

Update on the Regulatory Status of Copper in Europe

EU COPPER TASK FORCE
BERLIN, 13. NOV. 2025



INTRODUCTION

European Union Copper Task Force (EUCuTF) European Union Copper Task Force

New Chairman since September 2023: Daniele Ruccia (ERM)

12 member companies:

Albaugh Europe SARL

Cinkarna - Metallurgical & Chemical Industry Celje, INC.

Cosaco GmbH

Gowan Crop Protection Limited

Industrias Químicas del Valles, S.A.

Manica SpA

Montanwerke Brixlegg AG

Nordox AS

Nufarm Europe GmbH

Sales y Derivados de Cobre S.A.

UPL Europe Ltd.

Vibrantz Minerals SRL

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

- Copper hydroxide Bordeaux mixture
- Copper oxychloride Tribasic copper sulphate
- Copper(I)oxide

and Support for product authorizations

Regulatory status



Renewal in Europe... the three rounds



Dossier:
standard methods are not applicable
No alternative solutions have been presented
Authorities:
last time and only for 7 years

Dossier:
standard methods are not applicable and complete...
Alternatives have been presented in line with the EFSA statement
Long-term use should be advocated (Farm to Fork, 0 Pollution, accumulation)

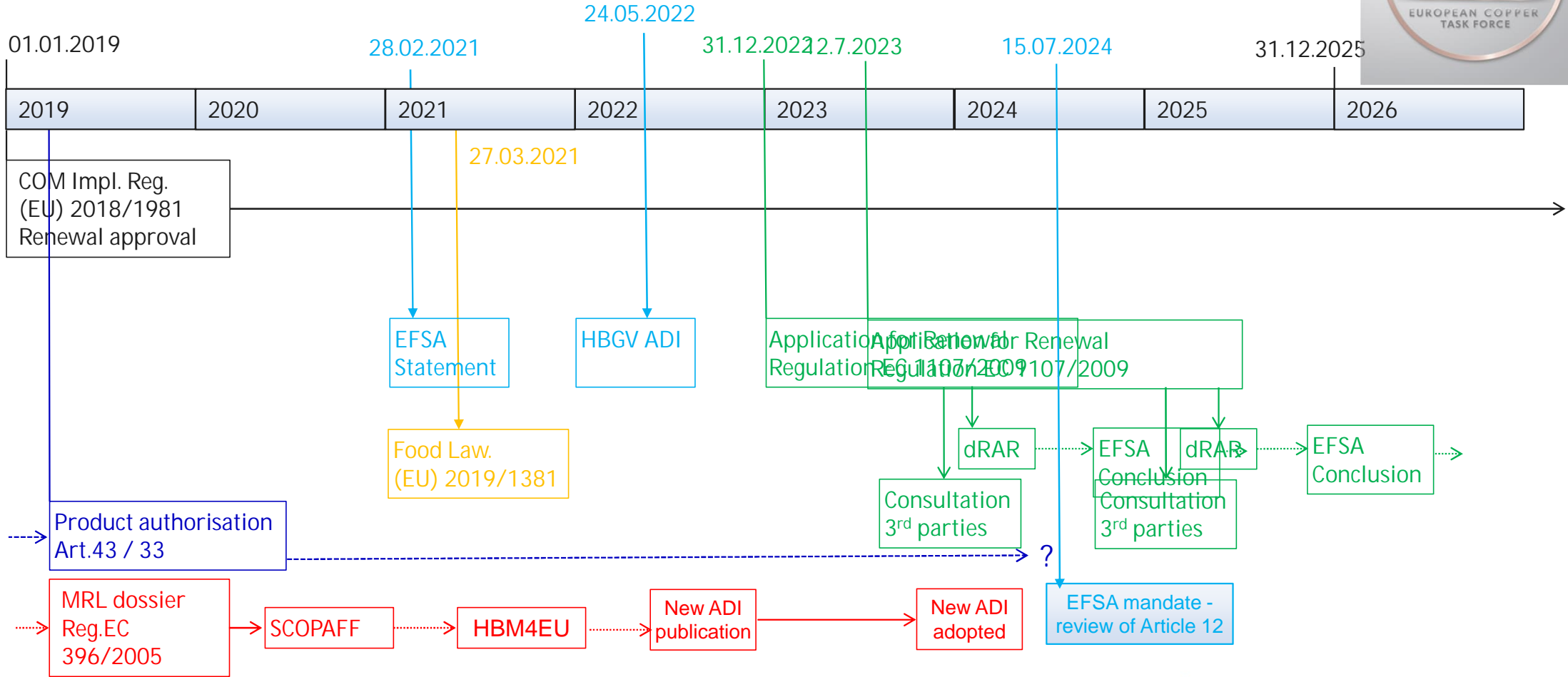
2009

2018

(2025)

Dossier:
standard methods are not applicable
Alternative solutions have been presented
Authorities:
interesting, but they can't agree; copper must be replaced as soon as possible; however: EFSA statements

Renewal of approval – ongoing Regulatory frames



SCOPAFF: Standing Committee on Plants, Animals, Food and Feed
 EU Copper Task Force – Berlin – 13 November 2025

HBGV: Health-based Guidance Values
 ADI: Acceptable Daily Intake



Regulatory state of play (following Reg. (UE) 2018/1981)

1) Average of 4 kg Cu/ha year

- Maximum dose of 28 kg Cu/ha in 7 years
- Possibility of using variable doses per year
- Many Member States have set the maximum dose at 4 kg/ha

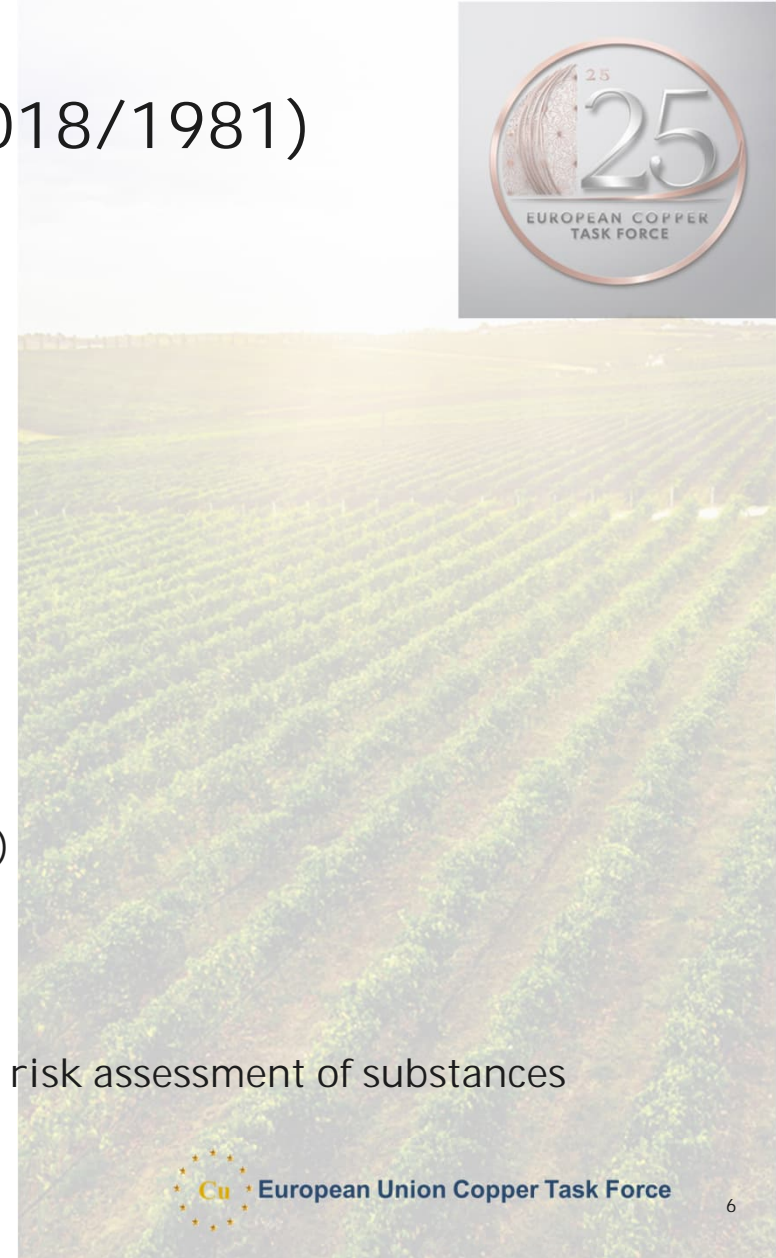
2) Copper compounds are classified as candidate for substitution (CfS)

