



Status Report

Renewal of Authorization for Copper Compounds

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European Union Copper Task Force (EUCuTF)

European Conference on « Copper in Plant
Protection » 17./18. November 2016



European Union Copper Task Force

- 13 member companies

Albaugh Europe SARL

Cinkarna - Metallurgical & Chemical Industry Celje, INC.

Erachem Comilog SPRL

Industrias Quimicas Del Valles, S.A.

Isagro S.p.A.

Kocide LLC

Manica SpA

Montanwerke Brixlegg AG

Nordox AS

Nufarm GmbH & Co KG

Sales y Derivados de Cobre S.A.

Spiess-Urania Chemicals GmbH

UPL Europe Ltd.

- Objective: Renewal of authorization of Copper compounds according to regulation (EU) 1107/2009

- Copper hydroxide

Bordeaux mixture

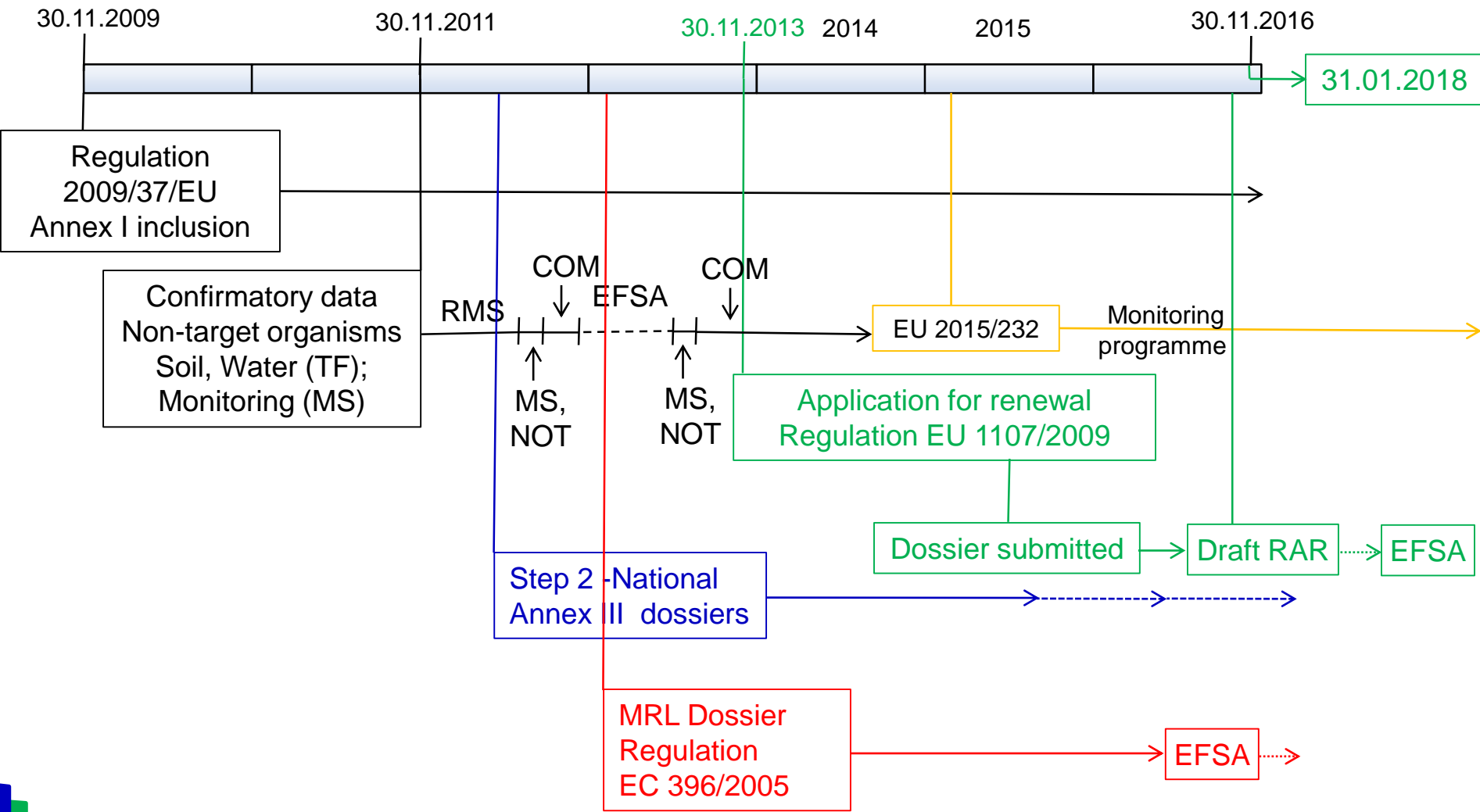
- Copper oxychloride

Tribasic copper sulphate

- Copper(I)oxide



Status of Authorization in the EU





Dossier and Draft RAR

- «Supplementary» dossier for renewal of authorization submitted July 2015
 - Ca. 5,300 pages and more than 40,000 report pages
 - GAP of 6 kg/ha, with flexible dose over 5 years
 - Complementary data request from ANSES in Jan 2016
 - EUCuTF reply in March and April 2016
- Draft RAR received on 24. Oct 2016
 - Includes review by France (RMS) and Germany (Co-RMS)
 - Ca. 2,300 pages a.s. and 2,300 pages p.p.p.
- EUCuTF comments (reporting table) on 8. Nov 2016
