciation) ○ Classification and Hazard Identification are run in parallel ○ Between Threshold derivation and Exposure assessment, it is important to ensure that the information flow goes in both directions ○ The scheme will be included in the internal guidance chapter, and explanations will be given for the various boxes/tools (e.g. MMD, Mease, Monitoring data) Agreed actions: update the RA scheme (see Annex 4 for an updated scheme reflecting already major comments collected during the meeting) • <u>Internal Guidance</u> Some input had been received from Euromines. Further updates foreseen for the coming weeks were highlighted: The feedback from Euromines focuses on the ‘political’ need to ensure that the inorganic UVCBs to which we refer are not comparable with ores and concentrates UVCBs for which exemptions exist for registration and on which it would not be opportune to have

additional official guidance. In order to underline this, a reference to existing Annex V exemptions, together with a few additional refinements, has been added to the internal Guidance.

- Some updates are foreseen; these will be included in the Guidance based on the classification of inorganic complex materials and MeClas meeting.
- In addition, based on the work progressing on the pilot cases, the RA chapter is undergoing refinement. The Guidance and RA chapter will shortly be re-circulated within the TF.

It was noted that the members of the task force who are now deeply involved in the development of the pilot cases might require more time in which to provide feedback.

Agreed actions:

- ***Update the Guidance based on MeClas meeting input (Federica)***
- ***Update RA Chapter with schemes (Federica)***
- ***Circulate Guidance and RA chapter (Federica - November)***

- ***IUCLID Template***

It was pointed out that it would have been relevant to harmonise the IUCLID entries while developing the Internal Guidance, where possible. At the start, a provisional IUCLID SOP document was developed, but it did not seem to be an ideal way of sharing common entries. An IUCLID template was therefore opted for as the best tool to fulfil such needs. The template is intended as a user-friendly source of generic statements for inorganics and a good basis for further completing substance IUCLID dossiers starting from pre-filled-in/partially pre-filled-in entries.

More specifically:

- the template covers IUCLID Sections 4, 5, 6, 7
- the template does not include metal-specific information or attachments
- IUCLID Sections 4, 5: waivers that are generically applicable for inorganics are reported for the entries in IUCLID Sections 6, 7: pre-filled-in box information in these sections is related to the inorganic UVCBs IUCLID approach proposed within the task force. A common text on endpoint summaries is provided (i.e. explaining that UVCB's assessment is based on the effect assessment of constituents). A common text on robust study summaries is reported for MeClas entries, and justifications are provided where MeClas entries are not required.

The IUCLID template was circulated at the beginning of October, with the consultants and consortia running the pilot cases. The consultants tested the template and provided some feedback prior to the meeting, which served as a basis for reporting on the template. Some further feedback was received during the meeting:

- It is important to ensure that the text is generic enough for the different specific situations
- How to report multiple classification grades was debated. Possibilities were to: a) report all grades in the same MeClas entry, or b) create additional MeClas entries for each grade. Option b) was chosen as being more transparent. An example will be included in the IUCLID Template to facilitate understanding
- It was recalled that naming of the entries needs to be handled carefully in order to limit formatting issues (advice given by ECHA at the June meeting): consequently, in the case of multiple grades, one simple naming should be identified, which will be preliminarily proposed in the updated IUCLID template
- A few specific items reported in the discussion box for MeClas entries were debated and will be included in the updated template, e.g.:

	○ terminology: avoid 'reference sample' in UVCBs discussion ○ based on discussion held during the MeClas meeting with ECHA, ensure that the description includes information on applicability of the tool (i.e. similar assumptions as when validating QSAR results) Note: it was recalled that information on target organs is relevant when dealing with combined toxicity, and that data are directly requested from the multi-metallic database contributors so as to allow for combined toxicity assessment Agreed actions: • Update the IUCLID template and recirculate it within the TF for final feedback (Federica) • Check whether a second IUCLID template including metal data from those metals that have already signed the data-sharing agreement (DSA) with ECI/ILA and EPMF can be created to allow for quicker IUCLID compilation of information (Federica) • Prepare a short note to explain how to import the inherited template in order to allow several summaries in the substance IUCLID dossier and circulate it with the updated IUCLID template (Federica) <u>Practical UVCBs assessment issues</u> A number of issues still need to be discussed to allow a consistent approach in RA. 1) <u>Concentration ranges</u> As anticipated during the ECHA meeting on MeClas, it is not clear whether registrants use typical or maximum concentrations when reporting constituent information. Based on practical experiences, consortia/consultants receive information on: - range of concentration (max/min) - average concentration (medium, median, how many samples? not known) - typical concentration (unclear definition) Frederik suggested that a distinction be made between the information on concentration used at consortia and at company level. This could also be helpful with respect to ECHA's concerns on MeClas use. At consortia level, it is suggested to take the maximum of typical concentrations and to take the maximum of the cut-off limits ('realistic worst case') for the risk drivers. This information will be included in the MeClas manual. At company level, and in order to avoid inconsistencies and situations where unrealistic worst-case classifications are used, it was suggested to: - Clarify which concentration is selected in MeClas (make a link between MeClas input and what is reported in IUCLID) and link it to the registration. - Since companies can run different analyses on which concentrations are based, it is reminded that specific information on concentration content be entered in IUCLID in Section 1.4 (analytics) and Section 1.2, using the "remarks" field. - Provide companies with some guidelines on how to report composition ranges: i.e. best practices across industry as based on the requests/questionnaires that ECI/EPMF/ILA/IZA have already used to retrieve such information. Provided consortia share these documents with EM, an updated definition on concentration and recommendations will be drafted by Federica and given back to consortia in the form of guidelines for members. - It has been largely debated whether it would be advisable to set up MeClas in such a way that a minimum concentration percentage would be necessary to give reliable results. It
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	was decided to add the sum of the elemental concentrations to the MeClas output summary. It is up to the MECLAS user to justify why, for example, 100% was not reached or, for example, to indicate that a worst-case classification was obtained because the sum is significantly larger than 100%. No consensus was reached to take further actions on the tool. Agreed actions: • Recommendations as to the concentrations that it is suggested the consortia should use when calculating classification will be reported in the MeClas Manual (Frederik) • An updated definition on the concentrations to use and recommendations will be drafted by Federica and given back to the consortia in the form of guidelines for members, provided that the consortia share guidelines previously sent to companies on how to report composition ranges. If provided by end of November, Federica will update definitions and recommendations the by end of 2013. 2) <u>Waste stage for intermediates</u> Article 3 (15) defines an intermediate as “a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance(s)”. This means that intermediates are not present in the final manufactured substance (except possibly as an impurity). Consequently, an assessment of the waste stage is not required, but a rationale is needed. It is proposed to draft and circulate a common statement that can be used by the inorganic UVCB intermediates’ assessment. Agreed action: • The rationale for UVBCs waste assessment will be finalised by Federica and Frederik and circulated within the TF in the coming weeks. 3) <u>IUCLID 3.7</u> We are aware that IUCLID Section 3.7 on ES is not yet mandatory. Furthermore, it is not suitable for multiple constituent entries. Information differs as to when it will become mandatory: - Inneke Claes reported that, during ECHA's regular calls with sectorial stakeholders on registration, it had mentioned that IUCLID 3.7 would become mandatory after the launch of IUCLID Version 6.1. Christine Spirlet reported that this section might not become mandatory before summer 2014 - Daniel also reported that this might not be an issue for this registration, but that we would need to follow it up carefully, as it will have a big impact on the multi-constituents approaches on which we are working Note: further collaboration on formatting tools and issues is foreseen with ECHA (as also reported previously), but the timing has not yet been defined, and considering that Article 10 dossiers need to be submitted in the next few months, the launch of this project with ECHA might well be delayed.
4.	AoB ECl, ILA and IZA reported the status of the on-going data-sharing activity. Overall, the following list of metal consortia have responded positively to the data sharing

	agreement finalised during the summer: - ILA: Pb - ECI: Cu - EPMF: Ag - IZA: Zn, Cd - IZA: Sb - Nickel Institute: Ni - As - Te/Se For substances such as Mn, negotiations have been launched by ILA and are still on-going. CoRC took a different stance, announcing that an administrative fee of £ 5000 was requested to retrieve Co data! The task force expressed disappointment regarding the CoRC's position. The latter explained its approach as follows: there is no charge for the data itself, but an Administrative fee is payable to CoRC. The reasons for this are that: (i) it allows it to recover costs incurred (it had to ask its lawyers to develop a new data access agreement for the UVCB case, as it did not agree with the Data-sharing agreement drafted), (ii) it supports the REACH Forum's approach to free data exchange "in principle", and (iii) it is consistent with their existing approach to data access agreements (i.e. License to Use), which includes an admin. fee, plus the data purchase costs. Unfortunately, it was expected that in some cases negotiations would be even more difficult (e.g. Mn), and overall the consortia were prepared to pay an acceptable fee if this was unavoidable. Further information was shared in order to pinpoint the best contact persons for other inorganics data (e.g. chromium, borates, mercury...) that are needed in the UVCB dossiers. Agreement on data gaps: it was agreed to report in IUCLID only data on which we have clear agreement, and the rest in the CSR the.
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Annex 1: Attendance list

Annex 2: Draft agenda

Annex 3: Slides

Annex 4: Risk Assessment scheme

Summary table of agreed actions:

What	Who	When
Update the UVCBs Guidance based on MeClas meeting input	Federica	November
Follow up MeClas updates	MeClas steering committee	On-going
Draft a joint industry statement on on-going work/research on additivity (combined toxicity) to be included as placeholder in registration dossiers	EM with Katrien Delbeke support	Asap
Update the Risk Assessment scheme	EM, Daniel Vetter and Frederik Verdonck	Done, see Annex 4
Update the Risk Assessment Chapter with schemes	Federica	November
Circulate the internal Guidance on UVCBs and the Risk Assessment Chapter	Federica	November
Update the IUCLID template and recirculate it within the TF for final feedbacks	Federica	Asap
Check whether a second IUCLID template including metal data from those metals that have already signed the data-sharing agreement (DSA) with ECI/ILA and EPMF can be created to allow for quicker IUCLID compilation of information	Federica	Asap
Prepare a short note to explain how to import the inherited template in order to allow several summaries in the substance IUCLID dossier	Federica	With the IUCLID Template
Recommendations for consortia: report how consortia are invited to select concentrations to derive classification. To be included in MeClas manual and internal Guidance on UVCBs.	Frederik	By end of the year
Provide EM with guidelines previously shared with companies on how to report composition ranges	Consortia	By end November
Update definition on concentrations to be used and recommendations, based on guidelines previously developed by Consortia	Federica	By end of the year – provided consortia deliver information by end November
Develop a common rationale for UVCBs waste assessment and circulate it within the TF	Federica and Frederik	Asap