- Considered having undesirable properties: **PBT**
- Approved for only 7 years
- Comparative assessment evaluation required for any new registration.

3) Member states should pay attention to:

- Operator exposure (in particular for workers entering vineyard after treatment)
- Non target organisms risk assessment (water, soil, plants, etc.)
 - To be noticed that most endpoints are below natural copper content concentrations
- Minimum effective dose use

4) The Commission mandated EFSA to develop appropriate guidances for the risk assessment of substances with similar characteristics to copper compounds



Extension of approval period



Official Journal
of the European Union

EN
L series



2025/1489

25.7.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1489 of 24 July 2025

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances ametoctradin, *Beauveria bassiana* strains ATCC 74040 and GHA, buprofezin, clodinafop, copper compounds, cyflumetofen, daminozide, flupyradifurone, *Helicoverpa armigera nucleopolyhedrovirus*, mandestrobin, mandipropamid, metam, pyraclostrobin, rescalure, *Spodoptera littoralis nucleopolyhedrovirus*, *Streptomyces lydicus* strain WYEC 108, *Trichoderma asperellum* strain T34 and *Trichoderma atroviride* strain I-1237

(Text with EEA relevance)

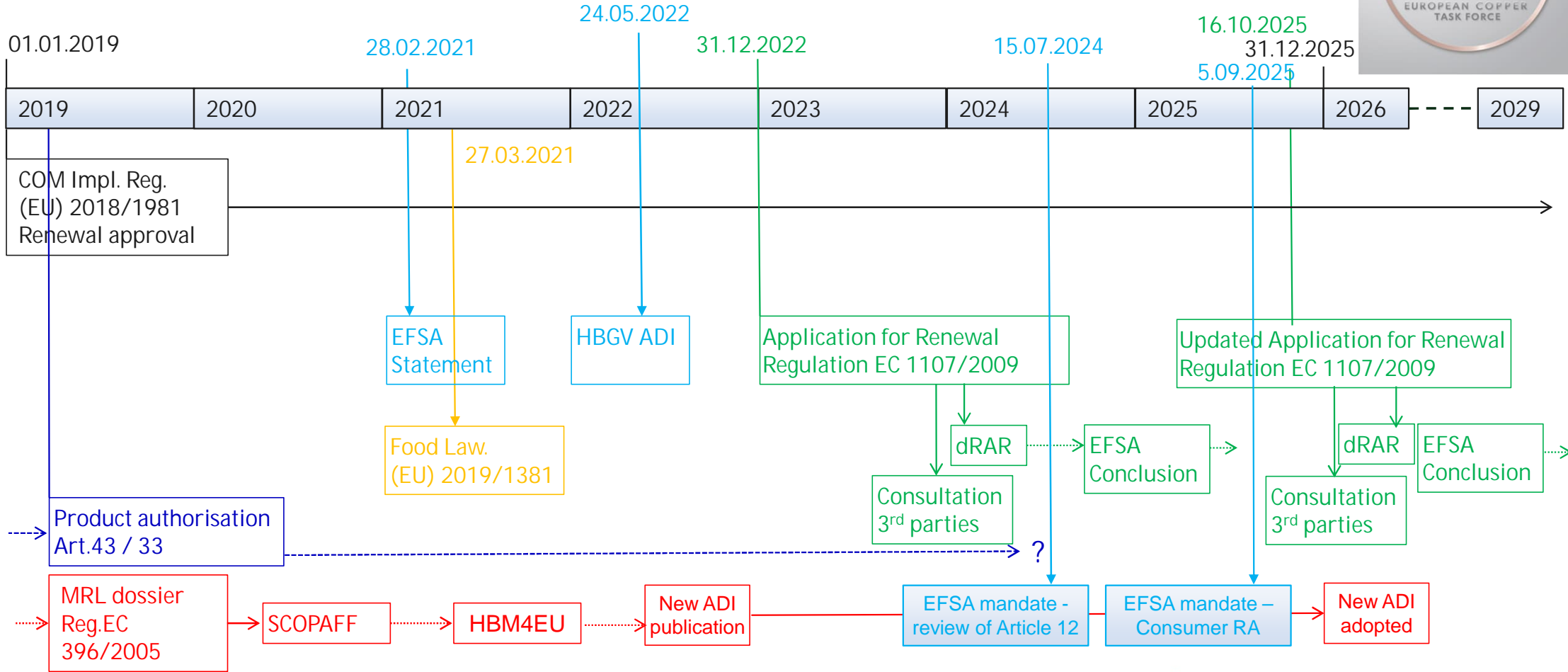
- (5) Commission Directive 2009/37/EC⁽⁷⁾ included copper compounds as an active substance in Annex I to Directive 91/414/EEC until 30 November 2016 and Commission Implementing Regulation (EU) 2018/1981⁽⁸⁾ renewed the approval of the active substance as candidate for substitution until 31 December 2025.

Extension of approval period (2)

- (33) Applications for the respective renewal of the approvals of the active substances copper compounds, flupyradifurone, mandestrobin, rescalure and *Streptomyces lydicus* strain WYEC 108 were submitted in accordance with Commission Implementing Regulation (EU) 2020/1740 ⁽²⁹⁾.
- (34) On 22 April 2024, 9 March 2023, 7 March 2023, and 15 December 2022, the rapporteur Member States for the active substances flupyradifurone, mandestrobin, rescalure and *Streptomyces lydicus* strain WYEC 108 informed the co-rapporteur Member States, the Commission and the Authority that they had assessed the admissibility pursuant to Article 8 of Implementing Regulation (EU) 2020/1740, and in particular the completeness and the timeliness, of each of the applications for renewal of the approval of each of those active substances and concluded that they were admissible. Those applications have been made public by the Authority pursuant to Article 10 of Implementing Regulation (EU) 2020/1740. The dossiers for the renewal of the approval of the active substance copper compounds were submitted in December 2022 and the rapporteur Member State is still in the process of assessing the admissibility of the application for renewal of the approval of that active substance pursuant to Article 8 of Implementing Regulation (EU) 2020/1740.
- (38) For the active substances ametoctradin, copper compounds, flupyradifurone, mandestrobin, mandipropamid and *Streptomyces lydicus* strain WYEC 108, the risk assessment has not been finalised yet by the rapporteur Member States. Taking into account the subsequent steps to be completed in each renewal procedure, the duration of the extension of the approval periods of these active substances should be set at 29 months for ametoctradin, and at 42 months for copper compounds, flupyradifurone, mandestrobin, mandipropamid and *Streptomyces lydicus* strain WYEC 108.
3. In Part E of the Annex to Implementing Regulation (EU) No 540/2011, in the sixth column, expiration of approval, of row 10, Copper compounds, the date is replaced by '30 June 2029'.



