Precious Metals Consortium

Precious Metals & Rhenium Consortium

PM Refiners Work Group Meeting

21 April 2016 | Brussels

Precious Metals Consortium

1. Welcome and introduction

Edwin Broekaert (Umicore, Belgium)

1.1 Reminder on confidentiality and competition law

DO	DON'T
Application of competition law	
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.
Consultation in Matters of Competition Law	
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.
Activities in any preliminary phase and at any other stage of operation of the Consortium	
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 of the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including: · 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.
Exchange of Confidential Information	
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 : · Production capacities; · Productions or sales volumes; · Import volumes; · Market shares; · Price policy; · Distribution and marketing terms; · Marketing strategies; · Information regarding the relationship with suppliers.
Documentation on Cooperation	
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 (13:30 – 13:45)
2. Substance Identity of PM Refinables (13:45 – 15:00)
   - 2.1 Update on ECHA / Eurometaux discussions
   - 2.2 Refined SID PM Refinables based on latest Eurometaux recommendations ('fixed' versus 'variable' parameters)
3. Combined toxicity: update on status (15:00 – 15:30)
4. Workplan and budget (11:30 – 11:45)
5. AOB, next meetings/calls and closing remarks (11:45 – 12:30)

1.4 Approval of the minutes of the last meeting (15 Oct. 2015) and status of action points

	What?	Who?	Status
Substance Identity (SID)			
1	Check if Doré slag number 7 is a Cu slag	PMC Sec + registrant	Ongoing
2	Send updated composition information PM Refinables to PMC Sec	Ref WG	
3	Identify parameters allowing a structural representation PM Refinables	PMC Sec	
4	Check which companies will need to register Fe bullion PGM rich and Cu bullion PGM rich	PMC Sec	
5	Update the PM Refinables decision tree / process definitions document following the outcome of the structural representation exercise	PMC Sec	
6	Draft internal document Refinables SID approach	PMC Sec	
7	Organise PM Ref WG call to review/finalise the internal document on the Refinables SID approach	PMC Sec	
8	Clarify during future dossier updates that it is common practice in the PM sector to process primary and secondary feeds together	PMC Sec	
9	Check possibility to register Doré as mono-constituent substance	PMC Sec	
10	Check statistical approach Heraeus to analyse PM sludges	PMC Sec	
Classification update			
11	Derive updated classifications based on updated SID	PMC Sec	Q3-Q4 2016
Environmental exposure assessment			
12	Return environmental exposure questionnaire with all available emissions data on the driving constituents present in the PM Refinables at their site	PM Ref WG	ASAP
13	Compilation of emission data from questionnaires for all driving constituents to update the environmental risk assessment	WCA	Q2-Q3 2016
14	Follow up access to exposure modelling parameter values and sign data-sharing agreements for all driving constituents	PMC Sec	Q2-Q3 2016

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2. Substance Identity (SID) of PM Refinables

2.1 Update on ECHA / Eurometaux discussions

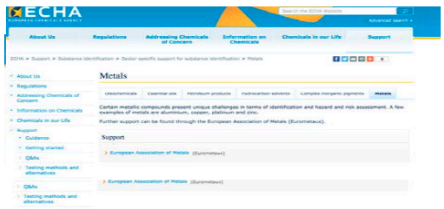
Inquiries: the (never ending)story

- Since 2012 industry submits iUVCB inquiries with the intention to join existing and known SIEFs
- iUVCBs inquiries resulted in negative feedback from ECHA
- Note: same feedback from PPORD submissions!!

- Typical messages from ECHA:
  - Data provided does not allow to prove substance can join the existing SIEF – substance sameness is questioned
  - SID is not correctly reported: elemental content cannot replace constituents information

Substance Identity of iUVCB: meeting with ECHA

- Following an additional iUVCB inquiry rejected by ECHA, EM further interacted with the ECHA SID unit before and after summer 2015
- On December 2nd a meeting was held with the ECHA SID team to discuss iUVCB SID approach
- The meeting was intense but overall positive
- ECHA showed openness to listen to iUVCB difficulties and to 'cooperate' with the NFM sector to develop a common approach and possibly publish it and referenced it on the ECHA website



ECHA key messages (1)

ECHA's concerns:

- Multiple "substances" are seemingly merged in one registration, which seems to refer to a group/category entry
- Overly generically defined sources and processes with broad ranges in composition, leading to a lack of transparency of the LE & joint submission dossier
- Speciation/mineralogical composition is insufficiently reported

ECHA's advise:

- Other sectors are progressing in SID
- Some are about to or have already published guidance documents (oleochemicals, essential oils)
- It's important to communicate with other actors in the inorganic sectors and find a way to align

ECHA key messages (2)

- Merging/re-scoping EINECS entries:
  - Often several EINECS synonym are kept in the dossier
  - But synonims refer to substances with different and even broader composition
- Overly broad processes/sources were merged
  - ECHA's assumption is that e.g. by-products from blast furnace and electric furnace are different
  - Wording used in the CSR introduction refers to a group/category and not to a substance
- Redefinition of substance composition is needed
  - Difficult to link LE composition to SIEF composition (e.g. Cu: 0 –almost 100%??)
  - Which oxides are 'truly' present??
  - How can commonalities between samples be recognised?

