Eurometaux
European Association of Metals

Further discussion on substance identity of complex inorganics

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Short report

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Jos Mossink (ECHA) opened the meeting, explaining that the idea for having this discussion dates from the summer, when the metals inorganic UVCB guidance was submitted. The SID unit realised that it would be beneficial to have a further discussion on the registration of difficult substances. Jos mentioned that SID discussions are also ongoing with Eurocolor and the inorganic pigments and that it would be good to ensure consistency. This meeting may be a first step in developing a common approach in what could be feasible from an industry point of view, and also realistic from an ECHA point of view. Guidance on essential oils has now been published and is referenced on the ECHA website. It is understood that the metal sector would like to go in the same direction. We should however realise that this required 1.5 year of discussions: it is a long process but ECHA would support a common approach.

EM thanked ECHA for setting up the meeting, reiterated that the aim is to have a metal iUVCB SID guidance compliant with the REACH regulation, and in particular as the sector is now confronted to 'new' cases, via registration or MSC.

ECHA started with a presentation aiming at providing a picture of the difficulties they are facing with the iUVCB SID, as outlined in already submitted registration dossiers. A brief re-cap on the history was shown: there have been several interactions between ECHA and Eurometaux, including workshops and a site visit. At the SID workshop organized in October 2014, the copper matte was discussed within a breakout but the overall picture remained complex. The inquiries over 2014-2015 demonstrated that there seem to be diverging views or misunderstandings between ECHA and dossier submitters on the role of the SID.

Main principles were recalled:

- Identification is the starting point of REACH and CLP
- Identification of the substance gives the scope of Annex VII-XI data (basis for the determination of the hazard profile)
- Sameness criteria needs to be in line with the objective of the Regulation

ECHA comments on the proposed iUVCB SID approach flagged concerns about:

- Merging/re-scoping EC entries
- Overly broad processes/sources to be merged
- Redefinition of substance composition
- Overly broad compositions merged
- Analytical data provided

resulting in lack of transparency of the dossier but also at the level of the joint submission.

ECHA had prepared several examples:

Example 1: Flue dust copper refining

- EC description:

From EINECS. But then in the dossier, synonyms were added with reference to EINECS numbers and descriptions related to waste and/or material recovered from scrubbers. This is confusing. In addition when those synonyms are looked for, it appears that compositions might be different, covering a range of constituents, from copper compounds to arsenic oxide, lead, mercury and selenium. ECHA then looked at composition (slide 7) and indicated it is not easy to make the link between the SIEF composition and the substance as it is manufactured and reported by the individual legal entity (e.g. in the SIEF composition, Cu content goes from zero to almost 100%). Also it is not clear what oxide forms present in minerals mean. It is acknowledged that the LE composition is narrower but still, the conclusion is that the composition does not readily refer to a manufacturing output. There is no transparency of what it means in practice or on what is intended to be covered in some cases (e.g. oxide forms). No information on chemical constituents is given (e.g. how can ECHA know that Mg, Si and oxides are not chrysotile?).

On analytics, ECHA referred to 3 samples analysed for flue dust and asked what the commonalities are. Each sample would normally refer to a substance: sources, processes and collection points are different (e.g. ECHA’s assumption is that, similar to the iron sector, by-products from blast furnace and electric furnace are different).

Example 2: wastes, lead battery reprocessing

The composition points towards a UVCB and analytics support this for the LE (mineralogy). Values are not overly variable for the LE. To the contrary, in the SIEF composition you can have a lot of different kinds of substances (slide 13). Tellurium can for example be very high (some sources where it is very high). Here the LE dossier is better described but the SIEF composition can cover a lot of substances.

