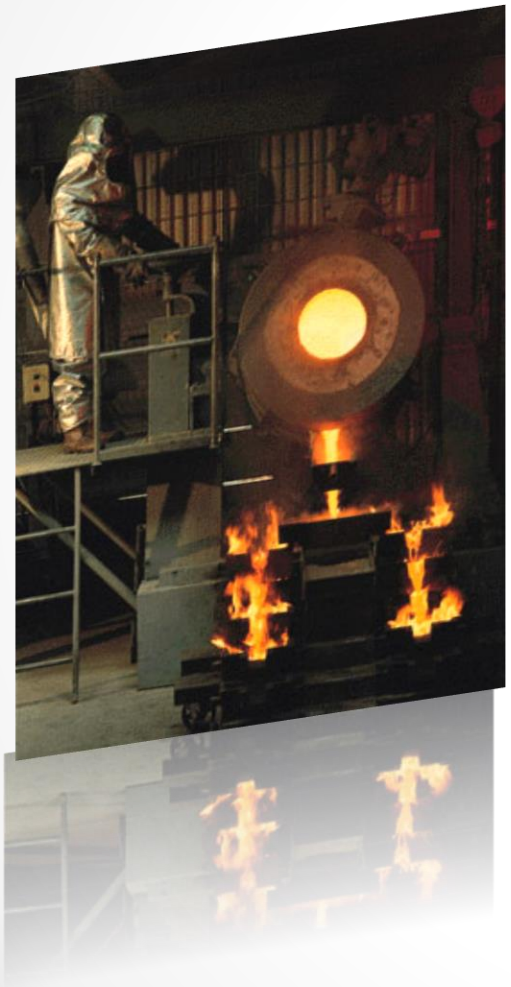
Precious Metals & Rhenium Consortium
Brussels, 1 April 2014, 10:30-16:00



PM Refiners

Work Group

Meeting

1. Welcome & Introduction

Daniela CHOLAKOVA

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Approval of the Agenda
- Approval of minutes of the last meeting (6 February 2014) – including status of action points

Agenda

1. Welcome and introduction
2. Substance identity (SID) of PM Refinables
3. Updated classifications PM Refinables
4. CSR generic and intro sections
5. CSR human health and occupational sections
6. CSR environmental sections
7. Submission upgraded PM Refinables dossiers
8. Next steps, AOB, next meetings/calls and closing remarks

Actions (1)

Action	Who?	Status
Show that we have considered the risks of combined toxicity in dossier 'upgrade' and indicate way forward / actions to be undertaken after 22 April 2014	EBRC & WCA led by EM	Done
Explain claimed 'conservatism' and limited or controlled 'uncertainty' in uncertainty analysis	EBRC & WCA with EM	Done
If further updates are announced in the dossier submitted in April, indicate the date of the update	PMC Sec, EBRC & WCA	Done
Check schedule of dossier updates with other metal consortia for dossiers where the use phase of the ES is in another dossier (e.g. Cu electrolytic slimes & sludges used in the production of Doré) to align update frequency and strive towards parallel updates	PMC Sec with EM	Q2 2014
Explicitly explain monitoring data and programme's limitations	WCA with EM	Done
Investigate need to derive surrogate values to function as DNEL for those constituents where no DNEL is available	EBRC with EM	Done
Explain industry's position on possible need for validation testing as part of the uncertainty analysis	EBRC & WCA led by EM	Done
Develop LE specific composition (typical + concentration range) with the typical composition adding up to 100% and excluding extreme outliers (properly / mathematically defined)	All PM Ref registrants	Done/Ongoing?
Update the generic composition in the Refinables ID cards as agreed + Indicate where further splitting may be needed (e.g. Doré)	PMC Sec	Done
Check > 80% metal contents in Doré and get explanation from relevant companies	PMC Sec	SID Doré to be refined
Consider splitting exercise for Doré	PM Ref WG	
Review classifications of the PM Refinables + Include updated classifications in ID cards	ARCHE/PMC Sec	Done
Recirculate MeClas reference sample codes for PM Ref Members to derive their own classification	PMC Sec	Done
Produce new ID Cards for PM slags (2) and PM slimes & sludges (3) and circulate for comment/finalization	PMC Sec	Done for slags SID Slimes & sludges to be refined
Once the dossiers have been finalized, review the LoA price to reflect the additional work done since the first submission in 2010	PMC Sec	After Apr 2014
After the separate dossiers have been submitted, inform the SIEF, together with the LoA Agreement/price announcement	PMC Sec	
Inform LoA purchaser of slag dossier about splitting and possible consequences (+ composition, etc.)	PMC Sec	Consequences still unclear

Actions (2)

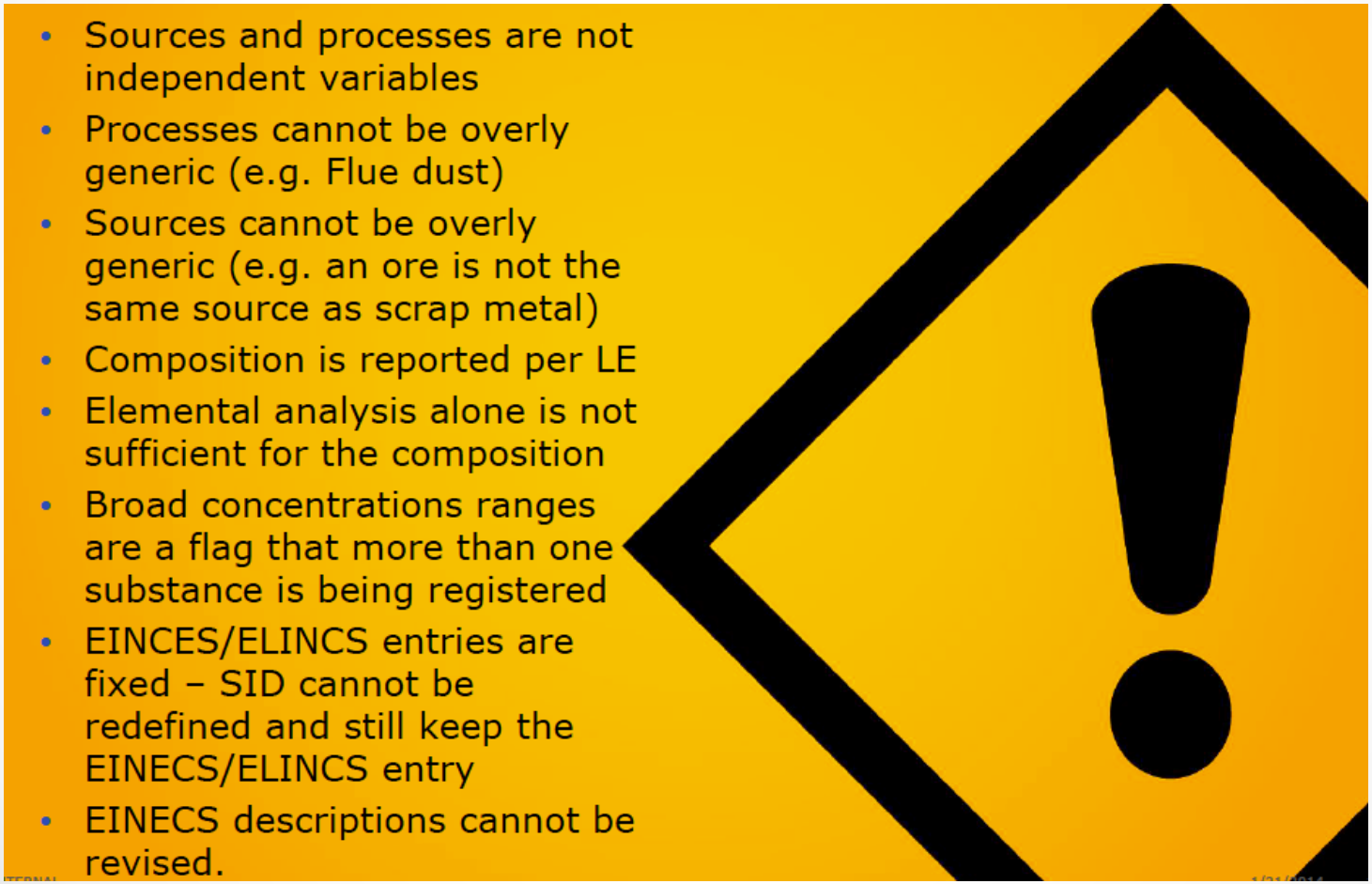
Action	Who?	Status
Develop example of impossibility to change EINECS description on registration updates and upgrades and pass through EM for discussion with ECHA; use PM slags scenario	PMC Sec with EM	Done
Develop example of typical organic process versus inorganic process of refining for presentation at ECHA's site visit with EM on 14 Feb 2014	PMC Sec to send to EM	Done
Prepare the following sections to be included in each Refinable dossier: • Justifications for deviating from ECHA's warning messages (cf. slide 33 in Annex 2) • Commentary to explain effort to refine substance ID • A decision tree to be used to define Refinable dossier scope / substance ID	PMC Sec; review by PM Ref WG	Ongoing Decision tree under development
Check all Refinables using the decision tree and consider further splitting	PM Ref WG	After Apr 2014
MEASE to be explained in Refinables' CSR unless a reference can be made to an externally published scientific reference	EBRC	Done
Produce 1 workplace-specific ES across Refinables instead of a UVCB-specific ES	EBRC	Done
Review/comment 2nd draft company-specific ES	PM Ref WG	Done
Decide if site-specific occupational ES will be attached to the dossier or not (if not, it should be indicated that they have one available on-site)	Each company	Ongoing?
Keep site-specific ES for occupational and environmental exposure separate to facilitate longer term updates without disclosing company specificities and/or delaying occ. versus env. work	WCA & EBRC	Done
Circulate one example CSR for comment (and next individual CSRs later, assuming less time will be required for comment)	WCA, EBRC & PMC Sec	Done
Justify use of SpERCs in environmental exposure assessment	WCA	Done
Design recommendation for monitoring programme of stack emissions considering all constituents with environmental relevance and for which an RCR < 1 cannot be achieved using SpERCs and/or in the GES (after assessment of constituents to be included)	WCA & EBRC	After Apr 2014
Develop common wording/approach across metals sector for use in the CSR of all inorganic UVCBs for the following sections: MvE, secondary poisoning, consideration of waste stage	PMC sec with EM	Done
If consortia request unreasonable payments for data-sharing agreements, invite the Ref WG to discuss, negotiate and/or approve the proposed amount	PMC Sec	Not applicable yet
Perform data-gap analysis for phys-chem endpoints for the 3 new sub-groups of slimes & sludges, PM Refining and submit to the PM Ref WG to check availability of info among PM Ref Members	PMC Sec with WCA	Postponed until after Apr 2014
Submission of new dossiers for PM slags and PM slimes & sludges by LRs	LRs	
Submission of dossier 'upgrades' by LRs	LRs	By 21 Apr 2014
Submission of new dossiers and dossier 'upgrades' by co-registrants	Co-registrants	By 30 Apr 2014
Set date for next PM Ref WG meeting once date of EM/ECHA workshop is confirmed	PMC Sec	Done

