Precious Metals & Rhenium Consortium
Brussels, 28 June 2012

Refinables

PM Refiners WG

Meeting

1. Welcome & Introduction

Edwin BROECKAERT

- Reminder on Confidentiality and Competition Law
- Tour de table and apologies
- Approval of the Agenda
- Aim of the meeting:
  - Recap on where we stand
  - Next steps and associated timeline
- Actions agreed at and approval of minutes of last meeting (22 Feb 2012)

Actions (1)

Action	Who?	Status
Classification & labelling		
Clarify outstanding questions on classification.	Eurométaux & ARCHE	Done
Update classifications and prepare overview of all updated classifications per Refinable for approval by PMC Members.	ARCHE	Done *(Cf. presentation ARCHE)*
Check updated classification overview before circulation to PMC Members.	CB & WCA	After today
Circulate updated classification overview for comments to all PMC Members (give 1 month for response), collect responses, update classifications with comments received (liaise with ARCHE, HW & CB if needed), re-circulate for approval and send approved version to WCA.	KA	Jun-Jul
After updated classifications are approved, update all IUCLID 5 files of all Refinables for re-submission to ECHA by LR and implementation by all concerned companies before Dec 2012.	WCA	Aug
Check IUCLID 5 files for each Refinable to make sure it reflects the latest info and send each LR the relevant IUCLID 5 files for submission to ECHA.	KA	Aug
Submit updated classification to the Registration Dossiers where needed.	LR	Aug-Sep
Derive own company-specific classification (with MECLAS or own derivation) if needed / wanted.	PM Ref WG	As needed
Eurométaux advocacy programme on SCC / upgrade strategy with ECHA		
Report ECHA feedback on SCC examples to PMC members.	Eurométaux / PMC sec	Done *(Cf. e-mail 8 May + formal paper to be circulated)*
Discuss way forward on dossier upgrades with ECHA.	Eurométaux	Ongoing & on agenda

Actions (2)

Action	Who?	Status
Rigorous Containment		
Reflect comments of PMC Members and finalise RiCoG for "public release" and use for RiCo assessment programme.	EBRC	Done
Circulate final RiCoG to PM Refiners WG for first tier RiCo determination. Together with RiCoG, circulate intermediate & UVCB papers and first survey inviting PM Refiners WG to summarise: • for which Refinables / process steps RiCo can be demonstrated by RiCoG and those where further (exposure assessment) work is needed; • for which Refinables the intermediate status can be justified; • for which Refinables the UVCB status can be justified.	KA/CB	RiCoG publicly available by end of June Intermediate/ UVCB papers in preparation Timing survey to be discussed
Run RiCoG formally for all PM Refinables in order to confirm for which Refinables RiCo can be demonstrated.	PM Ref WG	Timing to be discussed
Return first survey (RiCoG failed / passed + intermediate / UVCB status) to PMC secretariat.	PM Ref WG	
Compile answers to first survey in order to list Refinables: • for which RiCo is demonstrated; • for which RiCo has not been shown yet (and exposure assessment is needed) • for which an upgrade will definitely be required (if PMC Members have already provided such indication).	KA	

Actions (3)

Action	Who?	Status
Exposure assessment		
Send additional inhalation monitoring data to EBRC and – if requested - send additional data or clarification on environmental emission data to WCA.	PM Ref WG	Done
Further analysis of inhalation monitoring data and correction for physical form and concentration. Use these data for further grouping of workplaces. Circulate updated version of workplace grouping for PMC Members to check / comment on.	EBRC	Ongoing *(Cf. presentation EBRC)*
Measure total versus soluble boron emissions in aquatic effluents for those sites using borates as a flux agent.	PM Ref WG	Feedback from members?
Check the relationship between the Kd and the EF in more detail. Progress environmental modelling as far as possible bearing in mind that additional modelling parameters are required from sources outside the PM Ref WG before this can be finalised.	WCA	Ongoing *(Cf. presentation WCA)*
Gather DNELs/OELs/PNECs: • From the ECHA dissemination website; • From other consortia; • From PMC members / companies (national / regional OEL).	Eurométaux	Data collection started *(Cf. presentation FI)*
Agree on approach to identify driving constituents (MECLAS and/or the decisive DNEL approach).	PM Ref WG	Postponed – awaiting outcome Eurométaux / ECHA discussions non-testing RA approach
Identify driving constituents.	EBRC	
Calculate the RCR for the driving constituents to demonstrate whether the (residual) exposure is significantly higher or lower than the relevant DNEL/ OEL.	EBRC	

Actions (4)

Action	Who?	Status
Updates versus upgrades		
Prepare a list of aspects to be considered by registrants when making business decision to go for updates / upgrades.	FI	Ongoing *(to be circulated after the meeting)*
Check registration cost of an intermediate dossier upgrade.	Eurométeaux	Ongoing *(pending feedback ECHA helpdesk)*
Request non-confidential version of Cu slag IUCLID 5 file to ECI.	FI	Done *(waiting for version that can be circulated – after Jul 6)*
Prepare short papers highlighting the specific criteria embedded in the definition of an intermediate / UVCB.	FI	Ongoing *(to be circulated after today)*
Document intermediate and UVCB status of each Refinable to attach to each relevant IUCLID 5 file.	PM Ref WG	Intermediate/UVCB papers in preparation
Circulate second survey to PM Refiners WG inviting them to summarise for which Refinables SCC compliance can be demonstrated for an update, and those where upgrading of the files is necessary.	KA/CB	Timing to be discussed
Return second survey (update / upgrade) to PMC secretariat.	PM Ref WG	
Compile answers to second survey in order to list Refinables for which an update will be needed and for which an upgrade will be needed.	KA	
Prepare Appendix 2 & 3 with minor supervision by PMC secretariat. ➡ *Companies who are confident about their SCC status should prepare their Appendix 2 & 3 ASAP to prepare for inspections!!*	PM Ref needing update	Timing to be discussed
Agree on efficient data-sharing approach among metal consortia to formalise use of PNEC, DNEL and supporting rationale (cf. also AP20).	Eurométeaux / CB	Ongoing *(Cf. presentation FI)*
Once (E-)TRV and Cu slag Dossier are available, organise meeting(s)/call(s) with EBRC and WCA, EM and ECI, to refine upgrade approach in preparation of presentation to ECHA.	FI	Scope has broadened: MM db on its way & UVCB ECHA workshop in preparation