Renewal of approval – ongoing Regulatory frames



A "different" Plant protection product

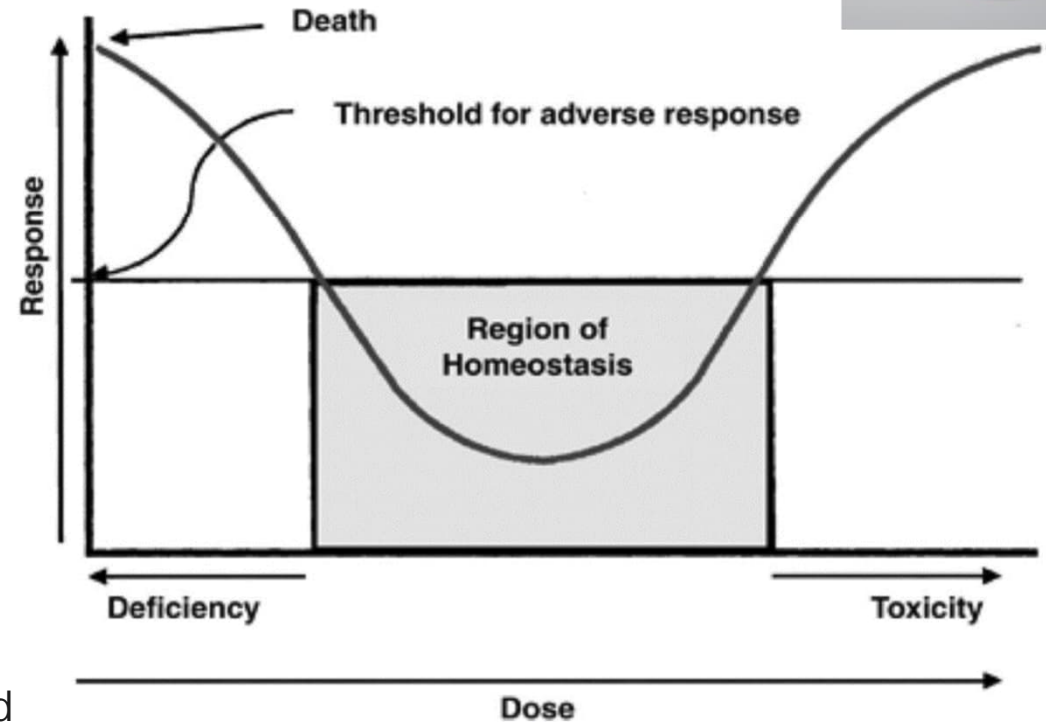


Essential Micronutrient

- Omnipresent (ubiquitous)
- Metal
- Homeostatic control

Assessment according to standard guidelines is often not adaptable or even impossible

- Current models are not applicable to metals and essential micronutrients
- Assessment factors are inappropriate as they are incompatible with the "U" shaped function
- For risk assessment it is necessary not to use standard parameters (e.g. EFSA LoE); position papers and weight of evidence (WoE) are essential



Just 1 example...



Aquatic organisms exposure and toxicity

Copper average concentration in European rivers is 0,9 $\mu\text{g}/\text{L}$, with 90 percentile of 2,4 $\mu\text{g}/\text{L}$.

Risk assessment value to be considered for the aquatic risk assessment is 0,37 $\mu\text{g}/\text{L}$ (EFSA + safety factor)

Example Risk assessment - Aquatics

Endpoints	Actual PNEC/RAC	Source	Update proposed 2022
Biocides	7.8 µg/L	VRAR 2008	7.8 µg/L
REACH	7.8 µg/L	VRAR 2008	6.3 µg/L
Plant protection	0.37 µg/L	EFSA 2018	4.8 µg/L

- Regulatory Acceptable Concentration (RAC) under EC 1107/2009 below natural concentration
 - Average natural concentration in European surface water is ca. 1 µg/L
 - Similar situation for river sediments
- ⊘ Impossible for any MS to authorize a product while sticking to the EU list of endpoints (LoEP)



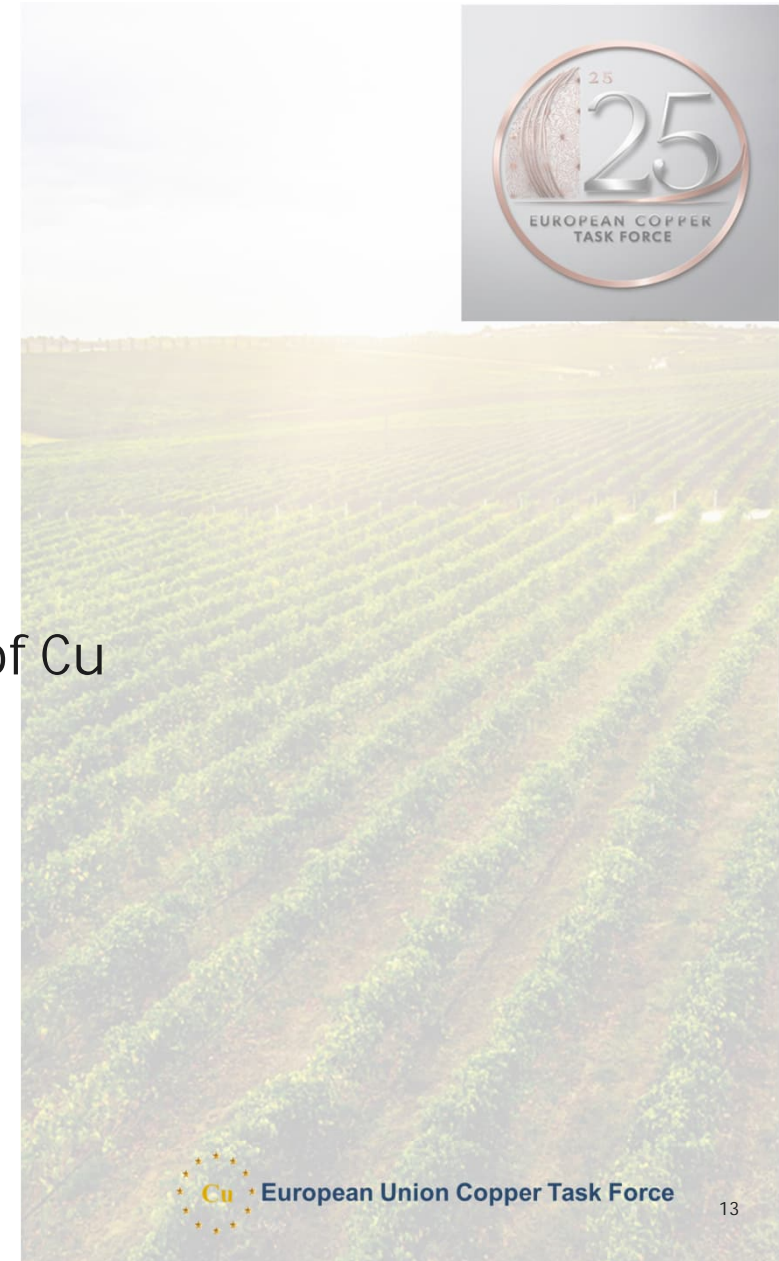
Interaction with RMS Italy and EFSA

1) Delay of dossier admissibility and assessment

- Mainly due to new format (IUCLID) and its updates
- Required “special” structure for a.s. with several variants
- Enabled EUCuTF to provide updates (e.g. earthworm study report)