2. Substance identity (SID) of PM Refinables

Katrien ARIJS

2.1. Feedback from ECHA (1)

- ECHA requested improved SID for existing UVCB registrations



Feedback from ECHA (2)

- One can update all parts of a dossier without having to re-pay a fee, except SID
  - Change SID -> new registration -> new registration fee!
  - ECHA SID unit is currently setting a process to give the possibility to change identifiers without having a new registration (+ fee) but it will take some time -> only service cost to be paid
- E.g. intermediate **A** that should be split in **B** and **C**:
  - Intermediate **B**: 'transform A in B' with that SID in development process so you would have intermediate A, change in SID required, fee: service cost
  - Intermediate **C**: new registration, fee: full registration fee

BUT:

  - Registrant only registering intermediate B would have to pay only service cost
  - Registrant only registering intermediate C would have to pay full fee!

=> Double registration fee for some members!

Feedback from ECHA (3)

- **Priority**: registrations to be upgraded by the agreed **deadline of 30 April** => dossiers can only be of a certain standard & will have to be improved.
- ECHA invited EM to submit '**SID plan**' describing current status SID part of dossiers, indicating which registrations will be kept, merged or split with the corresponding supporting rationale.
- Guidance foresees degree of flexibility:
  - Due to source and process variability, there is considerable variability in composition (a) between batches made by individual registrants & (b) between different registrants of the same substance -> large % ranges for many metals constituents reported for the registered substance (e.g. 0.1-99 % Pb); although the representative compositions registered at individual registrant dossier level is in general considerably less broad (e.g. 90-95 % Pb).
  - In terms of defining the scope of the descriptor & name for identifying what is considered as one substance (i.e. the 'source' & 'process'), it is important to consider the effect on the composition i.e. it may be that some feed stocks generate a comparable composition in the resulting UVCB, similarly some processes combined with source also generate comparable compositions. Note that extremely broad ranges would normally indicate that the source and process may be overly generically defined.
  - The priority now is to get a transparent SID for the registered substances, irrespective of the old EINECS descriptors.

SID of Refinables - issues

- ‘Reasoning’ cannot be applied consistently across all PMC UVCB and reflected in the relevant registration dossiers in time for the April 2014 deadline
- ECHA cannot confirm that adapting the SID of certain UVCB by splitting the registrations will not result in duplicate registration fees for some companies.
- Hence, PMC cannot fully implement SID rules in the April versions of the dossiers

SID of Refinables - Options forward

	Pros	Cons
1) Keep dossiers as is and develop SID approach documenting PMC reasoning for each Refinable	• Can be done by April 2014 • Does not trigger 'double' registration fees for concerned PMC Members	• Duplicates consultants' work for some Refinables • Can be seen by ECHA as lack of due diligence by PMC Members
2) Submit updates only for EINECS entry which have already been used in 2010 and await ECHA's feed-back on registration fees when submitting updates under different EINECS entries	• Can be done by April 2014 • Avoids duplication of work by consultants • Does not trigger 'double' registration fees for concerned PMC Members	• Would leave some UVCB streams temporarily unregistered (until registration fees issues resolved)
3) Submit separate dossiers	• Follows ECHA Guidance • Avoids duplication of work by consultants	• Is not fully aligned with other NFM consortia • May be very costly for some companies who will be charged a 'double' registration fee if they 'replace' their original registration by an update under a different EINECS entry

- PM Ref WG agreed on option 1
- Intentions communicated to ECHA in 'SID plan'

Scope for April registrations

Refinable	Nr of companies	Nr of updates	Nr of upgrades	Highest status	Highest tonnage band
1. Doré	8	4	4	Non-SCC intermediate	≥ 1000
2. Matte, PM Refining	4	0	4	Non-SCC intermediate	100-1000
3. Slags, PM Refining	8	2	6	Non-SCC intermediate	≥ 1000
4. Slimes & sludges, PM Refining	9	3	6	Non-SCC intermediate	≥ 1000
5.1. Matte leaching residues	3	0	3	Non-SCC intermediate	≥ 1000
5.2. Speiss leaching residues	0	-	-	REACH exempt	-
6.1. Ag electrolyte	3	3	0	SCC intermediate	≥ 1000
6.2. Au electrolyte	1	1	0	SCC intermediate	10-100
7. Flue dust, PM Refining	6	1	5	Non-SCC intermediate	100-1000
8. Residues, PM cementation and reduction	8	2	6	Non-SCC intermediate	100-1000
9.1. Materials for reclaim - PM w/ or w/o support	5	0	5	Non-SCC intermediate	100-1000
9.2. Materials for reclaim - PM in bricks, crucibles, trays, etc.	5	0	5	Non-SCC intermediate	100-1000
9.3. Materials for reclaim - PM production by-products	3	0	3	Non-SCC intermediate	100-1000
10. Pb bullion PM Rich	1	0	1	Non-SCC intermediate	10-100

11 dossier upgrades

2.2. UVCB identification rules: decision tree for SID

- Decision tree under development
- Taking into account:
  - Source
  - Process
  - Speciation

  } Sufficiently described? Possible/realistic to split (or e.g. captured together)? Justification needed?
  - Composition (validation purposes) – justification needed if ranges broad
  - Classification (validation purposes)

2.3. Updated ID cards (1)

- Composition is reported in IUCLID section 1.2
  - LE specific + Generic composition (+ classification specific compositions if relevant) with LE specific reported first
  - Typical + concentration ranges for all compositions
  - Typical composition should add up to 100%

- **Legal entity (LE) specific composition = across year(s)**, for each elemental constituent:
  - LE Typical concentration = +/- average concentration
  - LE Minimum concentration
  - LE Maximum concentration (without "outliers")

- **Generic composition = across industry** (used to derive verified classification), for each elemental constituent:
  - Typical concentration = average of LE typicals
  - Minimum concentration = minimum of LE typicals
  - Maximum concentration = maximum of LE typicals or (generic/specific) concentration limit

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Updated ID cards (2)

- Updated generic compositions:
  - Approach as agreed at the last Refinables meeting
  - Includes updated composition information received from some companies
  - Excludes those companies that are no longer registering
  - Speciation based on information available to registrants and/or mineralogical analysis
- Updated classifications
- PM matte: new LR proposed: Glencore Nikkelverk AS (Norway)
- PM slags: 2 ID cards following the splitting that was agreed in November 2013 BUT will be registered together for the April deadline as 2 grades of the same substance, with separate classifications -> note added to ID cards
- PM slimes & sludges: 1 ID card given the recent objections to the splitting

Updated ID cards (3)

- ID cards circulated 26 March
- Questions/comments/approval?

- Further updates:
  - Based on further refinement SID
  - Using updated company-specific compositions
  - Speciation to be further checked/refined

2.4. Splitting of PM slags and PM slimes & sludges: way forward

- PM slags:
  - To be split once we have clarity from ECHA regarding fees issue

- PM slimes & sludges:
  - Re-consider splitting, using decision tree
  - Using updated process/source information submitted by companies during previous splitting exercise

3. Updated classifications PM Refinables

Katrien ARIJS

Most important changes in MeClas since June 2012 affecting PM Ref

- Metals that are considered to be **removed from the water column** (Fe, Al, Sb, Sn, Mo, Cr, Pb, Cu, Zn, Ni, Cd): amended in MeClas database (impact on Tier 2 environmental classifications).
- Specific concentrations limits (SCL) for STOT Pb compounds were updated (proposed by ILA).

  Note: SCL for repro NOT updated in MeClas - still under discussion
- Implementation of additional mixture rule for skin corrosion and eye damage (combinations of generic & specific CL)
- Limits $CoCl_2$, $Co(NO_3)_2$, $CoSO_4$, $CoCO_3$ and CdS
- Several compounds added to the MeClas database.
- ERVs added/changed where needed.
- The output pdf and excel generation was supplemented with additional "in-between" supportive calculations information.

Updated classifications

- Updated compositions taken into account for classification -> some previous clusters became obsolete
- New cluster analysis for PM slimes & sludges using recent composition information received
- MeClas output sheets generated for all Refinables/clusters; will be added to IUCLID section 13
- Updated classifications circulated 26 March
- Questions/comments/approval?

Further updates

- For future updates: recommendation to **change the formulas for most PM Ref into elemental compositions** (max of typical) where possible because of following reasons:
  - CLP mixture ruling is quite complex with various metal compounds having a combination of generic and specific CL + calculations with TDP results require smart simplification of the solubility corrections and ERV with various metals being removed from the water column and others which are not readily removable -> Despite careful quality control, derivation of the formulas is vulnerable to errors.
  - MeClas is regularly updated with the latest harmonised and self-classifications as well as ERV values -> Each update would require a revision of the derived formulas.
  - In some Refinables, multiple speciations reported by members -> complicates the derivation of the formulas despite the fact that worst-case speciation selected where possible.
  - Formulas difficult to work with for full dossiers.
- Companies are strongly recommended to use MeClas which is freely available to check their classifications rather than the formulas.