ECHA key messages (3)

- Overly broad compositions were merged
  - LE dossier can be more or less better described, but SIEF composition can cover several substances
- Analytical data
  - What is the representative sample? Why it is representative for SID and not for testing?
  - How can it be representative for the group of iUVCB substances?
  - Annex VII-XI data in iUVCB Dossiers: 'elements' are not constituents – link unclear with RA

Timeline

EM was able to gain time to improve/refine the iUVCB dossiers before these are open for evaluation

- NEED TO ACT NOW:
  - → Improve/refine NFM iUVCB dossiers
  - → Ensure development of a transparent approach, both at SID and at hazard/risk assessment
- EM agreed with ECHA to avoid reworking the dossier now and to focus first on guidance and common principles
- EM met complex inorganic pigments (CIP) experts, as they are currently working on the same SID issues and are also in discussion with ECHA

iUVCB SID issue: looking ahead

Straight forward case: industry manages to ensure iUVBC sameness criteria and to support current iUVCB identification. Few actions are still required:

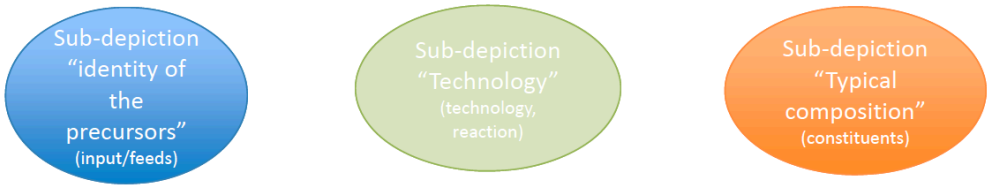
- Some cleaning in the dossiers (e.g. EINECS entries)
- Further IUCLID formatting development
- Refinement of Substance Identity Profile (SIP)

More complex case: split of existing iUVCB dossiers:

- Tonnage re-calculation will be necessary (and could also lead to lower tonnages for some iUVCBs)
- A group approach could be developed
- Splitting dossier would lead to submit new registration dossiers, with the same RA, but paying applicable fees to ECHA

UVCB substances depicted as the "output of a process"

- ECHA specified that iUVCB identification depends on three sub-depictions (source, process, composition)
- These can be variable, but fixed parameters per substances should be identifiable
- It is NOT defendable that the three have the same degree of variability!!



Source	Process	Constituents
Primary & secondary	Smelting	e.g. 0 -100%
'restrictively refined'	'restrictively refined'	variable
variable	'restrictively refined'	'restrictively refined'
'restrictively refined'	variable	'restrictively refined'
'restrictively refined'	'restrictively refined'	'restrictively refined'

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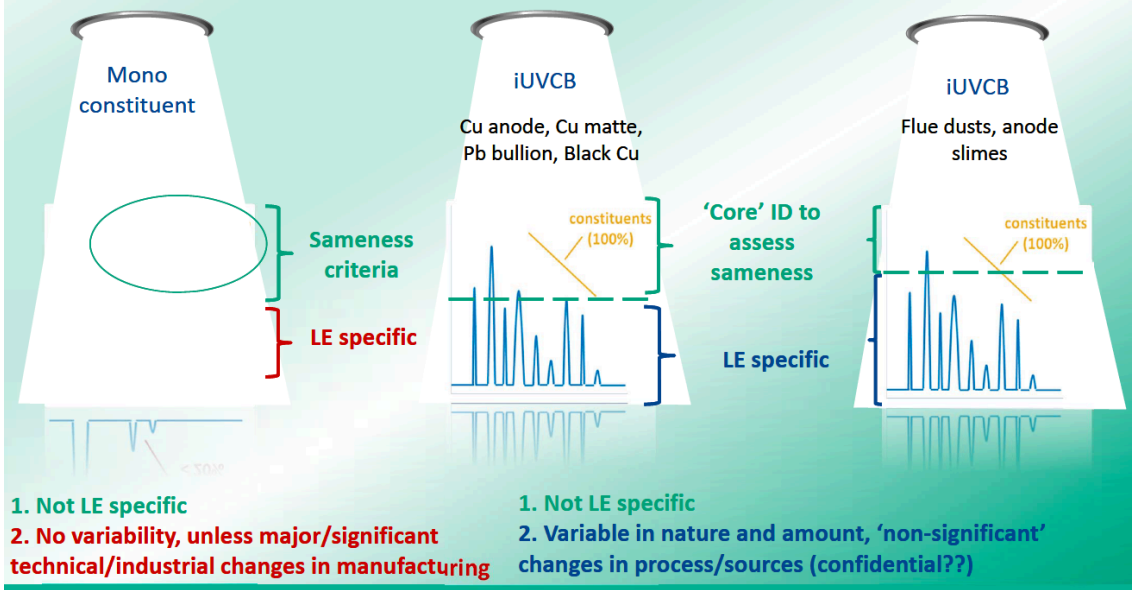
In practice: look at the whole picture (2)

Focus on **sameness criteria** as for a well-defined substance



1. Not LE specific
2. No variability, unless major/significant technical/industrial changes in manufacturing

1. Not LE specific
2. Variable in nature and amount, 'non-significant' changes in process/sources (confidential??)

EM strategy in practice: how ?

- **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)

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,…)		

- **SID:** assign weights to SID parameters to assess whether the iUVCB is sufficiently and uniquely identified

- **Reporting:** in a next step, work on how to report composition in IUCLID as based on combination of speciation/mineralogical (for the main constituents) and elemental analysis (for minor constituents) or provide both in parallel…

2.2 Refined SID PM Refinables

- Doré

Substance Name **Doré**	Substance Information Page http://echa.europa.eu/brief-profile/-/briefprofile/100.067.065			**Legend**	Decisive substance sameness criterion Indicative substance sameness criterion No substance sameness criterion
Substance description: SIEF description:	Metallic bars/ingots, grains or anodes and their residues (spent anodes) resulting from smelting processes applied on primary and secondary feeds with high silver and/or gold content. Doré mainly contains silver and/or gold and copper, lower quantities of platinum group metals (iridium, osmium, palladium, platinum, rhodium, and ruthenium) and other non-ferrous metals in varying concentrations.				
Substance Identity	EC/list name:	Doré		SMILES:	not applicable
	IUPAC name:			InChI:	not applicable
	Other names	Doré bars, Doré alloys, Precious metal rich bullion, Doré metal		Type of substance:	UVCB
	EC/List no.:	273-793-6		origin:	Inorganic
	CAS no.:	69029-47-6			
	Molecular formula:	not applicable		Substance listed	