2) RMS is cooperative and acknowledging special case of Cu

- Required several updates since first submission
- Open to discuss bioavailability use in risk assessment
- Easy communication channel



Status as Candidate for Substitution (CfS)



Modification / Withdrawal of CfS Status and Timeline



1) Scientific justification for removal of CfS status of copper

- (see details in EUCuTF presentation from last year)
- As practiced in REACH and BPR
- Agreed by EU Commission in meeting of 28. Jun. 2024
- However, challenged by some MS (incl. DE) in SCOPAFF meeting July 2025

2) Legal basis for changing CfS status

- Revision of CLP by delegated act of 19. Dec. 2022 introduces PBT classification
 - Only for organic compounds
- EU Commission agreed this prevails 1107/2009 in meeting of 28. Jun. 2024
- However, challenged by some MS (incl. DE) in SCOPAFF meeting July 2025



Modification / Withdrawal of CfS Status and Timeline (2)

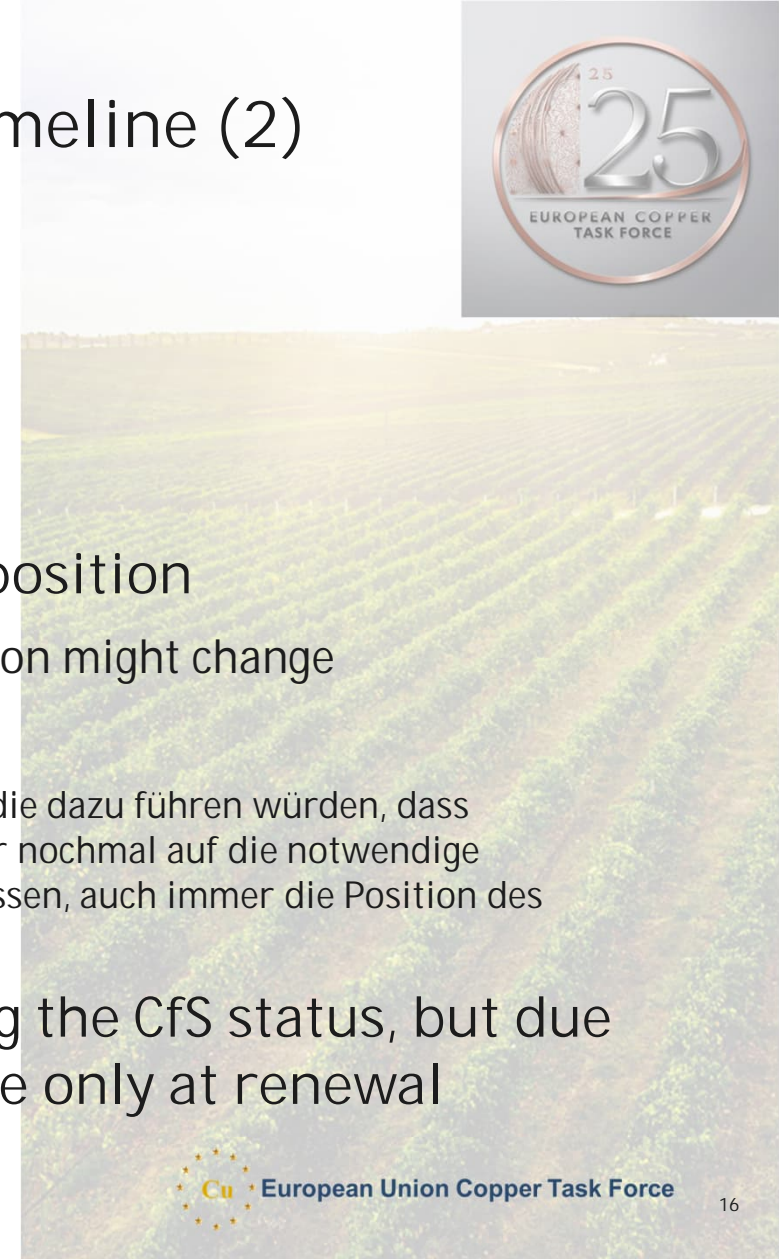


3) Removal of CfS status ahead of a.s. renewal

- Willingness by EU COM to try despite lack of established procedure
- Attempt stalled after MS /DE resistance in July 2024 SCOPAFF

4) EUCuTF met BMLEH on 17. Sep. 2025 to discuss DE position

- EUCuTF re-presented their position and asked if DE SCOPAFF opinion might change
- Reply received on 5. Nov. 2025:
 - Leider kann ich Ihnen nur mitteilen, dass uns keine neuen Erkenntnisse vorliegen, die dazu führen würden, dass Deutschland seine Position bei diesem Thema ändert. Insbesondere möchte ich hier nochmal auf die notwendige abgestimmte Position innerhalb der Bundesregierung hinweisen, wobei, wie sie wissen, auch immer die Position des BMUKN/UBA einfließt. Ich sehe hier keine Veränderungen in naher Zukunft.
- EU COM and majority of MS seem to agree with lifting the CfS status, but due to minority opinion (DE, DK, NL, AT) may get effective only at renewal



Risk Assessment Human Health – OPEX



Operator, Worker, Resident and Bystander exposure

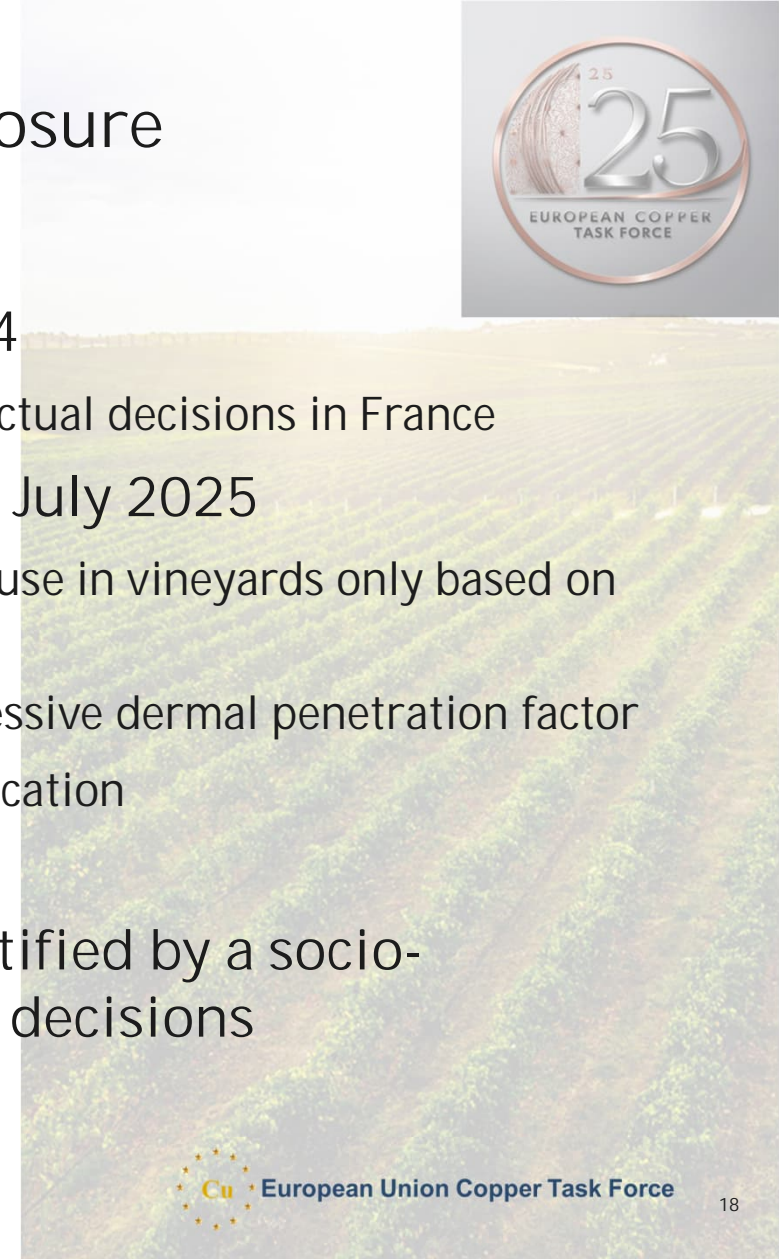


Details of EUCuTF position presented in 2019 and 2024

- Worker exposure and dermal penetration will be re-visited due to actual decisions in France