4. CSR generic and intro sections

Katrien ARIJS

1.0. Characterisation of the substance

- Introduction on PM Refinables and their UVCB status
- Characterisation composition: range in elemental compositions within and across all companies has been assessed
- Characterisation speciation: metal species were determined based on information available to registrants and/or mineralogical analysis
- Explain proposed name/description changes where relevant

1.1. Name and other identifiers of the substance

- For slags, slimes & sludges and flue dust, section has been added on further splitting efforts/difficulties, explaining complexity PM sector

1.2. Composition of the substance

- Introduction added on how full/generic composition was derived
- Explanation on classification related compositions and how they have been entered in IUCLID using the formulas

2. Manufacture and uses

- Introduction added to explain section is generic and it is the responsibility of each registrant to check if the reported PROCs are appropriate and to report only such PROCs in IUCLID section 3.5 (current RA restricted to the list of mentioned PROCs so only possible to delete PROCs)
- Description of manufacturing process + influx/outflux per Refinable
  - LRs asked to provide input by tomorrow
  - To be sent to co-registrants for approval by end of week
- Generic section 'Manufacture and use of PM Refinables'
  - Using NFM BREF
  - LRs asked to provide input by tomorrow
  - To be sent to co-registrants for approval by end of week

3.0. Introduction to classification

- 3.0.1. General approach
- 3.0.2. MeClas
- 3.0.3. UVCB specific approach
  - Explain derivation different grades (quantitative/qualitative approach)
  - Tier 1 / Tier 2 classification
  - Speciation taken forward for classification

Table 13. Summary of the information for the purpose of classification

UVCB constituent		Variability of elemental composition	Classification according each relevant endpoint
Element	Speciation* taken forward for classification		
Ag	Ag compounds	Maximum of typicals	Self-classification of the speciation, see MECLAS report in CSR Annex I
Au	Metal	Maximum of typicals	Not classified, see MECLAS report in CSR Annex I
Cu	98.52% Cu powder 1.48% Cu2O	Maximum of typicals	Harmonised and worse self-classification of the speciation, see MECLAS report in CSR Annex I
Sb	Sb compounds	Maximum of typicals	Harmonised classification of the speciation, see MECLAS report in CSR Annex I
As	As	Maximum of	Harmonised classification of the

Other generic/intro sections

- 4.0. Introduction on Environmental fate properties – in cooperation with EM + modifications for Refinables by WCA
- 5.0. Introduction on human health hazard assessment - in cooperation with EM + modifications for Refinables by EBRC
- 7.0. Introduction on environmental hazard assessment - in cooperation with EM + modifications for Refinables by WCA
- Annexes:
  - MeClas output sheets
  - Classification cluster analysis doc
  - GES environment (CSR chapters 9 & 10), incl. considerations combined toxicity
  - GES human health (CSR chapters 9 & 10) , incl. considerations combined toxicity
  - **Companies advised to attach their company specific ES human health or indicate they have one available**
- Note: LRs asked to check/update GoSU by tomorrow

Occupational exposure assessment and scenarios

Refinables WG Meeting

Brussels

01 April 2014

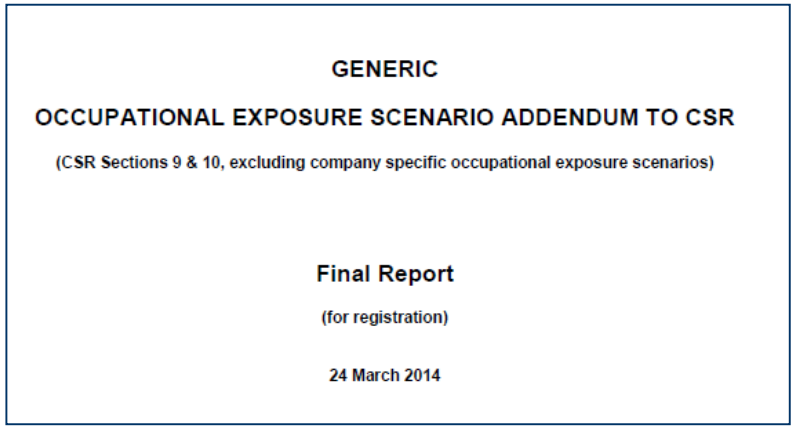
Daniel Vetter, Jutta Schade, Torsten Grewe, André Schäfer

EBRC Consulting

Hannover, Germany

Final occupational exposure scenarios

- 24 March 2014: 2 sets of documents sent to companies requiring “upgrades” in April 2014:
  - Generic occupational exposure scenario addendum to CSR (CSR Sections 9 & 10)
  - Company specific occupational exposure scenario (CSR Section 9.1)



GENERIC

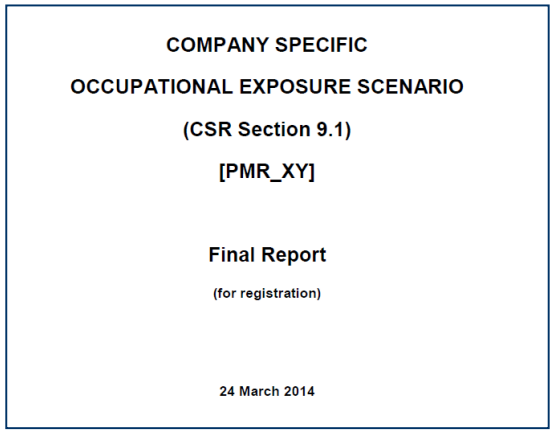
OCCUPATIONAL EXPOSURE SCENARIO ADDENDUM TO CSR

(CSR Sections 9 & 10, excluding company specific occupational exposure scenarios)

Final Report

(for registration)

24 March 2014



COMPANY SPECIFIC

OCCUPATIONAL EXPOSURE SCENARIO

(CSR Section 9.1)

[PMR_XY]

Final Report

(for registration)

24 March 2014

Generic occ. ES addendum I/IV

Table of contents

- New sections/information in comparison to previous version:
  - Overview table of DNELs and DNEL sources
  - Additional AC (AC4) included (closed processes, SCC)
  - Extrapolation factors for assessment of inhalation exposure included
  - Uncertainty analysis included
  - Section on combined toxicity included

Generic occ. ES addendum II/IV

Table 1: DNELs relevant for the workplace-specific risk assessment

Element	Chemical Species	Inhalation DNELs				Dermal DNELs				Eye	Ref.
		ISL	ISA	ILL	ILA	DSL	DSA	DLL	DLA		
Ag	Ag	100 µg/m³	NHI	NHI	NHI	NHI	NHI	NHI	NHI	NHI	RR
	$AgNO_3$	10 µg/m³	NHI	NHI	NHI	NHI	NHI	NHI	QA	medium	RR/ SV9
Al	$AlCl_3$	200 µg/m³	1000 µg/m³	200 µg/m³	2000 µg/m³	QA	NHI	NHI	QA	medium	SV0
As	As_2O_3	4 µg/m³	NHI	QA	QA	0.085 mg/kg bw.	NHI	QA	QA	medium	RR
Au	$[AuCl4]^-$	QA	NHI	NHI	NHI	NHI	NHI	QA	NHI	NHI	SV1
B	Borate	1439 µg/m³	QA*	2512 µg/m³	2512 µg/m³	67.89 mg/kg bw.	QA*	QA*	QA*	low	SV0
Ba	Ba soluble	500 µg/m³	NHI	500 µg/m³	NHI	NHI	NHI	NHI	NHI	low	SV2
Ca	CaO	NHI	NHI	1000 µg/m³	4000 µg/m³	NHI	NHI	NHI	QA	medium	SV10
Cd	Cd	4 µg/m³	NHI	NHI	NHI	QA*	QA*	QA*	QA*	NHI	RR
Co	Co	NHI	NHI	40 µg/m³	QA	NHI	NHI	QA	NHI	NHI	SV0
Cr	CrO_3	NHI	NHI	10 µg/m³	10 µg/m³	NHI	NHI	NHI	NHI	NHI	SV0
Cs	CsCl	1160 µg/m³	NHI	NHI	NHI	3.3 mg/kg bw.	NHI	NHI	NHI	NHI	SV0

Table 2: Overview of activity classes

AC	Short description of AC	Covered tasks	Modifier	Physical appearance
AC1	handling of dusty materials	transfer operations, cold furnace loading, packaging, mixing	ambient temperature, semi-automated/remote controlled	solid (dusty) materials
AC2	handling of materials with varying dustiness	transfer, cold furnace loading, packaging, mixing	ambient temperature, semi-automated/remote controlled	various
AC3	handling of very low to low dusty materials	storage, transfer/handling of containers, handling of damp materials (incl. filter cakes) and massive objects	ambient temperature	very low dusty
AC4	completely closed process (strictly controlled conditions)	no manual interventions, only supervision	completely enclosed	various

Generic occ. ES addendum III/IV

Table 5: Extrapolation factors for different types of LEV

Type of LEV	Efficiency	EF	Example
1 (no LEV)	0%	1.00	Extrapolation from LEV Type 4 to LEV Type 2 would be done by using an EF_{LEV} of 0.22/0.16 = 1.375.
2 (generic LEV)	78%	0.22	
3 (exterior LEV)	78%	0.22	
4 (integrated LEV)	84%	0.16	

For enclosing the emission source, the following extrapolation factors were used:

Table 6: Extrapolation factors for different levels of enclosure

Level of enclosure	Efficiency	EF	Example
1 (no enclosure)	0%	1.00	Extrapolation from enclosure level 3 to enclosure level 1 would be done by using an EF_{Enc} of 1.00/0.26 = 3.846.
2 (partly enclosed)	50%	0.50	
3 (fully enclosed)	74%	0.26	

For suppression measures, the following extrapolation factors were used:

Table 7: Extrapolation factors for different levels of suppression

Level of suppression	Efficiency	EF	Example
1 (not implemented)	0%	1.00	Extrapolation from suppression level 4 to suppression level 2 would be done by using an EF_{Sup} of 0.12/0.07 = 1.714.
2 (generic suppression technique)	88%	0.12	
3 (wet suppression)	89%	0.11	
4 (capture sprays)	93%	0.07	

Generic occ. ES addendum IV/IV

- Inhalation exposure estimates provided in Appendix 1 (except for estimates for AC4):

