

3rd European Conference on Copper in Plant Protection

15th-16th November in Berlin, Germany





The Re-Approval of Copper as Active Substance

State of Play from an Industry Perspective

Matthias Weidenauer

European Union Copper Task Force (EUCuTF)

3rd European Conference on « Copper in Plant
Protection » 15./16. November 2018

BATTELLE



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

Bordeaux mixture

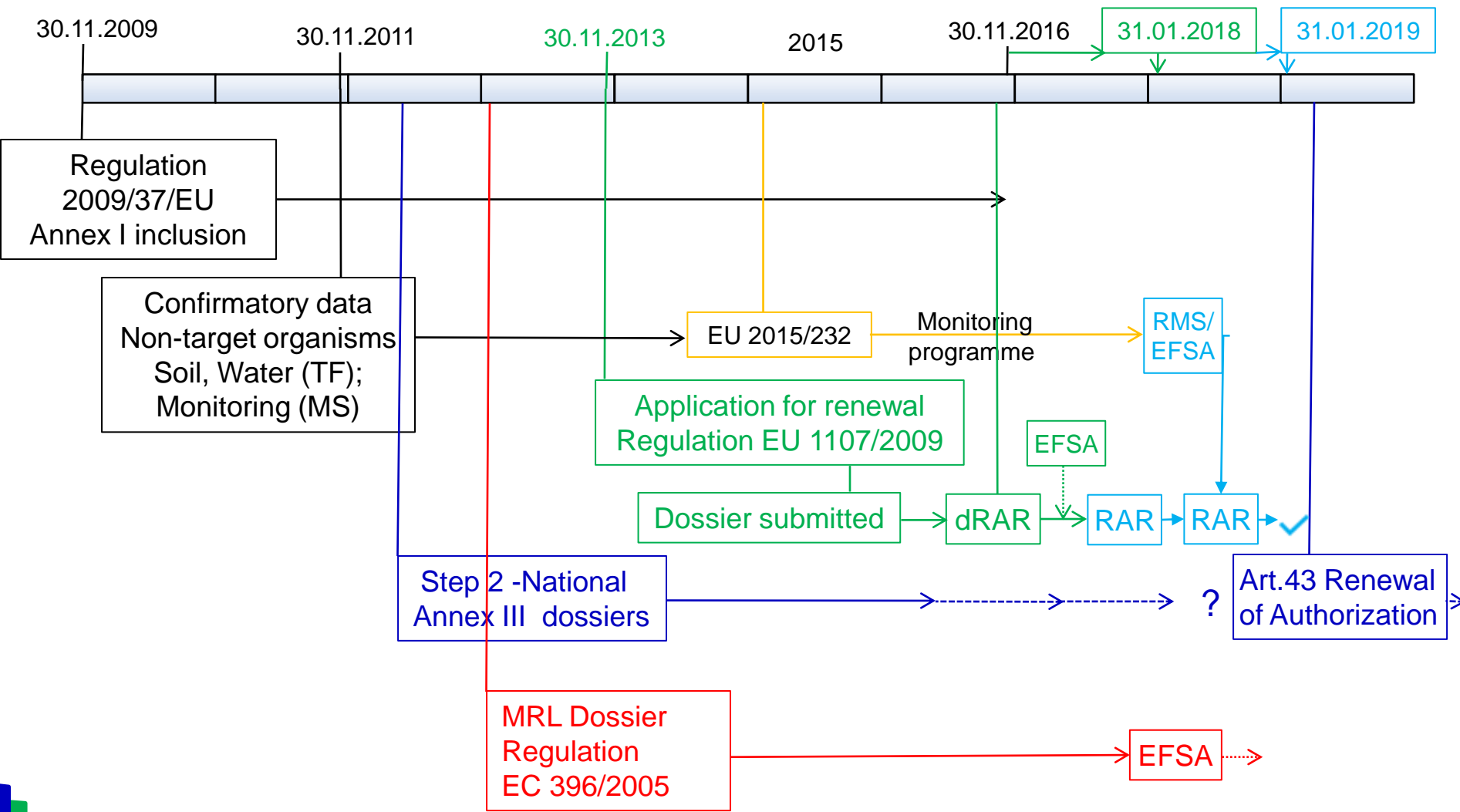
- Copper oxychloride

Tribasic copper sulphate

- Copper(I)oxide



Rapport d'état d'approbation CE





Dossier and RAR

- Proposed decision changed to
 - Based on available information, the evaluation of Copper compounds cannot be finalized
 - For GAP of 6 kg/ha, with flexible dose over 5 years
 - Areas of concern:
 - Specification
 - Risk to non-target terrestrial organisms (dose restriction)
 - Risk to aquatic organisms (PECsw and RACsw)
 - Consumer (residues) and Worker
- **A copper specific guidance will be developed !**
 - **mandate from COM to EFSA after renewal**
- But how to accomplish Art 43 MS re-authorization?