Example 3: slimes and sludges precious metal

In the EM presentation, it was mentioned that the iUVCB SID is explained in the CSR. ECHA looked at a CSR from the precious metals sector and used extracts to illustrate the difficulties (slides 14-18). Highlighted issues are for example:

- Wording used in the introduction refers to a group/category and not to a substance
- The elemental analysis –used to define composition- is not the composition in the context of REACH. The variability in composition is due to different substances being merged (chicken and egg problem)
- What is a representative sample? How can it be representative of a group whilst it should refer to one substance within the group entry
- Annex VII-XI data: the constituents referred to in this text are the ‘elements’ based on elemental analysis and not constituents
- There is a mismatch in rationale: in section 1.4 we propose mineralogy generated on a representative sample but then for testing, we say we cannot define one
- Variability comes from multiple substances: for a given substance no information is available on its variability in chemical composition

To summarise: the registration seems to refer to a group/category entry. Transparency on scope is lacking, multiple substances may have been merged and chemical compositions are not reported (i.e. constituents expressed as mineralogical/species and reported as such with their concentration ranges).

ECHA concluded that even though a lot of info has been gained, it still seems from information scrutinized by ECHA that multiple substances may have been merged in one registration dossier, that the chemical composition is not reported in sufficient details. This leads ECHA to the conclusion that the proposed iUVCB approach on SID is not consistent with the objective of REACH. Today's discussion should be a 360° overview of the proposed approach and consideration of some real/practice cases that would help Eurometaux to develop/improve the approach achieving transparency in the SID reporting and its relation between the hazard/risk data and the actual substances manufactured/put on the market and ECHA to better understand the specifics of the sector.

Eurometaux presented a couple of slides, recalling the importance of the iUVCBs in the non-ferrous metals industry but also on the acknowledgement that a correct and complete SID is a key pillar to ensure an appropriate risk assessment. A specific approach had to be developed to address the variability in concentration of constituents but also the different physical forms etc. The reasoning used in the risk assessment part is summarized on slide 6, based on parallel assessments of constituents. To ensure safe use, in the absence of information on speciation, a worst case speciation is used in the hazard and risk assessment part while the elemental composition is used in the SID part. The connection between both parts should be made consistent and clear. Important to realise also is that at the workplace, the exposure will be to more than one UVCB. The risk assessment part will be the same, irrespective of grouping or splitting UVCBs in the same workplace (for occupational exposure) or the same site (for environmental exposure).

The steps followed by industry to identify iUVCBs under REACH (start from the NFM BREF, develop a consistent approach with mapping of the streams…to move towards reporting in IUCLID) were explained by Katia. There are commonalities across metals: processes, sources, main types of iUVCB extracted (enriched metals or by-products). It is understood that the EINECs inventory does not aim at providing a substance identification under REACH, but at least some terminology exists and was used as a starting point. There have been cases of splitting and rewording of name and description, for the sake of clarifying and harmonizing naming across industry and public reference documents (e.g. NFM BREF).

The discussion highlighted the following issues:

- On the specificity/granularity of the description and naming and link with output:

The example of flue dust was further discussed: flue dust is generated by the collection and abatement of the dust at the workplace and is, in large plants, constituted of the different (exhaust gas) streams brought together. What the companies reported is the output as put on the market, emphasizing for e.g. rather its content in Zn or Sn (market reasons) than the specificities of the process. Whilst the market reasoning was acknowledged, it was reminded that REACH considers the actual manufacturing process as one of the material identifiers. ECHA insisted that small differences in the manufacturing technologies (or types of furnace) may affect composition. ECHA referred to the work done recently by the ashes producers. The NFM BREF information (where emissions are linked to stacks) was used as a starting point, with its 'translation' to IUCLID (i.e. measuring elemental metal emissions) has been really difficult. Industry agreed the EC names/synonyms as shown on slide 6 should be reconsidered in light of today's discussion (e.g. old EC numbers may have been included to increase coverage, with some even referring to obsolete processes).

- On the link between name, composition and hazard? Can we assume that flue dust with composition X is the same as the one with composition Y and has the same hazard profile? Does it make sense to have these grouped?

