Status Report

Renewal of Approval for Copper Compounds

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European Union Copper Task Force (EUCuTF)

2nd European Conference on « Copper in Plant Protection » 16./17. November 2017

European Union Copper Task Force

- 13 member companies

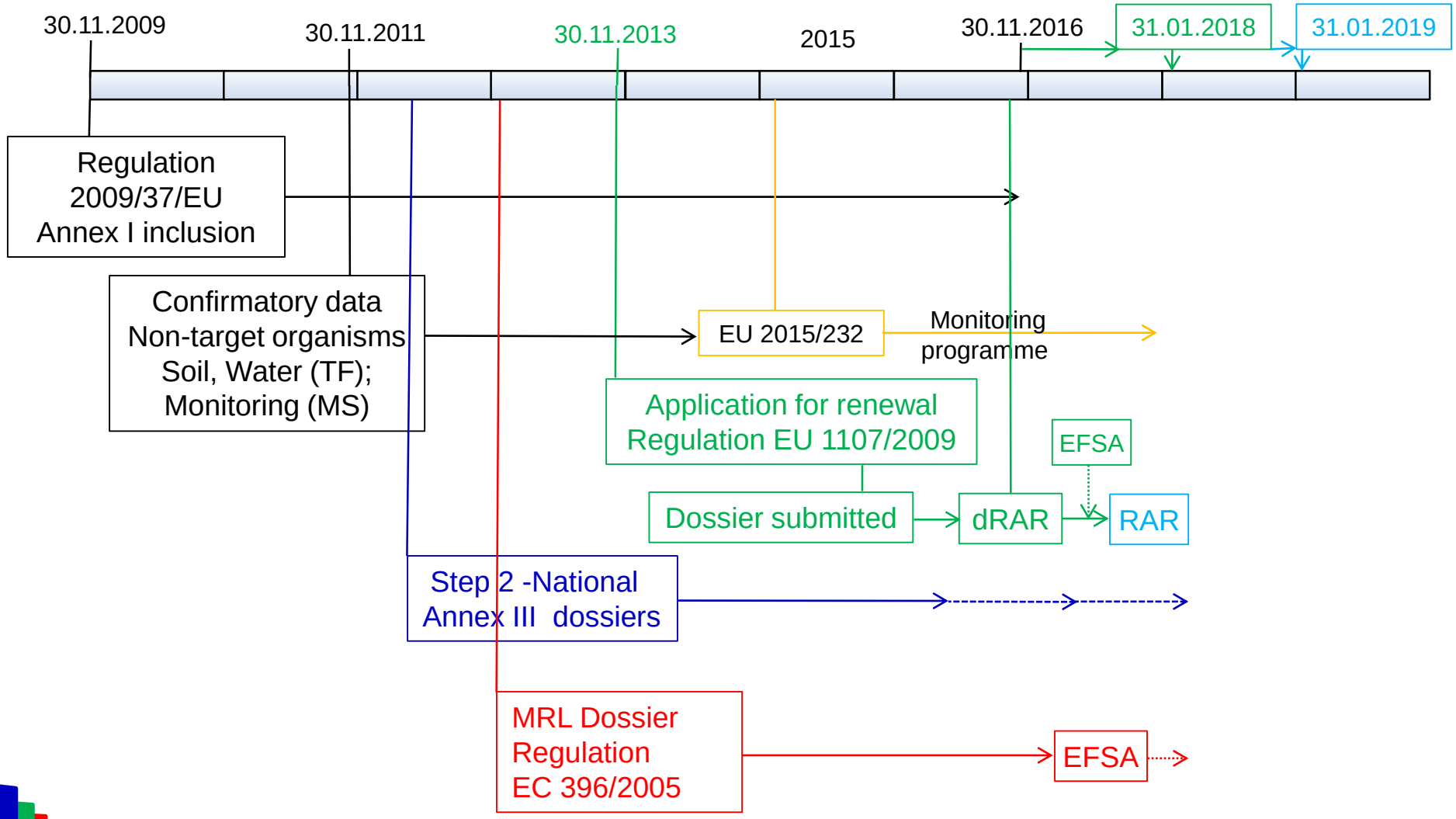
  Albaugh Europe SARL
  Cinkarna - Metallurgical & Chemical Industry Celje, INC.
  Erachem Comilog SPRL
  Industrias Quimicas Del Valles, S.A.
  Isagro S.p.A.
  Kocide LLC
  Manica SpA
  Montanwerke Brixlegg AG
  Nordox AS
  Nufarm GmbH & Co KG
  Sales y Derivados de Cobre S.A.
  Spiess-Urania Chemicals GmbH
  UPL Europe Ltd.

