



# Updates on the Regulatory Process and Copper Risk Assessment

Eleanor Long, Daniele Ruccia, Matthias Weidenauer  
European Union Copper Task Force (EUCuTF)

Online Event

Way forward in organic plant health care strategies

09.11.2023: Copper as a plant protection product

**BATTELLE**



# European Union Copper Task Force (EUCuTF)

- New chairman since Sep.23: Daniele Ruccia (ERM)
- Scientific Coordinator: Eleanor Long (Battelle)
- 12 member companies
 

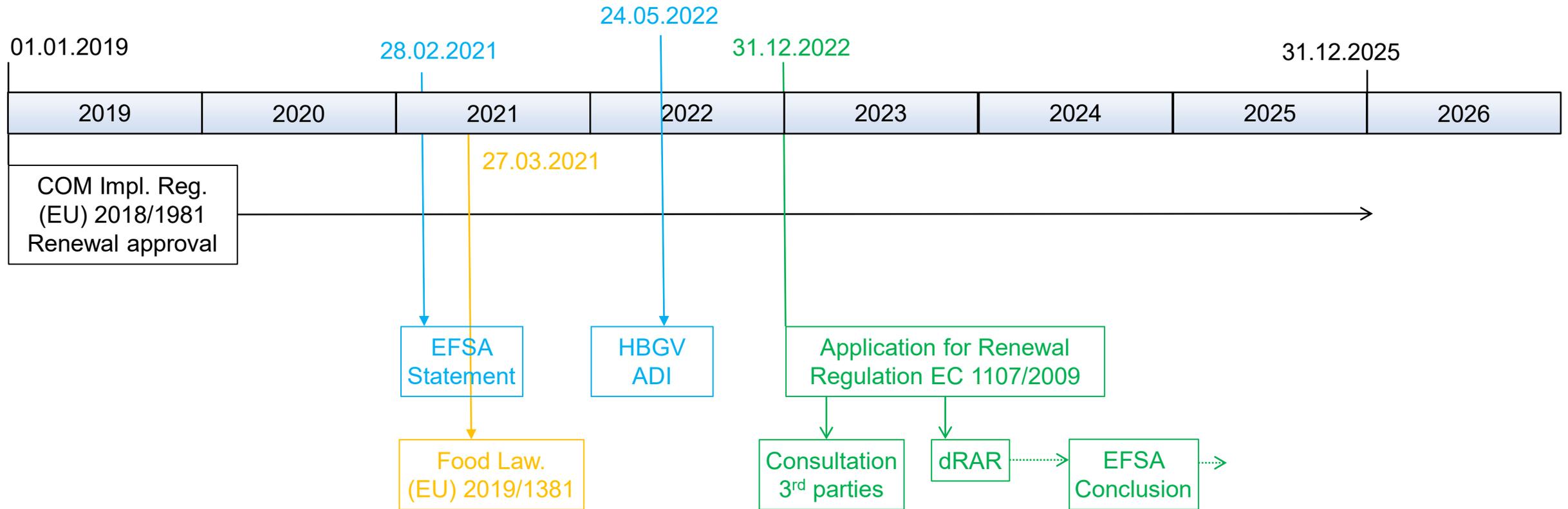
<p>Albaugh Europe SARL          Cinkarna - Metallurgical &amp; Chemical Industry Celje, INC.          Cosaco GmbH          Gowan Crop Protection Limited          Industrias Quimicas Del Valles, S.A.          Manica SpA</p>	<p>Montanwerke Brixlegg AG          Nordox AS          Nufarm Europe GmbH          Sales y Derivados de Cobre S.A.          UPL Europe Ltd.          Vibrantz Minerals SRL</p>
--	--
- Objective: Renewal of approval of Copper compounds according to regulation (EU) 1107/2009
 

<ul style="list-style-type: none"> <li>- Copper hydroxide</li> <li>- Copper oxychloride</li> <li>- Copper(I)oxide</li> </ul>	<ul style="list-style-type: none"> <li>Bordeaux mixture</li> <li>Tribasic copper sulphate</li> </ul>
--	--

  - Support for product authorizations



# Renewal of Approval – next round



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



# EFSA/IUCLID

- New dossier was submitted in IUCLID format.
  - Whole dossier has been reconstructed; EFSA portal requirements fulfilled.
- On 16. Dec.2022 EFSA/COM asked EUCuTF to provide 5 active substance dossiers
  - One dossier for each variant; was done after cloning
  - After technical issues, deadline for submission was extended into Jan. 23
- Following a letter to DG SANTE cc: EFSA, RMS in Jan. 23 the process was reverted to one ai: copper compounds
  - Technical coordination of dossier reconfiguration discussed with EFSA

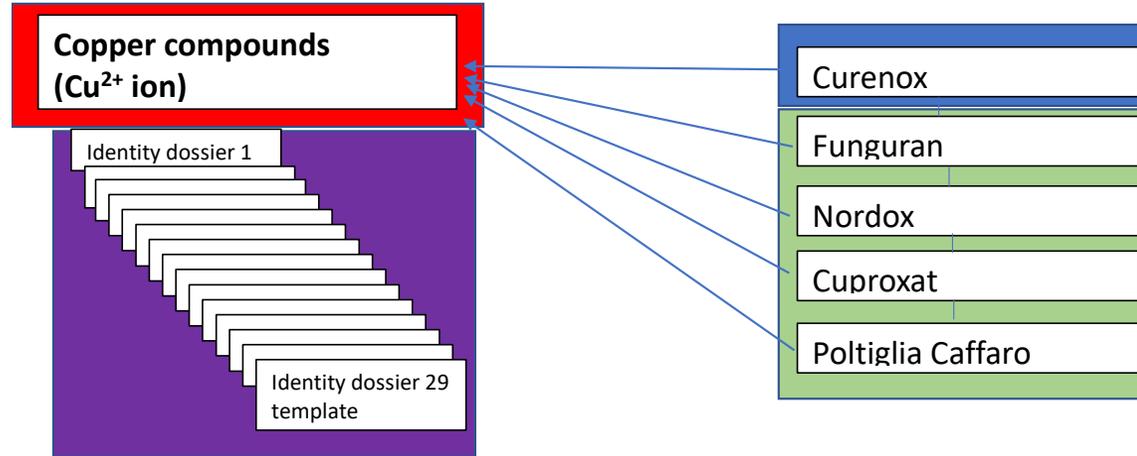


# EFSA/IUCLID

- EFSA advised on new structure of single dossier – to include a surrogate active substance.
  - The  $\text{Cu}^{2+}$  ion was chosen as the surrogate, but very careful wording was chosen to define this active substance in order to reflect the 5 supported forms of copper
- Major update of IUCLID (April/June 2023) caused significant delay and additional work for preparation of the combined dossier
  - Many template changes within the structure of the dossier, leading to re-writes of study summaries esp ecotoxicology, analytical methods
- Dossier submitted via EFSA portal on 12<sup>th</sup> July 2023.
  - Dossier size is too large to export into individual instances of IUCLID



# IUCLID dossier structure



	Lead product dataset – legal entity EUCuTF
	Additional representative products – legal entity EUCuTF
	Surrogate active substance dataset. This dataset contains all active substance data – owned by all members of EUCuTF. Legal entity EUCuTF
	“Identity dossier” inherited templates containing confidential data for each EUCuTF member for each form of copper supported. Each identity dossier has a different legal entity as it essentially constitutes a Document J*

\*The common mistakes in IUCLID training session indicated that the Document J template was no longer in use and that individual batch data should be placed in the IUCLID templates. I specifically asked a question about task force data and it was suggested that this identity dossier approach was the appropriate approach as each would be able to have its own legal entity.