Bottlenecks

RiCoG
- For which Refinables is Exposure Assessment needed

Multimetallic database
- Needed for Exposure Assessment

Decision update / upgrade
- Based on RiCoG + Exposure Assessment + expert judgement

2. Reminder on Background & Current State of Play

Caroline BRAIBANT

Scope of work

	Refinable	Intermediate status	Tonnage band	Lead Registrant
1	Doré	Transported	> 1000 t/a	Aurubis
2	Matte	Transported	> 1000 t/a	Umicore
3	Slags	Transported	> 1000 t/a	Umicore
4	Slimes and sludges	Transported	> 1000 t/a	Aurubis
5	Leaching residues (2)	Transported/On-site	> 1000 t/a	Umicore
6	Electrolytes (2)	On-site	> 1000/100-1000 t/a	KGHM/Aurubis
7	Flue dust	Transported/On-site	> 1000/100-1000 t/a	Johnson Matthey
8	Cements	Transported/On-site	> 1000/100-1000 t/a	Heraeus
9	Materials for reclaim (3)	Transported/On-site	> 1000/10-100 t/a	Johnson Matthey
10	Pb bullion, PGM rich	On-site	10 - 100 t/a	Vale

Legal background: Registration requirements (context and definition)

- Article 3:
  - Intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis)
  - Assumed to be handled in equipment including "reaction vessel", "continuous flow or batch process", "pipework for transfer from one vessel to another", "reaction step"
- Recital 41: For reasons of workability and because of their special nature, specific registration requirements should be laid down for intermediates
- Articles 17 and 18: Specific registration requirements shall apply only if the manufacturer or importer confirms himself (or states that he has received confirmation from the user) that the substance is only manufactured and used under SCC in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

Legal background: Registration requirements (context and definition)

SCC means:

a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;

b) procedural and control technologies shall be used that minimise emission and any resulting exposure;

c) only properly trained and authorised personnel handle the substance;

d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;

e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;

f) substance-handling procedures are well documented and strictly supervised by the site operator.

Legal background: Evaluation, Authorisation and restriction

- Article 49: For intermediates that are used in SCC, neither dossier nor substance evaluation apply; but if MS CA considers that a risk to HH or ENV , equivalent to the one triggering listing under Authorisation, it may require more information and RMM
- Article 57: No direct indication that intermediates are exempt from Authorisation…
- Article 2(8)b: Intermediates are exempted from Title VII (Authorisation)
- Article 68: Intermediates are exempt from restriction

Guidance: context

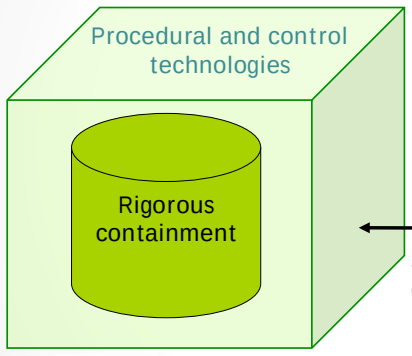
- Legislation not flexible/practical or fit-for-purpose for (NFM) industry, hence need for Guidance:
  - ECHA, Feb 2008
    → basis for 2010 registrations
  - ECHA, Dec 2010
    → 2010 registrations updates and future registrations
- Also: Eurométaux guidance, CEFIC guidance, etc.

Dec 2010 Guidance: Rigorous containment and SCC

- Rigorous containment (RC):
  - Definition: Technical hardware designed for preventing releases, taking into account the physical-chemical properties (not its HH or ENV hazards) of the substance and the process condition
  - Implementation: By one or several combinations of mechanical barriers and air dynamic as applicable in each processing steps (cf. Hirst *et al.*, 2002: Containment systems, strategies 3-5)

  - RC ≠ Procedural and control techniques :: Containment ≠ minimization of releases
  - RC ≠ SCC
  - SCC = RC + procedural and control techniques

All conditions shall apply and be met at the same time during the whole lifecycle of the intermediate



Trained and authorised personnel

Special procedures before entering the system

Well-documented procedures

Absence of confirmation of SCC for transported isolated intermediates over supply chain triggers full Dossier

Dec 2010 Guidance: Exposure/emission data

SCC = no significant/relevant (residual) exposure or emission

- Strictly controlled conditions must be achieved without taking into account the use of PPE (except for exceptional situations)
- Verification of achievement of RC can be based on measured or modelled emission/exposure data
  - RCR?
  - Which threshold?
  - Which DNEL or PNEC?
- Absence or lack of RC cannot be justified by using RCR

Dec 2010 Guidance: Other items

- Definition of intermediate: aim should be to transform it into another substance
  - Reactants are not intermediates unless they (partially or fully) transform into the resulting substance, product of the reaction
  - Catalysts are not intermediates unless they are not themselves converted into the manufactured substance
  - Processing agents aimed at optimising the physico-chemical environment of the reaction medium (e.g. dispersing agents, viscosity modifiers, lubricants, antistatic agents, fluxes?) are not intermediates even if they end up as impurities in the manufactured substance
- SCC need to be documented in Appendix 3, which needs to be attached to section 13 of each individual registrant's registration dossier without undue delay…

Dec 2010 Guidance: Demonstrating due diligence

	What?	When?
1a	Comparison of the 2008 and 2010 ECHA Guidance on intermediates	Oct 2010 – Feb 2011
1b	Assess potential impact of the 2010 guidance on NFM sector	Jan – Mar 2011
1c	Scope the Eurometaux priorities on SCC	Mar 2011
2	Develop tools to support Industry's decision	Apr 2011 – Dec 2012
3	Engage in advocacy activities on SCC metal specificities	May 2011 – March 2012
4	Address challenges related to Risk Assessment of UVCBs	Jun 2011 – on-going

1. RiCoG
2. Appendix 2 & 3 templates

1. Joint advocacy
2. SCC examples

1. 21 May 2012 EM + ECHA high level technical meeting
2. SCC TF sub-group
3. Autumn 2012 *ad hoc* EM + ECHA workshop

Outcomes 21 May EM mtg with ECHA on identification and risk assessment of UVCB under REACH

H. Waeterschoot

Reactions and conclusions (1)

Meeting objective: explore ECHA's openess for supporting a pragmatic solution for assessing UVCB's under REACH