Doré

SID parameters	Sameness criteria				Indication of variability (fixed, low or high variation)
Sources (input materials)	Gold and/or silver rich primary and secondary sources (anode slimes from copper electro-refining, precious metals enriched alloy from lead refining, leach residues and crude metal from zinc and lead production, returns and sweeps from silver and/or gold production (such as dust from bag filters, slimes from wet dedusting systems, silver cement obtained from spent silver and/or gold electrolyte, slags, crushed refractory) and silver and/or gold scrap)				medium variability
Process	Enriched phase from smelting with coke, silica, lime and sodium carbonate fluxes to maximise separation from other metals whilst controlling the formation of volatile metal compounds. Different combinations of batch wise processes can be used depending on the composition of the raw materials and the local conditions.				low variability
Elemental composition	**Core**	**min (% w/w)**	**max (% w/w)**	**Typical (%w/w)**	
	Silver	15	99	72	high variability
	Gold	0	83	9	high variability
	Copper	0	50	6	high variability
	Other constituents				medium variability
	Sum=			87	
Mineralogical composition	Total of metallic silver and gold (metallic silver encloses copper selenium silver tellurides, copper oxides and tellurium-bearing copper lead oxides which also fill the interstices of metallic silver. Therefore these intermetallic species shall be considered as inclusion and not as available compounds. The sample tested for speciation was prepared by drilling/sawing, which might have caused some oxidation.)	20,5	99,5	87	low variability
	Sum=			87	
Physical characteristics	**physical state (at 20°C, 1013 hPa)**	Solid massive form with grey to dark grey colour			fixed
Conclusion	**Doré is a solid massive form with grey to dark grey colour and is produced by means of smelting processes applied on primary and secondary feeds with high silver and/or gold content. Doré is rich in metallic silver and/or gold and copper.**				

Doré

SID parameters	Sameness criteria				Indication of variability (fixed, low or high variation)
Sources (input materials)	Gold and/or silver rich primary and secondary sources (anode slimes from copper electro-refining, precious metals enriched alloy from lead refining, leach residues and crude metal from zinc and lead producti from silver and/or gold production (such as dust from bag filters, slimes from wet dedusting s obtained from spent silver and/or gold electrolyte, slags, crushed refractory) and silver and/or gold scrap)				medium variability
Process	Enriched phase from smelting with coke, silica, lime and sodium carbonate fluxes to maximise separation from other metals whilst controlling the formation of volatile metal compounds. Different combinations of batch wise processes can be used depending on the composition of the raw materials and the local conditions.				low variability
Eleme		**min (% w/w)**	**max (% w/w)**	**Typical (%w/w)**	
		15	99	72	high variability
		0	83	9	high variability
	Copper	0	50		
	Other constituents				
	Sum=			87	
Mineralogical composition	Total of metallic silver and gold (metallic silver encloses copper selenium silver tellurides, copper oxides and tellurium-bearing copper lead oxides which also fill the interstices of metallic silver. Therefore these intermetallic species shall be considered as inclusion and not as available compounds. The sample tested for speciation was prepared by drilling/sawing, which might have caused some oxidation.)	20,5	99,5	87	low variability
	Sum=				
Physical characteristics	**physical state (at 20°C, 1013 hPa)**	Solid ma			
Conclusion	**Doré is a solid massive form with grey to dark grey colour and is produced by means of smelting processes applied on primary and secondary feeds with high silver and/or gold content. Doré is rich in metallic silver and/or gold and copper.**				

Is there min Au or Ag content of sources for doré production?

Can we further specify, e.g. type of furnace, min-max smelting t°, process conditions?

Can we increase the minimum?

"Although the individual Au and Ag content of doré can be very variable from registrant to registrant, and from day to day, due to the nr and type of sources that are available to that registrant on that day, for smelting, and whether that specific day the content will lead to a Ag, or a Au doré. It is only after the production of the Ag or Au doré that this is sent to a specialised step aimed at concentrating the Ag or Au. Also, because Ag is less scarce than Au, Ag doré is more common than Au doré. But the sources (because they are not necessarily pre-selected) and process to produce a Ag rich or a Au rich doré are the same."

→ Most doré samples ssem to have either high Au or high Ag content! Can we justify keeping them together?

• Matte

Substance Name	Substance Information Page				
Matte, precious metal	http://echa.europa.eu/brief-profile/-/briefprofile/100.098.593			**Legend**	Decisive substance sameness criterion
					Indicative substance sameness criterion
Substance description:	Substance resulting from the smelting of precious metals and its alloys obtained from primary and secondary sources and including recycled plant intermediates. Matte, precious metal is composed primarily of base metal sulfides containing precious metals and may contain other residual non-ferrous metals and their compounds in varying concentrations.				No substance sameness criterion
SIEF description:					
Substance Identity	EC/list name:	Matte, precious metal		SMILES:	not applicable
	IUPAC name:			InChI:	not applicable
	Other names			Type of substance:	UVCB
	EC/List no.:	308-506-6		origin:	Inorganic
	CAS no.:	98072-52-7			
	Molecular formula:	not applicable		Substance listed	

