Inorganic UVCBs Platform

1. Aim of the Platform

The Platform aims at harmonizing, avoiding duplication and aligning the iUVCB dossiers, to ensure consistent and coherent updates and refinements. The Platform is in charge of the dossiers technical refinements (i.e. covering the multimetallic nature of the dossiers) , whereas the full responsibility of the dossiers submission remains with the consortia. Annex 1 provides the background that led to the setting up of this Platform.

2. Mandate of the iUVCBs Platform

The iUVCB Platform represents all the consortia that have signed the MISA agreement and need to update or submit Article 10 dossiers for their iUVCBs. The current list of consortia includes: ECI, EPMF, ILA, IZA and Nickel Institute. Annex 2 provides the overview of the existing iUVCB substances covered by the Platform. For these susbtances, the Platform will screen, develop and implement all the needed multimetallic refinements and ensure smooth submission of the LR dossiers. Any substance specific assessment which might be considered relevant will fall under the responsibility of its consortium and might be subject to further contract agreement with Eurometaux or with the Consultants.

3. Structure of the iUVCBs Platform

The Platform will be organized such that each of the aspects related to the iUVCB dossiers submissions will be fully handled, completed and duly communicated to participants. To reach these objectives, three main areas of work have been identified and referred to as the three pillars of the iUVCB Platform, each having its specific expertise and objectives:

- **Administrative Working Group** dealing with costs/data sharing
- **Technical Working Group** responsible for finalizing/developing the iUVCBs dossiers
- **Coordination Working Group** taking care of dossiers' submissions.

The Working Groups will work under the responsibility of Federica Iaccino and their tasks descriptions are available in Annex 3.

4. Timing, resources and budget

4.1 iUVCB Substances already listed in MISA and having Article 10 dossiers

45 substances have been registered as Article 10 dossiers in 2014 and are listed under MISA. Since their submission, consortia have been working on updates and improvements following the exchanges and the informal agreements reached step by step with ECHA. The regular exchange with ECHA during the past years led to several improvements in the dossiers' explanations to meet Regulators' expectations. When preparing for the 5th November 2019 iUVCB MISA workshop, the SATs completed by each consortium showed a high level of understanding and commitment in the improving of the iUVCBs dossiers. During the workshop itself, specific formal agreements have been reached and listed in the minutes, to ensure complete explanation of the iUVCB assessment methodology, of the data selection in the dossiers, on what needs to be reported in each

section of the chemical safety report and IUCLID dossier. These agreements identified a general need to improve reporting in the existing dossiers, which describes the ultimate goal of the Platform, i.e. ensure consistency across dossiers to reach **as a minimum the same level of methodological explanation, formatting and reporting**, meaning that all dossiers with tonnage bands above 10 tpa will be refined equally. This was confirmed by the SATs. An overview table listing SATs information is available on request.

In order to develop and include the updates required by ECHA, the Platform would pragmatically work on all substances simultaneously, ensuring absence of work duplication and consistency in the assessment's steps such as to provide final updates by the end of 2020 / beginning of 2021.

The following Table 1 provides an overview of the full time equivalent (FTE) estimation prepared from Arche Consulting and EBRC to update **all 44 iUVCB existing dossiers**. Additionally, exposure scenarios developments in Chesar and new substances/ assessments can be further included in the offer upon agreement with the involved consortia and on a bilateral basis.

Costs are established to ensure fair and transparent sharing depending on the level of completeness of the iUVCB dossiers. As the quality of the dossiers can differ depending on which parts of the dossiers is assessed and because the aim of the Platform is to ensure a minimum set of harmonization across the dossiers (i.e. ensure that all the dossiers joining the Platform are harmonized and consistent), we have defined what 'must be done' on each dossier, assigning for such tasks an initial fixed contribution per substance. The 'must do' tasks are two:

- each and every substance being listed in the Platform activity will undergo an **initial screening (i.e. fixed 600€/substance)** to identify and evaluate available information in light of the latest MISA-development. The substance screening goes beyond the SATs outcome, as it allows to be more precise on the gaps/refinements by providing an overall 'quality factor' Qi to each assessment step (being substance identity (SID) and Classification (CL); hazard assessment (HA); Exposure Assessment (EA) and Man via the Environment (MvE)). The outcome of the screening phase will be a list of screened criteria with indications on refinement needs under SID&CL, HA, EA&MvE steps and will result in a quality factor assigned to each of these assessment steps. The quality factors are in turn translated into weighing factors (from "0= no need of refinement" to "1=major effort expected") to allow **weighing the substance contribution for each specific assessment step**.