Specification

- 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 limited, arbitrary data

The following impurities shall not exceed the following levels:

Arsenic max. 0.1 mg/g Cu

Cadmium max. 0.1 mg/g Cu

Lead max. 0.3 mg/g Cu

Nickel max. 1 mg/g Cu

Cobalt max. 3 mg/kg

Mercury max. 5 mg/kg

Chromium max. 100 mg/kg

Antimony max. 7 mg/kg

100 mg/kg

222 mg/kg

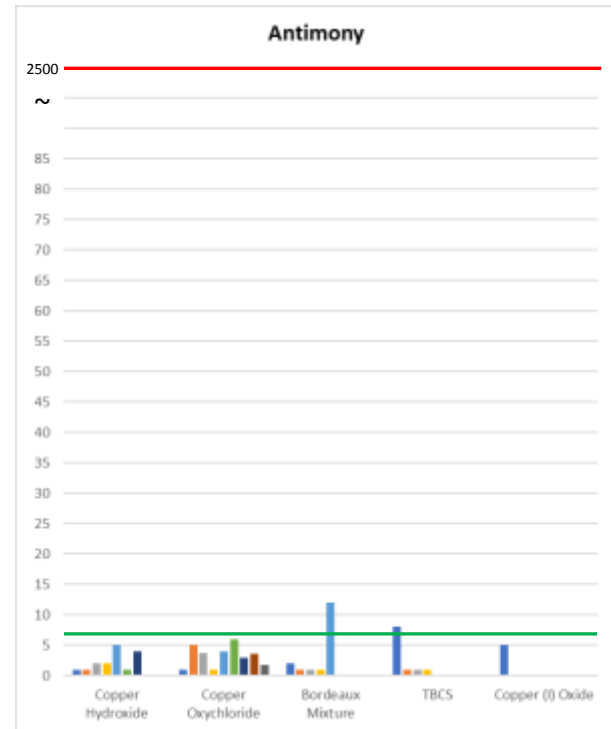
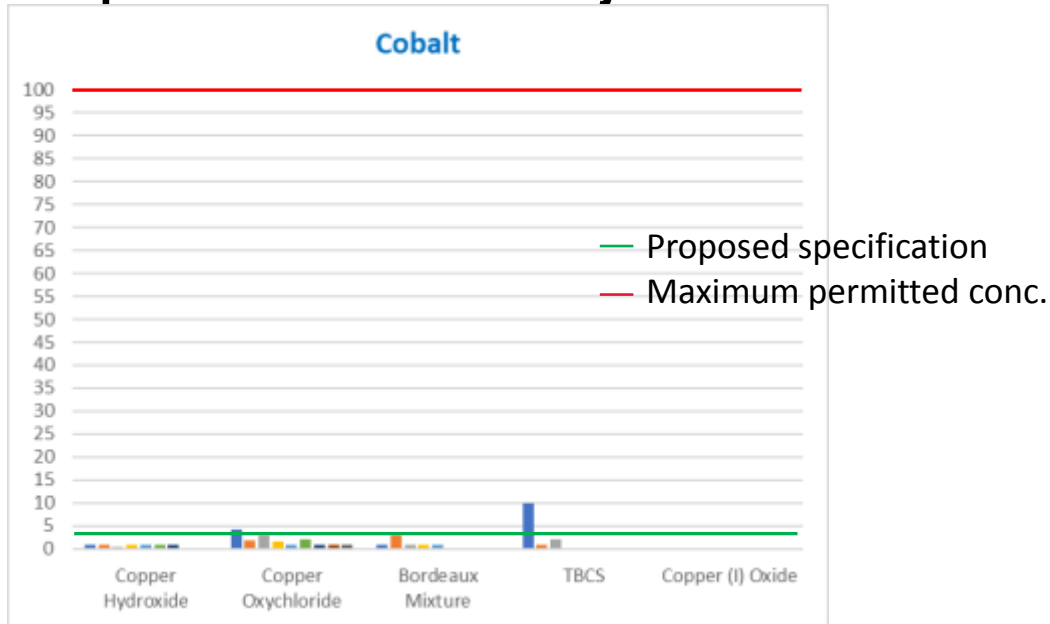
667 mg/kg

2500 mg/kg



Specification (2)

- EUCuTF provided 5 batch studies of all sources but spec was not adjusted in RAR



- All data are well below the maximum permitted conc,
- Specification shall be set to maximum permitted conc.
- Or at least to average + 3 σ of total data set



Non Target Terrestrial Organisms

- Earthworms GLP field study completed by the EUCuTF after 10 years
 - Submitted with 2015 dossier
 - Multiple statistics requested by the RMS