Matte

SID parameters	**Sameness criteria**				**Indication of variability** (fixed, low or high variation)
Sources (input materials)	Precious metal rich primary and secondary (sulfidic) sources and recycled plant intermediates				medium variability
Process	Enriched sulfidic phase from smelting process, separated by tapping.				low variability
Elemental composition	**Core**	**min (% w/w)**	**max (% w/w)**	**Typical (%w/w)**	
	Silver	0	25	11	high variability
	Copper	6	32	16	medium variability
	Iron	0	32	13	high variability
	Lead	0,5	10	6	medium variability
	Nickel	0,3	32	15	medium variability
	Sulfur	0	30	14	high variability
	Other constituents				medium variability
	Sum=			75	
Mineralogical composition	Total of base metal sulfides	43	84	63	medium variability
	Silver sulfide	0	29	13	high variability
	Sum=			76	
Physical characteristics	**physical state (at 20°C, 1013 hPa)**	Solid massive form with grey to black colour			fixed
Conclusion	**Matte, precious metal is a solid massive form with grey to black colour and is produced by means of smelting processes applied on primary and secondary sulfidic feeds with high precious metal content. Matte, precious metal is composed primarily of base metal sulfides containing precious metals.**				

Matte

SID parameters	Sameness criteria				Indication of variability (fixed, low or high variation)
Sources (input materials)	Precious metal rich primary and secondary (sulfidic) sources and recycled plant intermediates				medium variability
Process	Enriched sulfidic phase from smelting process, separated by tapping.				
Elemental composition	**Core**	**min (% w/w)**	**max (% w/w)**	**Typical (%w/w)**	
		0	25	11	high variability
		6	3		
		0	3		
		0,5	10	6	medium variability
	Nickel	0,3	32	15	medium variability
	Sulfur	0	30	14	high variability
	Other constituents				medium variability
	Sum=			75	
Mineralogical composition	Total of base metal sulfides	43	84	63	medium variability
	Silver sulfide	0	29	13	high variability
	Sum=			76	
Physical characteristics	**physical state (at 20°C, 1013 hPa)**	Solid massive form with grey to black colour			fixed
Conclusion	**Matte, precious metal is a solid massive form with grey to black colour and is produced by means of smelting processes applied on primary and secondary sulfidic feeds with high precious metal content. Matte, precious metal is composed primarily of base metal sulfides containing precious metals.**				

Can we be more specific? Min PM content of sources?

Can we further specify, e.g. type of furnace to smelt sulfidic sources, min-max smelting t°, process conditions?

Can we increase the minimum?

- Flue dust

Substance Name	Substance Information Page				
Flue dust, precious metal refining				**Legend**	Decisive substance sameness criterion
					Indicative substance sameness criterion
Substance description:	Product resulting from the smelting, refining and/or use of PMs and its alloys obtained from primary and secondary sources and including recycled plant intermediates. Recovered from exhaust air by filtration via cloth bags, arising from hygiene extraction systems on processes in the Precious metals recovery flowsheet. Flue dusts mainly contain metal oxides, hydroxides, sulphides and chlorides in varying concentrations, with some small quantities of precious metals.				No substance sameness criterion
SIEF description:					
Substance Identity	EC/list name:	Flue dust, precious metal refining		SMILES:	not applicable
	IUPAC name:			InChI:	not applicable
	Other names			Type of substance:	UVCB
	EC/List no.:	308-496-3		origin:	Inorganic
	CAS no.:	98072-44-7			
	Molecular formula:	not applicable		Substance listed	

Flue dust

SID parameters	Sameness criteria				Indication of variability (fixed, low or high variation)
Sources (input materials)	Precious metal rich primary and secondary (sulfidic) sources and recycled plant intermediates				medium variability
Process	In many processes during production or processing, also refining, of precious metal containing materials, dusts are generated and collected in appropriate facilities. These processes can include milling, thermal treatment, melting, smelting, grinding or polishing. Commonly, dusts from several processes are collected through a single exhaust gas filtering system at a site. This mixture of filter dusts is then sent to Refining to reclaim the precious metals.				medium variability
Elemental composition	Core	min (% w/w)	max (% w/w)	Typical (%w/w)	
	Silver	0,3	18	9	high variability
	PGMs	0	8	1,5	high variability
	Bismuth	0,1	8	2	high variability
	Calcium	0	11	3	high variability
	Chlorine	0	23	10	high variability
	Copper	0,5	10	4	high variability
	Lead	3	50	18	high variability
	Selenium	0	25	6	high variability
	Zinc	0	16	8	high variability
	Other constituents				high variability
	Sum=			61,5	
Mineralogical composition	?				high variability
	Sum=			0	
Physical characteristics	physical state (at 20°C, 1013 hPa)	Solid powder			fixed

Flue dust

SID parameters	Sameness criteria				Indication of variability (fixed, low or high variation)
Sources (input materials)	Precious metal rich primary and secondary (sulfidic) sources and recycled plant intermediates				medium variability
Process	In many processes during production or processing, also refining, of precious metal containing materials, dusts are generated and collected in appropriate facilities. These processes can include milling, thermal treatment, melting, smelting, grinding or polishing. Commonly, dusts from several processes are collected through a single exhaust gas filtering system at a site. This mixture of filter dusts is then sent to Refining to reclaim the precious metals.				medium variability
Elem		min (% w/w)	max (% w/w)	Typical (%w/w)	
	Silver	0,3	18		
	PGMs	0			
	Bismuth	0,1	8	2	high variability
	Calcium	0	11	3	high variability
	Chlorine	0	23	10	high variability
	Copper	0,5	10	4	high variability
	Lead	3	50	18	high variability
	Selenium	0	25	6	high variability
	Zinc	0	16	8	high variability
	Other constituents				high variability
	Sum=			61,5	
Mineralogical composition	?				high variability
	Sum=			0	
Physical characteristics	physical state (at 20°C, 1013 hPa)	Solid powder			fixed

Can we further specify, e.g. give more details on exhaust (dry/wet)?

Can we increase the minimum?