AND

- each and every substance dossier will be updated ensuring overall harmonization of dossiers reporting as crucial part of the assessment **(i.e. fixed 3000€/substance)**. This will ensure reaching a **minimum set of refinements** in the combined risk assessment Tiered approach, in the iUVCB uncertainty analysis and in the overall CSR/IU technical dossier.
  Note: *for those dossiers that have been updated after 2018, the IUCLID/CSR dossier harmonization is expected to be lower and effort/costs refinement will be evaluated.*

In practice, there will be an initial fee of 3600€ per substance, complemented with a specific contribution to refine SID/CL, HA and EA/MvE (using the weighing factors assigned to each substance in the screening phase). Details and examples are provided in ANNEX 4.

Substance Identity (SID) & Classification (CL)	Hazard Assessment (HA)	Exposure Assessment EA/ Man via Environment (MvE)	Combined Risk Assessment (cRA)	Uncertainty analysis	IUCLID Templates & Chemical Safety Report (CSR) development/update	Project management /meetings	Total (**for all 45 substances**)
An overall effort of 50 FTE days* is to be considered to finalise SID/CLA Refine SID across registrations. Classification will be checked for harmonisation of methodology and reporting *Should any mineralogical tests (or others e.g. TDP) needed, this will be organised via consortia and could affect timing.* *Should consortia agree to include name refining in this task, the overall effort under this task would be of 50 -60 FTE days.	An overall effort of 30 FTE days is anticipated for ENV. An overall effort of 30 FTE days is anticipated for HH. -AEs identification -AE justification of what we do not consider -AE/RSS selection (depending on ECHA's decision) ➢ Arche: ENV ➢ EBRC: HH	30 FTE days (ENV) + 45 FTE days (HH) to refine site specific, set 'typical conditions of use', generic text, … for the manufacture/use at industrial sites, when possible, otherwise maintain/improve current description of specificities ➢ Arche: ENV ➢ EBRC: HH *Note: following the REACH Intermediate TF decision, MvE will currently be based on parent dossiers assessment.*	5-10 FTE days (ENV) and 10 -15 days (HH) to harmonise existing assessment are expected. *For iUVCBs which have not been yet assessed for their cRA, about 5-10 days/substance can be accounted to develop industrial uses ESs and cRA.* ➢ Arche: ENV ➢ EBRC: HH *Note: a specific Chesar development offer will be prepared for those consortia requiring it.*	5-10 FTE days (ENV+HH) to develop a generic explanation on the iUVCB assessment approach and how this would overcome uncertainty (analysing each pillar). *However, for the risk assessment of workers additional efforts are required per substance. It is needed to check whether the parent dossiers cover the industrial processes and related physical forms as relevant for the individual iUVCB. 1-2 FTE days (HH) are anticipated for such tasks per substance.*	An overall effort of 50 -100 FTE days is to be considered to update the CSR (0,5 to 1 day per substance) and prepare the AE IUCLID template (1-2 days per AE)	40 FTE days (Arche and EBRC)	295-360 FTE days for all the substances or 305-370 FTE days (when naming refinement is included) *Note that additional substance specific efforts could be further added, as explained under substance identity, combined risk assessment and uncertainty analysis*

Table 1. Overview of FTEs needed to update existing iUVCB dossiers. (HH: human health; ENV: environment)

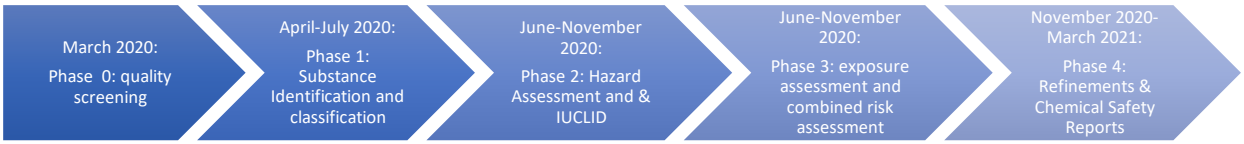
Short tasks description:

- SID & CL: Verify and harmonise substance identification for all iUVCBs in the Platform: the SID/SIP finalization step will be utterly crucial to define whether all iUVCBs have been correctly identified with their decisive/indicative criteria and whether any amendments in the existing registrations is to be considered across consortia to improve consistency. This will also allow to set good basis for any new iUVCB, facilitating assessment for joining existing registration dossiers. Ensure transparency between SID and Analytical analysis/Expert Judgment. For Substance Identity Profile: harmonise 'decisive/indicative'

constituents' identification in the EM Template. Run the exercise for all substances in the Platform such to ensure consistent approach. Prepare summary table with all constituents in elemental and mineralogical form and ensure consistency with IUCLID reporting. This table is further completed with CL and HA columns to identify which species are considered for CL and HA if unknown in composition. MeClas has been widely used, but some explanations on the constituents' species selected or the interim MeClas calculation extracts might still need to be extracted and included in the dossiers. Evaluate the need for multiple boundary compositions to report different classifications. Complete SID table to list how uncertainty in speciation was tackled when deriving classification

- HA: Define assessment entities (AEs) list to support hazard assessment across iUVCBs and ensure consistency across all substances (i.e. to identify *the* critical data to report in the dossiers and create a sort of 'template shop' for all 'major constituents' of the the iUVCBs to use, with data sharing rules defined by the Administrative working group). Complete the SID/CL table to show which constituents' speciation is selected for HA when unknown in composition (i.e. assessment entities, AEs) & justify why specific constituents are not assessed. the AEs set of data. Note: the AEs work is strictly linked to the Multi-metallic Database update, aiming at increasing data availability transparency and facilitating data screening, reporting and exchange.
- EA: harmonise exposure assessment refining the site-specific assessments (i.e. having # site specific data set, based on site specific monitoring/emission data wherever possible) and completing them with more general conditions of use and Tiered approach justifications. Include mass flow analysis information and indicate volume/percentage going to industrial use and to professional or consumer use (when applicable).
- cRA: harmonise explanations for cRA reporting and developing it when needed. Note: this step would be substance specific.
- Uncertainty Analysis: prepare a position paper on the uncertainty in the iUVCB risk assessment when applying the constituents approach (i.e. based on several levels of conservativism in each step of the risk assessment) compared to when applying a regular substance specific approach. Substance specific assessments analysis can be further developed for workers to complete the uncertainty assessment.
- Note: name refining is proposed as based on available information. Aim of the platform is to harmonize naming refinements as requested by ECHA and will do so with a multi-metallic approach. However, should the naming update proposal result in substance specific exchanges with the consortia members to face e.g. confidentiality issues, further discussion and final amendments can be done via consortia directly.

The Platform for the 45 existing dossiers aims at starting the work during January 2020. Consultants will start working on the iUVCB dossiers such to screen and finalise the SID, Classification and hazard assessment before the summer months. Once the hazard assessment task is finalized, the exposure assessment and combined risk assessment refinement/development can start. The aim is to complete the iUVCB dossiers' refinements by first months of 2021.
Here below an overview of the sought timeline is given:



However, for those substances requiring the generation of additional data (e.g. mineralogical or TDP) or the development of combined assessment, additional time might be necessary and will be defined in the first half of 2020. Coordination of these additional tests will not be carried out by the Platform, but will remain under the responsibility of the consortia.
A contract will be signed between Eurometaux and the consultants to cover the Technical Working Group activities. An agreement will be signed between Eurometaux and each Consortium Secretariat for the specific contribution and thus workload (as defined in the administrative working group and mainly based on the number of substances to update), to ensure proportional costs sharing between participants.

4.2 iUVCB substances that have not yet been upgraded to Article 10 dossiers

Some consortia inquired Eurometaux about the possibility to open the Platform to additional substances, which are not part of MISA and have not been upgraded as Article 10 iUVCBs yet. For these substances (about 19) analytics, physico-chemical testing and exposure data are not fully available yet. Preparing these dossiers will be more complex than refining existing ones and therefore their tasks estimations can only be given on substance basis: however, it is important to highlight that when the Platform assesses any 'new' iUVCB, consistency and efficiency will be boosted thanks to the parallel updates ongoing on the existing iUVCB dossiers.