Appendix 1: Generic exposure assessment table

Est#	Metal	AC	Content	LEV	Enc	Sup	N	MIN	P50	P75	P90	P95	MAX	GSD	N.Cat	GSD.Cat	RWC.Cat	RWC
1	Ag	1	6	2	2	1	12	0.4	0.9	1.8	8.2	11.1	14.0	3.5	4	3	B	8.2
2	Ag	2	7	4	2	1	1	14.0	14.0	14.0	14.0	14.0	14.0	NA	1	1	F	28.0
3	Ag	2	9	4	3	1	1	2.0	2.0	2.0	2.0	2.0	2.0	NA	1	1	F	4.0
4	Ag	2	10	4	2	2	1	39.7	39.7	39.7	39.7	39.7	39.7	NA	1	1	F	79.3
5	Ag	2	11	4	1	1	6	15.0	50.5	72.5	81.7	83.0	84.3	2.1	3	3	C	83.0
6	Ag	3	6	4	2	1	58	0.4	0.4	0.5	0.9	1.2	10.0	1.7	7	4	A	0.5
7	Ag	3	10	1	2	3	6	1.0	2.0	2.8	4.0	4.5	5.0	1.9	3	4	B	4.0
8	Ag	3	11	1	2	1	27	0.4	1.3	3.7	15.7	19.1	25.1	3.7	6	2	B	15.7
9	Ag	3	11	2	2	3	1	2.8	2.8	2.8	2.8	2.8	2.8	NA	1	1	F	5.6
10	Ag	5	6	2	2	1	35	0.4	0.4	0.9	1.2	4.1	5.9	2.1	6	3	B	1.2
11	Ag	5	11	2	2	1	63	1.3	16.7	29.2	44.4	62.4	272.0	2.9	7	3	A	29.2
12	Ag	5	11	3	1	2	4	2.0	11.0	12.0	13.8	14.4	15.0	2.5	2	3	D	15.0
13	Ag	6	6	2	2	1	35	0.4	0.4	0.7	1.0	1.2	1.4	1.5	6	4	A	0.7
14	Ag	6	11	2	2	2	4	13.3	19.1	23.2	26.2	27.1	28.1	1.4	2	4	C	27.1
15	Ag	6	11	3	2	2	3	2.0	2.0	4.5	6.0	6.5	7.0	2.1	2	3	D	7.0
16	Ag	7	10	4	2	1	5	1.0	1.0	1.0	14.8	19.4	24.0	4.1	2	2	E	36.0
17	Ag	7	11	2	2	2	5	3.2	17.6	45.5	88.5	102.8	117.1	4.1	2	2	E	175.7
18	Ag	7	11	4	2	3	1	30.0	30.0	30.0	30.0	30.0	30.0	NA	1	1	F	60.0
19	Ag	9	10	2	2	2	6	16.6	23.3	64.9	95.9	104.9	113.9	2.3	3	3	C	104.9

- Blood lead data: estimates derived for 3 distinct exp. settings
- Dermal exposure estimates derived from MEASE

Company specific occ. ES – CoU I/II

9.1.2 Workplace: 1

9.1.2.1 Conditions of use

The following conditions of use are prescribed at this workplace:

Workplace: 1		
Composition profile (overall content in all handled/processed materials)		
Element	upper limit concentration of the element in overall content	chemical species considered in risk assessment (worst-case considerations, SDNR=species differentiation not required)
Ag	<10 %	highly soluble
As	<5 %	As2O3
Ba	<1 %	readily soluble
Co	<1 %	SDNR
Pb	<10 %	SDNR
Pd	<25 %	highly soluble
Pt	<25 %	highly soluble
Sb	<10 %	Sb2O3
Se	<5 %	zinc selenite not relevant
Si	<10 %	no cryst.resp. SiO2 (RC not required)
Te	<25 %	SDNR
B, Cd, Hg, Os, Re, V	not expected (only traces)	
AC15 - Sampling and evaluation		
Covered task(s) and PROC(s) (as relevant)	Task(s): Including small scale milling and melting	PROC(s): 15
Physical form and maximum emission potential (EP)	materials of various physical forms (including dusty materials)	Max. EP: high
Process temperature	25°C	
Exposure duration	60 - 240 minutes	
Level of separation	no separation from emission source	
Localised controls	Small scale operations with effective (partly mobile) extraction devices	
Level of enclosure	partly enclosed	
Suppression technique	not implemented	
Personal protective equipment		
Type of respiratory protective equipment	APF = 10 (APF selected on worst case basis for Se)	
Type of dermal protection	Appropriate gloves have to be worn (acid-, heat-, mechanical-stress-resistant as relevant) to prevent from contact of the skin with any of the assessed substances (protection factor of 100 assumed) and must have a break-through time covering a full-shift.	
Type of eye protection	Eye protection has to be worn unless contact of the eye with the assessed substances can be excluded (e.g. in a control room).	
Type of further PPE	General good occupational hygiene practices to be followed are described in the introduction to this ES.	

Company specific occ. ES – CoU II/II

- Company-specific occ. ESs, containing as much company-specific information as possible:
  - WP names
  - “Overall composition”
  - OCs
  - RMMs
- OCs and RMMs to be seen as minimum requirement under REACH
  - higher protection always possible
  - national legislation to be respected in parallel

Company specific occ. ES – RC Table I/II

- Available inhalation monitoring data were pooled for all companies
- Extrapolation to specific company settings (e.g. for higher content of a specific constituent or different RMMs) required in some cases
- Full shift exposure estimates, peak exposure estimates and estimates for combined exposure provided (or data gap indicated)
- All available DNELs (or surrogate value) and references provided (or data gap indicated)

Company specific occ. ES – RC Table II/II

Workplace: 1

Activity class	Type of DNEL	Species considered in EA	EA source (EF)	RWC exposure (outside PPE)	Typical exposure (outside PPE)	Source: Threshold	Protection factor	RCR	RCR for CEA
15	ISL	Ag (highly soluble)	#29	6 µg/m³	1 µg/m³	DNEL: 10 µg/m³	10	0.06	0.01
		As (As2O3)	#56	2.2 µg/m³	1 µg/m³	DNEL: 4 µg/m³		0.06	0.02
		Ba (readily soluble)	E270 (1.2)	6.8 µg/m³	4.6 µg/m³	SV2: 500 µg/m³		<0.01	<0.01
		Pd (highly soluble)	#203	7.6 µg/m³	1.6 µg/m³	SV6: 20 µg/m³		0.04	<0.01
		Pt (highly soluble)	#220	5 µg/m³	0.2 µg/m³	SV6: 300 µg/m³		<0.01	<0.01
		Se (zinc selenite not relevant)	E270 (7.5)	40.5 µg/m³	27.6 µg/m³	DNEL: 50 µg/m³		0.08	0.06
		Te (SDNR)	#292	2.4 µg/m³	1 µg/m³	SV8: 100 µg/m³		<0.01	<0.01
		CEA	na	na	na	na		na	incl. BIO: 0.43
		As (As2O3)	QA	QA	QA	QA		QA	QA
		Ba (readily soluble)	E270 (1.2)	6.8 µg/m³	4.6 µg/m³	SV2: 500 µg/m³		<0.01	<0.01
		Co (SDNR)	E98 (1.2)	5.5 µg/m³	2.8 µg/m³	nda		0.01	<0.01
		Pt (highly soluble)	QA	QA	QA	QA		QA	QA
		Sb (Sb2O3)	E249 (3.8)	10.4 µg/m³	10.4 µg/m³	nda		<0.01	<0.01
		Se (zinc selenite not relevant)	QA	QA	QA	QA		QA	QA
		Te (SDNR)	#292	2.4 µg/m³	1 µg/m³	SV8: 100 µg/m³		<0.01	<0.01
		CEA	na	na	na	na		na	0.02
	ISA	Te (SDNR)	QA	QA	QA	QA		QA	QA
	ILA	As (As2O3)	QA	QA	QA	QA		QA	QA
		Co (SDNR)	QA	QA	QA	QA		QA	QA
		CEA	na	na	na	na		na	<0.01
		Al (AlCl3)	QA	QA	QA	QA		QA	QA
		As (As2O3)	MEASE	3.4 µg/kg bw/d	1.9 µg/kg bw/d	DNEL: 85 µg/kg bw/d		<0.01	<0.01
		Pd (highly soluble)	MEASE	10.2 µg/kg bw/d	5.6 µg/kg bw/d	SV6: 600 µg/kg		<0.01	<0.01
		CEA	na	na	na	na		na	QA
	BIO	Pb	BIO3	23.6 µg/dL	13 µg/dL	DNEL: 40 µg/dL	RPE: 10 Gloves: 100	0.59	0.32
	CSL	As (As2O3)	na	na	na	na		na	0.06
		Pd (highly soluble)	na	na	na	na		na	0.04
		Pt (highly soluble)	na	na	na	na		na	<0.01
		Se (zinc selenite not relevant)	na	na	na	na		na	0.08

Company specific occ. ES: CoU→RC

Workplace: 1		
Composition profile (overall content in all handled/processed materials)		
Element	upper limit concentration of the element in overall content	chemical species considered in risk assessment (worst-case considerations, SDNR=species differentiation not required)
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As	<5 %	As2O3
Ba	<1 %	readily soluble
Co	<1 %	SDNR
Pb	<10 %	SDNR
Pd	<25 %	highly soluble
Pt	<25 %	highly soluble
Sb	<10 %	Sb2O3
Se	<5 %	zinc selenite not relevant
Si	<10 %	no cryst.resp. SiO2 (RC not required)
Te	<25 %	SDNR
B, Cd, Hg, Os, Re, V	not expected (only traces)	

