Status Report

Renewal of Authorization for Copper Compounds

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European Union Copper Task Force (EUCuTF)

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European Union Copper Task Force

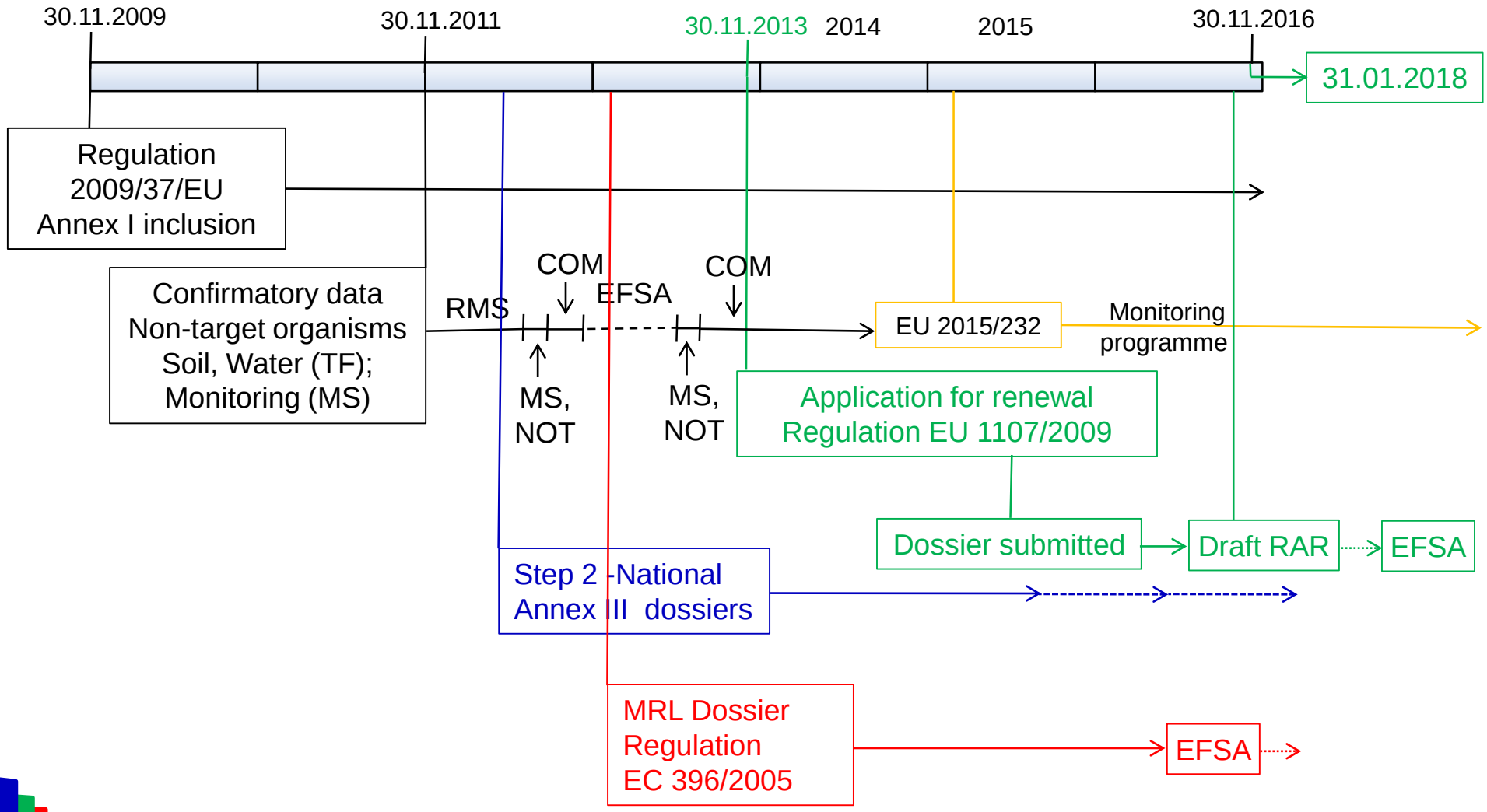
- 13 member companies

  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
  - Copper oxychloride
  - Copper(I)oxide

  Bordeaux mixture
  Tribasic copper sulphate

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…

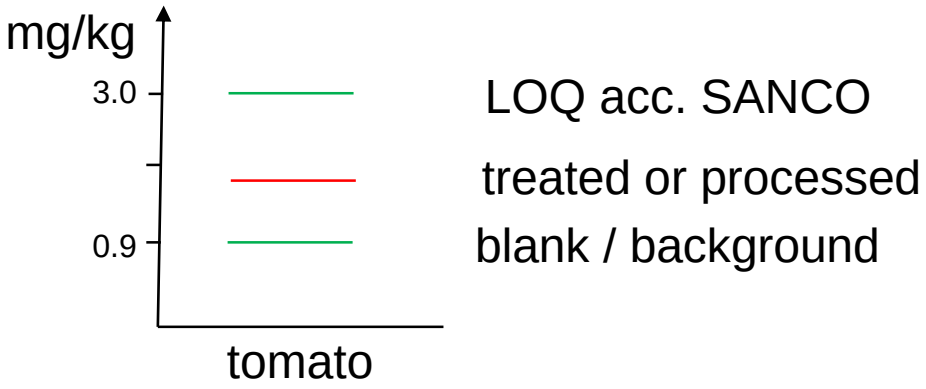
Copper – A Different Pesticide

- 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 µg/L

'Equilibrium' in ditch
non-pesticide PNEC 22.1 µg/L

River: non-pesticide
PNEC 7.8 – 17.6 µg/L

Lake: non-pesticide
PNEC 10.6 – 11.5 µg/L

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

Risk to Aquatic Organisms

- Exposure
  - PECsw submitted up to ca. 4 µg/L (5 m)
  - RMS: up to >25 µg/L

- Toxicity endpoint (RAC)
  - Derived from mesocosm: 4.8 µg/L diss. Cu
  - RMS:
    - Different endpoints plus Assessment factors RAC <1 µg/L
    - Background mean 0.6 µg/L and 90th percentile 2.4 µg/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**ersistency ✓
  - **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 to 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 !