- Critical but open and constructive mindset
- In-depth interest to understand particularities of inorganic UVCB substance ID and hazard/risk assessments
- ECHA is clearly expecting science based approaches
- Feedback at ECHA higher level:

> *"industry conducted really hard work and constructive thinking but needs to demonstrate now that (the proposed approach for risk assessing these UVCBs) is feasible in reality".*

Conclusion is much in line with *the Pilot approach of the PM sector*

Reactions and Feedback (2)

- *ECHA stressed* Importance of :
  - substance identification
  - explaining and understanding the reasons for the variability (V of UVCB): right FORMAT
- Important to understand *ECHA's concerns*:
  - a too wide substance ID could be used to include several (too) different UVCBs under one substance entry
  - access to justifications
  - remain in line with REACH legal text and guidance
  - hazard ID should drive risk assessment and characterization rather than the classification

Recommendations noted:

- Generic:

• Clarify generic flow of manufacturing of metals and how this can influence the speciation/variability (flowchart from BREF?)
• Clarify terminology (elements, constituents, species etc…) and ensure consistent use
• ECHA recognizes that the risk characterization phase for UVCB includes additional challenges that requires a cautionary but not overly conservative approach
• Explain, explain, explain and justify. Find a transparent clear format
• Validation of the outcome will be required certainly for the environment given the multitude of the assessments and hypotheses made
• Need for a good analysis on uncertainties for both the env and HH assessment and a consideration how that can be handled appropriately

Recommendations noted:

Actions on Substance Identification (SID)

• Composition ranges in registration dossier:
  • Ensure ECHA understands
  • What is “in” and “out” the scope of the UVCB dossier
  • Need to reflect “legal entity case” too (not only generic across industry)
  • Need for standardized and harmonized IUCLID sections on composition and analytical data across metal commodities

• SID is the basis also of effects assessment
• Sketch the overall philosophy of the characterization approach and steps: how do we do it? What do we use as information, what is routine info for substance ID and what is refinement?
• Show that there are different lines of evidence/information coming together when addressing SID: elemental analysis, speciation analysis, CEM to confirm, particle size/form of the material, crystallographic data….
• Demonstrate that the selected reference samples for mineralogical / speciation analysis are reasonably representative
• Explain how we use available information in Hazard ID and Risk Management: how do our tiered approaches work?

Recommendations noted:

Actions on Hazard assessment and Classification

• Multi-metallic database on ERVs and other parameters influencing the risk assessment will be crucial
• Importance of validation (representativeness of speciation analysis and/or TDp tests reference samples)
• Format to present the data used for classification of UVCBs, ensuring transparency, allowing authorities to find & understand where the data are coming from (background, data source including access rights (LOA?), RSS…). • Standardisation: harmonised format for IUCLID entry?
• MECLAS: make the slides UVCB specific and re-think figure to make it more UVCB-conceptual
• Include the use of phase diagrams in the overall reasoning

Recommendations noted

Actions on Risk Assessment

• Prepare a one-pager on GEMAS outcomes (question from ECHA on soil background concentrations)
• Reflect with consortia on integrated approach /site for emissions: what makes sense
• Work on the format to find something workable, allowing weight of evidence considerations, enough information on PNECs, DNELs, reference to the dossiers of the constituents, space for clever argumentation etc
• Explain clearly what is covered by local monitoring data and the regional assessment/reflect what is needed
• Work further out the driving DNEL/risk approach. Think about impact of physical form

Overall conclusion and Timing aspects

OVERALL CONCLUSIONS :

- ECHA confirmed relevance of a *more in-depth technical workshop* to present and discuss specific examples.
- *Scope* : HH/ENV, SID, meeting data needs, CSR, explanations and justification, weight of evidence and data access

TIMING ASPECTS: how urgent ??

Issues to consider :

- Targeted Compliance Checks on Intermediates files on-going ECHA
- EU-coordinated inspections from early 2013
- BUT some metal sectors not yet ready !

Question : PM sector views and needs in respect to timing and need for support from ECHA for the Refinables approach ?

Preparation for Autumn 2012 ECHA + EM workshop on substance identification and risk assessment of UVCB under REACH

F. Iaccino

Complex UVCBs assessment under REACH

- Metal UVCBs: appropriate identification and risk assessment methodologies despite spatial and temporal variability
- OECD: on going discussion on inorganic UVCB
- 21 May ECHA 'preliminary meeting'
- Autumn 2012: one day workshop @ ECHA

Tools: multi-metallic database, test cases

Bottlenecks: E-TRV, LoA Agreements, remaining consortia

Metallic UVCBs: a(nother) REACH challenge

- Complex Inorganic UVCBs contain varying amounts of metals, metal compounds and/or minerals

→ *the naturally occurring mineral ores & concentrates*

→ *the intermediates produced during the various refining and manufacturing streams of metals*

- Very complex materials, with high variability/ heterogeneity in composition and physical forms:

→ *high number of constituents*

→ *high number of streams*

Robust assessment under development & assessment with ECHA

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Next step: one day workshop on UVCBs

- Substance Identification is the basis (note: work at OECD on inorganic UVCB SID)
- **!!** The format of the metallic UVCB RA & Dossier is important to ECHA:
  - ✓ Transparent information, right information in the right box.
  - ✓ Need to have access to data from other metals
  - ✓ Need to demonstrate data access
- Need for examples, building up 'guidance' step by step, bringing together existing work

→ July 6: SCC voluntary taskforce will actively start preparing the workshop & developing examples

The Multi-metallic database

The complete database on effects assessment outcomes

- ✓ What for? E.g.
  - × Intermediate & mixture assessments
  - × Mixtures eSDS
- ✓ Why?
  - × Allow access to reliable/relevant data generated by consortia, 1 location
  - × Allow the appropriate use of the data
  - × Enable consistent approach & use of the data
- ✓ Where?
  - × Reach Metals Gateway (members only section)

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The Multi-metallic database & the 'ECHA-value'

- Substance Identification is the basis (work at OECD on inorganic UVCB SID)
- !! The format of the metallic UVCB RA& Dossier is important to ECHA:
  - ✓ Transparent information, right information in the right box.
  - ✓ Need to have access to data from other metals
  - ✓ Need to demonstrate data access

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Multi-metallic database-ENV: screenshot 1