Workplace: 1		
Activity class	Type of DNEL	Species considered in EA
15	ISL	Ag (highly soluble)
		As (As2O3)
		Ba (readily soluble)
		Pd (highly soluble)
		Pt (highly soluble)
		Se (zinc selenite not relevant)
		Te (SDNR)
		CEA
	ISL	As (As2O3)
		Ba (readily soluble)
		Co (SDNR)
		Pt (highly soluble)
		Sb (Sb2O3)
		Se (zinc selenite not relevant)
		Te (SDNR)
		CEA
	ISA	Te (SDNR)
	ILA	As (As2O3)
		Co (SDNR)
		CEA
	DSL	Al (AlCl3)
		As (As2O3)
		Pd (highly soluble)
		Pt (highly soluble)
		Sb (Sb2O3)
		Se (zinc selenite not relevant)
		Te (SDNR)
		CEA
	DLL	As (As2O3)
		Co (SDNR)
		Se (zinc selenite not relevant)
		Te (SDNR)
		CEA
	DLA	Ag (highly soluble)
		As (As2O3)
		CEA
	BIO	Pb
	CSL	As (As2O3)
		Pd (highly soluble)
		Pt (highly soluble)
		Se (zinc selenite not relevant)

Assessment of combined exposure/toxicity

- CSL = combined exposure assessment for systemic long-term effects, only relevant if systemic inhalation and dermal DNELs are available
  - → Derivation of RWC RCRs for ISL and DSL per element
  - → RCR ISL + RCR DSL (for 1 specific element)
- CEA = combined effects assessment for all metals with DNELs for a specific type of DNEL
  - → Derivation of typical exposure estimates
  - → Sum of RCRs of different elements per route

Uncertainty analysis – first attempt

- Three types of uncertainty considered:
  - conducted hazard and exposure assessment and resulting risk characterisation conducted as for any other (standard) substance
  - variability of and missing knowledge on the composition of the iUVCB to be assessed
  - specific approach followed in RA for iUVCBs
    - Physical form considered in DNEL derivation of individual constituent
    - PROCs covered in registration dossier of individual constituent

Way forward/Updates I/II

- AC4 for SCC:
  - To be included in next update for some companies?
  - To be used for all companies currently not requiring upgrades?
- Further species information required for refinements
- Additional monitoring data to be included:
  - Potentially new monitoring data (2013/2014) available from current data submitters
  - Monitoring data (20xx-2014) from current non-data submitters
- Current data gaps (data access, exposure estimates, DNELs) to be closed

Way forward/Updates II/II

- Minor issues already identified:
  - Inclusion of additional PROCs (4 and 27b) for some ACs
  - Although some elements are „not expected“ in the composition, these elements erroneously occur in the RC table (with no impact)
  - Line „CEA“ not required for routes being required for only one element
  - Additional information on assessment of typical dermal exposure levels to be included in methodology paper
- Major issues:
  - OCs and RMMs for lead (to be used as minimal requirement)
  - Closing of data gaps regarding exposure estimates (additional data, available company-specific data such as JR, further extrapolation…?)

Exposure of man via environment

Refinables WG Meeting

Brussels

01 April 2014

Maren Bode
EBRC Consulting
Hannover, Germany

Man exposed via the Environment (MvE) I/II

- Requirement under REACH
- Local and regional assessment
- ENV exposure concentrations / DNEL = RCR
  - PEC air, PEC water and concentration in food
  - $DNEL_{inh,\ long\text{-}term}$ and $DNEL_{oral,\ long\ term,\ systemic}$
- Waiving can be properly justified if:
  1. No hazard identified for oral or inhalation long-term
     → no MvE assessment
  2. No emissions to the environment
     → no MvE assessment

Man exposed via the Environment (MvE) II/II

- Waiving statement:
  - The assessment for humans exposed indirectly via the environment has already been covered by the relevant metals registration dossiers.
    - okay for regional assessment
    - however, access to these dossiers needs to be granted and a local assessment still needs to be performed

- Open questions
  - What about those metals which have not provided a REACH dossier so far?
  - What about combined toxicity?

CSR/IUCLID & hazard assessment human health

Refinables WG Meeting

Brussels

01 April 2014

Torsten Weil, Melanie Horzella
EBRC Consulting
Hannover, Germany

State of work – for HH

- March 24th, 2014: CSR and IUCLID files for the “upgrade” of PMRs sent out for submission in April 2014:

  - ID cards and/or MeClas output sheets used for robust study summary/endpoint summary generation
  - Template provided by Eurometaux was used as **start-up aid**
  - Individual/substance specific adaptation (waivers, e.g. rep. dose dermal; “applicant´s summary and conclusion”; endpoint summaries)
  - Summaries of LoA substances were included into IUCLID if provided by March 20th, 2014
  - All available DNELs of individual constituents are provided in an overview table

Navigation

Query results | Folders | Section tree

Complete

- Eye irritation_Material for r
- 7.4 Sensitisation
  - Sensitisation_Materials for recl
  - Sensitisation_Materials for recl
  - 7.4.1 Skin sensitisation
    - Skin sensitisation_Materials
    - Skin sensitisation_Materials
  - 7.4.2 Respiratory sensitisation
    - Respiratory sensitisation_M
- 7.5 Repeated dose toxicity
  - Repeated dose toxicity_Materia
  - **Repeated dose toxicity_Materi**
  - 7.5.1 Repeated dose toxicity: o
    - Repeated dose toxicity: ora
    - Repeated dose toxicity: ora
  - 7.5.2 Repeated dose toxicity: in
    - Repeated dose toxicity: inh
    - Repeated dose toxicity: inh
  - 7.5.3 Repeated dose toxicity: d
    - Waiver_Repeated dose toxi
  - 7.5.4 Repeated dose toxicity: o
- 7.6 Genetic toxicity
  - Genetic toxicity_Materials for r
  - 7.6.1 Genetic toxicity in vitro
    - Mutagenicity in vitro_Mater
    - Genotoxicity in vitro_Mater
  - 7.6.2 Genetic toxicity in vivo
    - Waiver_Materials for reclain
- 7.7 Carcinogenicity
  - Carcinogenicity_Materials for r
  - Carcinogenicity_Materials for r
  - Carcinogenicity_Materials for r
  - Carcinogenicity_Materials for r
- 7.8 Toxicity to reproduction
  - Toxicity to reproduction_Mater
  - Toxicity to reproduction_Mater
  - 7.8.1 Toxicity to reproduction
    - Toxicity to reproduction_M
    - Toxicity to reproduction_M
  - 7.8.2 Developmental toxicity / t
    - Developmental toxicity / te
    - Developmental toxicity / te
  - 7.8.3 Toxicity to reproduction:
- 7.9 Specific investigations

data are available for all components or only for some components of the mixture" with the MeClas tool.

Justification for classification or non-classification

Normal | Default font

Materials for reclaim, Precious Metals in Bricks, Pots, Crucibles and trays, etc. (Reclaim 3):

General note:
According to the self-classification of lead compounds the specific concentration limits (SCL) for STOT RE classification are as follows:
STOT RE 1; H372: C ≥ 0.5 %
STOT RE 2; H373: 0.05 % ≤ C < 0.5 %

The following C&L drivers were identified for "Materials for reclaim, Precious Metals in Bricks, Pots, Crucibles and trays, etc." (Reclaim 3):
(i) classification driver: Pb (oral route, systemic effects)
(ii):classification driver: NiO (inhalation route, local effects)

Classification of UVCB substances as being toxic to specific target organs after repeated dose application is based on the presence of a constituent ≥ 1 % classified as STOT-RE 1 and of a constituent ≥ 10 % classified as STOT-RE 2, respectively. However, for lead compounds there are specific concentration limits given for STOT RE classification assigned by the lead industry. According to Regulation (EC) 1272/2008 "specific concentration limits" should take precedence over any other concentration limits for the purpose of classification. Hence, the SCLs for lead compounds are used also for C&L. "Materials for reclaim, Precious Metals in Bricks, Pots, Crucibles and trays, etc. (Reclaim 2 and Reclaim 3)" contains > 2.5 % (w/w) Pb compounds classified as STOT RE 1. Hence, "Materials for reclaim, Precious Metals in Bricks, Pots, Crucibles and trays, etc." meets classification criteria for STOT-RE 1 (oral route) and requires labelling with H372 (causes damage to organs), in accordance with Regulation (EC) 1272/2008.

Further, "Materials for reclaim, Precious Metals in Bricks, Pots, Crucibles and trays, etc." (Reclaim 3) contains nickel oxide with a content >1.2 % (w/w). Thus, "Materials for reclaim, Precious Metals in Bricks, Pots, Crucibles and trays, etc." (Reclaim 3) must be classified as STOT-RE 2 (H373, inhalation route) in accordance with Regulation (EC) 1272/2008.

Attached document(s)

Add... | Edit... | Delete | Move up | Move down

Current DNEL table included in CSR

Route	Type of effect	Ag		As	B	Ba	Ca	Cd	Co	Cu		Mn	Mo
Species		Ag	$AgNO_3$	As_2O_3	Borate	Ba soluble	CaO	Cd	Co	Cu_2O	$CuSO_4$	MnO_2	MoO_3
Inhalation	Systemic long term	100 µg/m^3	10 µg/m^3	4 µg/m^3	SV0	500 µg/m^3	no hazard	4 µg/m^3	no hazard	1000 µg/m^3	1000 µg/m^3	SV0	11170 µg/m3
	Systemic acute	no hazard	no hazard	no hazard	Qualitative assessment *	no hazard	no hazard	no hazard	no hazard	no hazard	4000 µg/m^3	Qualitative assessment	no hazard
	Local long term	no hazard	no hazard	Qualitative assessment	SV0	500 µg/m^3	1000 µg/m^3	no hazard	SV0	1000 µg/m^3	1000 µg/m^3	no hazard	2000 µg/m^3
	Local acute	no hazard	no hazard	Qualitative assessment	SV0	no hazard	4000 µg/m^3	no hazard	Qualitative assessment	no hazard	4000 µg/m^3	no hazard	no hazard
Dermal	Systemic long term	no hazard	no hazard	0.085 mg/kg bw.	SV0	no hazard	no hazard	Qualitative assessment *	no hazard	no hazard	no hazard	SV0	no hazard
	Systemic acute	no hazard	no hazard	no hazard	Qualitative assessment *	no hazard	no hazard	Qualitative assessment *	no hazard	no hazard	no hazard	no hazard	no hazard
	Local long term	no hazard	no hazard	Qualitative assessment	Qualitative assessment *	no hazard	no hazard	Qualitative assessment *	Qualitative assessment	no hazard	no hazard	no hazard	no hazard
	Local acute	no hazard	Qualitative assessment	Qualitative assessment	Qualitative assessment *	no hazard	Qualitative assessment	Qualitative assessment *	no hazard	no hazard	no hazard	no hazard	no hazard
Eye		no hazard	medium hazard	medium hazard	low hazard	low hazard	medium hazard	no hazard	no hazard	low hazard	no hazard	no hazard	low hazard
Internal reference value													
Reference		RR	RR/SV9	RR	SV0	SV2	SV10	RR	SV0	SV3	SV3	SV0	SV5

