



Precious Metals & Rhenium Consortium PM Refiners Work Group meeting

BRUSSELS, 15 OCTOBER 2015, 13:00-15:00



1. Welcome and introduction



1.1 Confidentiality and competition law

DO	DON'T
<u>Application of competition law</u>	
Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
<u>Consultation in Matters of Competition Law</u>	
Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.	Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.
<u>Activities in any preliminary phase and at any other stage of operation of the Consortium</u>	
Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.	Pursuant to Art. 101 and 102 TFEU, activities which have the object or the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: <ul style="list-style-type: none"> - Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1 a)-e) TFEU); - Joint boycotting of other companies; - The unjustified unequal treatment of trade partners; - The abusive exploitation of a dominating market position.
<u>Exchange of Confidential Information</u>	
Involve a Trustee for the exchange of Confidential Information.	The exchange of Information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to : <ul style="list-style-type: none"> - Production capacities; - Productions or sales volumes; - Import volumes; - Market shares; - Price policy; - Distribution and marketing terms; - Marketing strategies; - Information regarding the relationship with suppliers.
<u>Documentation on Cooperation</u>	
Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	



1.2 Tour de table and apologies

Cf. participants list included in agenda



1.3 Approval of the agenda

1. Welcome and introduction
2. Substance identity (SID) of PM Refinables
 - 2.1 Further information from EC/ECHA
 - 2.2 Structural representation of PM Refinables
3. Classification update
4. Update on RA related issues
 - 4.1 Status of environmental exposure assessment of PM Refinables
 - 4.2 Combined toxicity
5. Workplan and budget
6. A.O.B., next meetings/calls and closing remarks

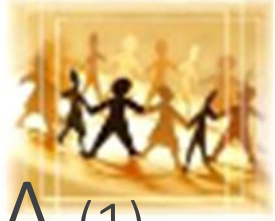


1.4 Minutes and actions 25 Mar 2015

What?	Who?	Status?
<i>Substance identification (SID)</i>		
1. Check what ECI did regarding speciation of their UVCBs	PMC Sec	Ongoing
2. Check if Doré slag number 7 is a Cu slag	PMC Sec with registrant	
3. Send updated composition info PM slags and PM slimes & sludges as requested in e-mail from PMC Sec 16-17 March	Ref WG	
4. Review structural representation PM slags based on additional information provided under AP3	PMC Sec	Delayed
5. Check composition data gaps other Ref & identify need for additional composition data collection	PMC Sec	
6. Additional composition data collection	PMC Sec	
7. Identify parameters allowing a structural representation of other Refinables	PMC Sec	
8. Check which companies will need to register Fe bullion PGM rich and Cu bullion PGM rich	PMC Sec	
9. Update the PM Refinables decision tree / process definitions document following the outcome of the structural representation exercise	PMC Sec	
10. Draft internal document Refinables SID approach	PMC Sec	
11. Organise WG call to review/finalise the internal document on the Refinables SID approach	PMC Sec	
<i>Environmental exposure assessment</i>		
12. Add additional constituents to their monitoring programme if not all driving constituents are currently being monitored	PM Ref WG	Done?
13. Return environmental exposure questionnaire with <u>all</u> available emissions data on the driving constituents present in the Ref at their site	PM Ref WG	
14. Compilation of emission data from questionnaires for all driving constituents to update the WCA environmental risk assessment		Ongoing
15. Follow up access to exposure modelling parameter values and sign data-sharing agreements for all driving constituents	PMC Sec	



2. Substance identity (SID) of PM Refinables



2.1 Further information from EC/ECHA (1)

European Commission SIDC project workshop 27-28 April 2015

Workshop on SID of UVCBs and other complex substances in REACH

- **EC project:** investigation of SID and sameness of complex substances, i.e. substances for which the application of the SID provisions of REACH and the rules and conventions of the SID guidance pose challenges.
- **Aim:** develop sector-specific factsheets providing key information and best practices in identification of complex substances in selected industry sectors.
- **EM** did not participate in the first phase of the project but had the opportunity to explain the specificities of the inorganic UVCB case to the project consultants, to ensure that the approach developed during the last years - and discussed with ECHA - can be referred to in the framework of the current project.
- **Project workshop:** DG GROW, project consultants, ECHA and industry gave presentations and exchanged practical experiences and knowledge during the breakout sessions (presentations and summary of breakout discussions are available via http://sidc.reach-2018.eu/sid_workshop.html).