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

  - Copper hydroxide
  - Copper oxychloride
  - Copper(I)oxide

  Bordeaux mixture
  Tribasic copper sulphate

Status of Approval in the EU



Dossier and Final RAR

- «Supplementary» dossier for renewal of authorization submitted July 2015
  - 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)
  - EUCuTF comments (reporting table) on 8. Nov 2016
- RAR sent to EFSA on 16. Dec 2016
  - Published by EFSA 3. Feb 2017
  - Commenting period until 5. Apr 2017
  - Consolidated commenting table received 20. Apr 2017
- EUCuTF comment to reporting table on 4. May 2017

Dossier and Final RAR (2)

- RMS assessed RT, sent to EFSA on 19. May 2017
  - RMS / EFSA teleconference on 1. Jun 2017
- EFSA request for additional information received on 8. Jun 2017
  - 89 items requested, to be provided within 1 month
  - EUCuTF submitted updated CADDY on 10. July 2017
- A revised RAR was prepared by the RMS and submitted to EFSA on 11. Sep 2017
- Pesticides Peer Review Experts Meetings in Oct 17
- Revised RAR received 10. Nov 2017

Dossier and RAR

- Proposed decision changed from
  - Copper compounds can be approved under regulation EC 1107/2009

  to

  - Based on available information, the evaluation of Copper compounds cannot be finalised

  For GAP of 6 kg/ha, with flexible dose over 5 years

- New (or worsened) areas of concern:
  - Specification
  - Residues
  - Risk to aquatic organisms (PECsw and RACsw)

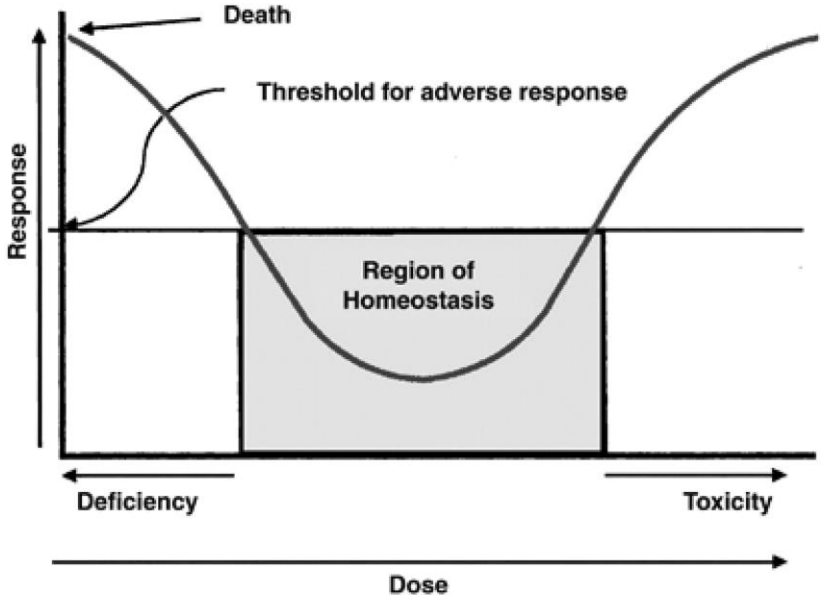
Specification

- Pre-Submission meeting identifided Ni as toxicological relevant impurity to be added
  - Previously As, Cd, Pb
  - EUCuTF provided method validation and 5 batch data for Ni
- dRAR proposed Hg, Cr, Sb, Co as new toxicological relevant impurities
  - RMS provided toxicological assessment and maximum permitted concentration (as per SANCO/10597/2003), but
  - Set specification at LOQ or mean + 3σ of arbitrary data
- EUCuTF provided 5 batch studies of all sources but spec was not adjusted in RAR