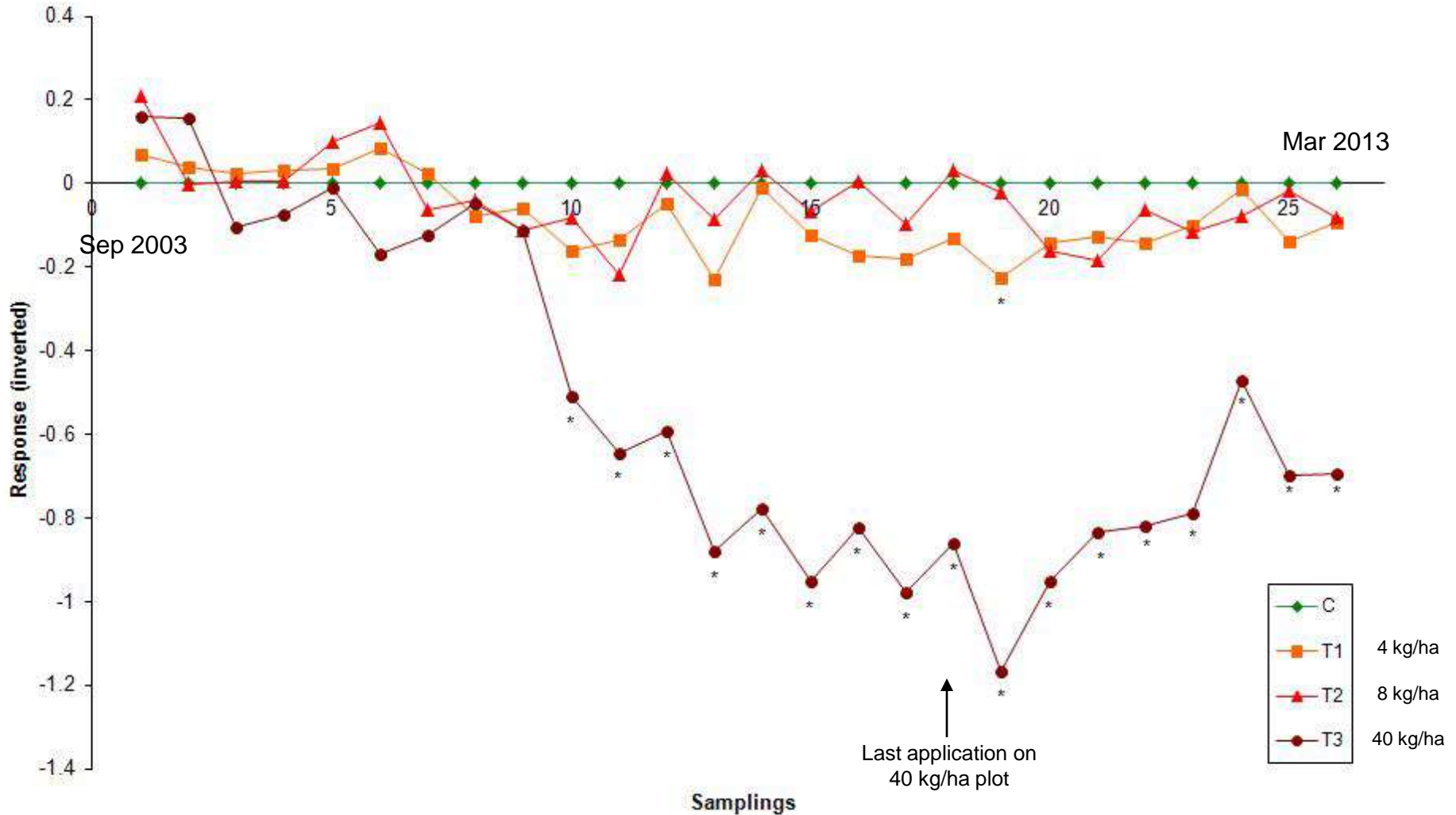


Test	Method	Significance	Result
ANOVA/ANCOVA	Covariance	Dunnett's test	NOEC 8 kg/ha
CANOCO PRC	Multivariate	Dunnett's test	NOEC 8 kg/ha
Linear mixed models	Multiple models with different Covariance	Tukey Test	NOEC 8 kg/ha
		Least Sign. Diff. test	N/A

- No statistically significant effects at 4 kg/ha/y and 8 kg/ha/y
- Confirmed by an Expert panel opinion