SOLUBILITY						EFFECTS	EFFECTS ASSESSMENT
	etal/Metal Compound	Chemical Formula	CAS number	EC number			
	Water solubility (µg Me/L)		Water solubility method				EFFECT ASSESSMENT BASED ON
	Substance		*or UVCB indication*				*Is the effect assessment performed on the substance itself (no read-across) / on the dissolved metal / is the toxicity driven by the soluble Me ions? Please fill the appropriate information, as it is important to define the assessment 'relevance domain'. If PNEC value not based on metal ion, has a translation been carried out (Mwt TD)?*
	enter ws data		*Specify method (OECD water solubility test) and main test conditions (pH, hardness,…). Mention if not applicable (refer to T/D tests)*				*Section 4.5*
	Section 4.8						

Multi-metallic database ENV: screenshot 2

RELEVANT PARAMETERS										
	Adsorption/desorption								JUSTIFICATION	
	Kp susp freshwater (l/kg)	Kd susp marine (l/kg)	Ksusp estuary (l/kg)	Kp sed freshwater (l/kg)	Kp sed marine (l/kg)	Kp sed estuary (l/kg)	Kp soil (l/kg)		COMMENTS	
	value or report the justification provided in IU	*units*			*drop down menu (as in the IU)*			*Please report procedure followed for (no) PNEC derivation, on how the effect assessment was conducted: AF comments? Effect assessment based on NOEC/ SSD? What is the lowest NOEC that allows to identify the most sensitive species?*		
	value or report the justification provided in IU	*value or report the justification provided in IU*	*value or report the justification provided in IU*	*value or report the justification provided in IU*	*value or report the justification provided in IU*	*value or report the justification provided in IU*	*value or report the justification provided in IU*	*Equilibrium partitioning used? Measured values form the field? Statistics used (median?)*		
	Section 6 - Summary of ecotoxicological endpoint							*Refer to "Justification" in IU*		
	Section 5.4 - Summary									

Multi-metallic database-HH: screenshot

EFFECTS		ACUTE, SHORT TERM SYSTEMIC EFFECTS						
EFFECTS ASSESSMENT		WORKERS						
EFFECT ASSESSMENT BASED ON		DN(M)EL DERMAL		AF	Dose descriptor starting point	Most sensitive endpoint	JUSTIFICATION	
Is the effect assessment performed on the substance itself, on read across / on the dissolved metal /its the toxicity driven by Me-ions?Please report here if any absorption factor was used (dermal/inhalation/oral). Please fill the appropriate information, as it is important to define the assessment 'relevance domain'.		*value*	*units*		*Drop down menu in IUJ*	*(as Drop down menu in IU)*	*(as Please report procedure followed for (no) DN(M)EL derivation/ applied assessment factor, as in IU*	
		Section 7 - Summary of toxicological endpoint						*Refer to "Justification" in IU*

Multi-metallic database-ERV&M: screenshot

Degradability			ACUTE					
FATE & BEHAVIOUR			ERV					
Removal from water-column	Justification		Freshwater Algae pH 6	Freshwater Algae pH 7	Freshwater Algae pH 8	Marine Algae	units	
Is the substance removed from the water column? Select from the drop down menu: yes/no	*Justification (eg UWM data, absence remobilization)*		L(E)C50	L(E)C50	L(E)C50	L(E)C50	*Drop down menu*	

Multi-metallic database-classification: screenshot

PHYS CHEM

IUCLID SECTION 2

Explosives	Classification	Flammable gases	Classification	Flammable aerosol	Classification	Gases under pressure	Classification
	Select from the drop down menu whether classification is based on Annex VI CLP or Self classification		*Select from the drop down menu whether classification is based on Annex VI CLP or Self classification*		*Select from the drop down menu whether classification is based on Annex VI CLP or Self classification*		*Select from the drop down menu whether classification is based on Annex VI CLP or Self classification*

Status of the multimetallic database

Extensive database: focused on information needed to develop the effects assessment (ENV/HH Endpoints & Justification) & classification information (available relevant data):

→ Yes: Cu, Al, Sb, Ag, B, Se, Mo, Iron Oxides
→ Ongoing: Co, Zn, Ni, Pb
→ Possibly: Cd, As, V, Sn
→ ??: Be, Mn

Bottlenecks:

- ☞ Strategy: are relevant metals covered? Input EBRC/WCA for Refinables needed to prioritize
- ☞ How to efficiently move further?
- ☞ Timing?
- ☞ Common LoA agreement needed

3. Workplace Exposure Assessment Update

Daniel VETTER
Jutta SCHADE
Torsten GREWE

4. Environmental Emissions Assessment Update

Claire MASSEY

5. Classification Update

Frederik VERDONCK

6. Preparing for Inspections

Caroline BRAIBANT

Targeted "Evaluations" and UVCB intermediates
Caracal document on ECHA activity on Intermediates

H. Waeterschoot

Evaluation:

Targeted Compliance to feed CoRAP

→ Targeted compliance checks launched by ECHA
- ✓ "virtually empty" dossiers with empty or limited CSR
- ✓ substances of the 2013 and 2014 CORAP lists (or containing those)
- ✓ …

→ Targeted compliance checks Themes for 2012:
- ✓ Eco-toxicity
- ✓ Genotoxicity
- ✓ Substance ID concerns

This (may) raise(s) attention for inorganic UVCB's !

ECHA intermediate sample

Issue	On-site intermediates	Transported isolated interm.	All
Total screened dossiers	115	299	414
Meeting all requirements for intermediates	6	50	56
N° Missing, insufficient or doubtfull info on RMM or interm. Status	109	245	354
% Missing, insufficient or doubfull info on RMM or interm. status	> 90 %	> 75 %	>80 %

- ECHA concluded that *"most intermediate files require significant improvements"* (updates or upgrades);
- Management Board requested ECHA *"to develop a compliance strategy (incl. Intermediates)"*, to promote role of ECHA in improving compliance.