Further information from EC/ECHA (2)

SIDC project workshop key messages

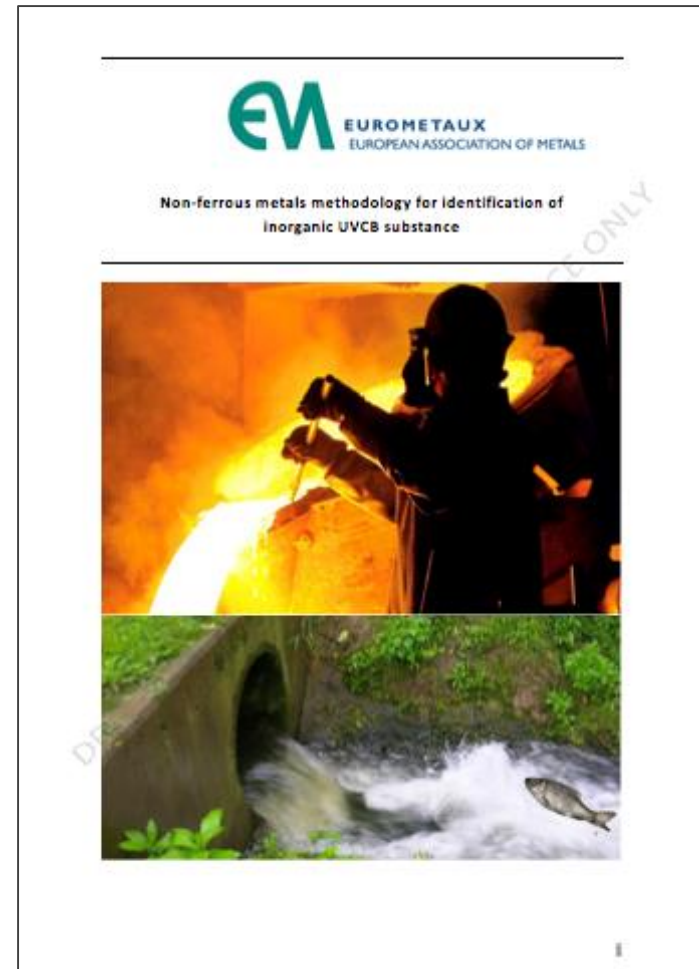
- Complex substances/UVCB issues are generally **sector specific**. ECHA considers communication with industry important to get the external perspective.
- Despite the complexity and the regulatory requirements, identification and sameness require **pragmatic approaches**. Deviation from the guidance is possible but needs to be justified.
- Substance Identity Profiles (**SIPs**) are relevant tools and have often been improved by SIEFs/Consortia/Associations to fit UVCB requirements, but are not always available.
- **Analytical testing** should be performed in a stepwise approach, starting with initial basic identification/characterisation and then adding more sophisticated methods. There is no need for a box ticking exercise of the analytical methods specified in Annex VI of REACH if they don't provide relevant information (but this needs to be justified).
- SID issues of complex substances will most probably not be solved within the duration of the project (ending Dec 2015). Since issues are sector-specific, harmonisation of approaches, analysis and information format is not always effective for registrants nor for regulators.



Further information from EC/ECHA (3)

Workshop aim: develop sector-specific factsheets providing key information and best practices in identification of complex substances in selected industry sectors.

-> EM provided DG GROW and ECHA with the SID section of the **EM inorganic UVCB Guidance** to avoid that information not fitting metal specificities is delivered as outcome of the project and used further for REACH 2018 registrations/updates.





ECHA informal feedback (1)

- Deviations from SID guidance possible with appropriate justification but SID principles may not be disregarded; dossier should not refer to a hypothetical chemical too generically defined.
- **EC entries** do not necessarily identify a substance under REACH. Revised entries cannot be used as identifiers under REACH.
- **Manufacturing process:**
 - Compositions generated from the same source & process can be considered to refer to one substance while compositions that differ significantly (e.g. constituents present from 0-90 %) are likely not to have been manufactured under the same process conditions.
 - A non-exhaustive list of sources (e.g. primary & secondary feeds) may not be combined with a generic process description (e.g. leaching, melting, etc.) -> would lead to huge variability in the substance composition, which would not refer to one substance.



ECHA informal feedback (2)

- **Composition:** reporting total **elemental** content is not sufficient; discounting the speciation can give the impression that different compositions are more similar than they are.
-> constituents such as metal, oxide, sulfate etc. will need to be differentiated and reported separately when present >10% / relevant for the PBT assessment. Groups of constituents with similar functional groups can be reported together when there are numerous constituents present but none > 10%.
- **Analytcs:** only analysing '**representative sample**' for speciation/mineralogical composition is not sufficient; not appropriate for reporting across LEs as there would be no means to verify decisions taken on identity (each registrant is required to provide sufficient information that allows unambiguous identification of the substance)

EM is currently communicating with ECHA to clarify some of the misunderstandings, explain the practical difficulties in strictly complying with the REACH requirements, and explain that a precautionary approach is adopted with respect to CL and HA.