ANSES decisions on product authorization delivered in July 2025

- Assessment in 2022 raised many issues, but negative decisions for use in vineyards only based on worker exposure
- No product passes risk assessment for vineyard worker due to excessive dermal penetration factor
- Disagreement with EUCuTF deviation from GD w/o scientific justification
- Rejection of in-vivo study for animal welfare reasons
- ANSES granted authorization only for 2 products justified by a socio-economic study published at the same time than the decisions



Operator, Worker, Resident and Bystander exposure (2)



Lack of copper specific guidance for OPEX / dermal penetration:

Dossier section	Cu specific guidance	Subject
Environment	EFSA Transition metal Statement	Exposure and Risk assessment
Human health - Consumer	EFSA HBGV; EFSA MRL; EFSA technical paper	Exposure, Risk assessment and MRL
Human health - OPEX	Not available /standard GD used)	Not available

After recognition by authorities that Cu requires specific methodology EU COM mandated EFSA to develop Cu specific GD

- Now available for significant parts of the dossier, while still requires validation
- Not available for OPEX





Operator, Worker, Resident and Bystander exposure (3)

EUCuTF presented wealth of studies and position papers justifying low dermal penetration factors for Cu products of 0.1/1% for concentrate and spray dilution

Lack of Cu specific GD and EU harmonizations leads to different outcomes in MS:

Member State	In-vitro studies	GD dermal penetration exception	In-vivo study	Dermal penetration Concentrate / spray dilution
France (EU)	✓	✗	n.a.	1% / 9%
France	✓	✗	✗	1% / 9%
Austria	✗	✗	✓	0.1% / 1.2%
Italy	✓	✓	n.a.	0.1% / 0.5%
Spain	✓	✓	n.a.	0.5% / 0.5%
Germany	✓	✗	✗	1% / 9%

* Reasons for rejecting in-vivo study not the same



Risk Assessment Human Health – Consumer



ADOPTED: 16 November 2022

doi: 10.2903/j.efsa.2023.7728

Re-evaluation of the existing health-based guidance values for copper and exposure assessment from all sources

EFSA Scientific Committee, Simon John More, Vasileios Bampidis, Diane R. ... Thorhallur Ingi Halldorsson, Antonio F. ... Kostas Koutsoumanis, Claude Lam ... Josef R. Schlatter, D ... Gordon AA F ... Agnès de

Abstract

Copper is a ... farming pes ... effects. In th ... guidance values ... resolve the diverg ... manifestation in the sh ... copper homeostasis and its ... retention is indicative of potential future ... of continuous intake. Hence, emphasis was placed on ... adverse effects. The relationships between (a) chronic copper ex ... particularly the liver, and (b) hepatic copper concentrations and e ... The Scientific Committee (SC) concludes that no retention of copper ... of 5 mg/day and established an Acceptable Daily Intake (ADI) of 0.07 mg/kg bw. A refined dietary exposure assessment was performed, assessing contrib ... from dietary and non-dietary sources. Background copper levels are a significant source ... plant protection product (PPP), food and feed a ... fertilisers or PPPs contributes to com ... important contribu ... oral sourc ... adu ...

Keywords: copper

Requestor: European Commission
Question number: EFSA-Q-2020-00399
Correspondence: MESE@efsa.europa.eu

Consumer risk assessment and MRL

EFSA opinion to Cu HBGV
November 2022

A refined dietary exposure assessment was performed, assessing contribution from dietary and non-dietary sources. Background copper levels are a significant source of copper. The contribution of copper from its use as PPP, food and feed additives, or fertilisers is negligible.

Required new EFA mandate to establish Cu specific procedure for MS for setting MRLs and to check for established MRLs

The SC concludes that no retention of copper is expected to occur with intake of 5 mg/day and established an ADI of 0.07 mg/kg bw.

January 2026

er 2025

available for commenting until



Consumer risk assessment and MRL (2)

Technical Report



APPROVED: XX Month 20XX
doi: 10.2903/sp.efsa.20YY.EN-NNNN

Approach for the risk assessment of copper compounds under different plant protection product (PPP) regulatory frameworks

European Food Safety Authority (EFSA)

DRAFT

Abstract

As copper is ubiquitous in the environment, is an essential micronutrient and it's not used only as a pesticide, EFSA recently performed a comprehensive dietary risk assessment based on food consumption data from the EFSA Comprehensive Database and updated occurrence data. This approach differs from the standard methodology using the Pesticide Residue Intake Model (PRIMo) for the consumer dietary risk assessment of pesticide residues in the framework of setting and reviewing MRLs and in the peer review of pesticides. Therefore, there is a need to clarify the methodology to be used by applicants and Member States to assess the consumer dietary risk of the Plant Protection Products(PPP) uses of copper compounds under different PPP regulatory frameworks with the exposure tools available to them. This technical report proposes a harmonised stepwise approach for the consumer dietary risk assessment of copper compounds under various PPP regulatory frameworks, using PRIMo 3.1. A case study on onions, head cabbages, and dry beans illustrates the application of the approach.



Draft published in November 2025:

<https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0ITk0000069DVd/pc1694>

Open for comments until 12. Jan. 2026

Intended to provide guidance to MS and applicants on how to deal with CRA and MRL setting process