➢ All data are well below max permitted conc, and spec shall be set to maximum permitted concentration

Copper – A Different Pesticide

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



Source: K. Oorts 2017

- Evaluation according to standard pesticides rules often not possible and not appropriate
  - Models not applicable to metals
  - Any assessment factor overly conservative

Residues in vines

- EUCuTF has submitted 26 residue trials
  - Not all to cGAP

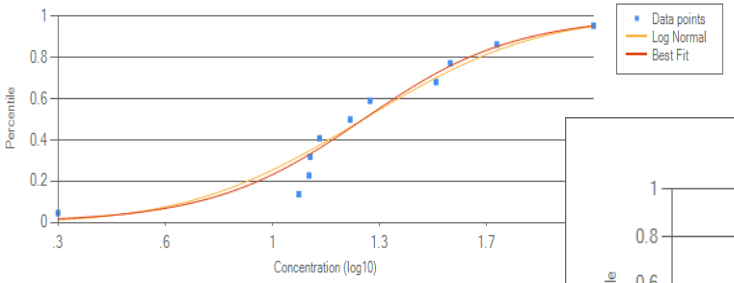
Commodity	Region	Outdoor/ Indoor	Number of trials	Individual trial results (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Grape, table	SEU	O	13	2.2, 4.1, 4.6, 5.1, 6.2, 7.0, 7.1, 7.5, 7.6, 8.7, 9.4, 11.0, 12.0	7.1	12
	Control			0.8, 1.2, 1.5, 1.5, 1.0, 2.4, 2.4, 1.7, 1.0, 1.9, 1.9, 1.2, 1.7		
Grape, wine	N & SEU	O	26	2.2, 4.1, 4×<5.0, 5.1, 5.2, 6.2, 6.8, 6.9, 7.0, 7.1, 2×7.5, 7.6, 8.7, 9.4, 9.9, 11.0, 2×12.0, 20.0, 30.0, 45.0, 56.0	7.3	56
	Control			0.8, 1.2, (1.2, 1.3, 1.5, 1.5), 1.5, 1.1, 1.0, 1.4, 1.3, 2.4, 2.4, (1.7, 3.2), 1.0, 1.9, 1.9, 3.2, 1.2, (1.4, 1.7), 1.5, 2.7, 2.7, 1.5		

- RMS applied proportionality principle, 1 trial missing
- EFSA expert meeting declined all trials!

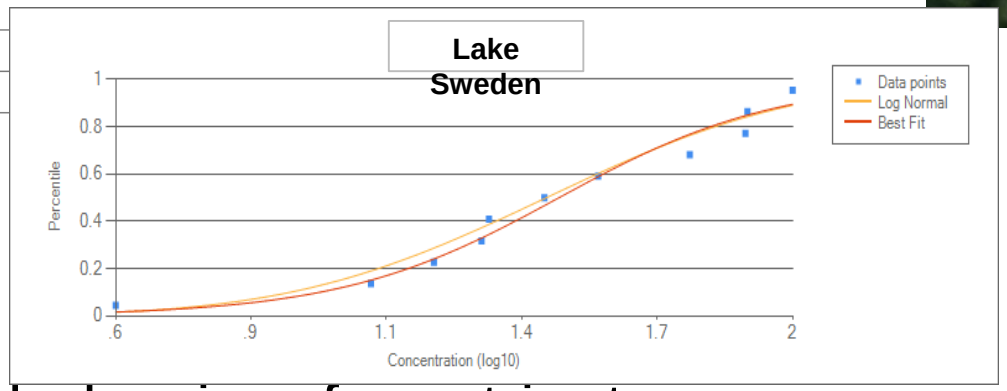
➢ Impact on PRIMo negligible; What do we want to learn from additional trials?