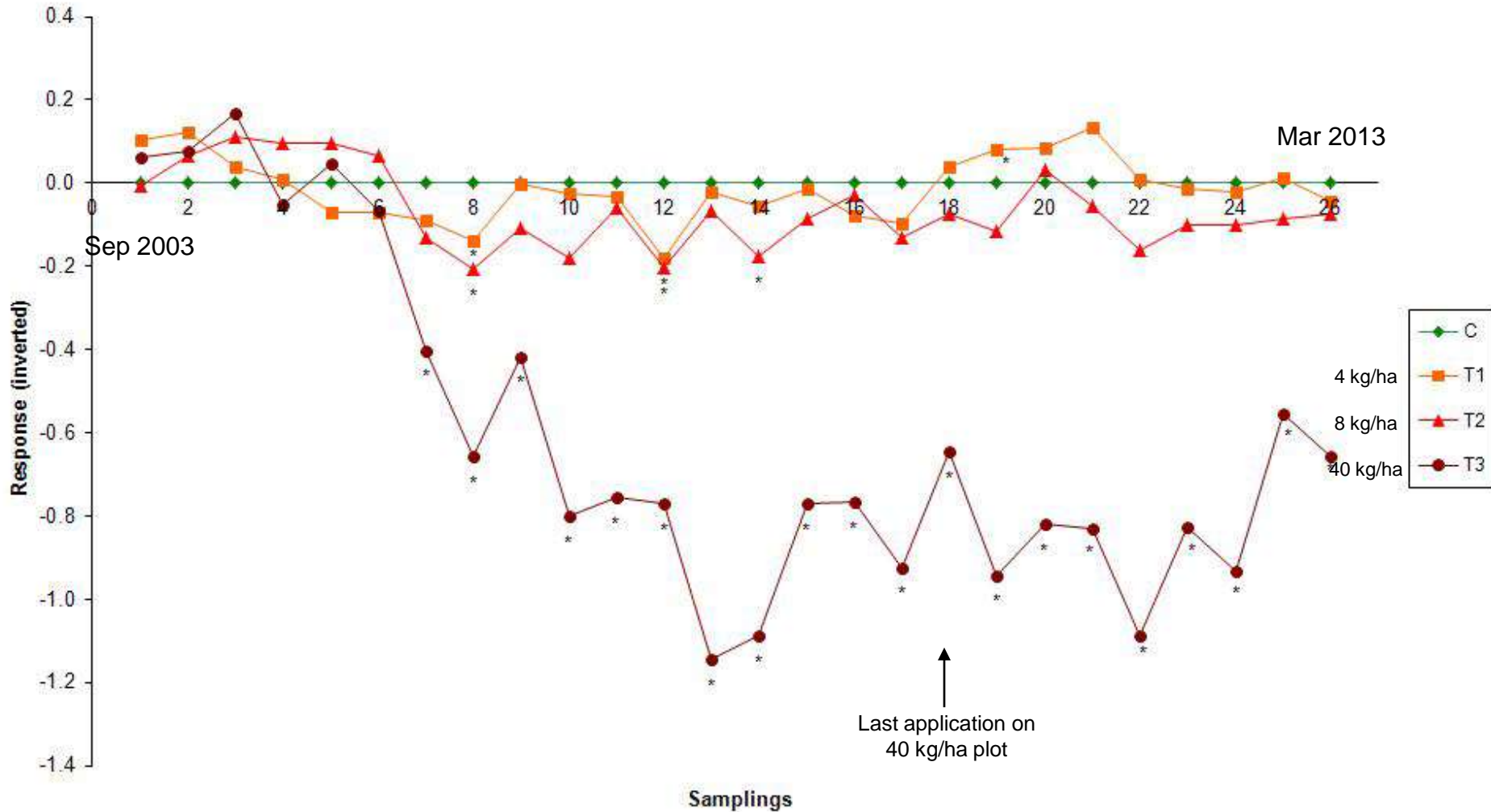


Analyse multivariate (PRC) - Heiligenzimmern





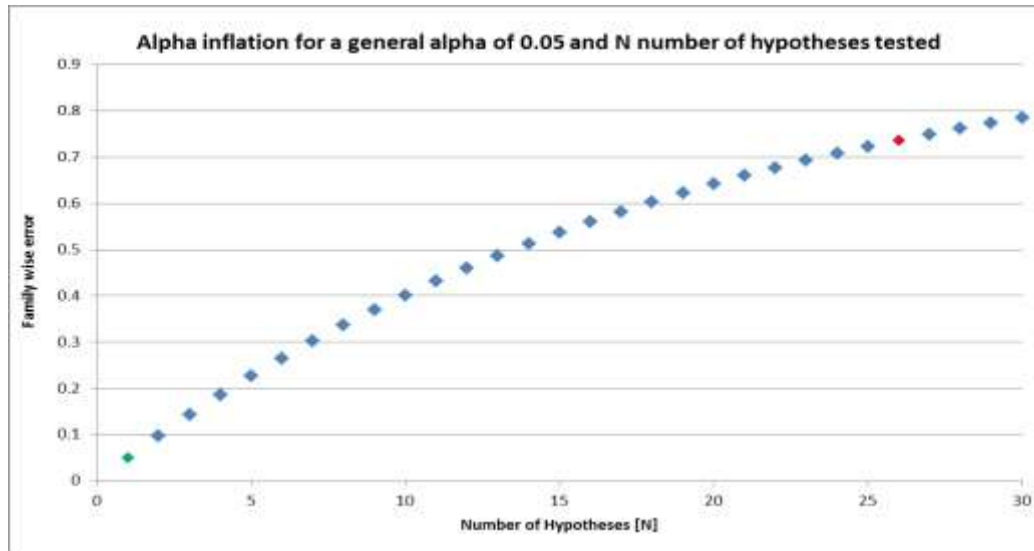
Analyse multivariate (PRC) – Niefern





Non Target Terrestrial Organisms

- A pre-selected Type I error rate (alpha), i.e. false positive, of 5% is generally used in ecotox field studies.



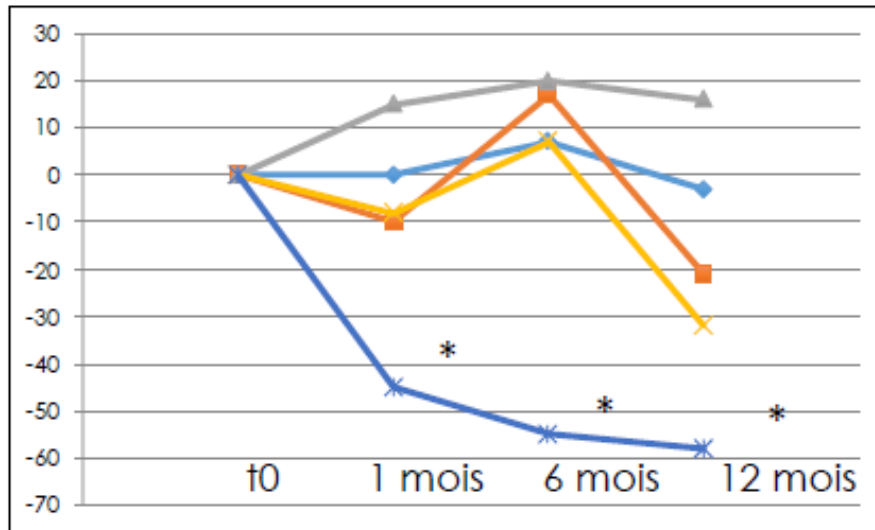
LMM and significance test without Type I error control