Refined SID PM Refinables: way forward

- Refined SID sheets will be circulated after the meeting
- PM Refiners to review/provide input by **27 May**
- Refined SID sheets will be updated by end of June

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3. Combined toxicity: update on status

Koen Oorts, ARCHE

Commitments industry took with ECHA

- Roadmap submitted to ECHA in January 2014 identified short, **medium** and long **term actions** to improve iUVCB Dossiers

Topic	Objective	Action	Main actor…
Hazard assessment	Clarify DNELs/PNECs data selection to ensure transparency on follow up when data are not yet available and updates are required	For cases where no DNELs/PNECs are available today, improve robustness of approach and justifications to limit the use of qualitative approaches and update the dossiers accordingly	Industry
Exposure assessment	Monitoring data – contextual data: demonstrate alignment with R14.	In the dossier: • E.g. explain as adequate the link between exposure data and concentration of constituents (%)	Industry
Uncertainty	Further improve uncertainty analysis and demonstration of robustness of methodology	In the dossier: • Ensure clear report on how conservatism is handed in hazard and exposure assessment • Assess uncertainty specifically addressing UVCB aspects (uncertainty analysis on individual elements should be part of the respective element dossiers).	Industry
Validation	Work on validation of the approach/methodology and enhance approach credibility/robustness	Improve uncertainty analysis aspects and include outcomes in the dossiers	Industry and further exchanges with ECHA are welcomed
Combined toxicity	Further improve dossiers with information on combined toxicity as becoming available from scientific progress	In the dossier: • Develop a paper on tiered approach for the environment combined effects that can be consistently referred to in the different dossiers	Industry and further exchanges with ECHA are welcomed

Environmental combined toxicity: where do we stand?

- Workshop at Eurometaux on October 20th 2015 with experts from industry, academia and regulators
- Aim of the workshop: the development of a pragmatic, scientific based approach to assess the environmental toxicity of complex multi-metallic substances, as iUVCBs
- The hybrid tiered approach proposed by ETAP (2015) was deeply discussed to analyse how to account and overcome typical complex multi-metallic substances difficulties (e.g. missing data)
- A refined Tiered Approach was developed and is currently being tested

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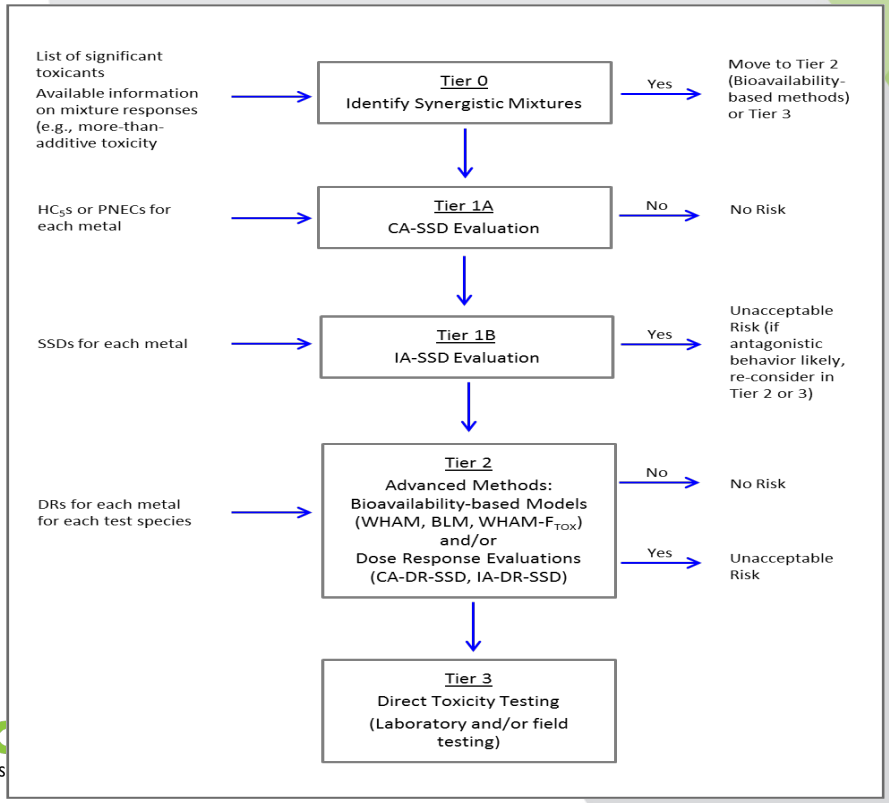
ETAP hybrid tiered approach



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ASSESSING RISKS

Proposed combined risk assessment approach for iUVCBs

List of constituents classified or identified as hazardous to the environment

Tier 0
Assume Concentration Addition (CA) between metal constituents, without synergistic effects

uncertainty assessment → Selection of appropriate metal specific assessment factors

PEC and PNEC values for each hazardous constituent

Tier 1
Calculate RCR_{mix} based on summation of PECanthropogenic/PNEC ratios

uncertainty assessment
$RCR_{mix} < 1/AF$ → No Risk

$RCR_{mix} \geq 1/AF$

Bioavailability corrections, SSD, refined exposure data, …

Tier 2a
Refined assessment (Bioavailability, SSD msPAF, allocation of emissions)

uncertainty assessment
$RCR_{mix} < 1/AF$ → No Risk

Toxicity data for each metal for each trophic level

Tier 2b
CA approach per trophic level

uncertainty assessment
$RCR_{mix} < 1/AF$ → No Risk

$RCR_{mix} \geq 1/AF$

Tier 3
Direct Toxicity Testing
(Risk management check)

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Tier 0

List of constituents classified or identified as hazardous to the environment → Tier 0: Assume Concentration Addition (CA) between metal constituents, without synergistic effects → uncertainty assessment → Selection of appropriate metal specific assessment factors

- Only constituents identified as classified or as hazardous to the environment (meeting the classification criteria) should be taken into account for the combined toxicity assessment.