Risk to Aquatic Organisms

- Toxicity endpoint (RAC)
  - Derived from mesocosm: 4.8 µg/L diss. Cu
  - SSD with 73 chronic fish data
  - and BLM normalization (most sensitive eco-region): 7.9 µg/L diss. Cu



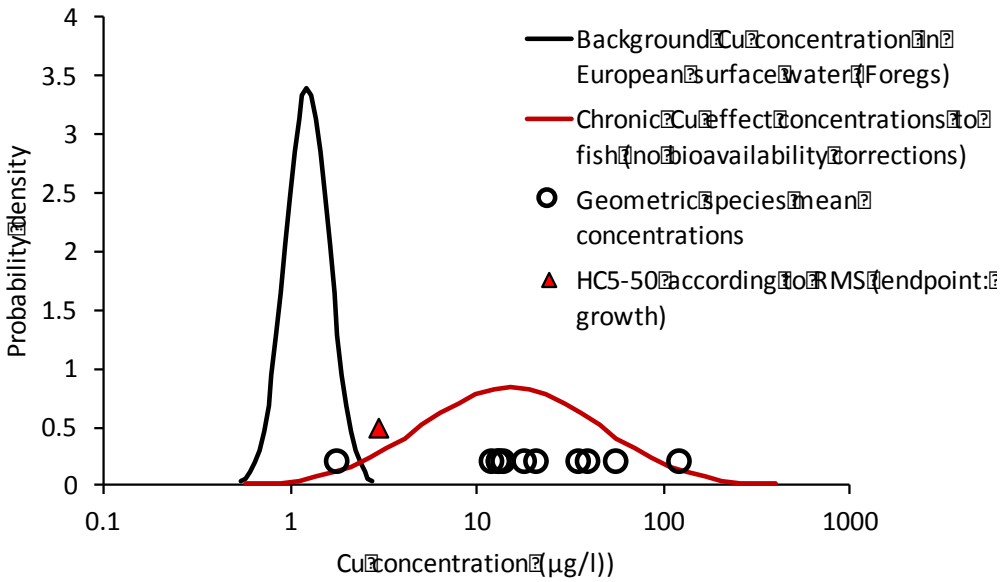
Source: P. van Sprang 2015



  - AF=1 for data rich dossier of a nutrient

Toxicity endpoint RAC (2)

- RMS:
  - Used different endpoints from data, declined data normalization: SSD-RACsw,ch 2.96 µg/L
  - applied Assessment factor 4: RAC 0.74 µg/L
- EFSA expert meeting:
  - Further refined endpoint/ SSD: RACsw,ch 1.1 µg/L
  - applied AF 3:
  - RACsw,ch 0.37 µg/L
- Background Cu:
  - mean 0.6 µg/L
  - 90th percentile 2.4 µg/L !



Source: K. Oorts 2017

➢ Addition of several worst-case assumptions plus application of AF are not an adequate way to assess Cu