Test	Significance	False positives	Result	
ANOVA/ANCOVA	Dunnett's test	5%	NOEC 8 kg/ha	✓
CANOCO PRC	Dunnett's test	5%	NOEC 8 kg/ha	✓
Linear mixed models LMM	Tukey Test	5%	NOEC 8 kg/ha	✓
	LSD test	74%	N/A	✗

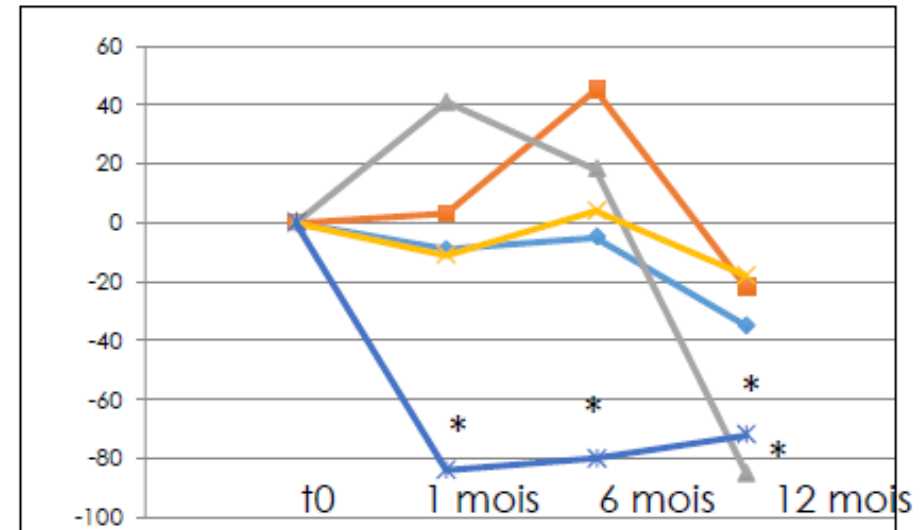


Etude ANSES (terrain)

Abondance totale (en % de l'initial)



Abondance anéciques (en % de l'initial)



Pas d'effet sur l'abondance totale
(fongicide de synthèse plus délétère)

Effet sur les vers anéciques à 10X après 12 mois ...
(à confirmer)

Témoin

Fongicide 1X

Fongicide 10X

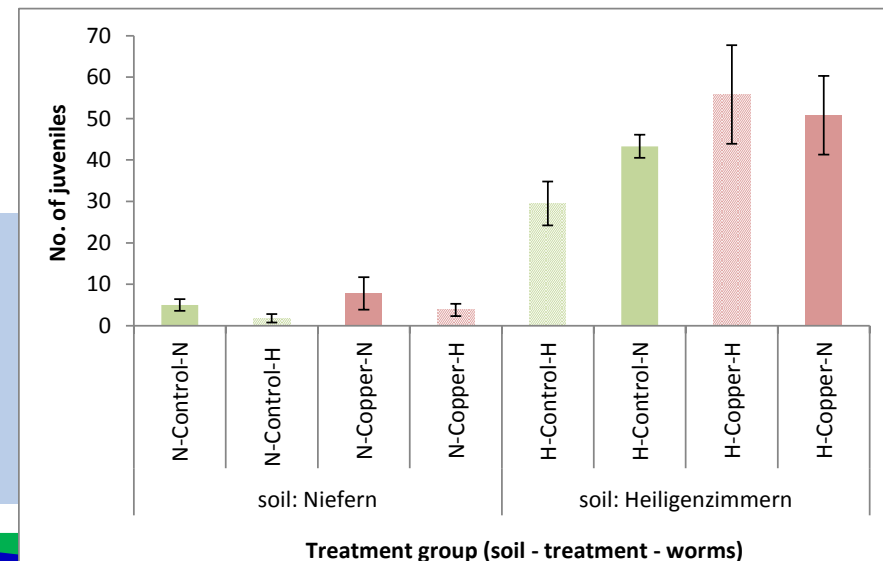
Cuivre 4 kg/ha

Cuivre 40 kg/ha



Non Target Terrestrial Organisms

- The RMS/EFSA position: RAC 4 kg/ha/y
- Does not reflect complexity of the system with annual application, decrease in bio-availability and soil Cu_{acc}
- So what will the EUCuTF members do for Art.43?
 - Submit report justifying statistical evaluation of field study
 - Submit all data (lab, field, literature, monitoring), incl. a new lab study on *A. caliginosa*