The following Table 2 provides an overview of the full time equivalent (FTE) estimation prepared from Arche Consulting and EBRC to cover the expected workload per substance. Note that additional exposure scenarios developments in Chesar can be further included in the offer upon agreement with the involved consortia and on a bilateral basis.

4.2.1 iUVCB substances that have not yet been upgraded to Article 10 dossiers and are resulting from splitting of Art 10 dossiers

Consortia have indicated that during the refinement of some of the existing Article 10 dossiers, some split were identified. For these substances, a similar approach as for Art 10 substances is used:

- a screening phase **(i.e. fixed 600 €/substance)** is anticipated for each and every 'new' substance deriving from an Art 10 split dossier to ensure clear picture and assessment on

available information on SID/CL, HA and EA/MvE and allow allocating Qi-quality weighing factors (ranging from 0,1 to 1)

- harmonization of the dossier is to be ensured as crucial to correctly and completely report on the assessment methodology **(i.e. 3000€/substance)**
- substance specific effort on SID/CL; HA; EA/MvE is assessed at 1,5 FTE and corrected by the overall Qi quality weighing factor
-

In practice, there will be an initial fee of 3600€ per substance complemented with a fixed 1,5 FTE corrected by the Qi of the substance to refine SID/CL, HA and EA/MvE. Details on the cost sharing formula are provided in ANNEX 5.

4.2.2 iUVCB substances that have not yet been upgraded to Article 10 dossiers: from Art 17 or Art 18 to Art 10 dossiers

Consortia have indicated that there will be substances that were never submitted as Art 10 dossiers and thus require full dossiers development. Here each assessment step provides a FTE estimation resulting in an overall cost/substance. As discussed during the call and presented in the Platform paper, further substance specific refinements are possible (e.g. Chesar development, Substance Specific Uncertainty analysis, …) and could be developed upon specific agreements, but are not a must to have and were therefore not included in the common Platform tasks and costs sharing.

Details on the cost sharing formula are provided in ANNEX 6.

SID & CL	HA	EA/(MvE) & cRA	Uncertainty analysis	IUCLID Templates & CSR development/update	Project management /meetings	Total to be refined with the number of 'new' substances
Covered by the above estimation *Should any new substance SID analysis be necessary, a 2-3 TFE days per substance is anticipated Should any mineralogical tests needed, this will be organised via consortia and could affect timing.*	Covered by the above estimation. ➢ Arche: ENV ➢ EBRC: HH	Covered by the above estimation for ENV for the refinement of existing assessment. Should additional monitoring/emission data need to be retrieved/Exposure assessment to be performed the EA, about 4-6 FTE days per substance per industrial use(s) needs to be considered for EA, cRA and Chesar development for ENV and 4-6 FTE days per substance per industrial use(s) for HH. ➢ Arche: ENV ➢ EBRC: HH For those iUVBCs that already have EAs but not cRA/Chesar, an additional 1-2 TFE days for cRA and 2-3 FTE days for developing the scenarios/assessment in Chesar are estimated Note: Chesar has many advantages but goes beyond the minimum requirements for iUVCBs refining and need to be harmonised harmonised with IUCLID, to meet new TCC requirements	Mainly, covered by the above estimation. *However, for the risk assessment of workers additional efforts are required per substance. It is needed to check whether the parent dossiers cover the industrial processes and related physical forms as relevant for the individual iUVCB. 1-2 FTE days (HH) are anticipated for such tasks per substance.*	*About 2 FTE day/substance should be added to the above estimation for appropriate development of the CSR.*	8-12 FTE days should be added to account for new substances' specific project management/meetings (Arche and EBRC)	19-29 FTE days *Note that additional substance specific efforts could be further added, as explained under substance identity, combined risk assessment and uncertainty analysis.*

Table 2. Overview of FTEs needed to update and finalise 'new' iUVCB dossiers/dossiers which did not develop cRA yet. (HH: human health; ENV: environment)