Industry explained that in 2010 the companies provided only LE specific elemental data (ensuring all elements were covered, even if only present under worst case conditions, e.g. Hg). Question is whether there are differences in the extraction process, e.g. in primary vs. secondary that may affect composition and hazard? Industry explained that in case of Copper smelters by-products making the differences between primary and secondary smelters is not appropriate in many cases as too restrictive, certainly for European smelters who all process a wide range/mix of primary and secondary materials. Flexibility on by-products identity is thus necessary to achieve resource efficiency and material efficiency at all levels (i.e. increased recycling rates of end-products and recovery of industrial by-products requires free movements of goods and improved access to raw materials for EU copper producers). REACH SID should not be too restrictive and based on the past/today's material compositions if business has to be based on future outlooks and challenges such as the ever increasing number of different metals in applications (e.g. smartphones), EU's increasing exports of scrap, etc. Business needs the flexibility. The example of secondary copper smelters that may also use sulfidic containing feeds for energy efficiency constraints was given. The example was taken of a company that may produce a sample comparable to …87 (see slide 24 EM presentation), and then a bit later a sample comparable to ...88 due to a trend in the market or a change in source material supplier: industry still considers this as the same substance 'copper rich' with copper mainly distributed as sulfide. This was challenged by ECHA based on the argument that different speciations should be different substances. Industry counter-argued that this reasoning (1 speciation = 1 substance) would be unrealistic if for example applied to PM refining from secondary/recycling materials, ultimately resulting in numerous registration dossiers of low tonnages situations (as % of PM are very low vs. other constituents). All participants agreed that there is a need to draw a line somewhere to achieve a realistic, transparent, manageable and reproducible SID. If for example a Zn smelter buys flue dust, he most probably needs to know what he is going to process (e.g. sulfides or metal or…). This kind of information shall be reported as well in section 1.2. Only mentioning 'copper' is considered too broad and does not allow ECHA to make the link with other parts of the assessment. Up to now, industry has reported elemental first but also speciation using e.g. remarks fields in IUCLID. This should be reconsidered so as to ensure that both elemental and speciation are reported for main constituents. The reporting should give confidence that the registered substance is the substance on the market. A hint was provided with regard to XRD: the detection limit of XRD is circa 5 % and therefore presence of constituents at concentration below 5% cannot be identified reliably by XRD. These constituents needs to be identified by elemental analysis or other methods. As a conclusion, each constituent (reliably) detected in the XRD analysis needs to be reported as constituents of the substance. To complete the composition to 100%, the constituents with low concentration or amorphous structure can be reported as hypothetical oxides.

- Besides the reporting, it was asked to reflect on what is called one substance? When should registrations be split up?

Complex iUVCBs are characterised by source and process, both affecting composition. Industry explained the struggle about the level of detail to provide to be able to assess sameness. The process definition is a challenge in particular: for a given process we may expect that 50-60% of it remains comparable across SIEF but this may depend also on how the process itself is defined: e.g. does it include extraction only or also post-treatment? In practice 1 process = 1 substance but this could easily lead to extremes as well: 6 differences in process (e.g. due to niche-business of producers) would mean 6 different substances to register. Here too, a realistic compromise will have to be found and described in the Eurometaux guidance, taking into account market & manufacturing reality and hazard, etc. ECHA mentioned that the petrochemicals were also struggling with the primary/secondary sources but now managed to make a difference between crude and recyclables. A balance between flexibility and precision of substance identity should be strived for but industry should make sure some variability parameters are better fixed in its substances identities. With variability on processes, source material and/or composition, there are seemingly too many variability parameters, making the sameness assessment non-transparent and impossible. Industry should look at all available parameters and identify the ‘wrapper’ that gives enough confidence in the data and try to identify a sameness protocol. For example, going back to flue dust: the approach could be to check on which of the 3-4 parameters (such as source, process, composition) there is the less variability and fix at least this one. Once it is fixed, the changes in the two other factors can be considered when defining the SID. In case no parameters can be fixed, there is a need to consider splitting.