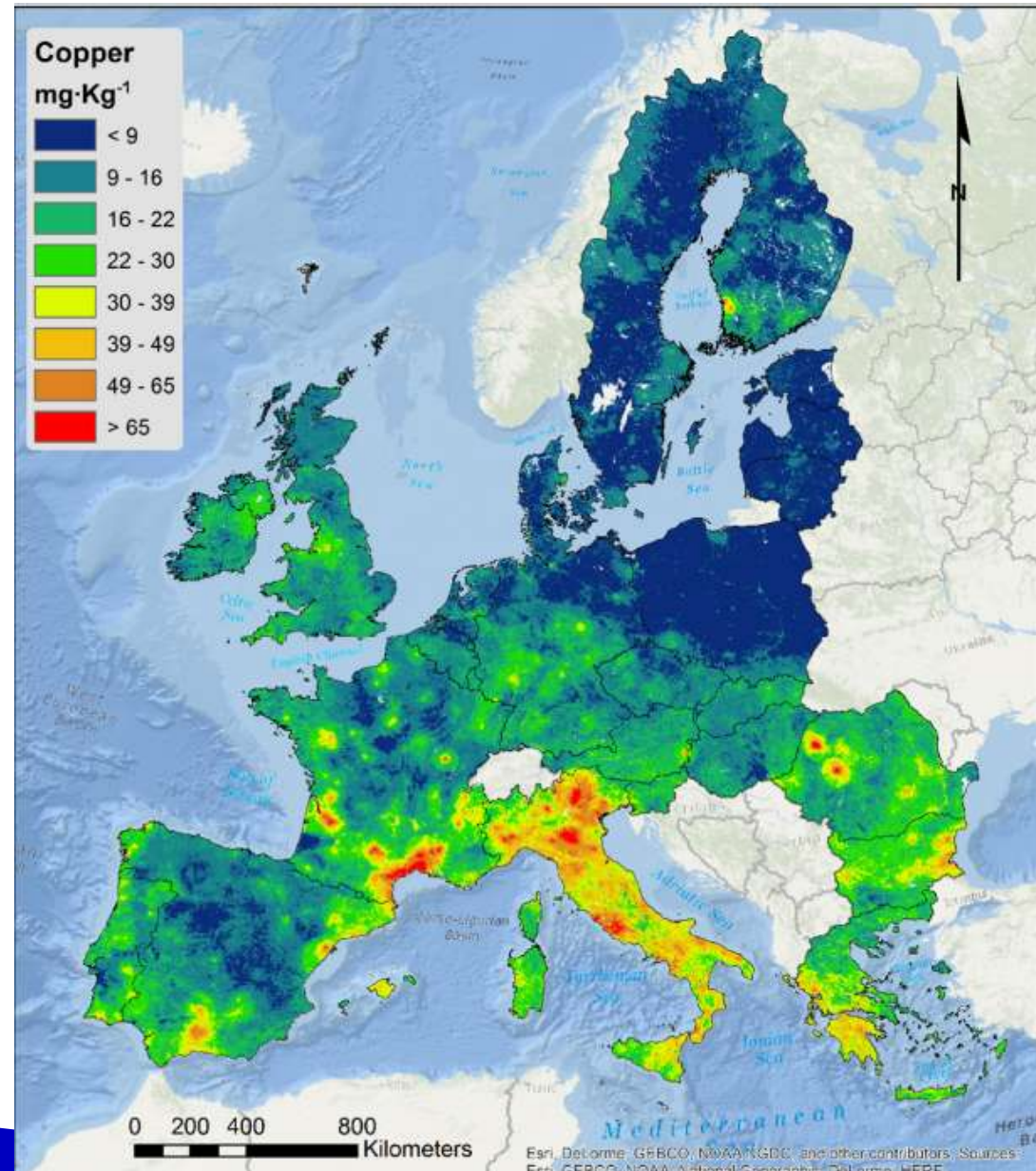


Number of juveniles (mean \pm sd) of *Aporrectodea caliginosa* after 112 days of exposure to the test soils (green columns: control soils, red columns: Copper-treated soils; filled columns: Niefern worms, dashed columns: Heiligenzimmern worms; naming of treatment groups: N-Control-N = Niefern soil / control treatment / Niefern worms, etc.)



Non Target Terrestrial Organisms

- Refine EU soil status
 - using data collected for monitoring 2017
 - EU LUCAS data set
 - 21682 soil samples
 - Less biased than open literature data
 - Calculate EU risk map
 - Using soil regression model
 - Access to full data set currently refused



Ballabio C. et al. 2018



Non Target Terrestrial Organisms

RAR values

Soil	Soil concentration (mg Cu/kg soil DM)	Source
Background level	11.5	Overall median value
Vineyards	28	Overall median 10 th percentile value
	72 66.4	Overall median value
	160	Overall median 90 th percentile value
	64-67 37.6 77.5	Overall mean value
Arable fields	32	EFSA (2013)
	5-7	Overall median 10 th percentile value
	13 13.4	Overall median value
	21 26	Overall median 90 th percentile value
Orchards	14-15 18.8 15.9	Overall mean value
	-	Overall median 10 th percentile value
	48.3	Overall median value
	58	Overall median 90 th percentile value
	22 22.5	Overall mean value

RAR version

When	What
December 2016	Initial RAR
September 2017	RAR revised in light of Data Requirements and Open Points reported in Evaluation Table Section 4
November 2017	RAR revised in light of the discussions at the E-fate Expert Meetings (Pesticide Peer Review Meeting TC152)
March 2018	RAR revised in light of the confirmatory information (monitoring programme)
August 2018	RAR revised in light of the confirmatory information (monitoring programme) following the peer-review and commenting by Member States, EFSA and applicant.