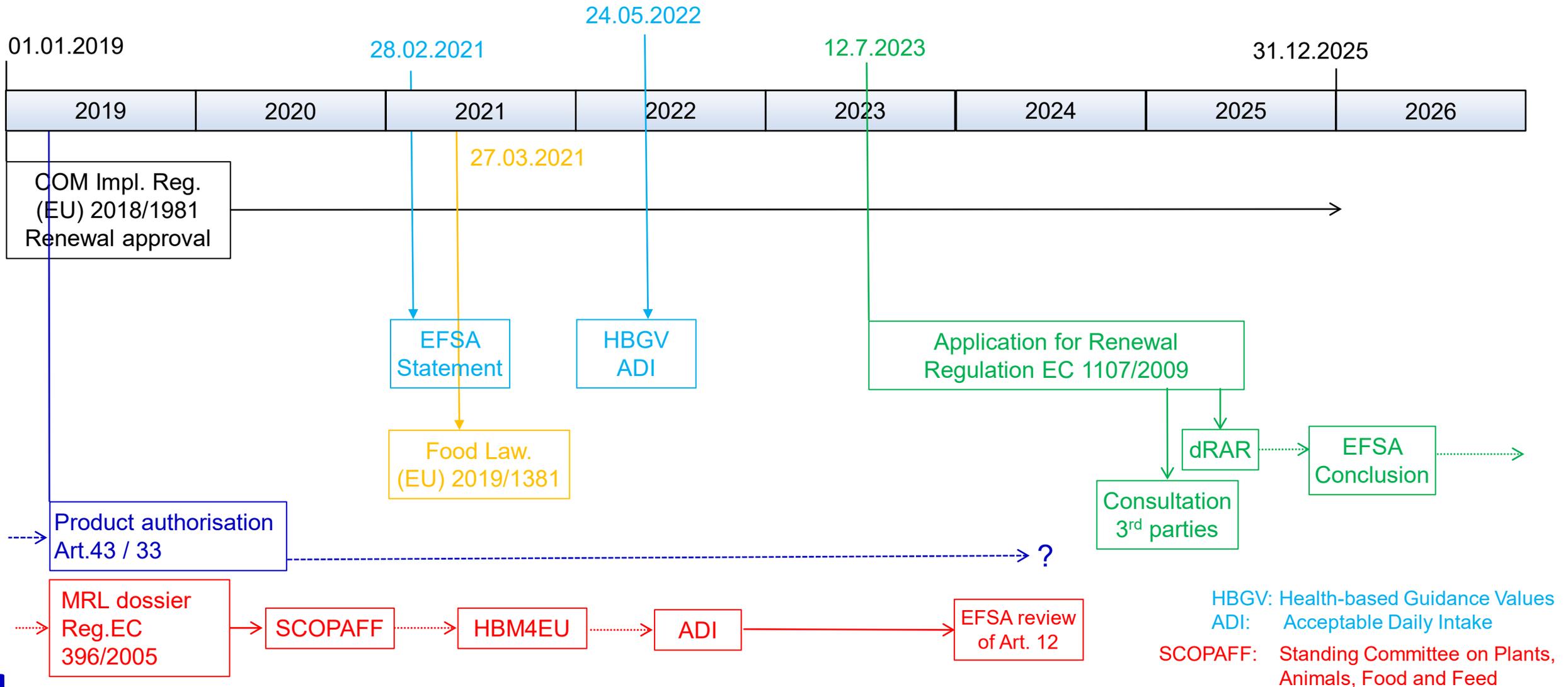


# Expectations for evaluation

- Confirmation received that admissibility check will be received October 2023
- RMS had issues as well with IUCLID, admissibility check not yet received
- dRAR not anticipated before 2025
- RMS indicates that issues will be raised as they occur, rather than waiting until the dRAR is produced
  - Opportunity to offer further data during year