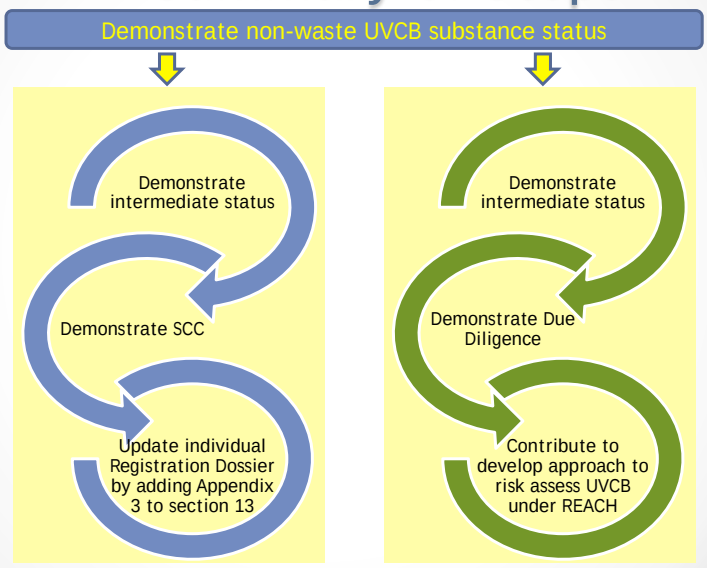
Caracal debriefing
on ECHA's activities on Intermediates

- → Overview *prepared by ECHA* for discussion on 28th June
- → Repeating *history of the intermediates* & SCC case
  - ✓ Discussion known exept outcome Caracal March 2012 concluding: "*no risk based approach allowed*" and "*no guidance update at this stage*"
- → "*ECHA art 36 letters*" requesting clarification from manufacturers on :
  - ✓ Use as intermediate
  - ✓ SSC compliance
  - ✓ DU's confirming SCC conditions
- → *Outcome presently under review* for recommending:
  - ✓ national site inspection,
  - ✓ dossier CC priorities
  - ✓ fine-tuning Forum program on Intermediates

Preparing for ECHA and local inspectors' questions…

C. Braibant

Summary of Steps



Step 0. Demonstrate substance status

Substance vs. Waste

Mono-consistuent vs Multi-constituent vs UVCB substance

Appropriate grouping of streams under one unique UVCB

Definition of waste

Waste: Any substance or object in the categories set out in Directive 2006/12/EC which the holder intends to, or is required to discard

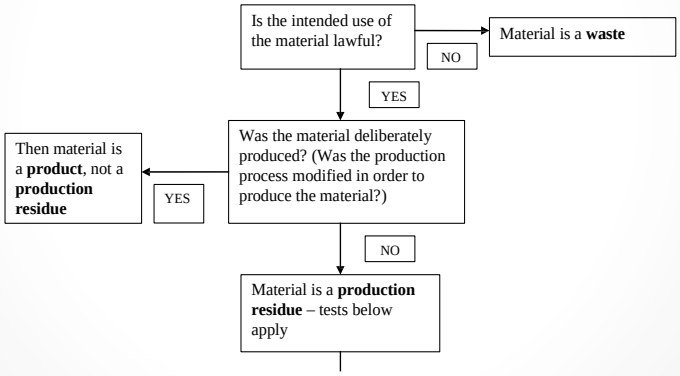
16 categories, including:

- Off specification batches
- Product or consumption residues not otherwise specified
- Residues of industrial processes (e.g. Slags)
- Unusable parts (e.g. reject batteries, exhausted catalysts, etc.)
- Residues from raw materials extraction and processing
- Any materials, substances or products which are not contained in the above categories

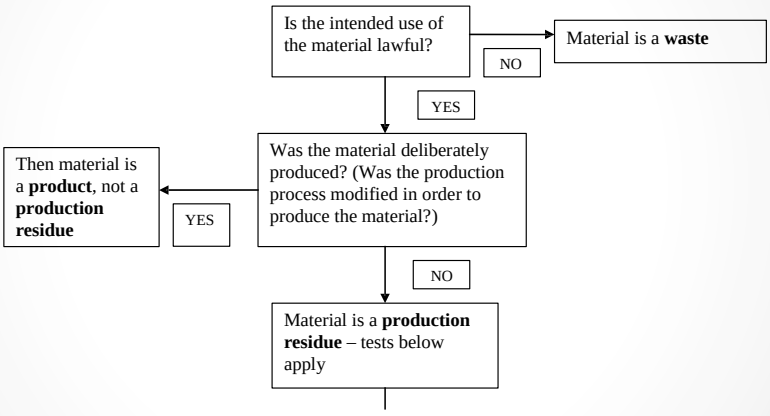
Almost anything can be considered waste…!

Waste and by-products

- Annex II of Communication from COM to EC and EP on the Interpretative Communication on waste and by-products:



Waste and by-products

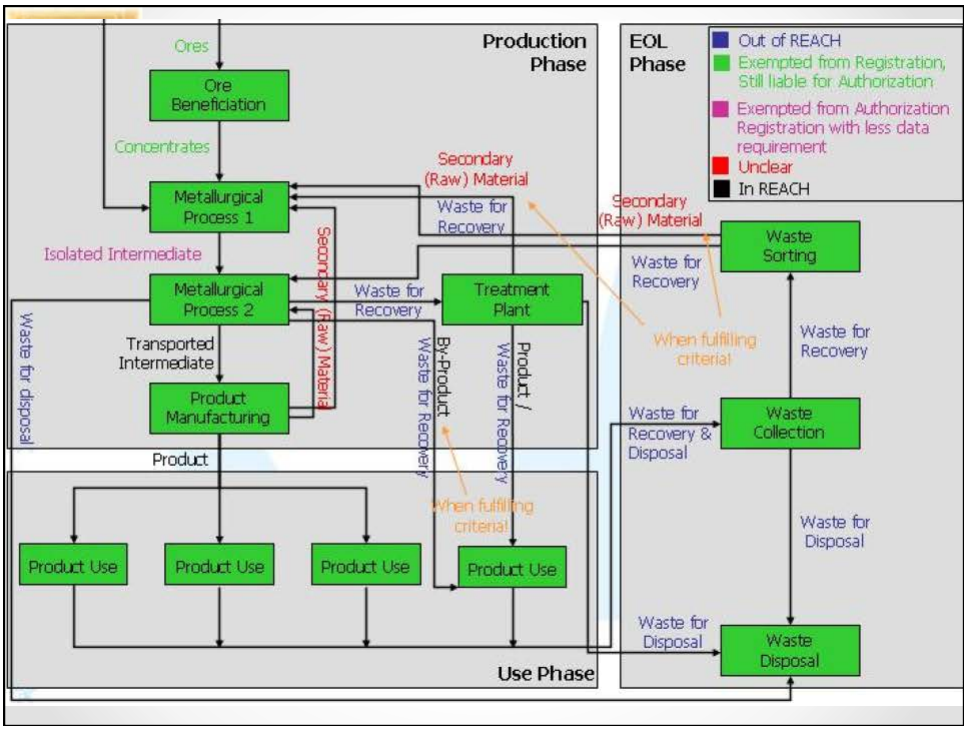


Waste and recovered substances: when waste ceases to be waste

ECHA Guidance - waste ceases to be waste when:

- The substance is commonly used for specific purposes
- A market or demand exists for such a substance or object
- The substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products
- The use of the substance or object will not lead to overall adverse ENV or HH impacts

EC regulation (EU) No 333/2011 of 31 March 2011



UVCB

Substances of Unknown or Variable composition, Complex reaction products or Biological materials

- The number of constituents is relatively large and/or
- The composition is, to a significant part, unknown and/or
- The variability of composition is relatively large or poorly predictable.