Non Target Terrestrial Organisms

Distribution of Cu concentration per land cover type

LUCAS land cover type		Total number of samples					Samples with Cu concentration >100 mg kg ⁻¹	
Code	Description	Number	Share	Mean Cu concentration (mg kg ⁻¹)	Median Cu conc. (mg kg ⁻¹)	St. Deviation of Cu conc. (mg kg ⁻¹)	No of samples	Share
A	Artificial land	45	0.2%	17.69	10.95	33.00	1	2.2%
B1	Cereals	6270	28.9%	16.11	12.48	17.14	39	0.6%
B2	Root crops	381	1.8%	13.02	10.21	13.93	1	0.3%
B3	Non-permanent industrial crops	1024	4.7%	18.84	14.32	20.90	11	1.1%
B4	Dry pulses vegetables flowers	270	1.2%	20.28	13.38	23.62	5	1.9%
B5	Fodder crops - legumes	736	3.4%	19.35	15.43	17.88	3	0.4%
B7	Fruit trees	321	1.5%	27.32	18.04	30.03	11	3.4%
B81	Olive groves	421	1.9%	33.49	24.68	32.01	20	4.8%
B82	Vineyards	342	1.6%	49.26	26.09	61.52	50	14.6%
C1	Broadland woodland	1682	7.8%	17.66	11.81	26.56	22	1.3%
C2	Coniferous woodland	2289	10.6%	9.37	5.77	16.05	8	0.3%
C3	Mixed woodland	1935	8.9%	10.13	6.80	11.52	2	0.1%
D	Shrubland	523	2.4%	21.42	14.00	27.49	12	2.3%
E	Grassland	4961	22.9%	18.23	13.52	19.29	59	1.2%
F	Bare land	382	1.8%	16.43	10.90	22.41	2	0.5%
G	Inland water	11	0.1%	19.82	11.60	24.83	0	0.0%
H	Peat-wetlands	89	0.4%	12.45	7.23	15.15	1	1.1%
Total		21682	100.0%	16.85	11.58	21.92	247	1.1%

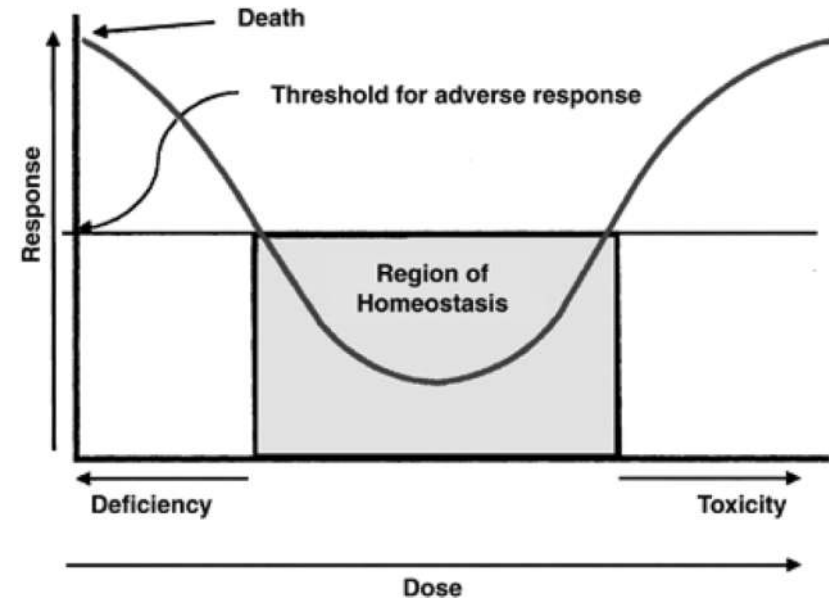
Ballabio C. et al. 2018

- For Art.43: Provide zonal or MS specific data with realistic risk estimates for soil organisms
- Simplistic 4 kg/ha/y not appropriate in most cases