- Will now start EFSA peer review (4-6 months)



Draft RAR Summary

- Proposed decision: Copper compounds can be approved under regulation EC 1107/2009
 - However, risk not acceptable for uses >4 kg/ha
- And still the known areas of concern:
 - Earthworm, soil organisms
 - The risk to aquatic organisms
 - The worker and resident risk



RAR Details

- Assessments often read like
 - The study is acceptable, however...
 - RMS disagrees with...
 - The RMS is still of the opinion that...
- or
 - The RMS acknowledged that Notifier included an extensive data package....with the latest scientific knowledge on copper bioavailability...
 - However, RMS doesn't agree with...



Copper – A Different Pesticide

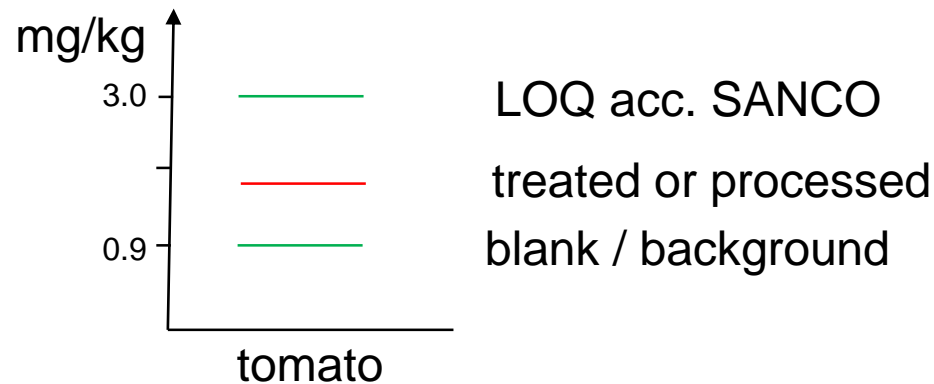
- Essential micronutrient
- Ubiquitous
- Metal
- High degree of homeostatic control

- Evaluation according to rules often not possible and not appropriate
 - Models not applicable to metals
 - Any assessment factor overly conservative
 - Is the precautionary principle appropriate for an essential micronutrient?
 - Many «issues» are not real but due to evaluation principles



Analytical Methods

- Assessed according to SANCO/3029/99 rev.4 or SANCO/825/00 rev. 8.1
 - Selectivity requires blank values not to exceed 30% of LOQ
- EUCuTF validated several methods for tomato:



- Tomatoes do not grow without copper, hence either selectivity or LOQ is not found appropriate!



