

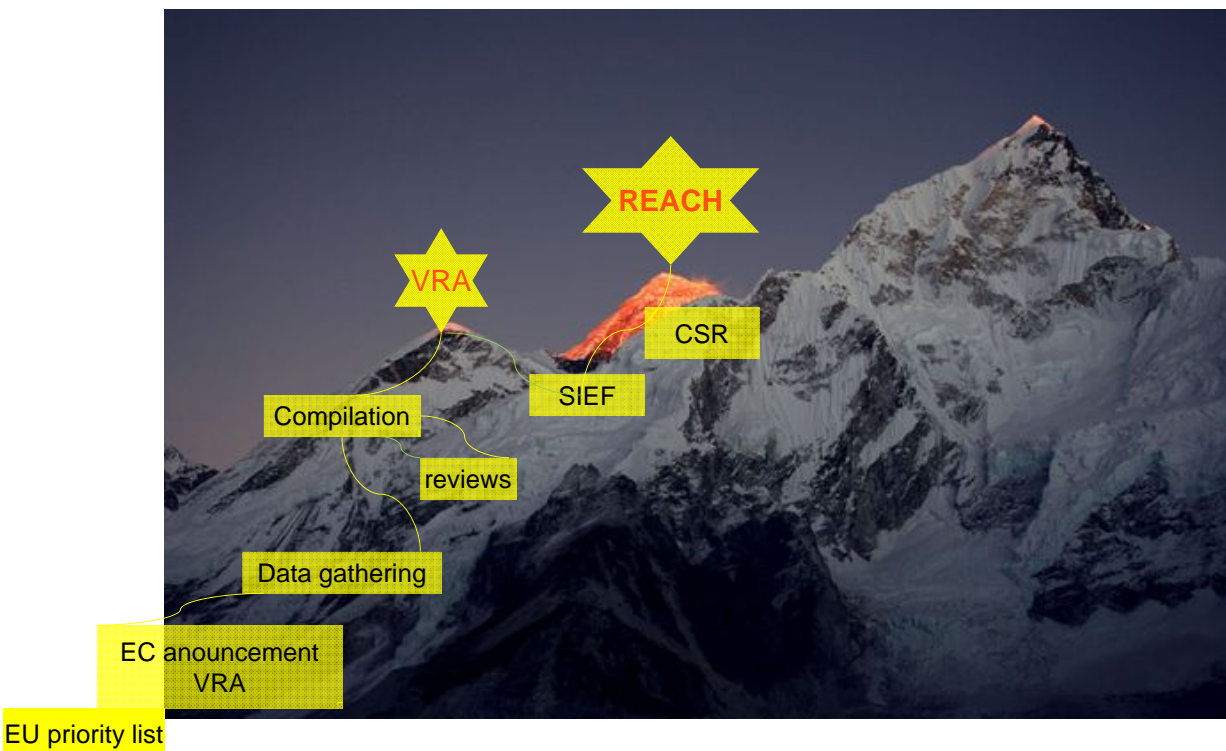


REACH is here to stay

Katrien Delbeke, Katia Lacasse



Substance evaluation mountain trek



History 2000-2008 the copper Voluntary risk assessment

Cu

Proactive project : PRE-REACH

=anticipating to market access issues on copper tubes and copper roofs

Result from 8 years work

- comprehensive data-gap analysis, research and data-compilation
- co-operation industry,, consultants and MS review country (Italy)
- 3 years review by TCNES, Biocidal Technical Meeting, SCHER
= Scientific responses to >300 Member State comments

Finalized in 2008 = <http://echa.europa.eu/web/guest/information-on-chemicals/transitional-measures/voluntary-risk-assessment-reports>