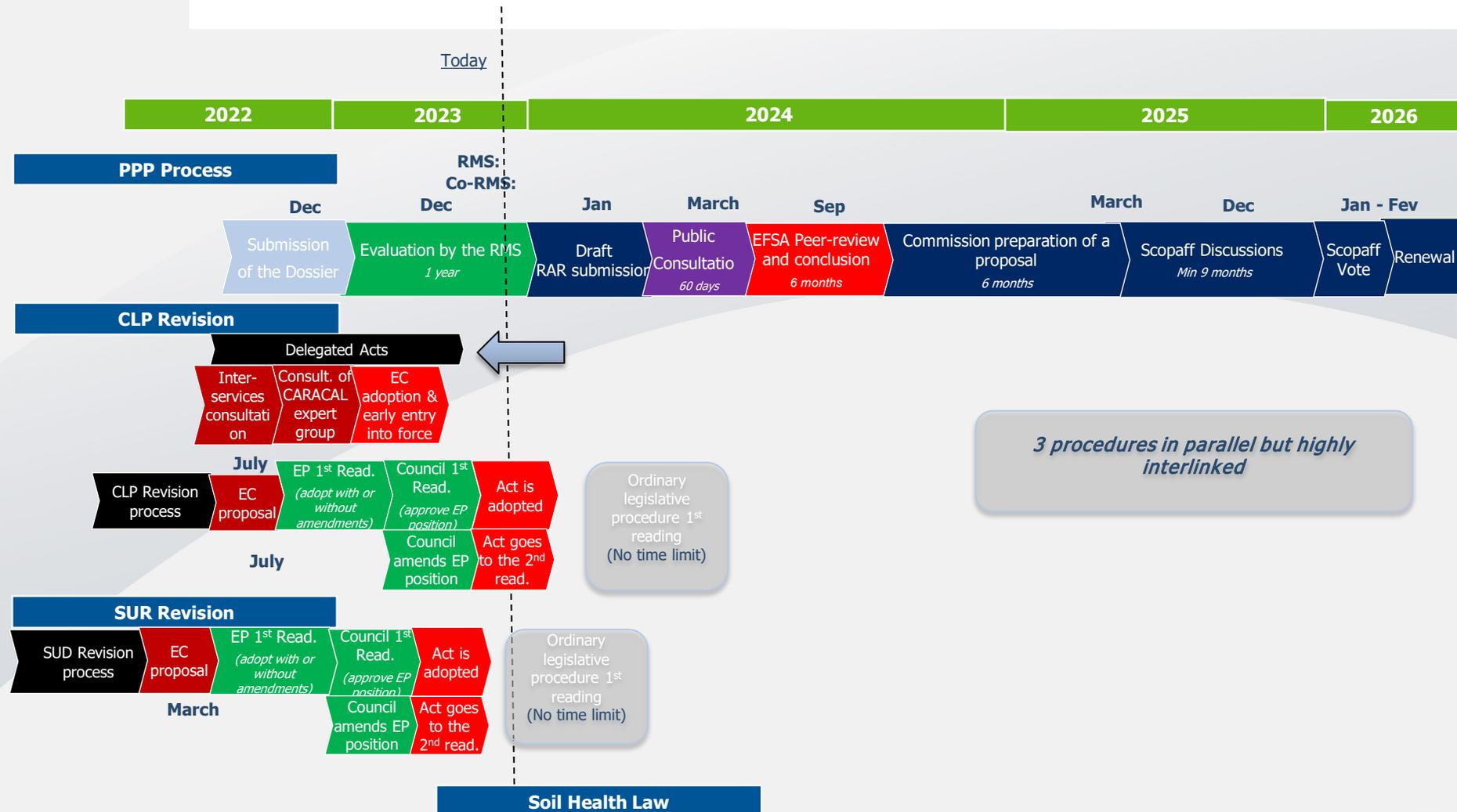
# Renewal of Approval – next round



HBGV: Health-based Guidance Values  
 ADI: Acceptable Daily Intake  
 SCOPAFF: Standing Committee on Plants, Animals, Food and Feed



# Copper Indicative Timeline





# Active substance approval under Reg. EC1107/2009

- Hazard assessment
  - Based on intrinsic properties
- Candidate for Substitution (CfS):
  - Cu does not fulfil exclusion criteria, but
    - Considered having undesirable properties
    - 2 **PBT** criteria
    - Issue: PBT assessment is not applicable to inorganic substances
- Correction via CLP revision underway
- Risk assessment
  - Based on use pattern
    - E.g. risk for aquatic organisms from use on vines
- Standard pesticide GD not applicable for Cu
- EU Commission / EFSA mandate :
  - EFSA Statement “transition metals”
  - published in March 2021



# Ongoing revision of CLP reg. (EC) 1272/2008

31.3.2023

EN

Official Journal of the European Union

L 93/7

COMMISSION DELEGATED REGULATION (EU) 2023/707  
of 19 December 2022

amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/540/EEC and 1909/45/EC, and amending Regulation (EC) No 1907/2006<sup>(1)</sup>, and in particular Article 53(1) thereof,

Whereas:

- (1) Parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008 contain harmonized criteria for the classification of substances, mixtures and certain articles in hazard classes and in differentiations of those hazard classes and set out provisions on how those criteria are to be met as well as the corresponding labelling requirements. Part 3 of Annex I to Regulation (EC) No 1272/2008 contains criteria on health hazards and Part 4 of that Annex contains criteria on environmental hazards.
- (2) The European Green Deal<sup>(2)</sup> sets out the goal to better protect human health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment.
- (3) The need to establish a legally binding hazard identification of endocrine disruptors, based on the definition established by the World Health Organization in 2002<sup>(3)</sup> and building on criteria already developed for plant protection products<sup>(4)</sup> and biocidal products<sup>(5)</sup>, and to apply it across all Union legislation, is highlighted in the Commission's Communication 'Chemicals strategy for sustainability towards a toxic-free environment'<sup>(6)</sup>. That Communication also points to the need to include new hazard classes and criteria in Regulation (EC) No 1272/2008 in order to fully address environmental toxicity, persistency, mobility and bioaccumulation.
- (4) The Commission has conducted an impact assessment on the addition of new hazard classes and criteria in Regulation (EC) No 1272/2008, which encompassed an open public consultation, as well as a stakeholder consultation. The Commission has also consulted the European Chemicals Agency's expert group on persistent, bioaccumulative and toxic chemicals, the competent authorities for REACH and CLP (CARACAL), as well as the subgroup on endocrine disruptors of that expert group, on the new hazard classes and criteria for classification and labelling of substances and mixtures, and has taken into account their scientific advice.

<sup>(1)</sup> OJ L 353, 31.12.2008, p. 1.

<sup>(2)</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal (COM(2019) 640 final, 11 December 2019).

<sup>(3)</sup> WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2002. Global assessment on the state of the science of endocrine disruptor (WHO/IPCS/EDC/02.2). [https://apps.who.int/iris/bitstream/handle/10665/67357/WHO\\_IPCS\\_EDC\\_02.2.pdf](https://apps.who.int/iris/bitstream/handle/10665/67357/WHO_IPCS_EDC_02.2.pdf)

<sup>(4)</sup> Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

<sup>(5)</sup> Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

<sup>(6)</sup> Chemicals Strategy for Sustainability, COM(2020) 667 final.

- Harmonization of hazard assessment
  - “one substance, one assessment”
- Delegated Act issued 19.Dec.2022
  - Introduces new hazard classes
    - ED, **PBT**, vPvB, vPvM, PMT
    - PBT criteria according to REACH provisions, thus excluding inorganic compounds from PBT assessment
- As horizontal legislation to be implemented in sectoral legislation, e.g. PPPR



# Ongoing revision of CLP reg. (EC) 1272/2008 (2)

- PBT assessment was developed for POPs (since 1973)
  - Examples DDT, PCB...
- Not for inorganic substances like minerals:
  - No increasing amounts
    - „hazard“ constant since earth exists
  - Persistency is protective: Not persistent **and** toxic, but persistent **or** toxic
- Confirmed by expert group (Pellston workshop, SETAC 2003)
  - All international conventions and laws adopted this and applied PBT assessment only to organic compounds
  - Same in Europe (REACH, BPR) except reg (EC) 1107/2009
- Harmonization through CLP revision is expected to result in a renewal without CfS status



# SUR: ENVI Draft Report adopted

## Article 3 Definitions

- (1) ‘chemical plant protection product’ means a plant protection product containing a chemical active substance **excluding** invertebrate macro-organisms and **plant protection products containing solely active substances that exert biological control**;
- (3) ‘chemical active substance’ means an active substance other than an active substance that exerts biological control;
- (23) ‘biological control’ means the control of organisms harmful to plants or plant products using invertebrate macro-organisms or an active substance that exerts biological control;
- (23a) ‘**active substance that exerts biological control**’ means an active substance that is
  - (a) a living micro-organism, or
  - (b) **naturally occurring, with the exception of heavy metals and their salts,**
  - or
  - (c) if synthesized, identical to a naturally occurring substance as referred to in Annex -I.