European Union Copper Task Force

Risk Assessment Environment – Accumulation in soil



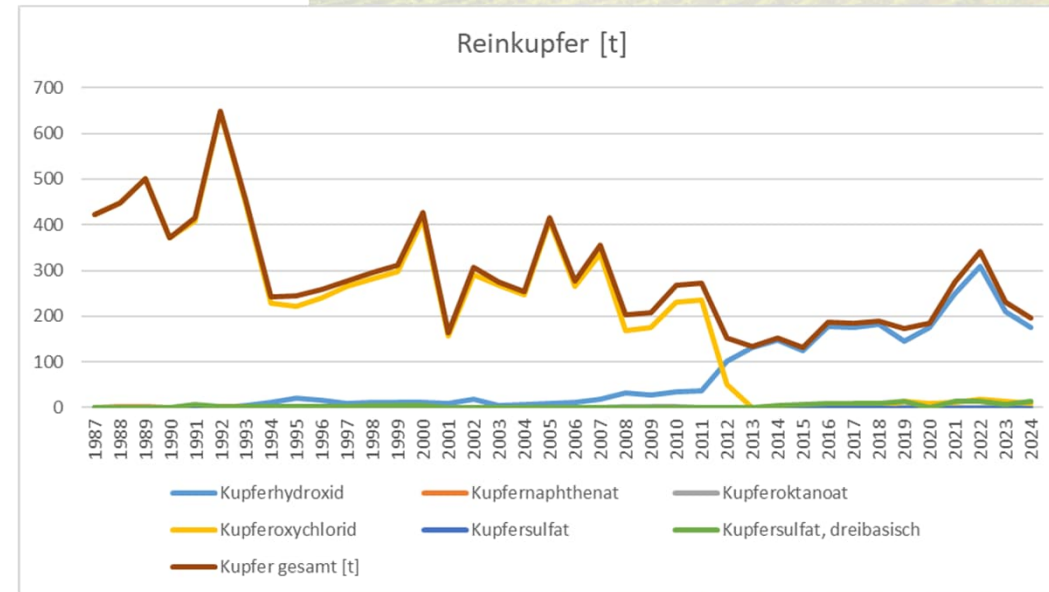
Potential accumulation in Soil

Main argument used for minimization strategy

- Based on simplistic PEC calculation:
"No loss" assumption too conservative
 - No plant intercept
 - Low export with harvest from treated plot
 - Low transport to lower soil horizons
- Ignores..
 - Crop rotation
 - Erosion (85% of soil re-deposited)
 - Export with crop harvest from total surface
 - Applying "P-nutrient cycle" from JRC:
 - 2640 t Cu/y removed with crops for EU27
 - 300 t Cu/y removed with crops for DE



Cu fungicide use in DE:

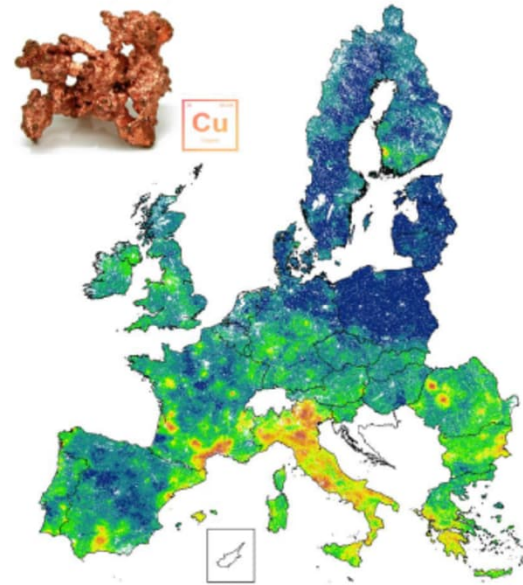


Potential accumulation in Soil – Impact of Erosion



Assessment according to JRC model

- 85% of eroded soil is redeposited
- Stocks determined based on LUCAS data set
 - Mainly naturally occurring
- Based on water erosion
- Does not yet include annual inputs and outputs



4439 t Cu/y transferred from soil to water

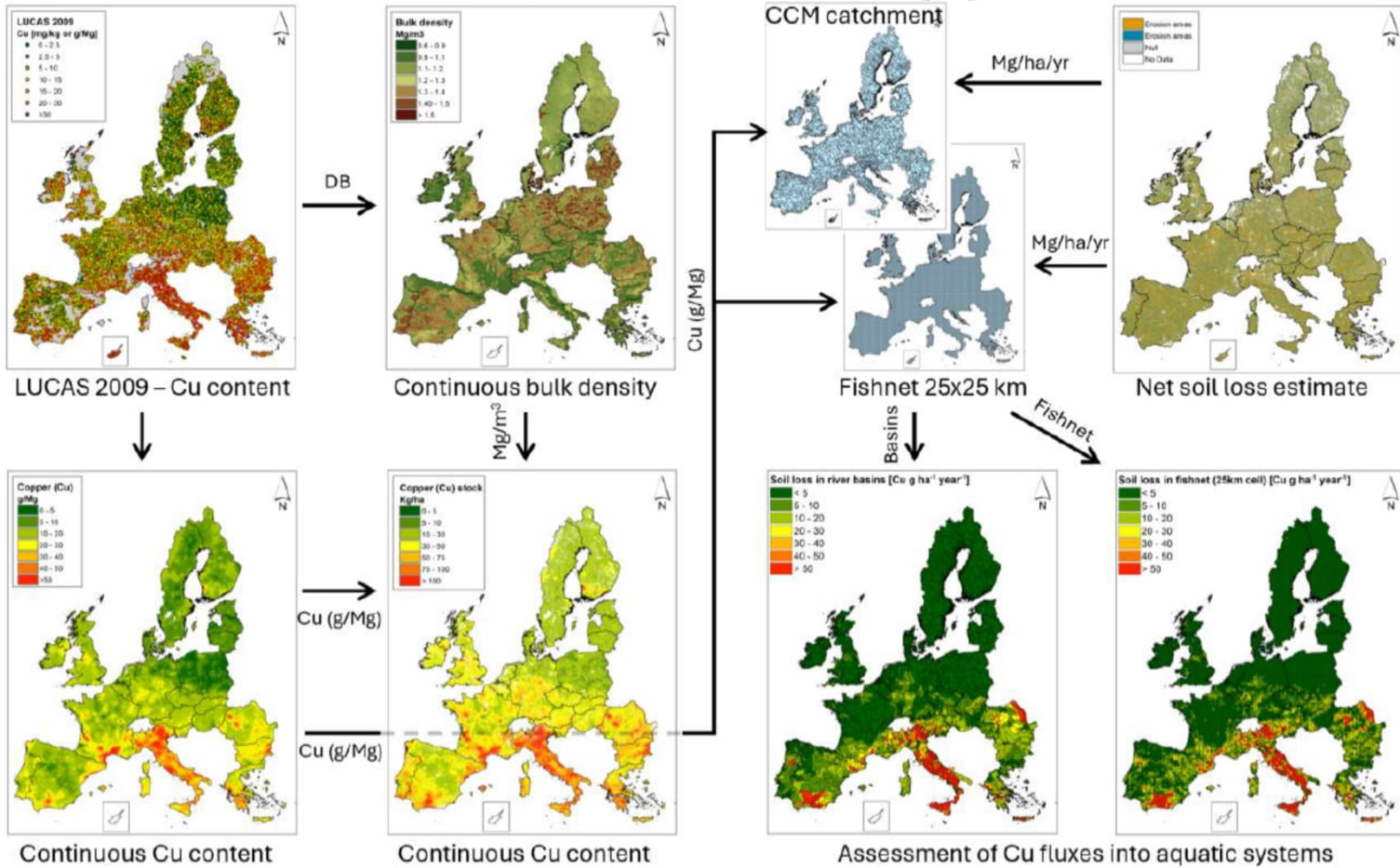
29576 t Cu/y Redistributed to other surfaces

ABS... This report... of the European Union (EU) and... (UK) due to water erosion by combining estimates of... content with net soil losses. Annually, approximately $4,439 \pm 355$ Mg of Cu is estimated to be transported from land to watercourses, accounting for about 15% of the total (gross) Cu displaced by water erosion, estimated at $29,576 \pm 2,369$ Mg yr⁻¹. The remaining $25,136 \pm 2,013$ Mg yr⁻¹ is deposited in areas with gentler slopes... semi-natural lands... 125.6 g ha⁻¹... agricultural... estimated... per... 054 ±... Mg yr⁻¹ for vineyards, ... 6,111 ± 489 Mg yr⁻¹ for olive groves, and 2,413 ± 193 Mg yr⁻¹ for other agricultural uses. Concerning (net) Cu losses, the agricultural land types show an overall loss estimated in $7,718 \pm 618$ Mg yr⁻¹. Arable lands alone are estimated to lose $5,375 \pm 430$ Mg Cu yr⁻¹, while olive orchards and vineyard to lose $2,324 \pm 186$ and 941 ± 75 Mg Cu yr⁻¹, respectively.