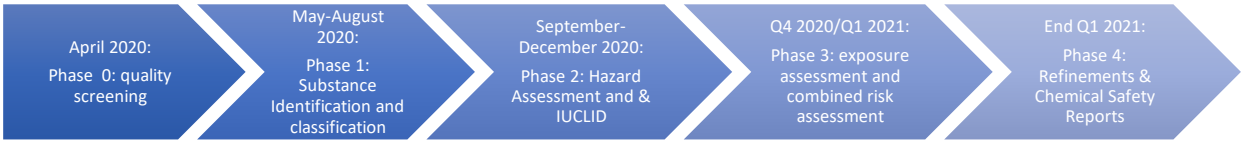
Short tasks description:

- SID & CL: Verify and harmonise substance identification for all iUVCBs in the Platform: the SID/SIP finalization step will be utterly crucial to define whether all iUVCBs have been correctly identified with their decisive/indicative criteria and whether any amendments in the existing registrations is to be considered

across consortia to improve consistency. This will also allow to set good basis for any new iUVCB, facilitating assessment for joining existing registration dossiers. Ensure transparency between SID and Analytical analysis/Expert Judgment. For Substance Identity Profile: harmonise 'decisive/indicative' constituents' identification in the EM Template. Run the exercise for all substances in the Platform such to ensure consistent approach. Prepare summary table with all constituents in elemental and mineralogical form and ensure consistency with IUCLID reporting. This table is further completed with CL and HA columns to identify which species are considered for CL and HA if unknown in composition. MeClas has been widely used, but some explanations on the constituents' species selected or the interim MeClas calculation extracts might still need to be extracted and included in the dossiers. Evaluate the need for multiple boundary compositions to report different classifications. Complete SID table to list how uncertainty in speciation was tackled when deriving classification

- HA: Define assessment entities (AEs) list to support hazard assessment across iUVCBs and ensure consistency across all substances (i.e. to identify *the* critical data to report in the dossiers and create a sort of 'template shop' for all 'major constituents' of the the iUVCBs to use, with data sharing rules defined by the Administrative working group). Complete the SID/CL table to show which constituents' speciation is selected for HA when unknown in composition (i.e. assessment entities, AEs) & justify why specific constituents are not assessed. the AEs set of data. Note: the AEs work is strictly linked to the Multimetallic Database update, aiming at increasing data availability transparency and facilitating data screening, reporting and exchange.
- EA: harmonise exposure assessment refining the site-specific assessments (i.e. having # site specific data set, based on site specific monitoring/emission data wherever possible) and completing them with more general conditions of use and Tiered approach justifications. Include mass flow analysis information and indicate volume/percentage going to industrial use and to professional or consumer use (when applicable).
- cRA: harmonise explanations for cRA reporting and developing it when needed. Note: this step would be substance specific.
- Uncertainty Analysis: prepare a position paper on the uncertainty in the iUVCB risk assessment when applying the constituents approach (i.e. based on several levels of conservativism in each step of the risk assessment) compared to when applying a regular substance specific approach. Substance specific assessments analysis can be further developed for workers to complete the uncertainty assessment.

The Platform for the new substances' aims at starting the work during January 2020. Following a similar pattern as for existing iUVCB dossiers, consultants will start working on the 'new' iUVCB substances such to screen and finalise the SID, Classification and hazard assessment before the summer months. Once the hazard assessment task is finalized, the exposure assessment and combined risk assessment refinement/development can start. For these substances as well, the aim is to complete the iUVCB refinements by the end of 2020/early 2021: however, these substances will require generation of additional data, development of combined assessment and/or Chesar dossier preparation, delaying their finalization to the first months of 2021. Refined working plans will be prepared in Q1 2020.



A contract will be signed between Eurometaux (cfr. contract name) and the consultants to cover the Technical Working Group activities. An agreement will be signed between Eurometaux and each Consortium Secretariat for the specific contribution and thus workload (as defined in the administrative working group and mainly based on the number of substances to update), to ensure proportional costs sharing between participants.