EM further asked for practical examples to clarify what ECHA's concerns refer to.



2.2 Structural representation of PM Ref

- ECHA proposed methodology sets priority to the **structural representation** followed by the reaction scheme and the process output.
- The methodology entails the identification of systematic structural characteristics which, if the substances were to be well-defined, would constitute substance sameness criteria. The structural depiction therefore relies on the “**80% rules**” established for well-defined substances.
- ECHA SID guidance:
 - “ $\geq 80\%$ ” rule for mono-constituent substances (i.e. one main constituent present to at least 80%) as well as the “ $< 80\%/ \geq 10\%$ ” rule for multi-constituent substances (i.e. several main constituents present at concentrations $\geq 10\%$ and $< 80\%$) should be applied to check if substances are the same.
 - Well-defined substances should contain the same main constituent(s).
 - A multi-constituent substance of main constituents A, B and C shall not be regarded the same as a multi-constituent substance of main constituents A and B or as a reaction mass of A, B, C and D.



Structural representation of the slags: conclusions

- Two approaches were used for the structural representation: the species and elements representation. The **elements representation** is most in line with how the composition was reported in the Registration Dossiers of the Refinables.
- If the main (elemental) constituents are defined in line with the ECHA SID guidance (i.e. typical conc. for main constituents should be $\geq 10\%$), we can show **presence of the same main constituents across companies for both types of slags**. However, when using this approach, we cannot define sameness up to 80%, but we can justify this based on the presence of a lot of 'minor' constituents in the Refinables (present in small concentrations).

The PM Refinables WG agreed that we continue the structural representation exercise with the other Refinables on elemental basis.

PM Sec is going through additional data provided for PM slimes & sludges and will be collecting further information for the other Refinables.



3. Classification update



Classification approach

- For the purpose of classification, the compositions of the PM Refinable clusters are defined by means of formulas.
-> agreed previously by the Ref WG to change these formulas into elemental compositions (max of typical) where possible for next update.
- Once SID finalised, updated compositions will be entered into MeClas and updated classifications will be derived.
- Samples will be grouped per classification and composition ranges will be derived per classification



4. Update on RA related issues



4.1 Status of environmental exposure assessment of PM Refinables

- Additional driving constituents added last year.
- Limited dataset on which to base an exposure scenario (for some constituents, only 2 sites provided emission data).
- **Did all companies provide emission data?**
- If so, WCA will check possibility of use of SpERCs across this range of metals/metalloids and their emissions during Refinable processing.



4.2 Combined toxicity

EM Workshop 20 Oct: Combined toxicity of metals in the environment: Bridging the gap between science and regulatory requirements

9:00	Welcome and introduction
9:10	Problem formulation: Current approaches and regulatory requirements for registration of multi-metallic substances (e.g. inorganic UVCBs) under REACH <i>(Eurometaux)</i>
9:30	Overview of regulatory interest in combined toxicity assessment: outcome of a survey
9:50	A metal mixtures research in Japan <i>(Masashi Kamo and Wataru Naito, Japanese National Institute of Advanced Industrial Science and Technology)</i>
10:10	Metal mixture toxicity, experimental evidence and potential mechanisms <i>(Ronny Blust, University of Antwerp)</i>
10:30	Low level chronic effects of metal mixtures on plants, invertebrates and fish reveal contrasting metals interactions <i>(Erik Smolders, KU Leuven)</i>
10:50	Thought starter for discussions: Options for refinement of the standard combined toxicity approaches for environmental risk assessment of multi-metallic substances <i>(Koen Oorts, ARCHE)</i>
11:10	Break
11:30	Break-out sessions (examples of hypothetical mixtures will be provided as test cases). <u>Tiered approach for combined toxicity assessment of metals</u> <ul style="list-style-type: none">• Summary of available approaches• Justification for (de)selection of constituents of a multi-metallic substance to be included in a combined risk effects assessment• Which are the most appropriate models for assessing combined risks of metals in a generic approach considering the difference in data availability among different metals?• When is experimental testing required? <u>Toxicity related questions</u> <ul style="list-style-type: none">• Is there evidence for combined toxicity of metals at PNEC levels?• Are interactions dependent on effect levels (e.g. EC₁₀ versus EC₅₀)?• Which models do best explain interactions among metals (IA, CA, IA-SSD, CA-SSD, BLM-based, ...)?• How to deal with differences in data availability on toxicity of the mixture constituents? <u>Exposure related questions</u> <ul style="list-style-type: none">• How to deal with predicted risk at natural background concentrations: added versus total approach?• Effects on chemical interactions on the bioavailability of the constituents• How to deal with differences in data availability on bioavailability of the mixture constituents?
13:00	Lunch
14:00	Presentation of the results of the break-out groups + plenary discussion
15:00	Plenary discussion: identification of a generic tiered approach for assessment of combined toxicity of metals in the environment
16:30	Conclusions



