



Refinables Work Group Webinar

Minutes, 21 April 2020 (11:00-12:30 CET)

Chairs: Sylvaine Duarri D'Haene (Umicore) and Daniela Cholakova (Aurubis)

Actions	Who?	When?
AP 1 – update monitoring data and EA <ul style="list-style-type: none">- Specify/Identify number of sites and new monitoring data- Check need SCC intermediates to upgrade?	AV + members	End of April 2020
AP 2 and 4 - update and distribute + organize sub-WG meetings to review and finalize Refinables substance ID packages including for Material for reclaim dossier	AV	May 2020
AP 3 – send invoices (or provide estimate costs) to EPMF for reimbursement of costs of the sample(s) and shipping expenses	Test sample providers	End of April 2020

1. Welcome and Introduction

1.1. Reminder on Confidentiality and Competition Law

Participants are reminded on their obligation to comply with Confidentiality and Competition Law.

1.2. Tour de table and apologies

The list of participants is available in Annex 1.

1.3. Approval of the agenda

The agenda is approved as distributed and is available in Annex 1 and on slide 4 in Annex 2.

1.4. Approval of the minutes of last meeting (B2B, 10/03/2020)

No remarks/additions; minutes of the meeting of 10 March 2020 were approved.

2. iUVCB platform

The UVCB platform is a first action point resulting from MISA 3. The modalities of the platform were distributed together with the minutes of the previous WG meeting on 17 March 2020.

Because of questions regarding the extent of the platform tasks and the minimal dossiers requirements the general multi-metallic refinements lined out in MISA 3 were listed (slide 8, Annex 2). These are linked with the requested improvement of the transparency of the methodology and data selection, the consistent data reporting of the different dossier steps and an alignment with the CSR (upcoming revised TCC



requirement). Any additional dossier refinements (e.g. Chesar, update monitoring data) fall outside the general tasks of the platform and should be requested separately.

The platform finalized its initial screening of all registered Art.10 dossiers in its work package. Quality scores were given to each dossier step reflecting the platform effort needed for its update and linked to weighing factors for cost sharing calculation (slide 9, Annex 2).

Note: The quality screening was done on completeness not on content of the dossiers but the UVCB platform will communicate content issues deemed possible insufficient for smooth registration submission (e.g. poor substance manufacturing description) to allow consortia to evaluate and refine these.

The result of the screening of all 45 existing Art.10 dossiers in all 5 consortia illustrates an overall good quality of the different dossier steps (slide 10, Annex 2).

Specifically for EPMF, screening of the 10 registered Art.10 dossiers similarly results in a good quality level of the different dossier steps (slide 11, Annex 2).

Details of the quality score assignment of the different dossier steps of the EPMF registered Art.10 dossiers are available in slides 12 and 13, Annex 2.

EPMF has in total 19 Refinables in its portfolio (slide 14, Annex 2). Ten Refinables dossiers will be updated/refined and 4 split and 2 new dossiers will be prepared. Cost calculation for split dossiers follows a calculation key based on the quality of the parent dossier and an additional platform effort to update incomplete dossier steps. For totally new dossiers a fixed cost to prepare the complete registration dossier is foreseen. 2 new dossiers preparations are requested. EPMF will re-check the registration interest for the Fe bullion, PGM rich substance and ask the UVCB platform to screen within other consortia for substance sameness before initiating a substance inquiry for ECHA. One of the solutions from PM leaching and dissolution is considered as new since split from an SCC Article 17/18 dossiers. The second solution substance will be considered as a split of the newly prepared good quality dossier.

Based on this screening the total cost for updating/preparing 16 dossiers (10 updates, 4 splits, 2 new) according to the minimal UVCB dossier requirements is 136.400 €.

The screening exercise showed a good quality of existing dossiers. The exercise to work on all the dossiers in parallel under the iUVCB platform demonstrated already good efficiency on a time and resource point of view.

Note: Currently presented/summarised as quality per dossier step or total dossier quality per substance the UVCB platform will also distribute/communicate the detailed screening results of the quality of each dossier step per substance.