Current DNEL table included in CSR

Route	Type of effect	Ni				Pb		Pd	Pt	Sb	Se	Si	Te
Species		Ni	$NiSO_4$	NiO	NiS/Ni_3S_2	Pb	Pb comp.	soluble	soluble	Sb_2O_3	Se	SiO_2 cryst. respirable	Te
Inhalation	Systemic long term	50 µg/m³	50 µg/m³	50 µg/m³	50 µg/m³	see internal reference value	see internal reference value	20 µg/m³	300 µg/m³	no hazard	50 µg/m³	no hazard	100 µg/m³
	Systemic acute	680000 µg/m³	16000 µg/m³	520000 µg/m³	16800 µg/m³	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	Qualitative assessment
	Local long term	50 µg/m³	50 µg/m³	50 µg/m³	50 µg/m³	no hazard	no hazard	no hazard	Qualitative assessment	500 µg/m³	Qualitative assessment	49 µg/m³	100 µg/m³
	Local acute	4000 µg/m³	700 µg/m³	3900 µg/m³	470 µg/m³	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard
Dermal	Systemic long term	no hazard	no hazard	no hazard	no hazard	see internal reference value	see internal reference value	0.6 mg/kg bw.	0.1 mg/kg bw.	234.7 mg/kg bw.	7 mg/kg bw.	no hazard	Qualitative assessment
	Systemic acute	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	Qualitative assessment	no hazard	Qualitative assessment
	Local long term	70 µg/cm²	0.44 µg/cm²	0.024 mg/kg bw.	0.0048 mg/kg bw.	no hazard	no hazard	no hazard	no hazard	no hazard	Qualitative assessment	no hazard	Qualitative assessment
	Local acute	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard
Eye		no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard	no hazard
Internal reference value						40 µg/dL	40 µg/dL						
Reference		RR	RR	RR	RR	RR	RR	SV6	SV6	RR	RR	SV7	RR/SV8

Current DNEL table included in CSR

- Explanation

RR	REACH registration dossier IUCLID section 7 data access
SV0	ECHA dissemination website; no official data access yet, currently deleted for copyright issues
SV2	Commission Directive 91/322/EEC, May 29th, 1991
SV3	MAK value in former times; values for acute inhalation DNEL: extrapolation from long term value multiplied with 4
SV5	Values given for MoO3 under GESTIS DNEL database; values recalculated to Mo metal
SV6	Anonymous (2013) Tentative DNELs for Platinum and Palladium, bibra toxicology advice & consulting, October 2013, for the sake of this assessment, a dermal absorption factor of 1 % for palladium substances was assumed
SV7	Anonymous (2003) Recommendation from the Scientific Committee on occupational exposure limits for silica, crystalline (respirable dust), SCOEL/SUM/94, November 2003
SV9	Qualitative assessment for local acute effects on the skin and the eyes are triggered by the corrosivity of the substance.
SV10	Anonymous (2008) Recommendation from the Scientific Committee on occupational exposure limits for calcium oxide (CaO) and calcium hydroxide (Ca(OH)2, SCOEL/SUM/137, February 2008

LoAs received after March 20th, 2014 not included in REACH registration dossiers

→ dossier update needed!

DNEL table – update needed

- Constituents not yet considered for hazard assessment:

  - CrO_3, Hg: further discussed with industry since substances are present in workplaces?!?

  - CsCl, Li, LiCl: further discussed with industry; substances available in PMR?

  - HCl, HNO_3: previously relevant for Slimes&Sludges; or if relevant for Au/Ag electrolytes or workplaces

  - H_2SO_4: used for C&L Slimes & Sludges; LoA needed

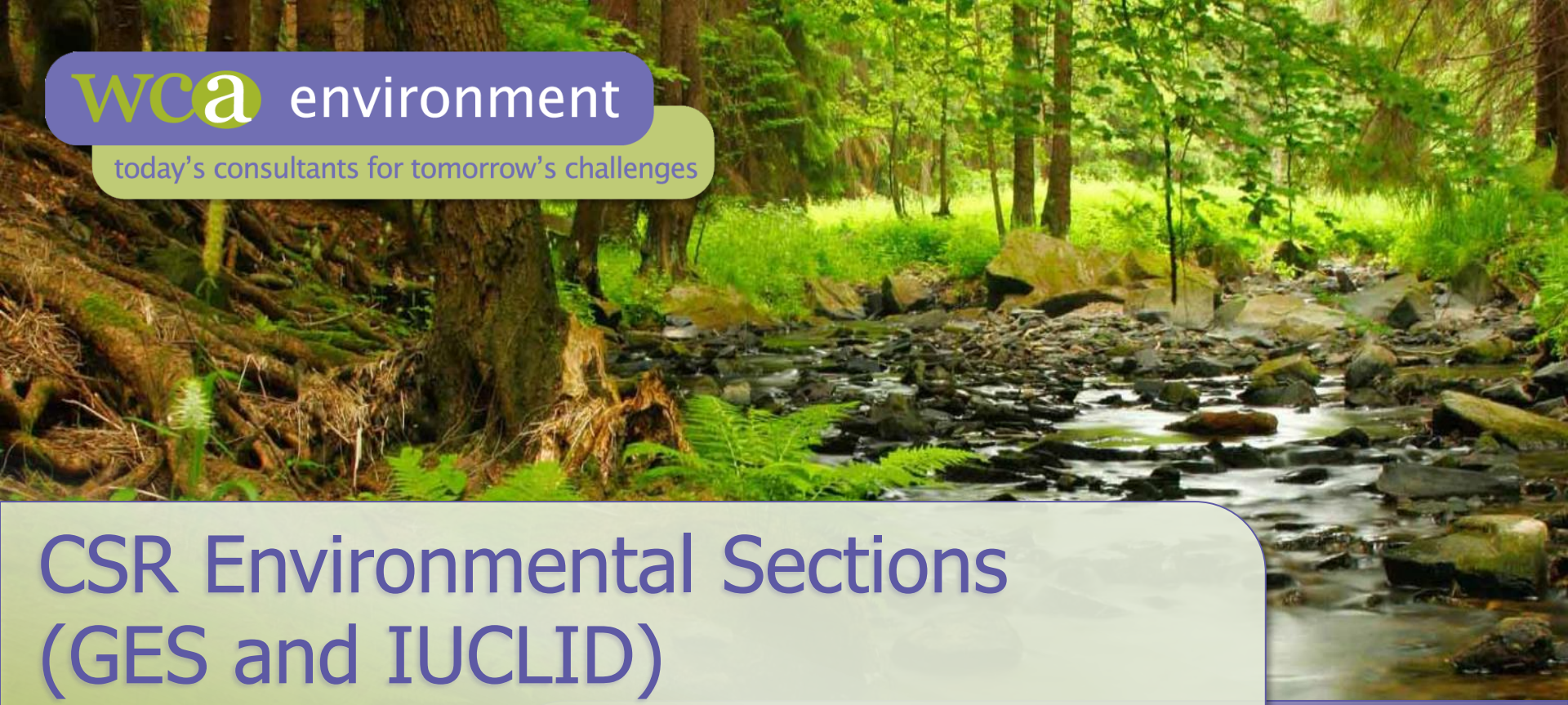
  - P_2O_5: corrosive; LoA formally needed (Slags)

Way forward

- Updates: Ag electrolytes and Au electrolytes
  → Timeline IUCLID file for HH
- Splitting of substances: Slags and Slimes & Sludges
  → dossier update needed?
- Questionnaire needed?
- Closing of data gaps

Thank you for your attention!

…and good luck for registration ☺!



wca environment

today's consultants for tomorrow's challenges

CSR Environmental Sections (GES and IUCLID)

Ed Stutt, Iain Wilson, Rhiannon Smith & Becky Marks

Employee Ownership Association

ISO 9001 REGISTERED FIRM

ISO 14001 REGISTERED FIRM

Overview

- Exposure assessment and risk characterisation in the Generic Exposure Scenario
  - Changes since previous meeting
- Selection of constituents and data requirements for future update (→ looking ahead)
- CSR
- IUCLID

Environmental exposure and risk characterisation

- Focussing on selected refinables components for environmental hazard/exposure ('driving constituents')
  - » Ag, As, ~~B~~, Cd, ~~Cr~~, Cu, Ni, Pb, Zn
- Assess each constituent separately (no consideration of additivity at present .... but this will change)
- EUSES modelling to estimate PECs
  - » Same approach for GES and SSRA* (*to be revised)

Generic Exposure Scenarios

- 2 environmental exposure scenarios for 'processing of refinables'
- Based on characteristics of aquatic emissions:
  - ES1: Discharge to freshwater or marine waters via STP
  - ES2: Direct discharge to freshwater and marine

Refinements to Exposure Assessment

- Changes since last draft of GES
- GES narratives include detailed justification for all assumptions and choices of parameter values, including SpERCs and monitoring data
- Addition of marine waters via STP *(ES1)*
- Assessment of secondary poisoning
- Removed consideration of man via the environment (MvE) for stack emissions to air
- Justification for selection of driving constituents
- *Placeholder text on combined toxicity*

Refinements to Exposure Assessment

- Selection of driving constituents for environmental exposure assessment
  - » Classified as hazardous to the environment
  - » Availability of PNEC for risk characterisation
  - » Availability of monitoring data to enable exposure assessment.
- Boron and Cr(III) excluded from previous list of driving constituents
- Se, Te, Co & Sn to be added based on these criteria
  - » Potential risk currently addressed based on assessment for other constituents with higher tonnage & lower PNEC (e.g. Ag)