**Annex -I lists the categories of active substances that exert biological control. The Commission shall assess, on a yearly basis, the technical progress and scientific developments with regard to biocontrol with a view to making additions, as appropriate, to the categories listed in Annex -1. For this purpose, the Commission is empowered to adopt delegated acts in accordance with Article 40.**

*ANNEX -I*  
*CATEGORIES OF ACTIVE SUBSTANCES*  
*THAT EXERT BIOLOGICAL CONTROL*

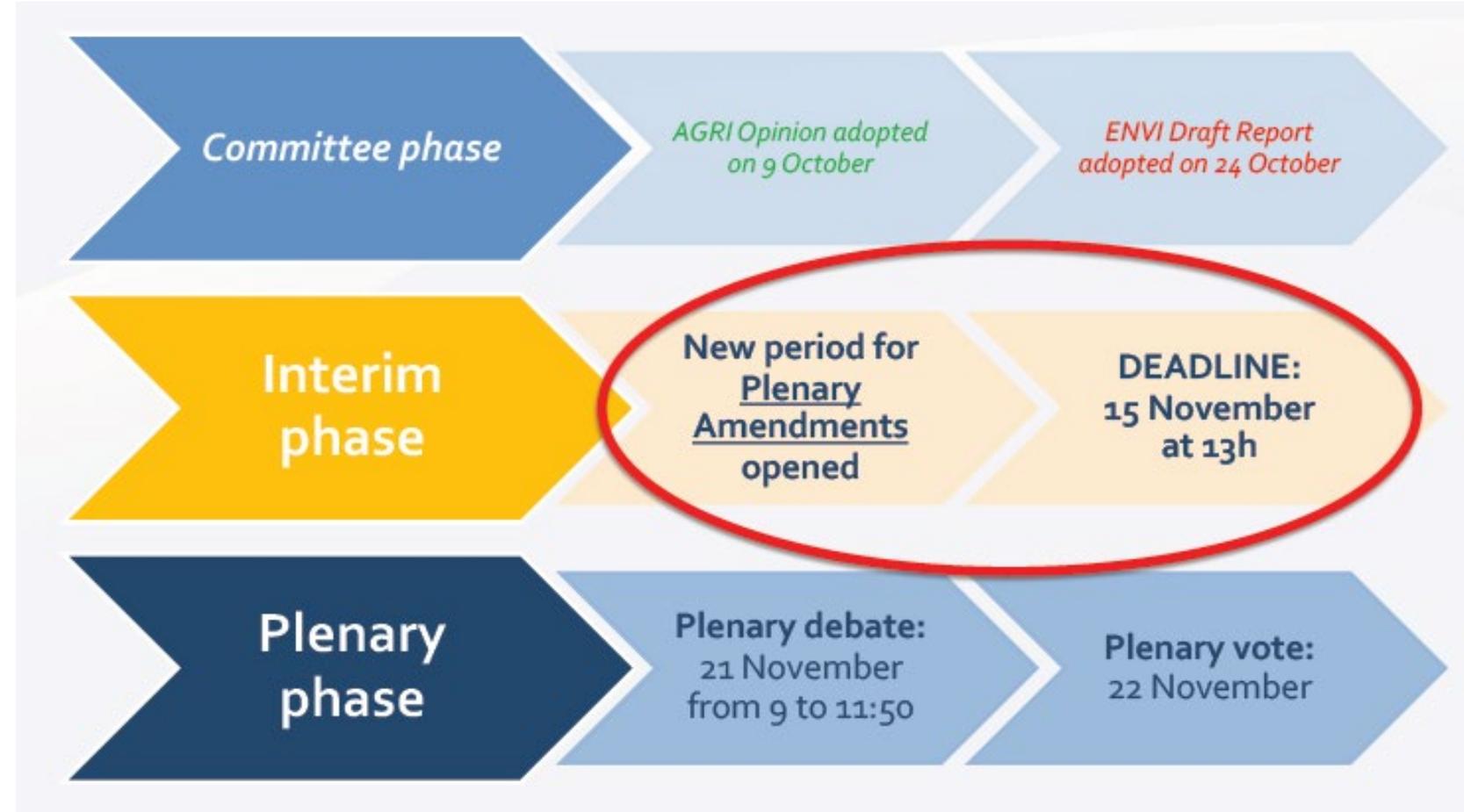
1. Living microorganisms
2. Semiochemicals
3. Extracts from natural sources, in particular plants and algae, and substances produced by microorganisms
4. Substances identical to those produced by biological organisms or that are constituents of biological organisms
- 5. Inorganic substances as occurring in nature, with the exception of heavy metals and their salts**





## SUR – Next steps

- “heavy metal” is a meaningless term according to IUPAC
- Should be avoided in legislation like SUR
- EUCuTF supports amendment to either remove or replace with CFS



Further hurdle: EU Council



# Long-term regulatory process – soil health law

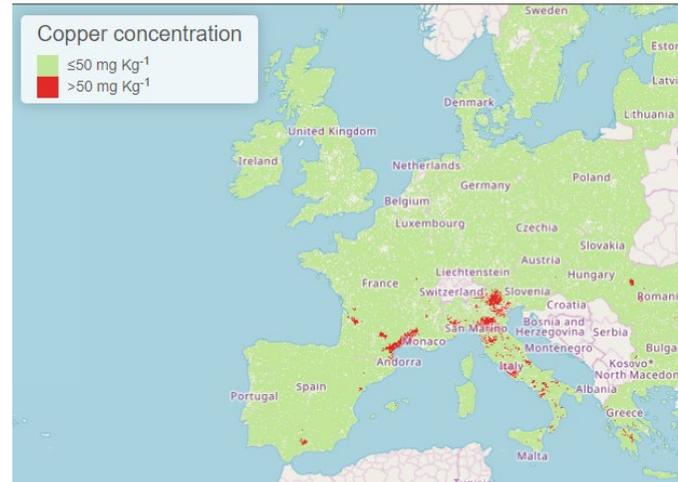
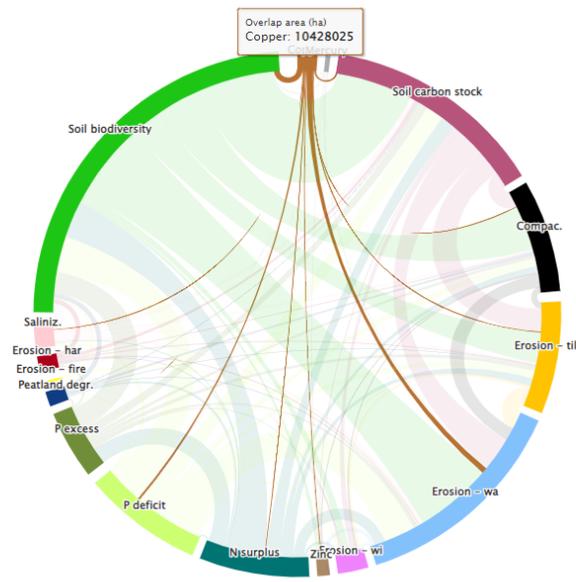
- Proposed legislation issued in 2023
  - EU Soil strategy for 2030 (Brussels, 17.11.2021 COM(2021) 699 final)
    - Mission board advocated to aim for 75% of the soils of the European Union (EU) to be healthy or improving by 2030
  - Zero pollution policy ( Brussels, 8.12.2022 COM(2022) 674 final)
  - Proposal for a Directive on soil monitoring and resilience (soil monitoring law) (Brussels, 5.7.2023) COM(2023) 416 final
    - open for consultation until 3 Nov 2023
    - Annex lists copper as one of the soil contaminants