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

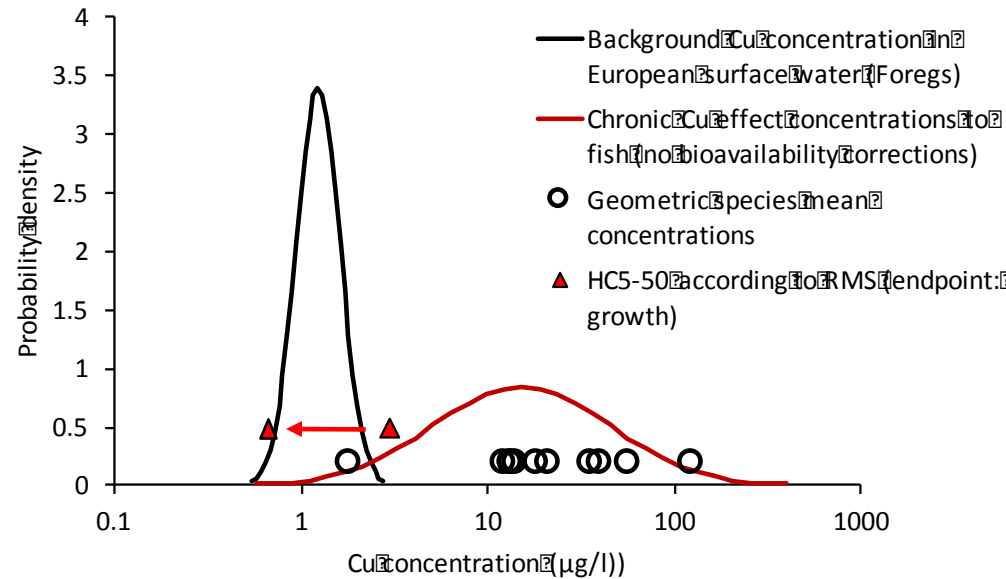
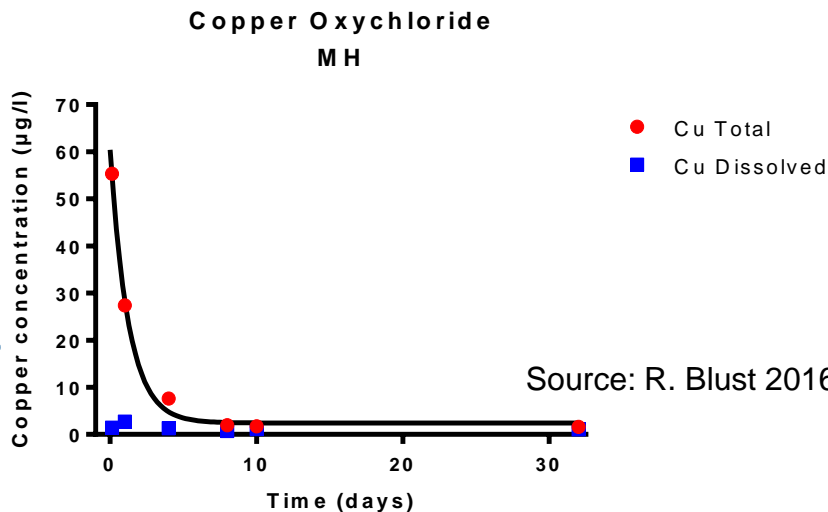


Risk to Aquatic Organisms

- Toxicity endpoint $RAC_{sw,ch}$ $0.37 \mu\text{g/L}$
 - Applied different assessment factors (AF)
 - rejected BLM normalization
 - below natural background



Exposure



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



BLM still best choice

1260

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Critical Review

Protectiveness of Cu Water Quality Criteria Against Impairment of Behavior and Chemo/Mechanosensory Responses: An Update

Joseph S. Meyer^{a,*} and David K. DeForest^b^aApplied Limnology Professionals LLC, Golden, Colorado, USA^bWindward Environmental LLC, Seattle, Washington, USA

ENVIRONMENTAL
Science & Technology

Article

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Use of Multiple Linear Regression Models for Setting Water Quality Criteria for Copper: A Complementary Approach to the Biotic Ligand Model

Kevin V. Brix,^{*,†,‡,§} David K. DeForest,[§] Lucinda Tear,[§] Martin Grosell,[‡] and William J. Adams^{||}[†]EcoTox, 2263 SW 37th Avenue, #816, Miami, Florida 33145, United States[‡]University of Miami, RSMAS 4600 Rickenbacker Causeway, Miami, Florida 33149, United States[§]Windward Environmental, 200 West Mercer Street, Suite 401, Seattle, Washington 98119, United States



Risk to Aquatic Organisms

- So what will the EUCuTF members do for Art.43?

➤ Toxicity

- AF=1 for data rich dossier of a nutrient
 - Update justification and explain necessity
 - Update justification for BLM
 - Launched fish population modelling



➤ Exposure

- Dissolved Cu always \ll Total Cu in natural system
 - EUCuTF will support again 3 as conservative, include monitoring
- Rapid dissipation for total Cu and any free Cu^{2+}
 - EUCuTF uses $\text{DT}_{\text{diss50}} < 1\text{d}$

- **This approach is not an option, but a necessity!**





Copper – Candidate for Substitution

- Cu listed as CfS under 1107 based on PBT criteria
 - P**ersistence ✓ **T**oxicity ✓ proposed again in RAR
- PBT not appropriate for inorganic compounds
 - REACH & BPR Regs do not apply PBT for inorganics
 - Low risk criteria exclude persistence criteria for minerals
- EUCuTF appealed against (EC) 2015/408 in Jun 2015
 - Hearing 6 Jun 2017 CJEU
 - Advocate General proposed the CJEU to set aside the GC's ruling and declare appeal admissible
 - **Judgement 13 Mar 2018: CJEU dismissed appeal**
 - TF has no standing; not individually concerned
 - ...more to come...



Copper as a Plant Protection Product

- As sole applicant the EUCuTF continues to support Copper compounds as active substance
 - Reapproval expected before 31.Jan 2019
 - Likely to adopt simplistic EU wide dose restrictions
 - Might trigger a high number of exempt authorizations and further increased fertilizer misuse
 - But hopefully with provisions for flexible dose
- Underrated benefits, e.g. bacterial diseases
 - Rare opportunity for agriculture to maintain an essential element as a fungicide
- **Cu guidance foreseen, but not before re-approval**
 - And also not before Art 43 re-authorizations
- **EUCuTF will provide its members with guidance**