Additional data (and future monitoring) requirements

- Need waste-water monitoring data for Se, Te, Co & Sn .....and PGMs
- PGMs are not yet registered under REACH
- PGM compounds are or will be classified for environmental hazard following generation of test data (many will have low PNECs)

Looking ahead

- Additional exposure monitoring requirements (for waste water and stack emissions for MvE)
- Combined toxicity assessment
  - » ECHA have indicated that they want combined risk assessment for various constituents that may act in additive, synergistic or antagonistic fashion
  - » Holding position prepared by Eurometaux, 'placeholder document' summarises current thinking and ongoing research/approaches under development in metals sector
  - » Initial approach could be simple additivity but acknowledged to be overly conservative, especially when considering background concentrations of metals in water, sediments & soil

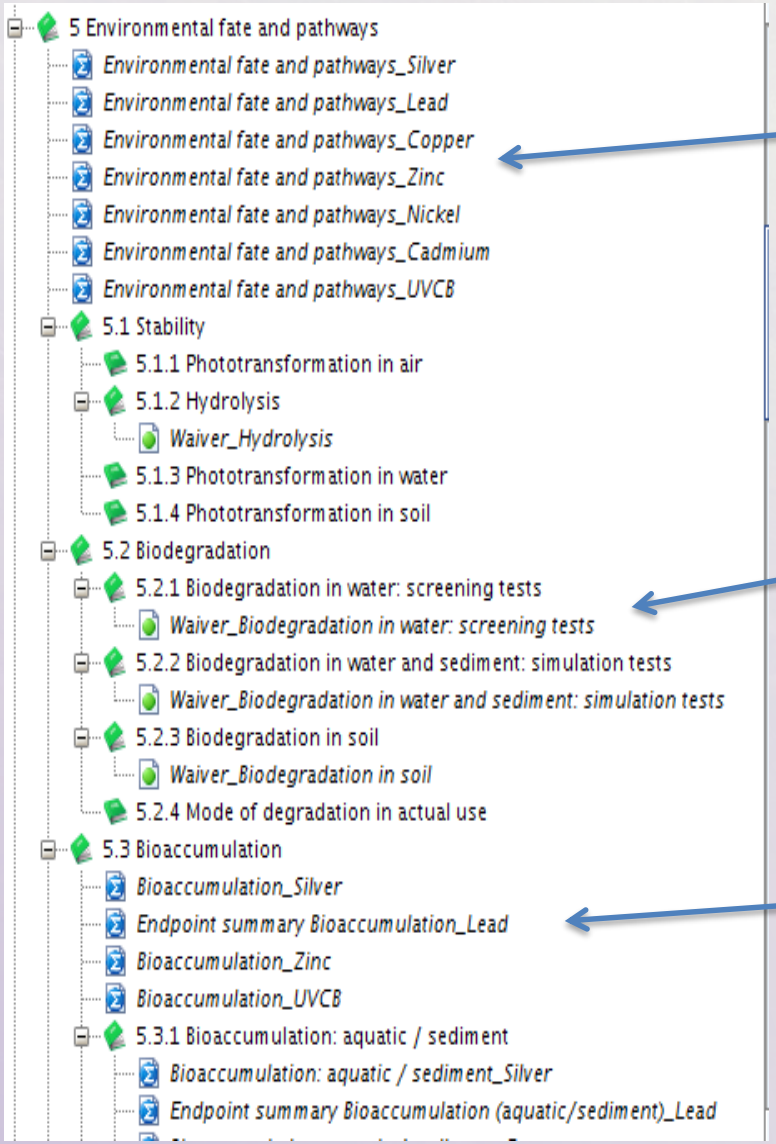
Looking ahead

- Combined toxicity
  - » Assessment of individual (driving) constituents for April update submission
  - » Further research to develop approach on combined toxicity for future updates (months → years)
  - » ECHA proposed publishing a paper on tiered approach for assessment of combined environmental effects (SETAC 2014)

CSR

- Changes since CSR last reviewed:
  - Generic sections added at start of Sections 4 (Environmental fate) and 7 (Environmental hazard assessment)
  - Discuss general approach for UVCBs (text developed by Eurometaux) and selection of driving constituents for each refinable substance
  - Constituent data moved to a separate annex of the CSR – improves readability
  - Data access now agreed for all constituents covered in environmental assessment – may be additional constituents in future updates

IUCLID: Environmental fate

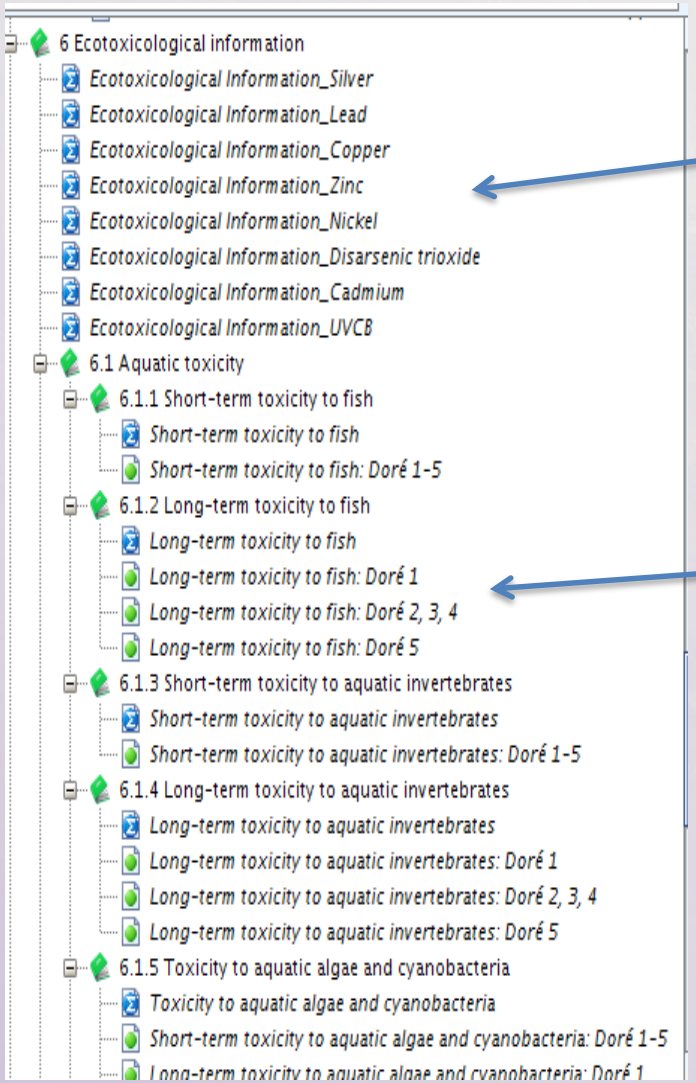


Constituent data
UVCB summary explaining constituent approach

Waivers included as substances inorganic

Constituent data included

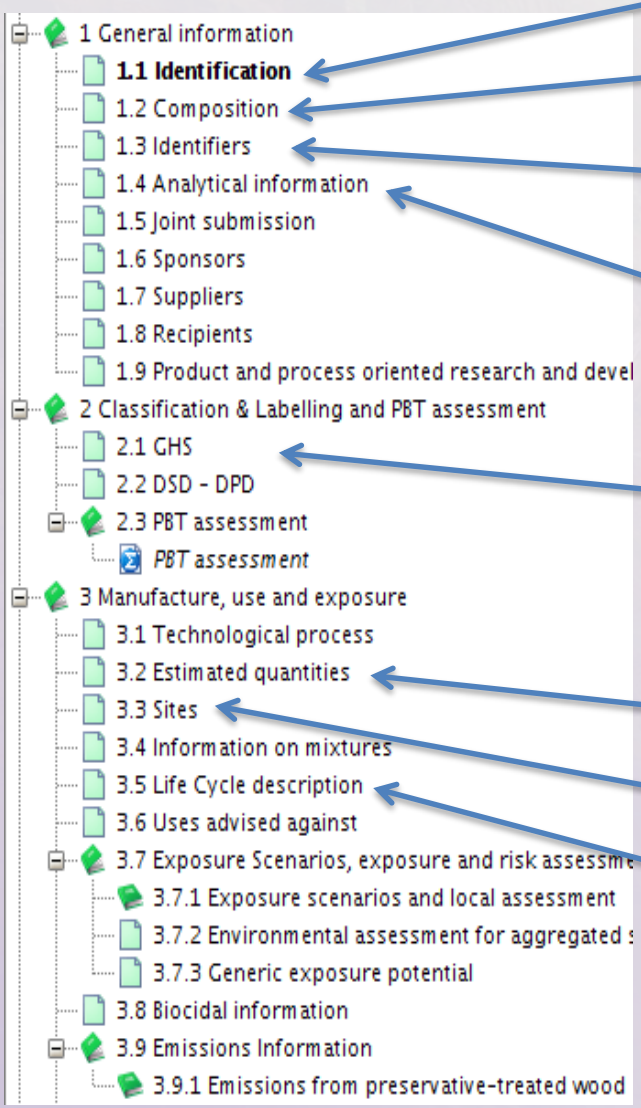
IUCLID: Ecotoxicity



Constituent PNECs
UVCB summary including classification justification based on MeClas results

MeClas entries – UVCB grades grouped based on environmental classification

IUCLID: Sections 1 -3



Role in the supply chain to be entered

Generic and cluster compositions entered
Registrant to include own composition

Registration / pre-registration number

Outotec reports (sample characterisation) attached where available
Registrants to include own analytical data

Grouped classifications entered

Registrant to complete

Registrant to complete

Completed
List of PROCs can be edited by registrant

Next steps (before registration)

- SSRAs
  - » Updated to remove MvE and environmental exposure assessment of B and Cr(III) as no longer driving constituents
  - » Add secondary poisoning assessment
- Finalisation of IUCLID files and CSRs

7. Submission upgraded PM Refinables dossiers

Katrien ARIJS & Caroline BRAIBANT

7.1. Status data-sharing agreements

- Data-sharing agreements signed with As, Cd, Co, Cu, Mn, Mo, Ni, Pb, Sb, Se, Te, Zn
- Data-sharing agreements being finalised for CaO, Cu20, CuSO4
- Data-sharing agreement requests sent for B, borax, Cr, H2SO4, HCl, HNO3, ZnSO4
- Enough information for current updates
- Further data sharing agreements will be needed for further updates