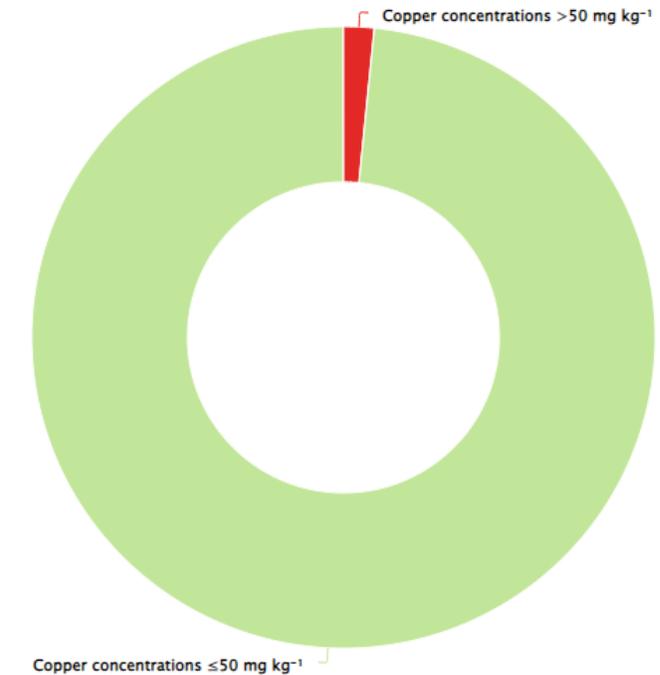
# Long-term regulatory process – soil health law (2)

- JRC EU Soil Observatory Dashboard

Combination of soil degradation indicators by area



Areas with copper concentrations >50 mg kg<sup>-1</sup>, in % (based on areas with data)



Represents 1.6% of soils

Soil degradation indicators

- Copper: copper contamination
- Mercury: mercury contamination
- Zinc: zinc contamination
- Compac.: soil compaction
- Erosion - till: tillage erosion
- Erosion - wa: water erosion
- Erosion - wi: wind erosion
- N surplus: nitrogen surplus
- P deficit: phosphorus deficiency
- P excess: phosphorus excess
- Peatland degr.: loss of organic soils
- Erosion - fire: fire erosion
- Erosion - har: harvest erosion
- Saliniz.: soil salinization
- Soil bio.: loss of soil biodiversity
- SOC: loss of soil organic carbon



## Long-term regulatory process – soil health law (3)

- As Cu does not hamper achieving the EU soil strategy objective, why bother?
  - Being a Directive, individual Member State objectives may be different
  - Ongoing accumulation may be seen as making soils “unhealthier”
- EUCuTF works on demonstrating that arable soils are not accumulating Cu due to fungicide uses
  - Could conclude that vast majority of EU soil health unaffected by Cu (>95%)
- Need to decide how to treat the part of permanent crops exceeding any MS trigger
  - And how to avoid future accumulation



# PEC<sub>soil</sub> and potential accumulation

- “No loss” assumption too conservative
  - No plant intercept
  - Low export with harvest from treated plot
  - Low transport to lower soil horizons
- However...
- For arable crops
  - 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
  - **Confirm with monitoring data**
    - **Access to LUCAS data finally obtained**

Environmental Research 161 (2018) 291–298



Contents lists available at ScienceDirect

Environmental Research

journal homepage: [www.elsevier.com/locate/envres](http://www.elsevier.com/locate/envres)

A step towards a holistic assessment of soil degradation in Europe: Coupling on-site erosion with sediment transfer and carbon fluxes



P. Borrelli<sup>a,b,\*</sup>, K. Van Oost<sup>c</sup>, K. Meusburger<sup>b</sup>, C. Alewell<sup>b</sup>, E. Lugato<sup>a</sup>, P. Panagos<sup>a</sup>

<sup>a</sup> European Commission, Joint Research Centre, Directorate for Sustainable Resources, Ispra, Italy

<sup>b</sup> Environmental Geosciences, University of Basel, Switzerland

<sup>c</sup> TECLIM - Georges Lemaitre Centre for Earth and Climate Research, Université Catholique de Louvain, Louvain-la-Neuve BE 1348, Belgium

## ABSTRACT

Soil degradation due to erosion is connected to two serious environmental impacts: (i) on-site soil loss and (ii) off-site effects of sediment transfer through the landscape. The potential impact of soil erosion processes on biogeochemical cycles has received increasing attention in the last two decades. Properly designed modelling assumptions on effective soil loss are a key pre-requisite to improve our understanding of the magnitude of nutrients that are mobilized through soil erosion and the resultant effects. The aim of this study is to quantify the potential spatial displacement and transport of soil sediments due to water erosion at European scale. We computed long-term averages of annual soil loss and deposition rates by means of the extensively tested spatially distributed WaTEM/SEDEM model. Our findings indicate that soil loss from Europe in the riverine systems is about 15% of the estimated gross on-site erosion. The estimated sediment yield totals  $0.164 \pm 0.013 \text{ Pg yr}^{-1}$  (which corresponds to  $4.62 \pm 0.37 \text{ Mg ha}^{-1} \text{ yr}^{-1}$  in the erosion area). The greatest amount of gross on-site erosion as well as soil loss to rivers occurs in the agricultural land (93.5%). By contrast, forestland and other semi-natural vegetation areas experience an overall surplus of sediments which is driven by a re-deposition of sediments eroded from agricultural land. Combining the predicted soil loss rates with the European soil organic carbon (SOC) stock, we estimate a SOC displacement by water erosion of  $14.5 \text{ Tg yr}^{-1}$ . The SOC potentially transferred to the riverine system equals to  $2.2 \text{ Tg yr}^{-1}$  (~15%). Integrated sediment delivery-biogeochemical models need to answer the question on how carbon mineralization during detachment and transport might be balanced or even off-set by carbon sequestration due to dynamic replacement and sediment burial.