In addition, EPMF will perform an update of emission/exposure monitoring data and Chesar implementation. For this, proposals have been received from Arche (ENV) and EBRC (HH) that will be refined upon information/confirmation of the WG members on the provision of new monitoring data and the number of sites. Members with SCC intermediates can join the EA/RA if their Article 17/18 dossiers would need to be upgraded to Article 10 dossiers **(AP 1)**.

3. iUVCB MISA 3

The aim and current status of MISA 3 is summarised on slide 17, Annex 2.

The iUVCB assessment approach is approved but a remaining issue is the reporting of the hazard data.



Our current AE 'upper summary' approach, reporting upper study summaries comprising AE key hazard data only (hazard conclusions & effect values (Kd/BCFs/PNECs/DNELs)) is not legally compliant and should, based on legal text, be replaced by providing all information (robust study summaries, RSS) of all AEs.

ECHA admits that this is not workable for iUVCBs and agreed to evaluate/consider a 'lead' AE robust study summary approach reporting full data sets (RSS) for 'lead' AEs and upper summaries (key data only) for all other AEs. Eurometaux provided ECHA different possible 'lead' AE identification options using the EPMF Slags, doré furnace example.

ECHA came back on this and asks Eurometaux to work out the hazard assessment-based approach for identifying lead AEs. This approach is aligned with the LCID (Lead Component Identification) methodology principle developed by CEFIC. The EPMF Slags, doré furnace IU dossier will be prepared comprising full data reports of the 'lead' AEs and upper summaries for the other AEs. This dossier will be evaluated (TCC and ECHA evaluation unit) before formal reporting agreements can be made and new data sharing agreements strategies can be set up.

4. EPMF Refinables

Tasks and activities of EPMF are the delivery/gathering of all information/data/studies for the UVCB platform and dossier registrations.

Update testing

Testing is foreseen:

- to include analytical data reports supporting the elemental and mineralogical/speciation information of the generic/boundary composition in all JS dossiers.
- for all Annex VII-X phys-chem data point requirements of the split dossiers
- to fill phys-chem data-gaps and replace expert judgement waived endpoints in registered dossiers

All CRO's are contracted, representative test samples have been or will soon be send and all data is expected by the end of July.

Status substance identity

The refinement of boundary compositions, update of flowcharts (visualising the manufacturing/sources/life cycle of the Refinables) and drafting of substance sameness (SIP) and ID cards by EPMF is ongoing.

Current Refinables names and EC descriptions need to be re-evaluated by EPMF and the registrants for consistency with ECHA requirements/rules. Main points to look at are substance manufacturing descriptions and whether EC descriptions adequately reflect the substance (e.g. for split substances).

To enhance efficiency all substance identity documents per Refinable (SIP, ID card, flowchart, ...) will be, once updated/drafted, distributed in 1 package for review. EPMF will organize sub-WG meetings among registrants shortly after distribution of this information to discuss and finalise all documents **(AP 2)**.

5. Budget 2020 status

The outcome of the iUVCB platform screening and refinement/finalisation of some contracts allowed a refinement of the 2020 budget status (slide 24, Annex 2). The MISA section includes the iUVCB platform



refinement/preparation of the Refinables dossiers and the update of monitoring data and exposure scenarios (part 1 of update EA and Chesar). The REACH dossier maintenance budget comprises all testing (analytics, phys-chem and TDp) and a conservative estimation of sample values and shipment expenses. Test sample material providers are kindly reminded to provide information (invoices or an estimation) on these costs to allow final refinement of the budget for presentation to the Board beginning of May **(AP 3)**.

6. Draft budget 2021

The 2021 draft budget was presented. It comprises the implementation in Chesar and refinement of cRA (part 2 of update EA and Chesar) and a contingency budget for unforeseen/unexpected tasks linked with the final dossier submissions. Not included is a budget for the LtU agreements as to early and unpredictable to estimate. No comments have been made by the participants. **A budget of 147.000€ will be proposed at the EPMF Board.**

7. A.O.B.

EPMF will send a doodle poll to fix a new date to discuss among the registrants of the Materials for Reclaim substances the status/naming and description of these Refinables **(AP 4)**.

List of annexes

1. Agenda & list of participants
2. Presentation