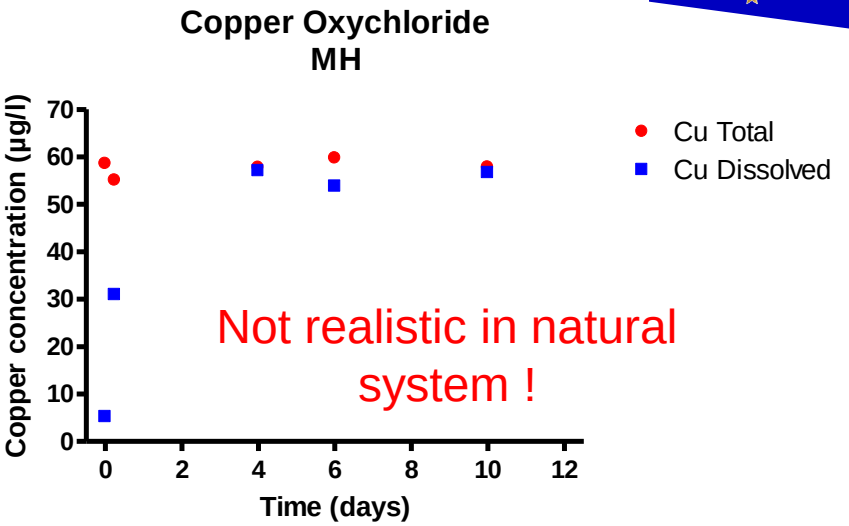
Exposure

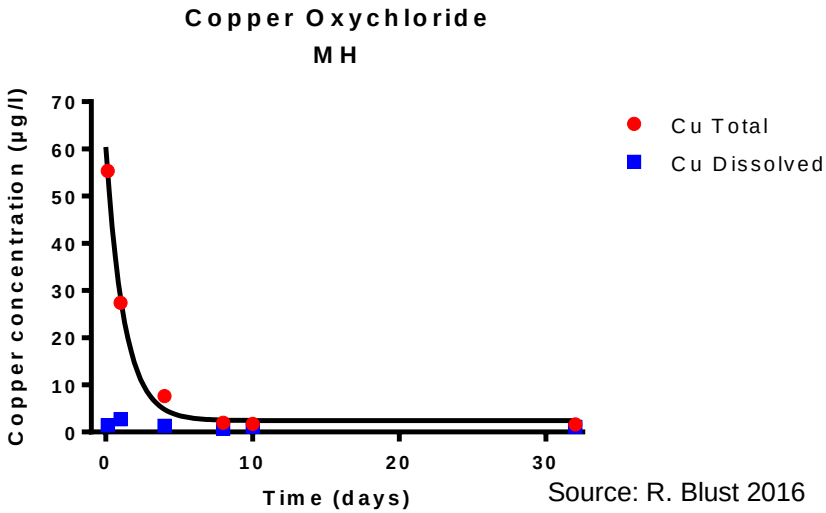
Drift

'Non-equilibrium'

River

'Equilibrium' in ditch



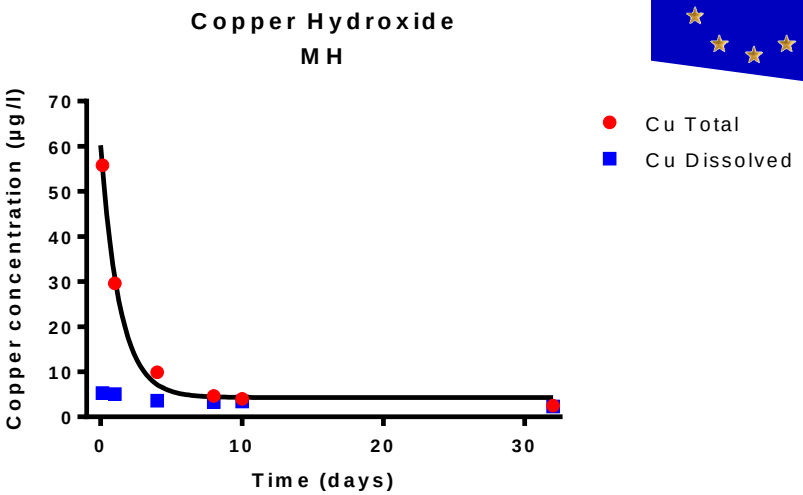


Source: R. Blust 2016

- Dissolved Cu always << Total Cu in natural system

Exposure

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



- Correction for total to dissolved Cu appropriate
  - EUCuTF suggested 3 as conservative
  - RMS used 2
  - Expert meeting: total = dissolved
- Rapid dissipation for total Cu and any free Cu
  - EUCuTF DTdiss50 < 1d
  - RMS and Expert meeting: no dissipation
- PECsw: EUCuTF 1.4 - 4.3 µg/L (5m)
- RAR: 3.6 – 4.6 µg/L (20m)

Copper – Candidate for Substitution

- Cu listed as CfS under 1107/2009 based on PBT criteria

  Persistency ✓ **T**oxicity ✓ proposed again in RAR

- PBT not appropriate for inorganic compounds
  - ➢REACh & BPR Regs do not apply PBT for inorganics
  - ➢ Low risk criteria (EU 2017/1432) exclude persistence criteria for minerals
- In June 2015 EUCuTF appealed against Regulation (EC) 2015/408

➢In Feb 17 notification for hearing

- ➢Took place June 6, Grand Chamber of the Court of Justice of the European Union

Copper – CfS (2)

- Outcome communicated in Sep 17
- Advocate General proposes the CJEU to set aside the General Court's ruling,
  - declare the Task Force's appeal admissible,
  - and refer the case back to the General Court for a judgment on the substance of the 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
  - Rare opportunity for agriculture to maintain an essential element as a fungicide
- Find a way to agree on Cu specific assessments to ensure re-approval
  - Urgent post-submission meeting with RMS and EFSA requested
- Underrated benefits, e.g. bacterial diseases will amplify its need
- Avoid simplistic EU wide restrictions

Vielen Dank !