Journal of Consumer Protection and Food Safety (2022) 17:5–20  
<https://doi.org/10.1007/s00003-022-01363-3>

Journal of Consumer Protection and Food Safety  
 Journal für Verbraucherschutz und Lebensmittelsicherheit

## RESEARCH ARTICLE



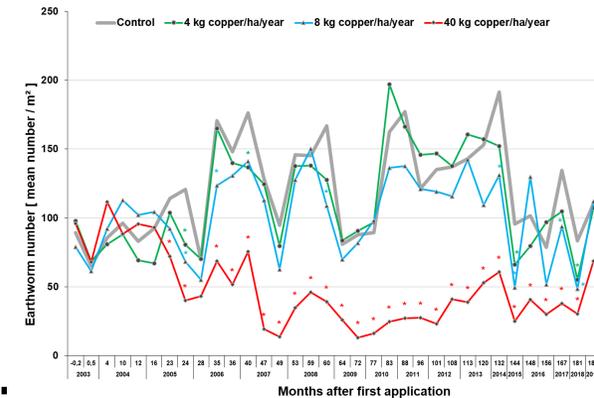
## Phosphorus plant removal from European agricultural land

Panos Panagos<sup>1</sup> · Anna Muntwyler<sup>1</sup> · Leonidas Liakos<sup>1</sup> · Pasquale Borrelli<sup>2</sup> · Irene Blavetti<sup>1</sup> · Marilja Bogonos<sup>3</sup> · Emanuele Lugato<sup>1</sup>



# Environmental Risk Assessment - Terrestrial

- GLP long-term earthworm field study continued
  - New independent Expert panel of 5 independent scientists will be called on after 2023 fall sampling
- Other parameter measured to assess ecosystem service and soil health
  - Soil bulk density (also suggested in soil health law)
  - Water infiltration capacity
  - Water Holding Capacity (WHC) (also suggested in soil health law)
  - Soil penetration resistance
  - Microbial biomass (also suggested in soil health law)
- **No obvious influence on those parameter observed with increasing Cu concentration**



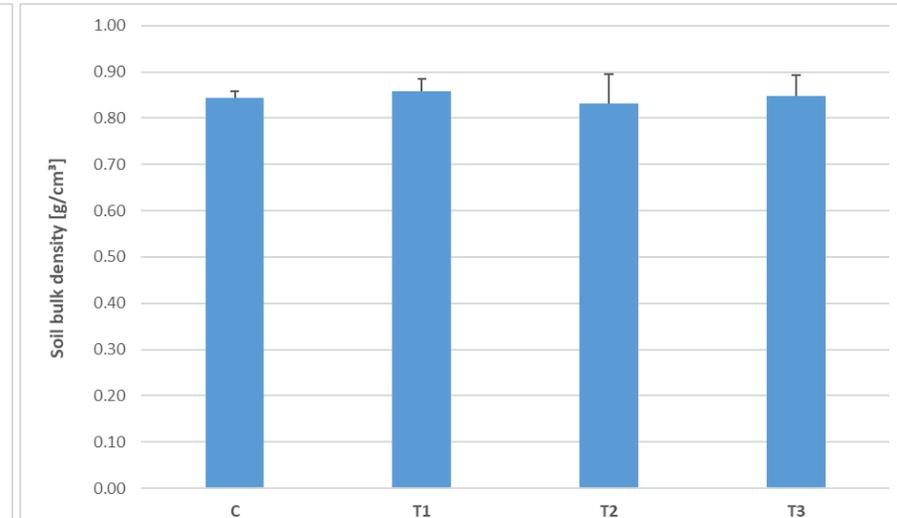
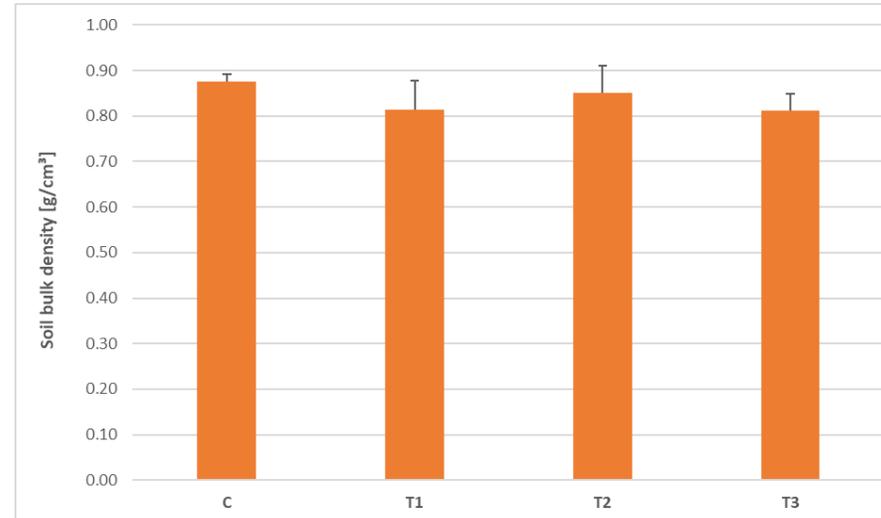


# Phys-chem parameter long-term field study

- Soil density

- Niefern

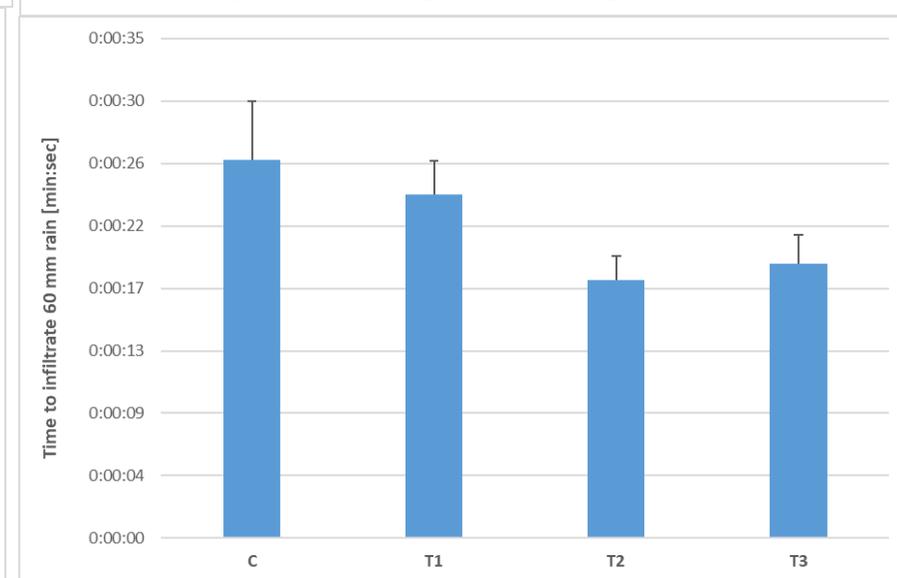
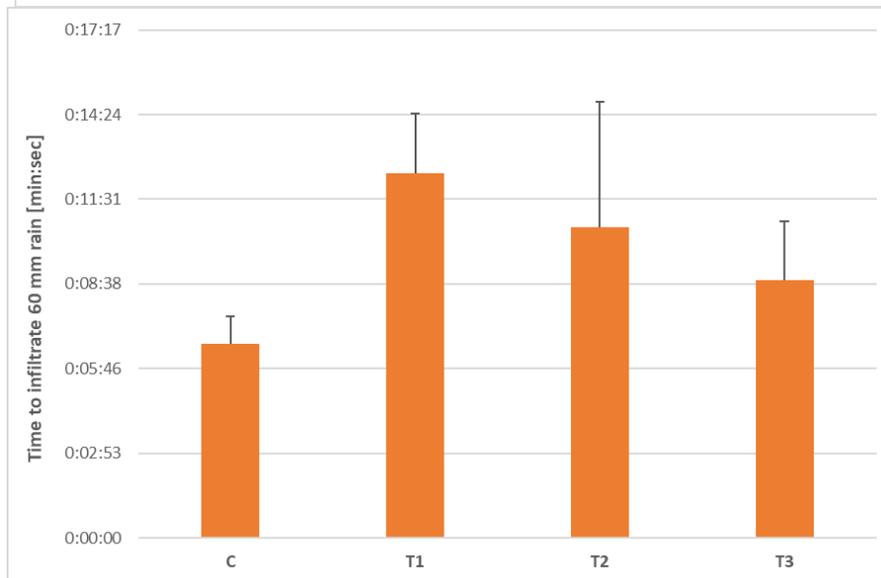
- Heiligenzimmern