ANNEX 1: HISTORICAL BACKGROUND

Registration of inorganics UVCB has been a cumbersome process and has kept the EM consortia busy since many years. The SIDs, the methodology to address combined toxicity and/or the reporting in the registration dossiers have been largely debated and have been accompanied by additional issues, like the consistency with other sectors having UVCBs (in particular the testing or constituents' based approach), access to the data etc. On this topic several exchanges have occurred with ECHA on how to tackle SIDs and Risk Assessment of iUVCBs, but without clear conclusions nor definitive way forward. Therefore, iUVCB assessment was prioritized under the MISA framework and discussed at the MISA workshop on 5 November 2019.

As matter of fact, the lack of understanding of our constituents' based approach for iUVCBs and thus of its acceptance by some ECHA units triggered a significant burden for consortia who are responsible to update the iUVCBs dossiers. This very often requires "creative adjustments" of the IUCLID dossiers to ensure that the manual completeness check is passed but without a lot of added value when it comes to content and understanding safe use. On the other hand, the approach followed until now, i.e. reporting only summaries on constituents may put the iUVCB dossiers at danger of a non-compliance as the evaluators cannot find all data they would look for. The best (workable) reporting strategy in IUCLID is still under discussion with ECHA and we aimed at identifying a solution as soon by early 2020.

In the meantime, there is a need to define the way forward on how to successfully update and align iUVCB dossiers. At the time being, there are still inconsistencies and efficiency issues in the way iUVCBs are dealt with by the different consortia triggering concerns and comments by ECHA on the approaches followed, requiring solutions to further prepare MISA work-plans.

This paper outlines the identified way forward for consortia/commodities to update their iUVCB dossiers towards a consistent approach. The starting point is that ECHA looks at the iUVCB submissions in a holistic way, i.e. not making differences between iUVCBs depending on the consortium it pertains to: looking at the composition of these iUVCBs, it is indeed not always obvious to which consortium a specific iUVCB is associated due to the variability of the constituents.

The proposal is to efficiently consider the inorganics UVCBs as a single product portfolio and work on their registration/update jointly with a common methodology rather than consortium by consortium. This would lead to setting up a multi-metallic **inorganic UVCBs Platform** that would handle all the iUVCBs in a coordinated way, with the support of the technical expertise of the consortia and their consultants in charge of the dossiers. This will allow to share the expertise developed by the different consortia, improve efficiency in refining the dossiers, but also facilitate data-sharing.

ANNEX 2: LIST OF iUVCB SUSTANCES PREVIOUSLY REGISTERED AS ARTICLE 10

1	Doré
2	Matte, PM
3	Slags, PM refining
4	Slags, doré furnace
5	Slags, other
6	Slimes and Sludges, PM refining
7	Slimes , Ag electrolysis - SCC
8	Slimes , Au electrolysis - SCC
9	Residues from PM leaching and dissolution
10	Precipitates from PM refining
11	Matte leaching residue
12	Ag electrolyte - SCC
13	Au electrolyte - SCC
14	Nitric acid solutions from PM leaching and dissolution
15	Hydrochloric acid solutions from PM leaching and dissolution
16	Flue dust, PM refining
17	Residues cementation and reduction, PM refining
18	Materials for reclaim, PM with or without support
19	Materials for reclaim, PM in bricks, crucibles, trays, etc.
20	Materials for reclaim, PM production by-products
21	Pb bullion, PGM rich
22	Fe bullion, PGM rich
23	Zinc cement copper
24	Zinc Wastewater, zinc sulfate electrolytic, acid
25	Zinc Leach residues, zinc ore, lead-contg.
26	Zinc Calcines, zinc ore-conc.
27	Calcines, lead-zinc ore conc. (305-411-1)
28	Flue dust, zinc-refining (273-760-6)
29	Leach residues, cadmium cake (293-309-7)
30	Leach residues, zinc ore-calcine, zinc cobalt (273-769-5)
31	Wastewater, cadmium sulfate electrolytic, acid (273-721-3)
32	Slimes and Sludges, zinc sulfate electrolytic (273-742-8)
33	Waste solids, lead silver anode (305-449-9)
34	Residues, zinc smelting (273-824-3)
35	Zinc, dross (273-694-8)
36	Cadmium, dross (273-707-7)