5. Workplan and budget



2015 finance (Jan-Aug 2015)

	Budget	Real	Delta
2.7 Refinables-specific costs	365.824 €	15.774 €	350.050 €
2.7.1 Refinables REACH registration and CLP notification work programme	365.824 €	15.774 €	350.050 €
2.7.1.1 Phase 1: Identification and speciation	0 €		0 €
2.7.1.2 Phase 2: Experimental studies (e.g. validation tests)	0 €		0 €
2.7.1.3 Phase 3: Effects, exposure and classification	0 €		0 €
2.7.1.4 Phase 4: Generation of IUCLID 5 Files and Registration Dossiers	0 €		0 €
IUCLID 5 Hosting System	3.150 €	1.351 €	1.799 €
2.7.1.6 Phase 6: Post-registration work (>2014)			0 €
I. Scoping	5.360 €		5.360 €
II. Substance identification	0 €	2.488 €	-2.488 €
III. Effects assessment and classification	176.250 €	3.000 €	173.250 €
IV. Exposure and risk assessment	78.266 €	4.539 €	73.727 €
V. Compilation of IUCLID 5 file & Registration Dossiers	97.438 €	0 €	97.438 €
VI. Administration / other	5.360 €	4.396 €	964 €



2016 workplan

Dossier maintenance

1. Scoping: ECHA advocacy
2. Substance identification: speciation testing **if needed**
3. Effects assessment and classification:
 - T/D testing & phys-chem testing for splitted dossiers (costs will not be invoiced as already invoiced 2015)
 - validation testing **if needed** (costs will not be invoiced as already invoiced 2015)
4. Exposure and risk assessment: MvE assessment, update exposure & risk assessment
5. Compilation of IUCLID 5 file & Registration Dossiers: dossier updates to be submitted in 2016
6. IUCLID 5 Hosting System



2016 draft budget

	PMC 2016 Budget to be spent	PMC 2016 Budget to be invoiced	PMC 2016 HR
2.7 Refinables-specific costs	495.300 €	207.300 €	0,4
2.7.1 Refinables REACH registration	0 €	0 €	
2.7.1.1 Phase 1: Identification and speciation	0 €	0 €	
2.7.1.2 Phase 2: Experimental studies (e.g. validation tests)	0 €	0 €	
2.7.1.3 Phase 3: Effects, exposure and classification	0 €	0 €	
2.7.2 Refinables REACH dossier maintenance	495.300 €	207.300 €	
2.7.2.1 Phase 1: Scoping	5.000 €	5.000 €	
2.7.2.2 Phase 2: Substance identification	89.000 €	89.000 €	
2.7.2.3 Phase 3: Effects assessment and classification	296.300 €	8.300 €	
2.7.2.4 Phase 4: Exposure and risk assessment	70.000 €	70.000 €	
2.7.2.5a Phase 5a: Compilation of IUCLID 5 file & Registration Dossiers	30.000 €	30.000 €	
2.7.2.5b Phase 5b: IUCLID 5 Hosting System	5.000 €	5.000 €	
2.7.2.6 Phase 6: Admin/others (Sec. work for project mgmt., org. & particip. in meetings, communication)			
2.7.3 Refinables REACH evaluation	0 €	0 €	
2.7.3.1 Dossier evaluation	0 €	0 €	
2.7.3.2 Substance evaluation	0 €	0 €	
2.7.4 Refinables REACH classification & labelling	0 €	0 €	
2.7.5 Refinables REACH authorisation	0 €	0 €	

-> 288.000 € already invoiced in 2015 but budgeted again in 2016



6. AOB, next meetings/calls and closing remarks



AOB

MSC 43 - Dossier Compliance Check (CCH) on “Slimes and sludges from the steel sector”: unclear on how MSC agreed on an inorganic UVCB

- CCH to investigate for any data gaps specific to Annexes IX and X.
- ECHA suggested that the MSC agree with a (first step) testing proposal on the UVCB itself, instead of applying the strategy based on the constituents’ approach that had been agreed between the metals sector and ECHA.
- It is expected that MSC would indicate in the Decision that alternative approaches can be followed as long as the LR can satisfy the data gaps in the registration file by the fixed deadline.
- EM provided technical support to the involved LR and raised some principles of concern with ECHA in advance of the MSC meeting.
- Outcome of decision not known.



Next meetings/calls and closing remarks

- AOB?
- Next Ref WG meetings:
 - 21 April 2016
 - 6 October 2016