- **Excellent acceptance BUT a few data-gaps identified**

*TCNES = EC Technical Committee for New and Existing Substances

**SCHER = Scientific Committee for Health and Environmental Risk

2009...towards REACH

Cu



Copper Consortium: core members involved in copper RA

- Copper
- Final slag
- Intermediates

Copper compounds consortium : core members involved in biocidal notifications

- Copper containing compounds

REACH Strategy for copper

- **Use 2008 copper RA report**
- **Additional research from comments on copper RA**
 - Marine mesocosm for refining the marine PNEC
 - Soil monitoring (GEMAS) for refined assessment on the applicability of the terrestrial Bioavailability models across Europe
 - Inhalation toxicity = data-gap
- **Refined classification based on new guidelines and new data from consortium members**
- **Reach-specific exposure scenario's**

Main outcome for copper REACH dossier

Cu

Classification : 3 grades

- Copper massive : not classified
- Copper powder : Env acute 1, chronic 3 (2nd ATP)
- Coated copper flakes : Env acute 1, chronic 2 (2nd ATP)
HH : Acute oral and Acute inhalation : Harmful

New :

= Powders vs flakes

= ENV Classifications with “removal from the water-column”

= assessment of STOT

Risk characterisation – new hazard ID since RA

- Revised marine and terrestrial PNEC
- Human Health read-across from in vitro bio-elution tests
- Human Health - Inhalation toxicity study

Main approach/outcome UVCB dossiers

Cu

• Extensive effort on Substance ID

- Source material, Process, Elemental and mineral composition

• Hazard evaluation and classification = read across and WOE approach

- Elemental and mineral composition and particle sizes
- Known hazards of the ions, the compounds, the metals (MECLAS)
- Releases during transformation dissolution for environmental classification
- Releases during bio-elution tests (gastric and dermal) for human health classification –oral and dermal exposures

• Additional data and research on read-across assumptions – for slag dossier

- Available toxicity and ecotoxicity data on slags (across consortium)
- Slag freshwater PNEC validated with additional ecotoxicity testing

End 2010 in a winning mood...

Cu



2011-2012...realities of acceptance and implementation

Cu



2011- 2012 Secretariat Activities

Cu

-
- Safety data-sheets
 - Classification : 2nd Adaptation to Technical Progress (ATP)
 - Follow-up on ECHA revised procedures and guidelines
 - New IUCLID versions
 - Classification : 2nd Adaptation to Technical Progress (ATP) required check (MeClas tool)
 - Strictly controlled conditions

2012.... Secretariat Activities

Cu

Copper relevant consortium and ECHA activities

- OEL Harmonized classification at **EC**
- Copper - inhalation at **ECHA and SCOEL and MAK**
- Extend particle size of copper powders = dossier updates
- New exposure scenario on slags = dossier updates

Acceptance : EM-umbrella, ECHA, EU MS, ... Outside EU

- Env : Removal from Water-column ... ECHA and MS
- In vitro- bio-elution tests....Consortia, ECHA
- Freshwater and Marine PNEC... UK (EQS-WFD)

- Hazard dataOECD
- Mixture toxicity profiles.... EU, OECD....

2012.... Bio-elution

Cu

... Importance of acceptance...Cu

Powders and massive different classification than flakes and compounds

- Acute toxicity for copper flakes
 - 2 flakes (2 coatings) = no difference =harmful after oral exposure
 - Copper powders and copper massive : no need for classification 'RA (=conclusion with RA recommendation : in-vitro-solubility)



Relative bio-accessibility in gastric fluids (ASTM 5517-07)

Material tested	Bio-accessibility (% of Cu content)
Cu massive	≤0.1
Cu powder	+/- 1
Cu flake - biocidal product	42-71
Cu flake - non-biocidal product	44-60
CuO	68-84
CuSO4	100

13

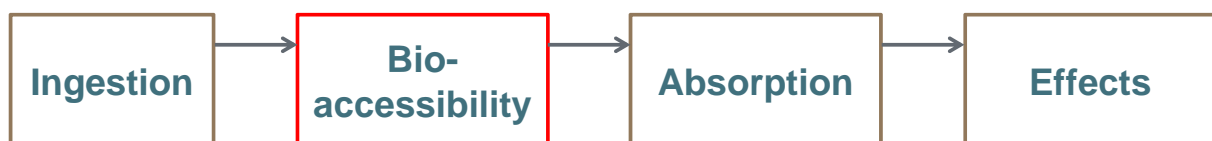
2012.... Bio-elution

Cu

... Importance of acceptance...slags

Copper Slag

- Minor amounts of Pb, As, Ni may for some slags lead to Human Health classifications if complete bio-availability is assumed
- BUT the Pb, As, Ni are integrated in glass phases = limited bioaccessibility?