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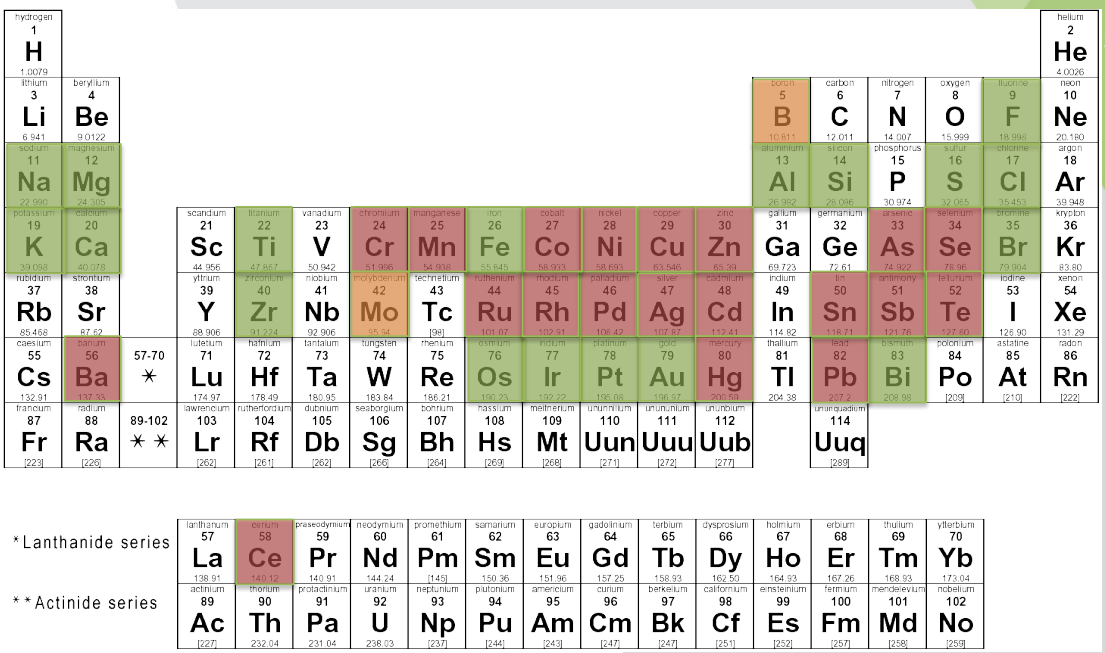
Classified or hazardous metals for environment



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ASSESSING RISKS OF CHEMICALS

Tier 0

List of constituents classified or identified as hazardous to the environment → Tier 0: Assume Concentration Addition (CA) between metal constituents, without synergistic effects → uncertainty assessment → Selection of appropriate metal specific assessment factors

- Only constituents identified as classified or as hazardous to the environment (meeting the classification criteria) should be taken into account for the combined toxicity assessment.
- General assumption:
  Concentration Addition (CA) is conservative and there is **no need to considered specific synergistic effects among metals**
  - ➢ Need for comprehensive review on interactions of metals focused at low concentrations, compared to CA and Independent Action (IA)
  - ➢ Information to be used to quantify uncertainty on the potential occurrence of synergistic effects

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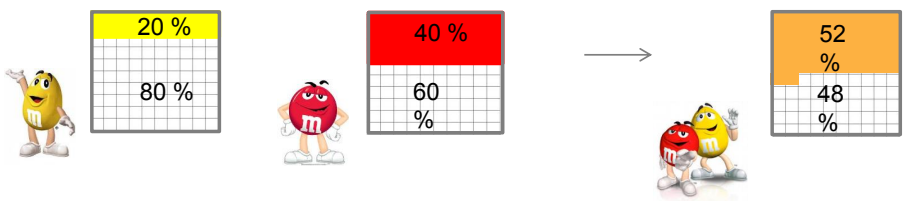
Concentration addition versus Independent action

- **Concentration addition (CA)**

similar modes of action *(ex. PCB's)* $\sum TU_M = \sum \frac{C_M}{EC50_M}$

- **Independent action (IA)**

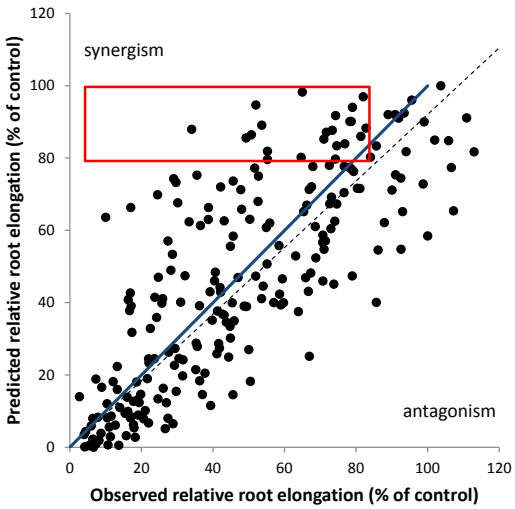
different modes of action $Y(Cmix) = \prod_{i=1}^{n}[Y(Ci)]$



Concentration addition versus Independent action

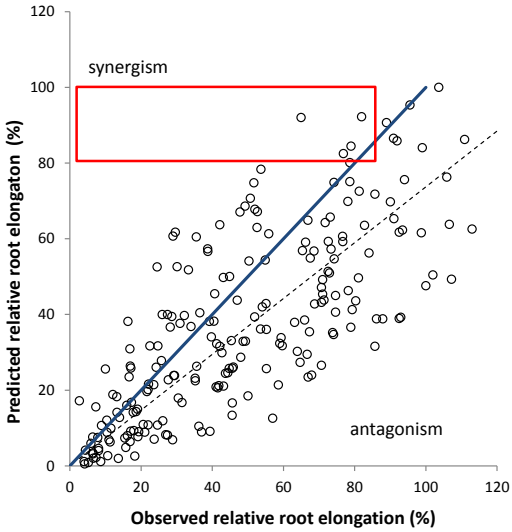
Hordeum vulgare FIAM

Independent action



RMSE= 19
Y= 0.92 x

Concentration addition



RMSE= 23
Y=0.73x

Concentration addition versus Independent action

Based on free ion activities (except *Danio rerio*)