37	Copper Anode, copper
38	Copper Matte, copper
39	Copper Black copper, copper smelting
40	Copper Slimes and sludges, copper electrolytic
41	Copper Speiss, copper
42	Copper Slags, copper refining
43	Copper Scale, Copper
44	Copper Flue dust, copper refining
45	Copper Electrolyte, copper manufacturing, spent
46	Copper Sulfuric acid, waste gas washing, copper smelting
47	Copper Residue, nickel matte leaching
48	Copper Cupro, copper processing
49	Copper Slags, copper smelting
50	ILA Flue dust, lead refining
51	ILA Lead alloy, base, Sn, Pb, dross
52	ILA Lead antimonial dross
53	ILA Lead dross
54	ILA Lead dross antimony
55	ILA Lead dross, bismuth rich
56	ILA Lead, Bullion
57	ILA Lead, dross, copper rich
58	ILA Matte, lead
59	ILA Slags, lead reverbatory smelting
60	ILA Slags, Lead smelting
61	ILA Slimes & sludges, battery scrap antimony & lead-rich
62	ILA Speiss, Lead
63	ILA Wastes, lead battery reprocessing
64	ILA Zinc, desilverising skims
65	Nickel matte

ANNEX 3: TASKS OF THE iUVCB PLATFORM WORKING GROUPS

- **Tasks of the Administrative Working Group**

The Administrative Working Group will work on the following tasks:

- Define expected workload per consortium to set up objective criteria for weighing the specific consortia contribution to the Platform work. SATs results are the basis for this task.
- Define costs sharing for each consortium participating to the Platform.
- Define data sharing agreements to facilitate data exchange (upon definition of IUCLID Reporting Strategy with ECHA)

- **Tasks of the Technical Working Group**

The Technical Working Group will work on update/preparation of the iUVCB dossiers and more specific details on modalities for developing the specific tasks will be shared upon finalization of the iUVCB list and of the working plans. To avoid increasing workloads for consortia and companies, the specific work on each milestone (substance identity, classification, hazard assessment, exposure assessment, combined risk assessment) will follow the (summary) guidelines streamlined as follow up of the November MISA workshop. While IUCLID reporting strategy is currently under refinements with ECHA, the entire work can already start. The working group will be in charge of completing each iUVCB dossier milestone to ensure consistency and completeness of the dossiers by improving each section (i.e. Substance Identity, Classification, Hazard assessment, Exposure assessment, Combined toxicity assessment, Man via Environment and Uncertainty analysis). The work will be performed by milestone, defining a *decision-making phase* that would focus on methodology for the specific substances, direct communication with consortia/registrants and an *implementation phase* (e.g. refining SID/SIP&CL exchange with consortia/regstrants to finalize it; check of potential duplications between consortia, etc.).
Note that the following items are not included in the current mandate and are subject to further discussion with Consortia:

- Additional testing requirements (e.g. phys-chem testing as TDP) and analytics, which shall be conducted by consortia with the shortest delays to avoid becoming a bottleneck in the implementation of the work-plans.
- Chesar implementation in the dossiers is to be discussed with Consortia to define the willingness to develop it and to define which server and level of implementation will be required from Arche and EBRC.
- Discuss whether a specific IUCLID/CHESAR server could be identified for the iUVCB Platform, to increase work efficiency between assessors and allow better coordination with consortia (e.g. entailing dossiers maintenance and updates performed by the Platform) or whether consortia prefer having their separate servers and organize IUCLID/Chesar translation using the generic texts/conditions of use set up by the executive group.

- **Tasks of the Coordination Working Group**

The dossiers submission is often under evaluated and yet a major source of difficulties. The Coordination Working Group will ensure to hold necessary exchanges with the consortia and,

when needed, with ECHA to ensure smooth submissions of updated information (e.g. when splitting occurs and new EC identifiers are needed) and final dossiers submissions.

ANNEX 4: COST DETAILS FOR EXISTING ARTICLE 10 DOSSIERS

Attach Object

ANNEX 5: COST DETAILS FOR SUBSTANCES RESULTING FROM SPLITTING OF ARTICLE 10 DOSSIERS

Attach Object

ANNEX 6: COST DETAILS FOR 'NEW' SUBSTANCES WHICH WERE NEVER UPGRADED TO ARTICLE 10 DOSSIERS

Attach Object