Chemical composition and the identity of the constituents should still be given as far as known:

- all known constituents and all constituents present at concentrations ≥ 10% should be specified
- Unknown constituents should be identified as far as possible by a generic description of their chemical nature

Terms “main constituents” and “impurities” not relevant

Identified by its name, its origin or source and the most relevant steps taken during processing; to be described together with the generic composition of the resulting substance

UVCB

	Refinable	Description	Composition	Comment / Question
1	Doré	Metallic bars/ingots, grains or anodes and their residues (spent anodes) resulting from pyro-metallurgy processes applied on primary and secondary feeds with high precious metal 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.	Ag, Au, PGM, Sb, As, Bi, Cd, Cu, Pb, Fe, Mg, Ni, Se, Te, Sn, Zn	
2	Matte, PM refining	Substance resulting from the smelting of precious metals and its alloys obtained from primary and secondary sources and including recycled plant intermediates. Precious metal matte is composed primarily of base metal sulphides containing precious metals and may contain other residual non-ferrous metals and their compounds in varying concentrations.	Ag, Au, Ir, Pd, Pt, Rh, Ru, Al, Sb, As, Ca, Cr, Co, Cu, Pb, Fe, Mg, Ni, Te, Sn	

UVCB

	Refinable	Description	Composition	Comment / Question
3	Slags, PM refining	Heterogeneous solids (e.g.: lumps) resulting from pyro-metallurgy processes applied on precious metals containing-primary and secondary feeds, using several fluxing agents such as sodium borate or borax, sodium carbonate, sodium phosphate, silica, and aluminium silicate amongst others. Depending on the fluxing agent used, slags resulting from the refining of precious metals may contain ferrous and non ferrous metal oxides, carbonates, phosphates, silicates, and/or fused salts in varying concentrations, with some quantities of precious metals.	Ag, Au, PGM, Al, Sb, As, Ba, Bi, Ca, Ce, Cu, Pb, Fe, Mg, Ni, PO4, Se, Si, Na, Sr, Te, Sn, Ti, Zn, Zr, Cl	
4	Slimes and sludges, PM refining	Dry or wet residues resulting from hydro-metallurgical and/or electrolysis processes used in the refining of precious metals. Slimes and sludges from precious metals refining generally contain precious and base metals, and insoluble inorganic compounds in varying concentrations.	Ag, Au, PGM, Al, Sb, As, Ba, Bi, Cd, Ca, Cr, Co, Cu, Pb, Fe, Ni, Se, Si, Na, Te, Sn, Zn, NH3/NH4+, C, HCl or Cl-, N	

UVCB

	Refinable	Description	Composition	Comment / Question
5.1	Matte leaching residue	Dry or wet insoluble residues resulting from successive sulfuric acid-based leaching and/or pyro-metallurgical processes applied on primary and secondary streams resulting from the refining of copper, nickel and other base metals-containing ores and concentrates. Residues from copper-iron-lead-nickel matte leaching mainly contain precious and base metals such as copper, nickel and iron in metallic, sulphate, hydroxide and other mineral forms in varying concentrations.	Ag, Au, PGM, Al, Sb, As, Ba, Bi, Ca, Cr, Co, Cu, Pb, Fe, Mg, Mn, Ni, Se, Si, Te, Sn	
5.2	Speiss leaching residue	Dry or wet insoluble residues resulting from leaching processes applied on copper speiss resulting from refining of primary and secondary copper feeds. Residues from copper speiss leaching mainly contain precious and base metal (e.g.: copper, lead, nickel) sulfo-arsenides complexes in varying concentrations.	Ag, Au, PGM, Sb, As, Cu, Cu, Pb, Ni, S	

UVCB

	Refinable	Description	Composition	Comment / Question
6.1	Ag Electrolytes	Fresh or spent aqueous silver nitrate solution used in and resulting from the electrolytic refining of silver. This electrolyte is constituted of silver nitrate, copper dinitrate, nitric acid, and it may contain some other metallic and non-metallic ions in varying concentrations, which will vary depending on the nature and composition of the primary or secondary raw material from which silver is recovered.	AgNO3, AuNO3, PGM Nitrates, Cu(NO3)2, Pb (NO3)2, HNO3, Water, H2SO4	
6.2	Au electrolyte	Fresh or spent aqueous gold trichloride solution used in and resulting from the electrolytic refining of gold. This electrolyte is constituted of gold trichloride, clorhidric acid, and it may contain some other metallic and non-metallic ions in varying concentrations, which will vary depending on the nature and composition of the primary or secondary raw material from which gold is recovered.	AuCl4, PtCl4 or PtCl2, PdCl4 or PdCl 2, Other PGM chlorides, HCl, Water	

UVCB

	Refinable	Description	Composition	Comment / Question
7	Flue dust, PM refining	Dust collected from high temperature treatments and processes applied on primary and secondary feeds with a range of precious metal contents. Flue dusts mainly contain metal oxides, hydroxides, sulphides and chlorides in varying concentrations, with some small quantities of precious metals.	Ag, Au, PGM, Al, Sb, As, Bi, Cd, Ca, Ce, Cr, Cu, Pb, Fe, Ni, K, Se, Si, Na, Te, Sn, Zn, Cl, F	
8	Residues cementation and reduction, PM refining	Dry and wet residues recovered through cementation and/or reduction with a reducing agent (such as aluminium, copper, iron, zinc or organic agents) of precious metal refining streams before release to waste water treatment operations. Residues include cements and polishing sludges which generally contain precious metals, metal oxides, and metal chlorides in varying concentrations.	Ag, Au, PGM, Al, Sb, As, Bi, Ca, Cr, Cu, Pb, Fe, Ni, Se, Si, S, Te, Zn, Cl	