- Link to risk assessment:

Industry explained the use of the worst case speciation in case speciation is unknown (or cannot be made sufficiently precise) to make the link with the DNELs but also the concept of aggregated exposure assessment. Speciation of the substance may be different than speciation for the risk assessment. The Pb for example is coming from different UVCBs/processes at the workplace. The aggregated exposure and risk assessment was copy-pasted in each relevant UVCB dossier and is thus conservative as it considers multiple UVCB substance sources of exposure (and more than what “one substance only” driven REACH Regulation requires). This is however starting from the back-end (workplace and environment assessment) while REACH requires the substance assessment: how to link exposure, hazard and substance? There is an ongoing discussion on how far you can consider hazard in SID. Initially SID covered purely chemical aspects while now other considerations may be included (how to test? what to test? what is the relevant dataset for RMM?). It is crucial to also ensure we have the information requirements fulfilled on the substance under consideration? How to make the link between composition, uses and exposure: for metals, the assessment ‘unit’ is the bioavailable soluble metal ion, somehow making the link (although particle effects for example may have to be considered in addition). If the starting point ‘composition’ is very broad, how could one make a clear link to the other sections of the dossier. The assessment entity tool as reporting tool will help.

It was concluded that the substance identity issue cannot be solved only by SID data. We need to think in a broader manner: what kind of data would need to be generated, how to comply with REACH Annexes (information requirements), how to make links between different parts of the registration whilst remaining compliant and realistic. ECHA referred to a possible comparable framework as the PETCO one to be set up for metals. ECHA confirmed they would still be interested in having a sector specific guidance but recommended also to have a look at what is being done or ongoing, for consistency reasons:

- Essential oils

- Inorganic pigments
- Oleochemicals
- Hydrocarbon solvents

Eurometaux mentioned that they will test the new assessment entity concept in IUCLID 6.0 using an iUVCB: some learnings may come from there as well.

It was proposed to circulate a short report of the discussions summarizing understandings and making a proposal for resulting actions, to be completed/corrected by all participants. Eurometaux will inform its members' consortia on 19/01/2015 and come back to ECHA afterwards with more concrete proposals in terms of timings/cases.

Annex: proposed actions

Aim: address main concerns iUVCB SID, e.g.

- multiple "substances" seemingly merged in one registration
- too many sources of variability to allow a straightforward identification of the UVCB (variability in processes, sources and composition: e.g. overly generically defined sources and processes with broad ranges in composition)
- speciation/mineralogical composition insufficiently reported
- lack of transparent link with other parts of the dossier (information requirements, hazard, exposure)

by developing an agreed approach that would increase transparency in the SID and relation with the hazard/risk assessment

It is proposed to focus work on guidance and common principles and not to start by revising the submitted UVCB dossiers)

Actions:

- Gather more information on speciation/mineralogical analysis at legal entity level (at least for the main constituents and/or constituents that largely impact process)
- Assess if the generic/SIEF composition ranges, sources (and processes if relevant) can be narrowed down
- Demonstrate/assess that variability across legal entities reflects variability in time (past and future (circular economy, resource efficiency, energy efficiency)) within a legal entity
- Reconsider older EC-entries, descriptions and synonyms. Explain changes in technologies compared to the time of the EINECS inventory building
- Develop for each iUVCB a clear overview focusing only on sameness criteria for those substance parameters with least variation or fixed in the ideal case, for example below:

Substance identity parameters*	Sameness criteria (try to be as specific, measurable, reproducible and accurate as possible)	Indication of variability: describe if FIXED or with very low variation
Process		
Sources (input materials)		
Elemental composition		
Speciation/mineralogical information/composition		
Physical characteristics (e.g. physical state and form, particle size distribution,…)		

* parameters with large variability should not be specified

- Assign weights to the substance identity parameters and assess whether the iUVCB is sufficiently & uniquely identified
- In a next step, try out alternative composition reporting in IUCLID based on mixed combination of speciation/mineralogical (for the main constituents) and elemental analysis (for minor constituents) or provide both in parallel
- Assess possible consistency