Prof. Dr. Pasquale Borrelli

Copper in European topsoil: Estimates of stocks and fluxes
December 2024 V1.1

Potential accumulation in Soil (2) – Stocks and Fluxes



Among the results:

- Stock DE: 1.1 Mt (36 kg/ha)
- 1016 t Cu are redistributed per y, out of which 123 t enter surface water
- DE vineyards redistribute 78 t Cu/y, losing 27 t to other surfaces
- Rhein catchment redistributes 643 t Cu/y, losing 83 t/y

Fig. 2: Workflow - Data inputs and modelling for estimating Cu stocks and Cu fluxes to aquatic systems.

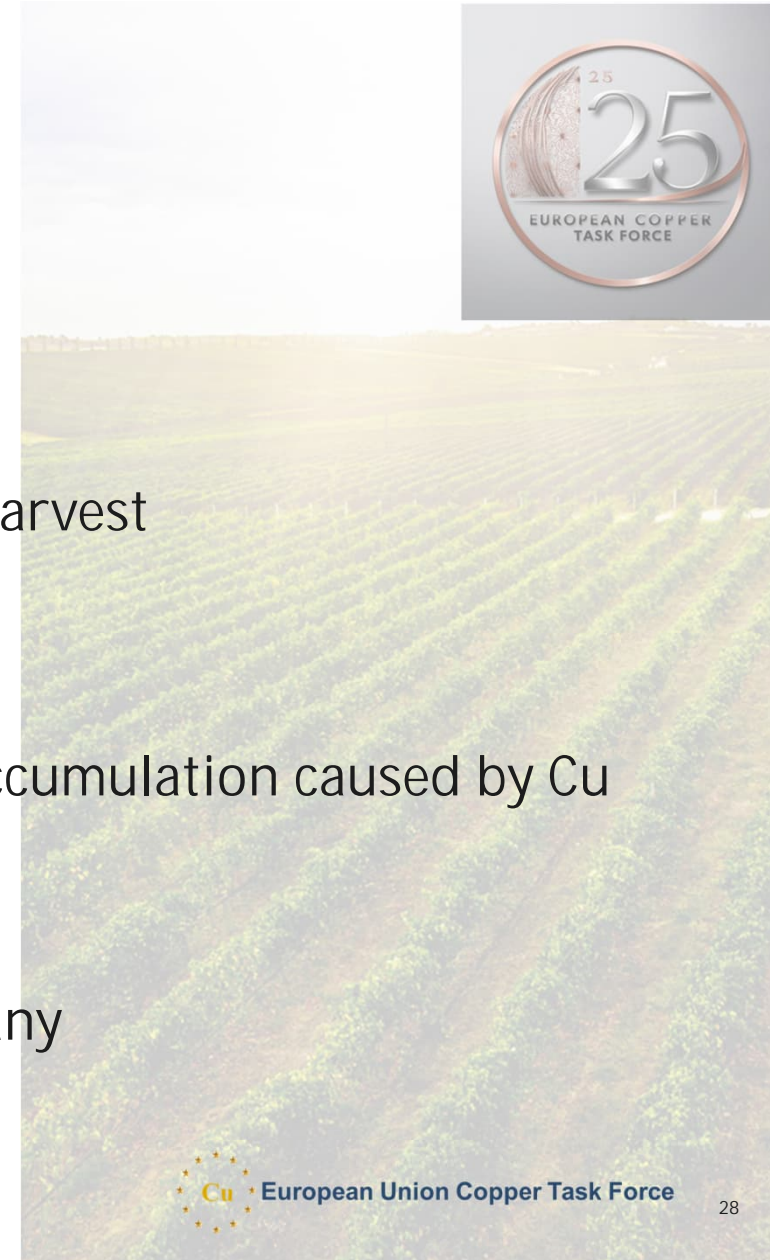
Potential accumulation in Soil (3)

Further work ongoing

- Include other erosion pathways
- Include annual fungicide inputs and outputs from crop harvest

Can already conclude...

- Simplistic PEC calculation considerably overestimates accumulation caused by Cu fungicides, in particular in long-term scenarios
- Impact of Cu fungicides difficult to isolate
- No accumulation for arable soil in general and for Germany



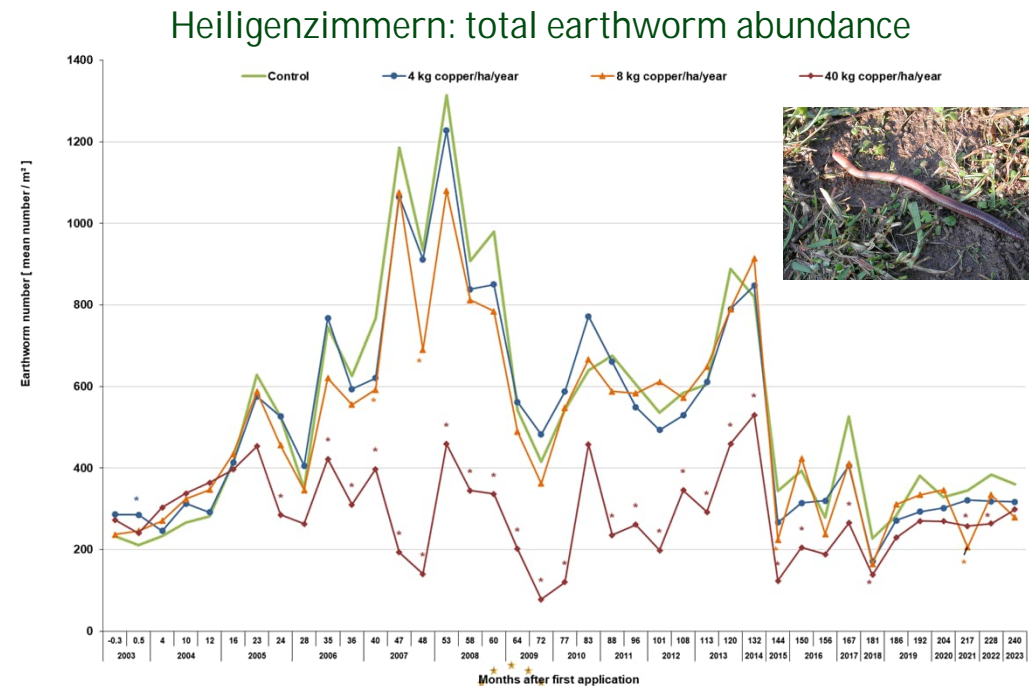
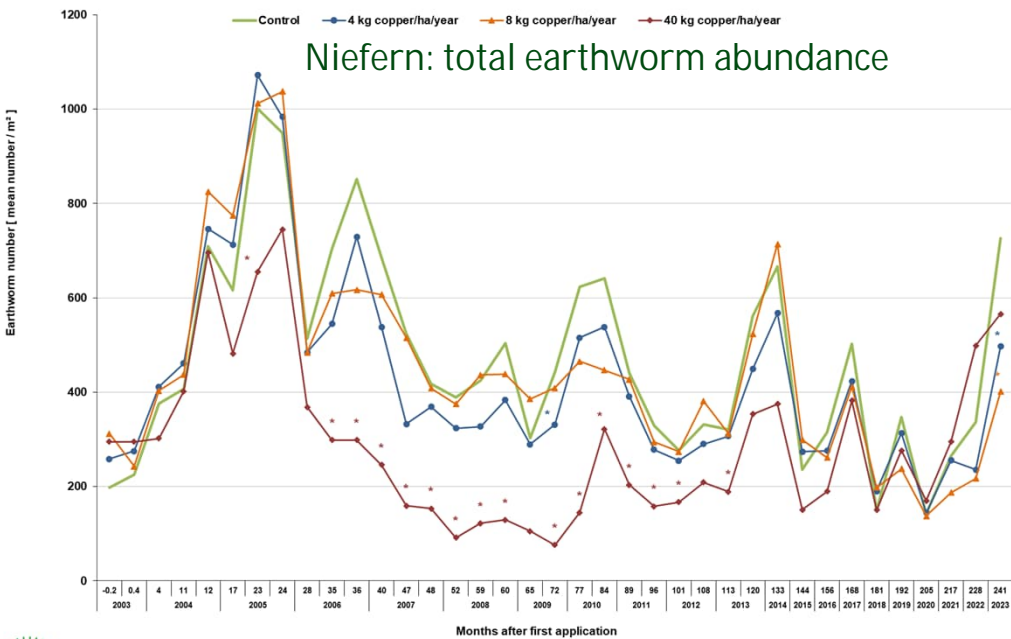
Risk Assessment Environment – Ecotoxicology