UVCB

	Refinable	Description	Composition	Comment / Question
9.1	Materials for reclaim, PM with or without support	Primary and secondary sources of precious metals in metallic, oxide, chloride and other forms in varying concentrations, resulting from the application of thermal or thermo-chemical processes or end-of-life criteria whose supports may, where present, include varying amounts of: • Ceramics (such as silica, alumina and zeolites), • Carbon or organics (such as carbon, paper, or plastics), and/or • Metallics (such as stainless steel or other transition metal alloys).	Ag, Au, PGM, Al, Sb, As, Ba, Bi, B, Cd, Ca, Ce, Cr, Co, Cu, La2O3, Pb, Fe, Mg, Mn, Mo, Ni, Nb, P, K, Se, Si, Sr, S, Tl, Ta, Te, Sn, Ti, W, Zn, Zr, C, Cl, H2O	
9.2	Materials for reclaim, PM on bricks, crucibles, trays, etc.	Spent artifacts used in the processing of precious metal streams that have retained fractions of precious metals from/during processing and that are reclaimed as secondary sources of precious metals. These materials may be silicate or refractory based, and contain low and varying concentrations of precious metals in metallic, oxide, and other forms.	Ag, Au, PGM, Al, Sb, As, Bi, B, Ca, Cr, Co, Cu, Pb, Fe, Mg, Ni, Se, Si, Te, C,	

UVCB

	Refinable	Description	Composition	Comment / Question
9.3	Materials for reclaim, PM production by-products	Materials that are non-intentional products of the production and refining of precious metals, which contain precious metals as well as other metals and their compounds (oxides and others) in varying concentrations. One example of such refining by-products are so-called production “sweeps” and dusts.	Ag, Au, PGM, Al, Sb, As, Ba, Br, Ca, Cr, Cu, Pb, Fe, Mg, Ni, K, Si, Na, Sn, Ti, Zn, C, Cl	
10	Pb bullion, PGM rich	Primary and secondary feed materials usually in the form of residues containing low concentrations of precious metals, together with higher and variable concentrations of base metals and refractory materials that are mixed with fluxes and smelted with a lead collector, resulting in two phases: a lead one which concentrates precious metals, and a silicate slag phase (Slags, precious metals refining). The lead phase, or Platinum Group Metal Rich Lead Bullion is used as a feed in the hydrometallurgical upgrading of platinum group metals; it contains predominantly lead with lower concentrations of platinum group metals, silver and gold and other non-ferrous metals in varying concentrations.	Ag, Au, PGM, Sb, As, Bi, Cd, Cu, Pb, Fe, Ni, Se, Te, Sn, Zn	

UVCB

Are all our Refinables true UVCB?

Is each UVCB a standalone group of streams (not of substances)?

Need for external reality-check?

Step 1. Demonstrate intermediate status

Definition of intermediate: aim should be to transform it into another substance

Reactants are not intermediates unless they (partially or fully) transform into the resulting substance, product of the reaction

Catalysts are not intermediates unless they are not themselves converted into the manufactured substance

Processing agents aimed at optimising the physico-chemical environment of the reaction medium (e.g. dispersing agents, viscosity modifiers, lubricants, antistatic agents, fluxes?) are not intermediates even if they end up as impurities in the manufactured substance

Step 1. Demonstrate intermediate status

Chemical modification:

Mineral, Ore, Ore Concentrate Processing Step	Chemical modification?	
Optical/Mechanised Sorting		No
Magnetic/Electrostatic Separation		No
Gravity or Dense Medium Separation		No
Preferential Crushing, Grinding or Milling		No
Screening, hydrocycloning or Classification		No
Agglomeration or Froth Flotation		No
Thickening & Filtration		No
Drying (or calcination that results in removal of water & impurities only)		No
Pelletising by granulation only		No
Leaching/washing Processes to remove impurities		No
Leaching processes to extract the value-mineral	Yes	
Pelletising with sintering	Yes	
Ion-exchange,solvent extraction or electro-winning	Yes	
Pressure Digestion in aqueous NaOH	Yes	
Sintering, Roasting & Smelting	Yes	
Calcination involving changes in the chemical structure (e.g., CO_2 release)	Yes	
Precipitation and gas precipitation	Yes	

Step 2. Demonstrate SCC

Legal background:

a) the substance is rigorously contained by technical means during its whole lifecycle
b) procedural and control technologies to minimise emission and any resulting exposure
c) only properly trained and authorised personnel
d) in the case of cleaning and maintenance works, special procedures
e) in cases of accident and where waste is generated, procedural and/or control technologies
f) substance-handling procedures are well documented and strictly supervised

Guidance:

- Rigorous containment → One or combination of technical hardware, mechanical barriers and air dynamic as applicable to each process step to prevent release considering the physical-chemical properties (not its HH or ENV hazards) of the substance and the process condition
- Exposure and emission data → to demonstrate achievement of RC

Expert judgement:

Legal background + RiCoG + RC as per BRef + Residual release

Competent Authorities:

Legal background + RiCoG + RC as per BRef + Residual release + aim of REACH + opinion of CA

Step 2. Demonstrate SCC

Appendix 2:

To be ready in-house to each registrant individually and be made available to inspecting authorities

Appendix 3:

To be prepared and submitted to ECHA by each registrant individually (attached to section 13 of IUCLID 5 file)

Article 36 information:

To be provided to ECHA in response to specific request

Step 2bis. Demonstrate due diligence

If not SCC, demonstrate that you are implementing the Dec 2010 ECHA Guidance on intermediates:

- with a larger multi-metallic forum → for consistency across sector
- under the umbrella of Eurométaux → credible REACH partner
- without undue delay → involving all stakeholders, including ECHA, to develop best approach to risk assess UVCB materials under REACH (requires time)

	What?	When?
1a	Comparison of the 2008 and 2010 ECHA Guidance on intermediates	Oct 2010 – Feb 2011
1b	Assess potential impact of the 2010 guidance on NFM sector	Jan – Mar 2011
1c	Scope the Eurometaux priorities on SCC	Mar 2011
2	Develop tools to support Industry's decision	Apr 2011 – Dec 2012
3	Engage in advocacy activities on SCC metal specificities	May 2011 – March 2012
4	Address challenges related to Risk Assessment of UVCBs	Jun 2011 – on-going