		Cerodapnia dubia		Daphnia magna		Danio rerio		Hordeum vulgare	
Dataset		CA	IA	CA	IA	CA	IA	CA	IA
Cu-Zn								a	a
Cu-Ni								s	s
Cu-Cd						?	s	0	0
Ni-Zn		a	0	0	s			a	a
Ni-Cd								0	0
Zn-Cd								a	a
Pb-Zn		a	a						
Pb-Ni		a	0						
Cu-Cd-Zn								a	a
Ni-Cd-Zn								a	a
Cu-Ni-Cd								0	0
Cu-Ni-Zn		a	a					a	a
Ni-Zn-Pb		a	0						
Cu-Cd-Ni-Zn		0	0					a	a/0

Tier 1

PEC and PNEC values for each hazardous constituent → Tier 1: Calculate RCR_{mix} based on summation of PECanthropogenic/PNEC ratios → uncertainty assessment → $RCR_{mix} < 1/AF$ → No Risk

$$RCR_{mix} = \sum_{i=1}^{n} \frac{PEC_i}{PNEC_i}$$

- CA approach (PEC/PNEC summation) is propagated as default tier 1 approach for environment
- PEC:
  - Based on effluent concentrations and EUSES modelling
    - Commonly measured elements: Cu, Ni, Zn, Pb, Cd and As
    - What about iUVCB constituents not measured or below detection limit? (e.g. spERCs, DL/2, …)
  - Natural background concentrations not considered

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Tier 1

PEC and PNEC values for each hazardous constituent → Tier 1: Calculate RCR_{mix} based on summation of PECanthropogenic/PNEC ratios → uncertainty assessment → $RCR_{mix} < 1/AF$ → No Risk

$$RCR_{mix} = \sum_{i=1}^{n} \frac{PEC_i}{PNEC_i}$$

- PNEC:
  - What about data poor constituents?
    - QICAR (quantitative ion character-activity relationships) available for prediction of toxicity data to aquatic organisms
  - PNEC added?

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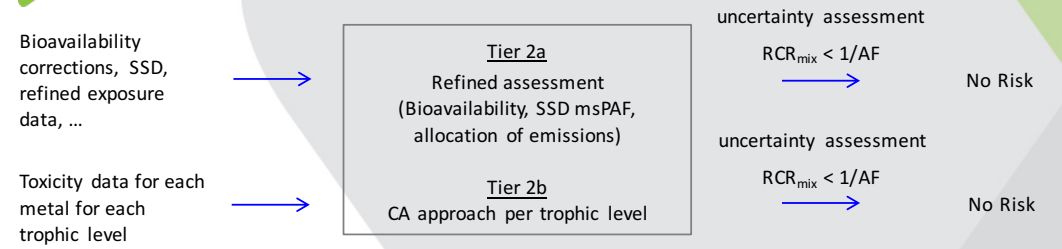
Tier 2



- Tier 2a: refinement of tier 1 based on:
  - Effects (PNEC): e.g. bioavailability
  - Exposure (PEC): e.g. allocation of emission streams
  - Risk summation: e.g. use of msPAF approach for those metals with a SSD, IA approach
  - Focus on constituents contributing most to RCR_{mix}

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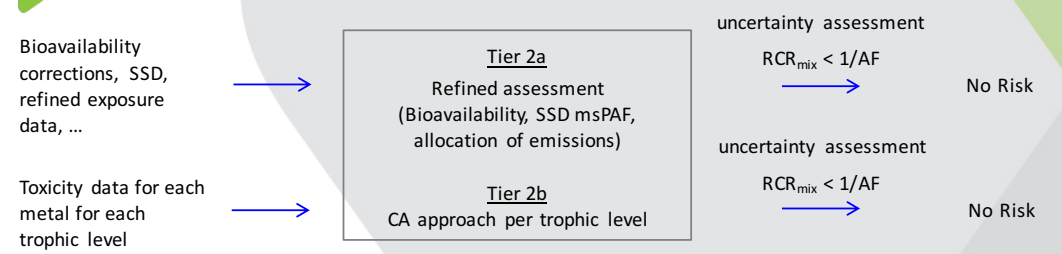
Tier 2



- Tier 2b: CA approach per trophic level

$$RCR_{mix} = \max\left(\sum_{i=1}^{n} \frac{PEC_i}{EC_{10,i,j} / AF_i}\right)$$

$EC_{10,i,j}$: lowest EC_{10} (or HC_5) for constituent i and trophic level or species j

AF_i: Assessment factor for calculating PNEC for constituent i

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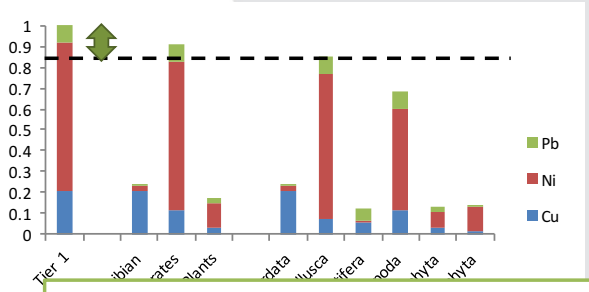
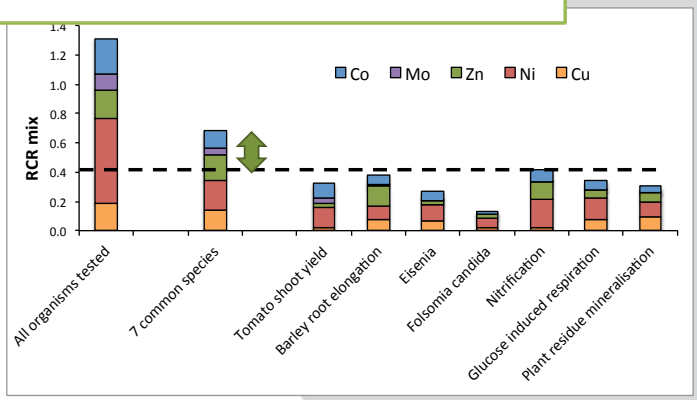
Toxic unit summation per trophic or species level