- Water infiltration Capacity

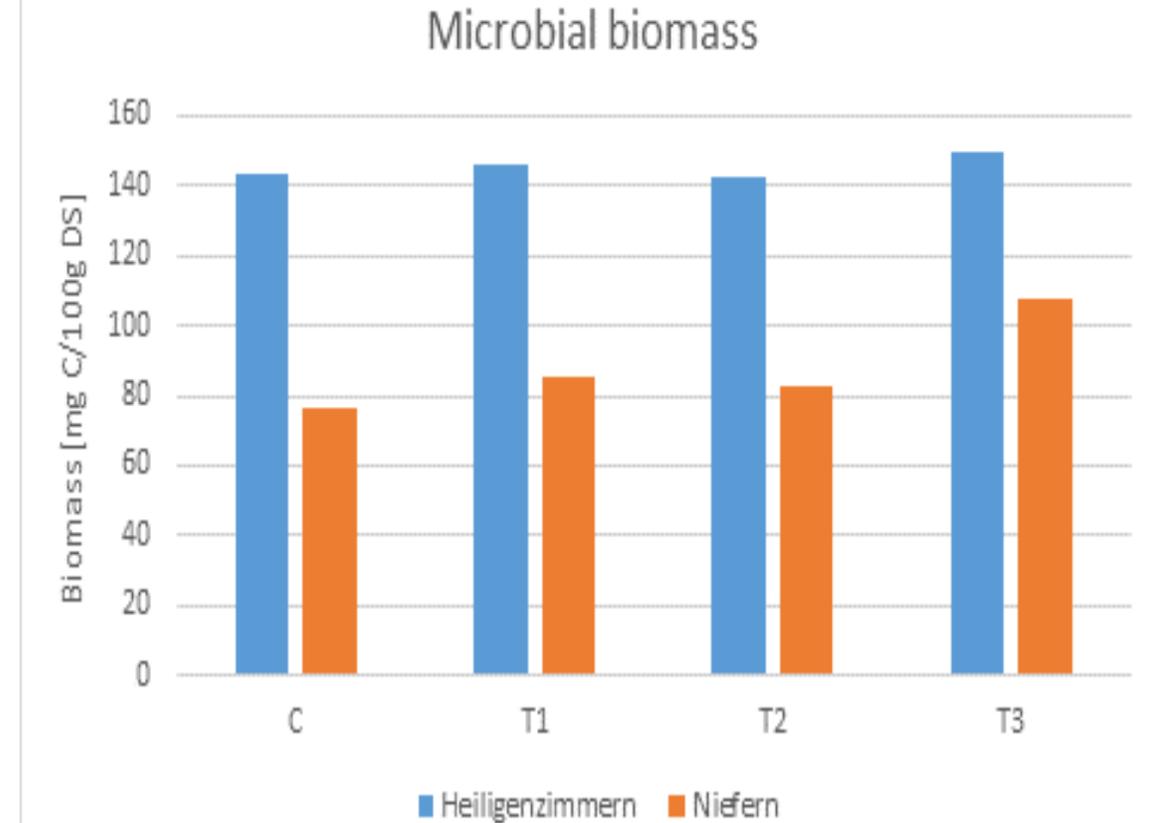
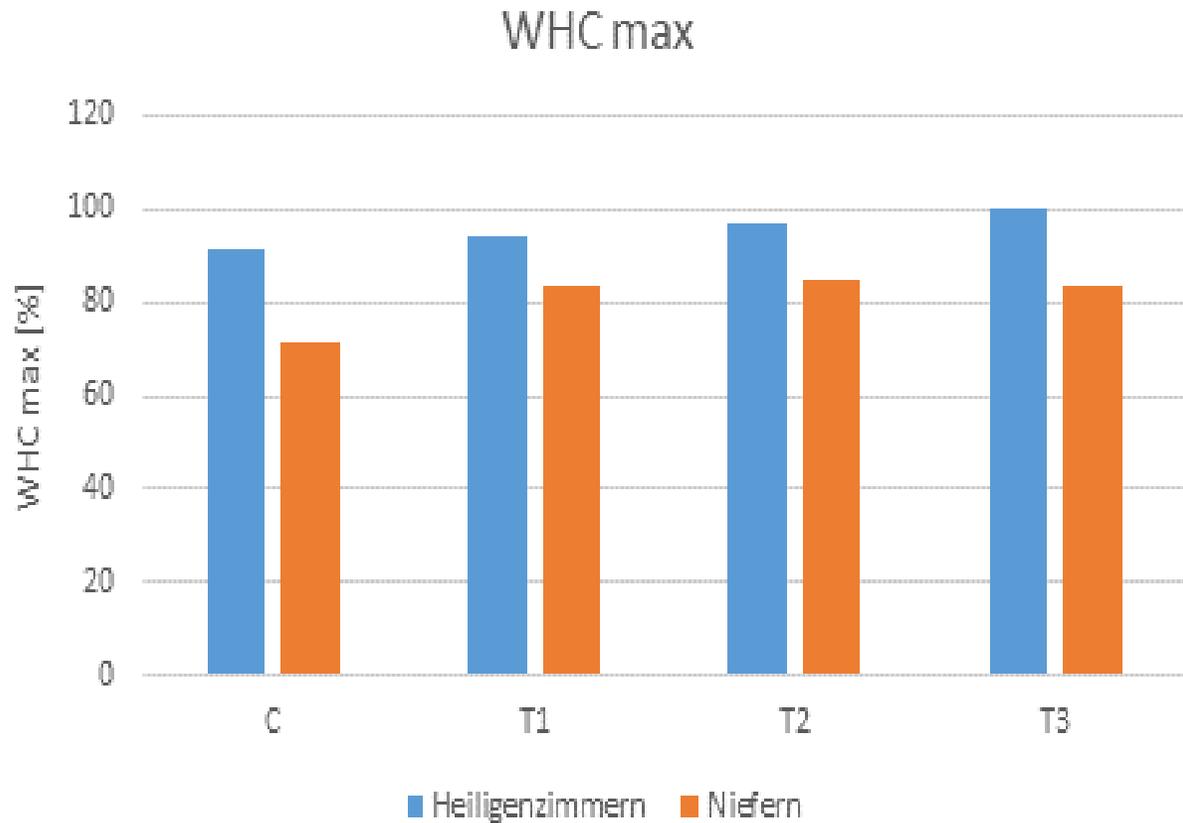
- Niefern