Environmental Risk Assessment - Earthworm

Long-term grassland study ongoing since 2003

- Updated report available, will be submitted to BVL/UBA end of Nov. 2025
- Independent expert panel ongoing

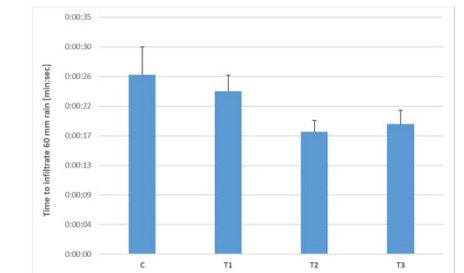
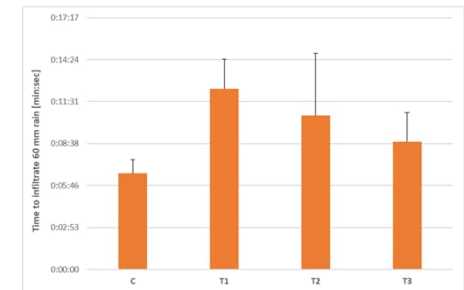
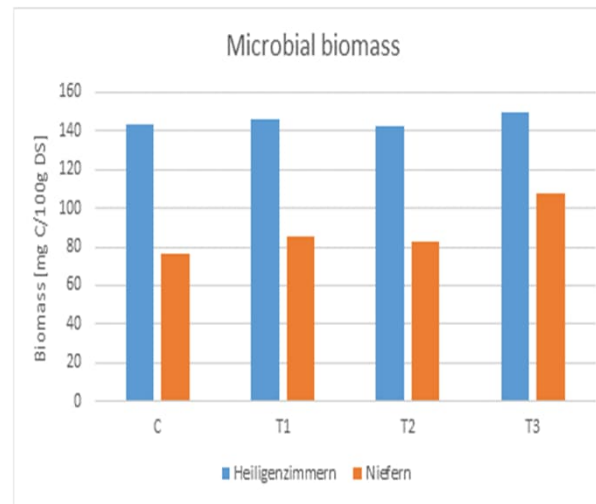
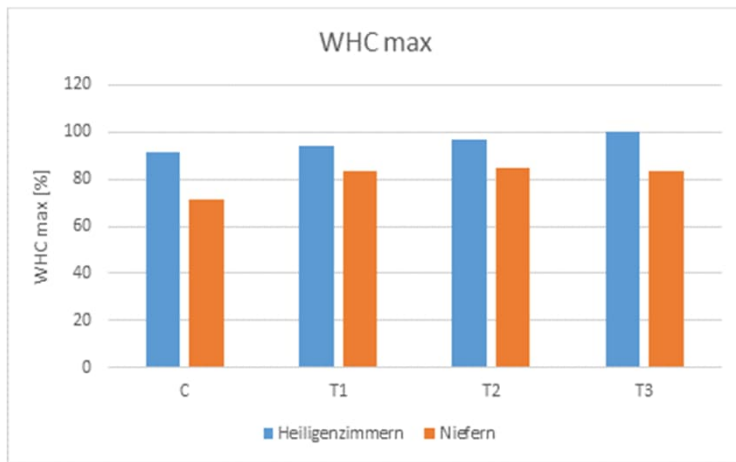




Environmental Risk Assessment – Soil health

EU's Soil Monitoring and Resilience Directive, formally adopted in September 2025 by EU Council

- Some soil health parameter included in long-term study



C = control T1 = 4 kg/ha T2 = 8 kg/ha T3 = 40 kg/ha, plus de traitement

Is ecosystem service provided?

Water infiltration capacity



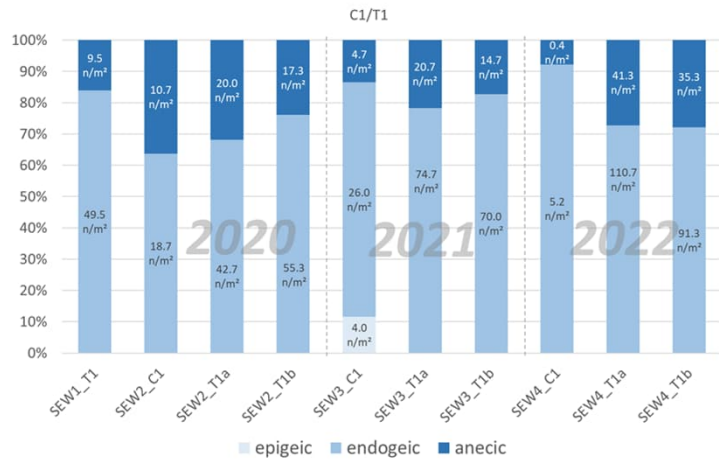
Environmental Risk Assessment – Earthworm (2)

Vineyard studies in DE and FR continued (2nd 3-year cycle)

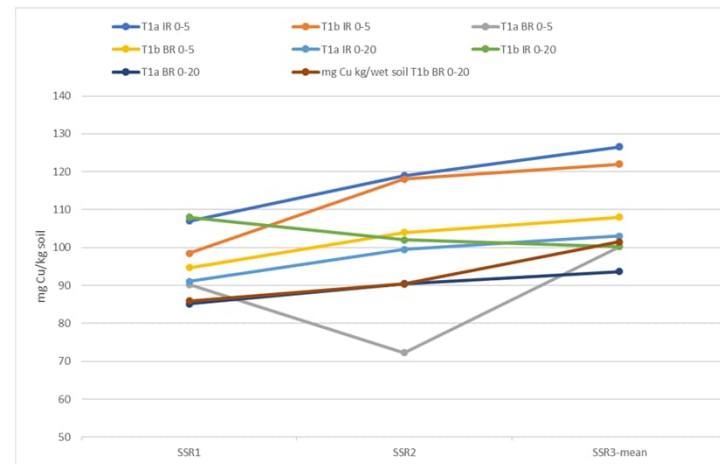
- Updated report available, will be submitted to BVL/UBA end of Nov. 2025
- Supporting flexible dose schemes
- Healthy earthworm populations, soil residues to be improved



Site Neckarwestheim



Site France



Union

Conclusions

Conclusions

The regulatory status of copper is evolving. Although challenges remain, a balanced, science-based approach is paving the way for the continued use of copper.

Primary importance, practically irreplaceable.

The EU Copper Task Force is committed to working with EU authorities to ensure that copper remains a vital tool for sustainable agriculture.



Thank you

Daniele Ruccia

EU Copper Task Force Chairman

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ERM Partner – CP Lead (Sustainable Product & Supply Chain)