Separating trophic levels or species and endpoints can result in up to a factor 2 reduction of RCR_{mix}



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Tier 3

Tier 3
Direct Toxicity Testing
(Risk management check)

- Toxicity testing to be used as a "**risk management check**" in case the component-based predictions still identify risks.
- **Effluents** are the most relevant starting point for testing.
- Testing should not be used to derive a PNEC for the iUVCB
- Focus on the **most sensitive trophic levels** identified in tier 2b
- Different approaches:
  - Dilution series in local receiving water
  - Dilution series in a "standard" water medium

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Way forward

What	Who	Timing	Sponsor
Check proposed draft approach with two possible case studies: a iUVCB from EPMF (slags doré) and a iUVCB from ECI (flue dust)	Arche	February-May 2016	EPMF, ECI, Eurometaux
Compilation of added PNEC values for common (hazardous) metal constituents in iUVCBs	Arche	February-May 2016	Eurometaux
Check usefulness and relevance of existing QICARs: review of available models: what can be predicted for which endpoints + assessment of the uncertainty	Arche	February-May 2016	Eurometaux
Update approach based on comments from industry and learning lessons from testing. Share approach with academics and regulators + presentation at Risk Assessment Taskforce meeting on 4-5 April and SETAC Europe meeting in Nantes (22-26 May)	Arche + industry	March-May 2016	Eurometaux

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Way forward

What	Who	Timing	Sponsor
Publication of review of existing experience on synergism/antagonism compared to CA and IA for chronic endpoints + uncertainty assessment (exact scope still to be discussed)	Erik Smolders, Karel De Schamphelaere, … + Arche (still to be discussed)	2016	Eurometaux + Metal commodities
Assessment of potential of WHAM-FTox for test iUVCB from ECI: identification of data gaps and weaknesses	Ed Tipping (+ Arche)	2016?	ECI
Summary of knowledge on MoA of metals for all levels of organisms in water, sediment and soil	ETAP?	?	?

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4. Workplan and budget

2015 finances after audit

		Budget	Real	Delta
2.7	***Refinables-specific costs***	***365.824 €***	***17.685 €***	***348.139 €***
2.7.1	**Refinables REACH registration and CLP notification work programme**	***365.824 €***	***17.685 €***	***348.139 €***
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 €	5 €	*-5 €*
	IUCLID 5 Hosting System	3.150 €		*3.150 €*
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 €	5.130 €	*73.136 €*
	V. Compilation of IUCLID 5 file & Registration Dossiers	97.438 €	2.666 €	*94.772 €*
	VI. Administration / other	5.360 €	4.396 €	*964 €*

2017 draft budget

	PMC 2017 Budget *to be spent*	PMC 2017 Budget *to be invoiced*	PMC 2017 HR
2.7 Refinables-specific costs	***441.100 €***	***118.600 €***	***0,3***
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	**375.500 €**	**53.000 €**	
2.7.2.1 Phase 1: Scoping	5.000 €	5.000 €	
2.7.2.2 Phase 2: Substance identification	87.500 €	0 €	
2.7.2.3 Phase 3: Effects assessment and classification	238.000 €	3.000 €	
2.7.2.4 Phase 4: Exposure and risk assessment	20.000 €	20.000 €	
2.7.2.5a Phase 5a: Compilation of IUCLID 5 file & Registration Dossiers	20.000 €	20.000 €	
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 €**	
2.7.4 Refinables REACH classification & labelling	**0 €**	**0 €**	
2.7.5 Refinables REACH authorisation	**0 €**	**0 €**	
2.7.6 Refinables internal and external fixed Scientific Manager	**65.600 €**	**65.600 €**	
2.7.7 Refinables Building reserves			

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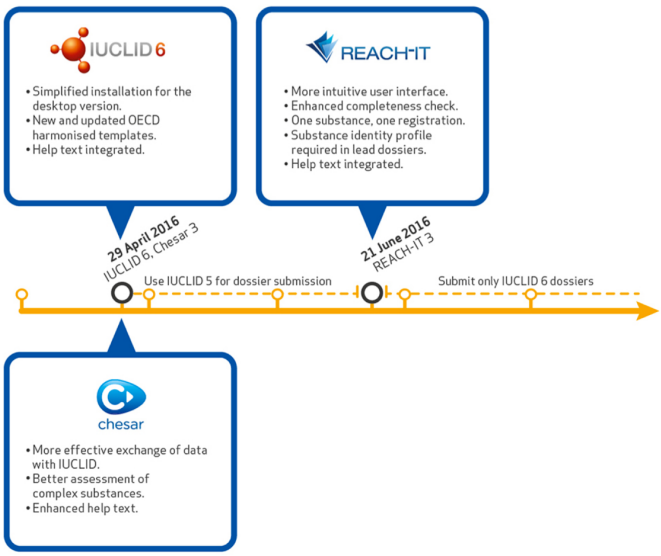
5. AOB, next meetings/calls and closing remarks

AOB

- Release dates updated REACH IT tools:
  - IUCLID 6/CHESAR3 available 29th April
  - REACH-IT 3 scheduled for 21st June



AOB

- Thank you Edwin!

THANK YOU

www.epmf.be | info@epmf.be

Avenue de Broqueville 12, B-1150 Brussels
+32 (0)2 775 63 86