7.2. Physico-chemical endpoints

- Some testing conducted in-house by registrants – results received and entered into IUCLID
- Testing being conducted at Harlan:
  - Flue dust, PM refining: Flammability
  - Lead bullion, PGM metal rich: Melting point, relative density
  - Slags, production of PM containing materials other than Doré: Melting point, relative density, auto-flammability
- Testing is ongoing for Flue dust and Lead bullion
- Slags: Sample being selected
- Results may not be available in time for April submissions
- 'Holding statement' is currently included in IUCLID explaining testing in progress – passes TCC
- Will be updated with results when available

wca environment
today's consultants for tomorrow's challenges

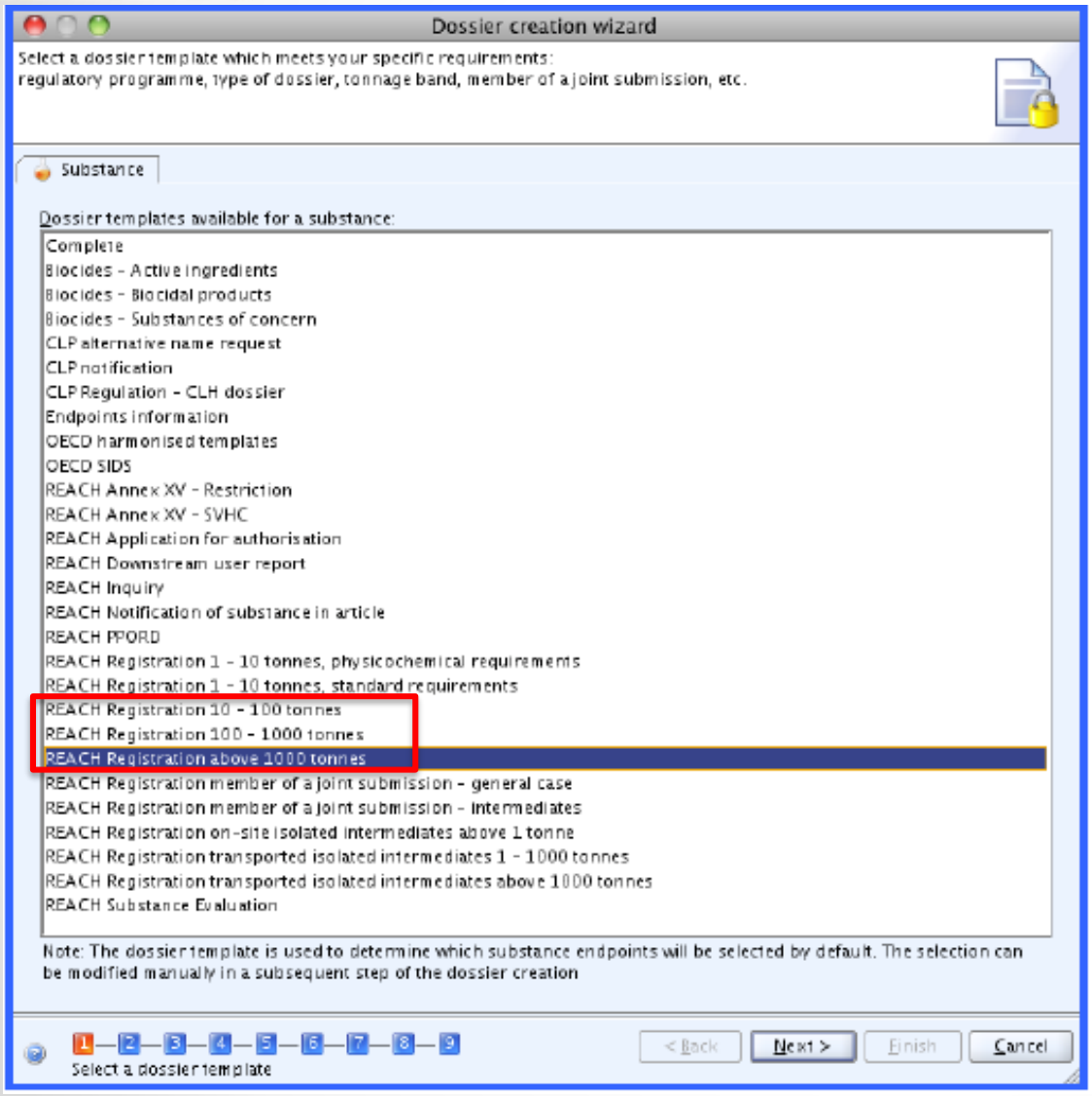
Physico-chemical endpoints

- Flue dust – water solubility testing was proposed
- Following further discussion, a TD test is considered to be more appropriate
- TD test cannot be conducted before April updates – holding statement included in IUCLID
- TD tests may also be required for other substances for classification purposes, or if substances split
- TD tests to be conducted at ECTX

7.3. Timing & procedure submission

- Timing:
  - **8 April**: CSRs/IUCLIDs to be finalised & circulated
  - **21 April**: Deadline for LRs to submit updated dossier
  - **30 April**: Deadline for co-registrants to submit updated dossier
- Procedure:
  - Companies to add company-specific information to IUCLID sections 1 and 3 - Cf. slides WCA + guidance PMC (will be sent together with IUCLID file)
  - Submit update: SCC intermediate dossier to a full Article 10 dossier:
    - Tick box “spontaneous update” in the dossier header
    - Justification for the update: select “change of tonnage band” -> due to technical constraints even if there is no actual change of tonnage band
    - Add in the remark field “voluntary upgrade to full dossier”

Timing & procedure submission (2)

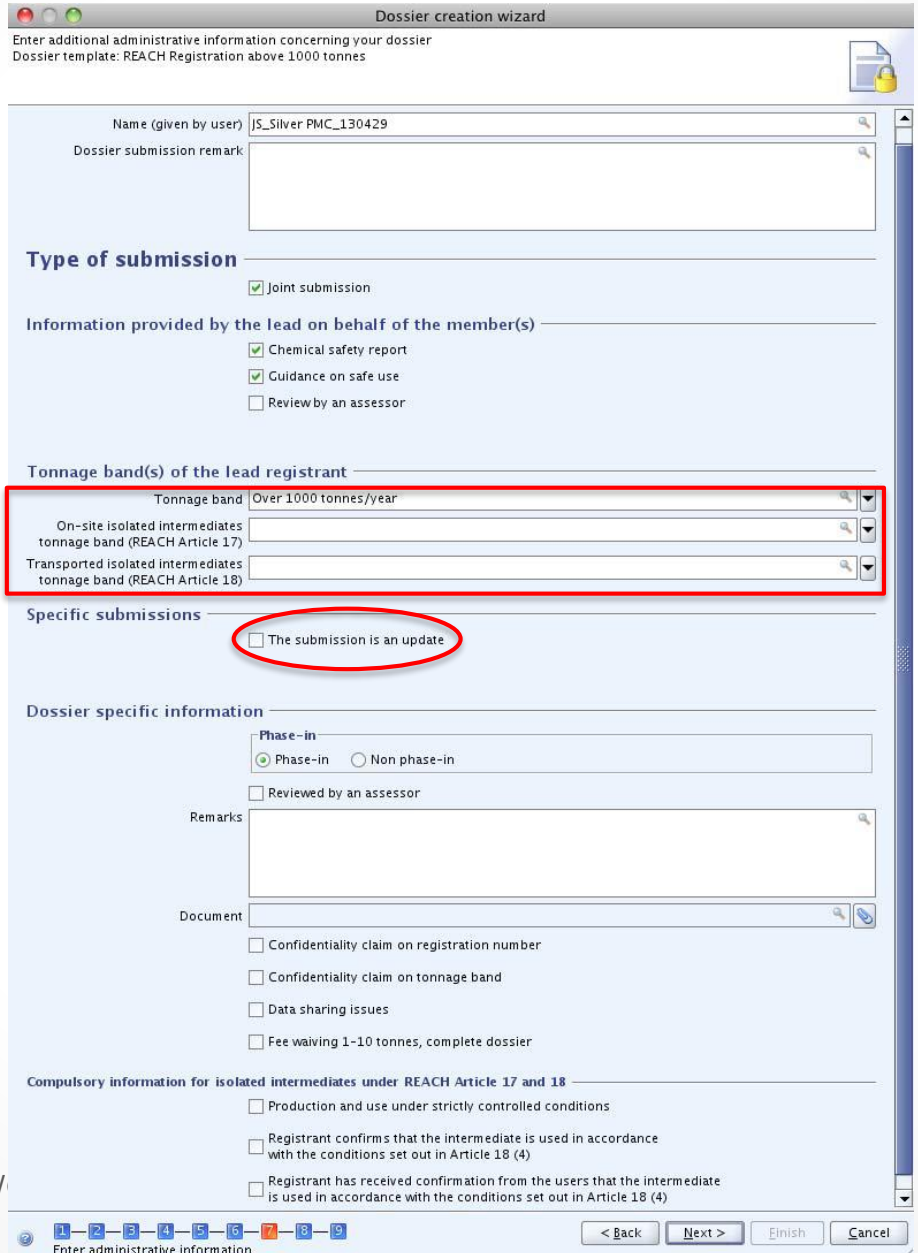


The LR can submit an Article 10 dossier on behalf of the others ('upgrade'), while he only needs to register an SCC intermediate ('update') by:

- selecting the Article 10 template, and
- indicating his own SCC status/tonnage in the dossier header.

The LR should then receive an invoice only for the SCC tonnage.

Timing & procedure submission (3)



7.4. Updates foreseen after April 2014

- Compositions to be updated with company-specific information submitted by companies for this update
- Classification-related compositions: convert formulas
- Other updates depending on SID refinement (splitting slags, slimes & sludges, doré?)
- Cf. relevant sections WCA & EBRC for updates env/HH assessment

8. Next steps, AOB, next Meetings/Calls & Closing Remarks

Daniela CHOLAKOVA

Thank you!

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