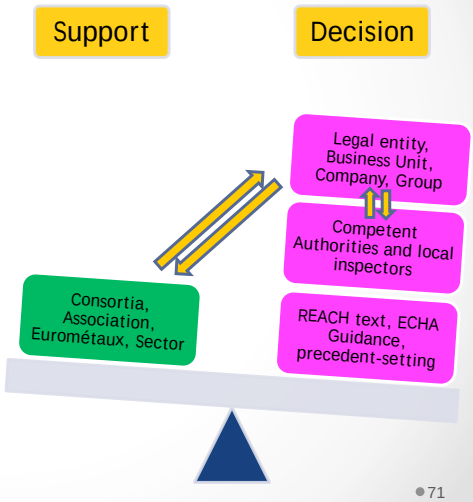
Step 3: Decide and document decision

As from mid-2012:

Based on the information, precedents, and tools available…

Need to potentially re-evaluate registration strategy and decide:

- Update Dossier to include Appendix 3
  And/or
- Contribute to development of risk assessment approach for UVCB



Reminder…

- The registrant of an intermediate can choose between two registration routes:
  - Article 17/18 route if SCC (including RC) are in place, or
  - Article 10 route, if control of risk is achieved by other means than strictly controlled conditions
- If two or more registrants choose different registration routes for the same intermediate, joint registration still applies:
  - Full Dossier submitted by the LR
  - Individual registrants fulfilling SCC include Appendix 3 to their individual files
- Companies can/must decide for their individual registration, not for the joint registration (consortia's responsibility)

Article 10 (Full) vs Article 17/18 (Light) registration

	Update (Article 17/18)	Upgrade (Article 10)

Dossier preparation	• Follow ECHA Guidance on intermediates; prepare Appendix 3 and attach to individual IUCLID 5 file
	• "Light+Appendix 3" LR and individual dossiers
	• + any other item requiring update (e.g. CLP)
		• Multi-metallic approach developed under Eurométaux with ECHA; develop and follow-up test-cases
		• "Full" LR Dossier and "Light" individual dossiers:
		  • REACH data points
		  • CSA/CSR + ES
		• + any other item requiring update (e.g. CLP)

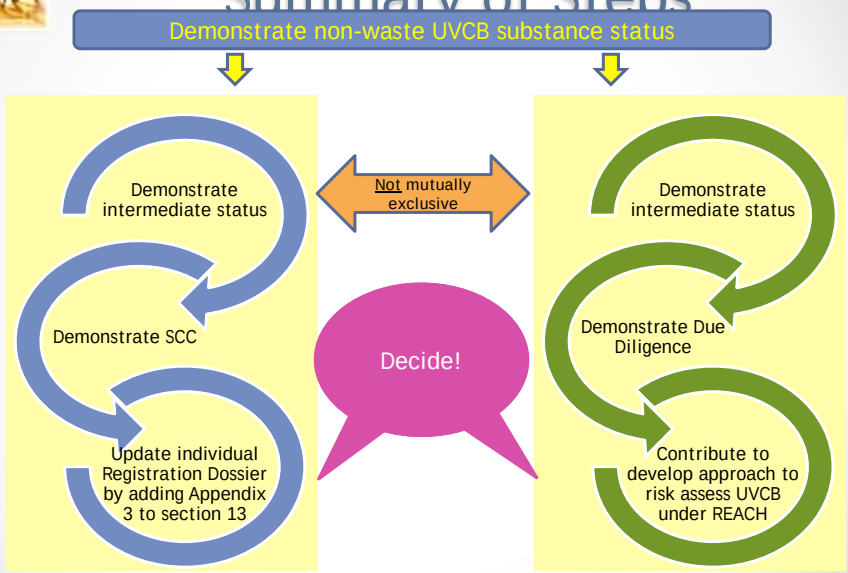
ECHA fees	None (if voluntary update)	Equivalent to Substance registration costs*, depending on registered tonnage band

Administrative work (e.g. inspections**)	• Demonstrate intermediate status
	• Demonstrate SCC***
	  • With Appendix 1 and 2 information in-house
	  • Throughout entire life-cycle (up and downstream)
		• Demonstrate intermediate status

Risk of being challenged	Higher	Lower

* Dossier remains an Intermediate Dossier in IUCLID 5 / REACH-IT
** Depends on relationship with local inspectors
*** For every new stream/process/source/customer/supplier

Summary of Steps



7. AOB, Next Meetings/Calls & Closing Remarks

Edwin BROECKAERT

Summary of work programme

C. Braibant

Summarised work programme

SCC determination & Decision	REACH text + Guidance + RiCoG + exposure/emission assessment + expert judgement + view of authorities + risk assessment
Updates preparation	- Appendix 2 (in-house) - Appendix 3 (section 13 of IUCLID 5)
Risk assessment of UVCB	- UVCB identification - Effects assessment - Exposure assessment - Risk characterisation - CSA/CSR + ES
Classification	- MECLAS - ATPs to CLP

Authorisation

H. Waeterschoot

Authorisation
draft 4th priority list

Taken forward for Public Consultation on 20th of June.

Substance name	EC
Strontium chromate	232-142-6
Potassium hydroxyoctaoxodizincatedichromate (1-)	234-329-8
Pentazinc chromate octahydroxide	256-418-0
Dichromium tris(chromate)	246-356-2
Bis(2-methoxyethyl) ether (Diglyme)	203-924-4
N,N-Dimethylacetamide (DMAC)	204-826-4
1-Methyl-2-pyrrolidone (NMP)	212-828-1
1,2-Dichloroethane (EDC)	203-458-1
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1
Arsenic Acid	231-901-9

No real concern with what is on the list BUT ….

Authorisation :
chemicals used in PM refining/extraction

→ Ceramic Refractory Fibers : POSTPONED
- ✓ Uncertainty in respect to scope of fibers covered
- ✓ Resolved and will be reprioritised in 2013

→ Hydrazine: NOT Prioritised
- ✓ Comments precious metals fully recognised
- ✓ Moderate priority due to low volume & controlled uses

→ Borates : POSTPONED
- ✓ Untill grouped with Diboron trioxide
- ✓ Will be up for reprioritisation in 2013

Thank you!