Risk to Worker and Resident

- AOEL – new proposal rejected, only marginal increase
- Worker exposure
 - Dermal absorption as one main parameter



Study	EUCuTF	RMS / Agencies	Comments
In vitro 2003/4	0.12% / <5%*	Default values	
In vitro 2012	0.11% / 3.97%*	0.3% / 40%*	Extrapolation
In vitro 2015	0.1% / 1%*	1% / 9%*	Stable isotope, full spray dilution

* for concentrated product / spray dilution

➤ **Copper is safe for humans (consumer, operator, residents & bystander)**



Exposure



Drift



'Non-equilibrium' in ditch:
non-pesticide PNEC
5.5 – 7.4 $\mu\text{g/L}$



'Equilibrium' in ditch
non-pesticide PNEC 22.1 $\mu\text{g/L}$



River: non-pesticide
PNEC 7.8 – 17.6 $\mu\text{g/L}$



Lake: non-pesticide
PNEC 10.6 – 11.5 $\mu\text{g/L}$

- Standard PEC models not applicable for Cu
 - Speciation, bio-availability, solubility, distribution



Risk to Aquatic Organisms

- Exposure
 - PECsw submitted up to ca. 4 $\mu\text{g/L}$ (5 m)
 - RMS: up to $>25 \mu\text{g/L}$
 - Toxicity endpoint (RAC)
 - Derived from mesocosm: 4.8 $\mu\text{g/L}$ diss. Cu
 - RMS:
 - Different endpoints plus Assessment factors RAC $<1 \mu\text{g/L}$
 - Background mean 0.6 $\mu\text{g/L}$ and 90th percentile 2.4 $\mu\text{g/L}$
- Addition of several worst-case assumptions plus application of assessment factors are not an adequate way to assess Cu





Risk to Non Target Terrestrial Organisms

- Using all available data from
 - Literature and lab studies (normalized)
 - GLP field study and biomonitoring
- A consistent RAC of > 150 mg/kg Cu in soil was derived for earthworm
 - Toxicity / bio-availability as function of soil type
- Concluded no issue for arable crops and orchards
- Concluded safe uses for vine exist
 - with restrictions for sites with high Cu content and unfavorable soil type
- Combination of dose rate and soil content matters





Risk to Non Target Terrestrial Organisms

- RMS derived a 4 kg/ha restriction from the GLP field study
 - Worst-case statistical evaluation
 - Expert panel opinion outdated
- Does not do justice to the complexity of the system with annual applications, decrease in bio-availability and accumulated soil Cu
 - EUCuTF will re-convene an expert panel and further generate and evaluate data





Copper – Candidate for Substitution

- Cu listed as CfS under 1107/2009 based on PBT criteria
 - **P**ersistence ✓
 - **B**ioaccumulation
 - **T**oxicity ✓
- PBT not appropriate for inorganic compounds
 - REACH & BPR Regs do not apply PBT for inorganics
- In June 2015 EUCuTF appealed against Regulation (EC) 2015/408
 - **Case likely to be dismissed by the Court of Justice: no impact, not directly concerned**
 - **Subject of appeal not assessed; EUCuTF will pursue case**



Copper as a Plant Protection Product

- As sole applicant the EUCuTF continues to support Copper compounds as active substance
 - Defending 6 kg/ha flexible dose and organic farming needs
 - 2016 season demonstrated appropriateness of approach
 - Underrated benefits, e.g. bacterial diseases will amplify its need
- Rare opportunity for agriculture to maintain an essential element as a fungicide
- Avoid simplistic EU wide restriction to 4 kg/ha
 - Does not take into account local situation in a MS and unnecessarily increases need for exemption authorizations
 - Promotes misuse of Cu fertilizer
- Find a way to agree on Cu specific assessments



Vielen Dank !