= demonstrated low relative bio-accessibility in gastric fluids (ASTM 5517-07) for Pb, As, Ni and in dermal fluids (Ni)

with bio-elution = no classification warranted

14

2012.... Bio-elution ... Concerns raised ... Research launched

Cu

Other commodities, researchers

- ✓ Need for intercalibration exercise?
= Done under Eurometaux
- ✓ Bio-accessibility = exposure-specific?
= Yes : agreed
- ✓ Are gastric bio-elution data sufficiently conservative?
= additional testing by “Barge group” : including saliva, gastric, intestinal
- Can bio-elution be used for all metals? All chronic endpoints? CMRs?
= under discussion at EM level

15 | Introduction

2012.... Removal from water-column ... Importance of acceptance... Cu

Cu

Environmental classification - 2nd ATP		
	Rapid removal of Cu-ions from the water-	
	YES	NO
Copper flakes	Acute 1 (M=10) Chronic 1	Acute 1 (M=10) Chronic 2
Copper powders	Acute 1 (M=1) Chronic 1	Acute 1 (M=1) Chronic 2
Copper massive	No classification	No classification

16 | Introduction

2012.... Derived PNECs

... Importance of acceptance... Cu



Cu PNEC includes bio-availability – what if not accepted

Region	Freshwater sites with Cu-WFD status "no good"		source
	Based on old sdt	Based on bio-available sdt	
Wales	35%	1%	UKTAG, 2012
Scotland	2%	0%	UKTAG, 2012
England	12%	5%	UKTAG, 2012
Netherlands	>80%	0%	Bonten et al, 2011

BUT : still comments formulated to UKTAG on freshwater and marine EQS derivation based on the Cu RA/REACH data-set

2012.... Cu-dossier

... Need for OECD acceptance...



.... Do not want to redo ... Acceptance.... Accross the world....

2012... anticipating issues

“Mixture toxicity- cocktail effects”

Cu

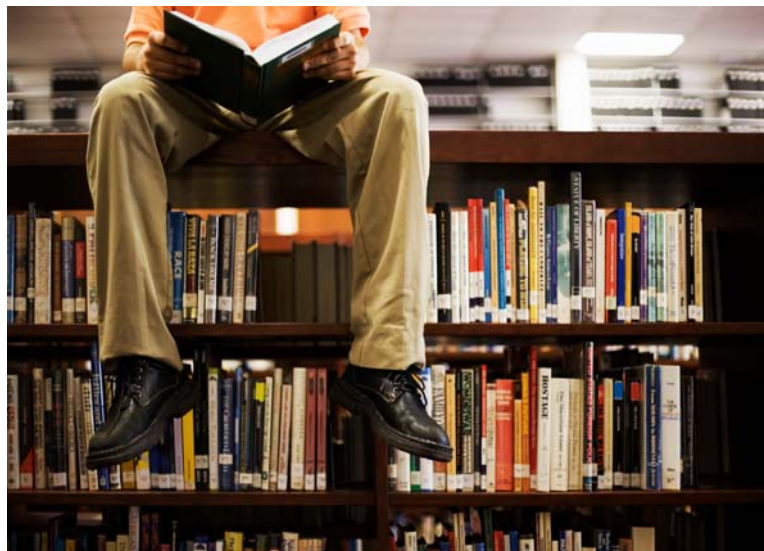
- SCHER opinion (February 2012) on how to assess mixture toxicity
- Chemical watch (31-May-2012) EU Commission promises action on cocktail effects : Commission pledges to set up a working group to promote integrated assessment of priority mixtures

- Alloy classification (for 2015)

= Multi metal- co-operation under ETAP and initiatives lead by Zn, Ni, Cu...

To avoid ...the slippery road ... down-hill.....

Cu



.....watch... be alert...anticipate