- Heiligenzimmern



C = control T1 = 4 kg/ha T2 = 8 kg/ha T3 = 40 kg/ha, no more application

# Phys-chem parameter long-term field study

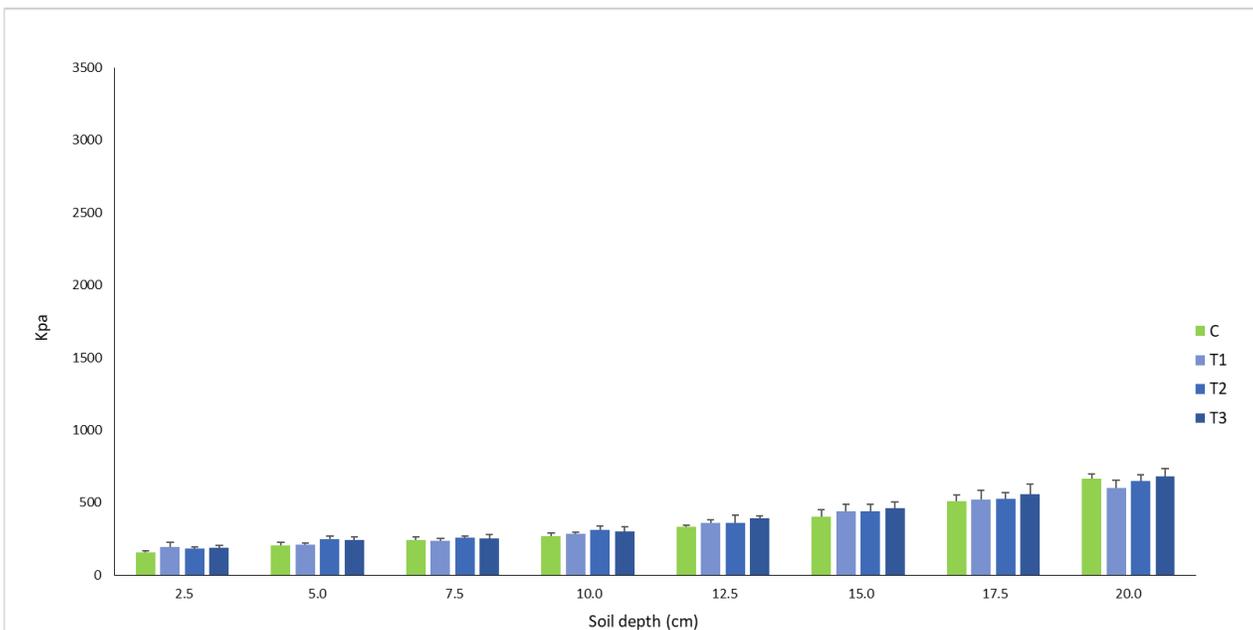
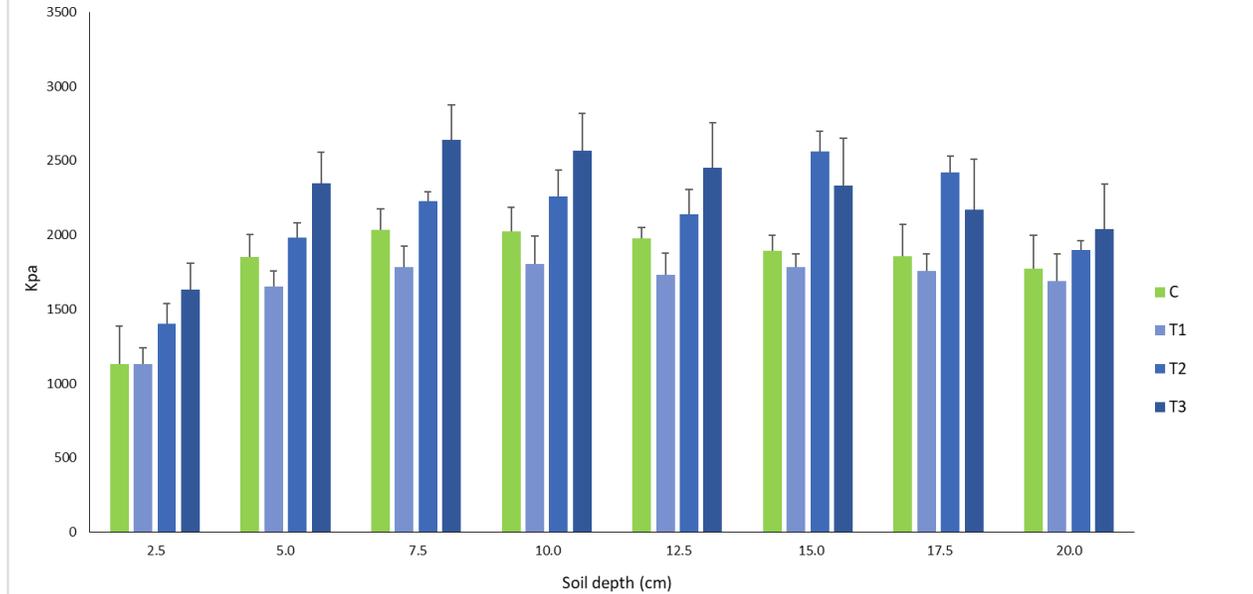


C = control T1 = 4 kg/ha T2 = 8 kg/ha T3 = 40 kg/ha, no more application

# Phys-chem parameter long-term field study

- Soil penetration resistance
  - Heiligenzimmern
  - Niefern

C = control T1 = 4 kg/ha T2 = 8 kg/ha  
T3 = 40 kg/ha, no more application





# Earthworm vineyard study – DE since 2020

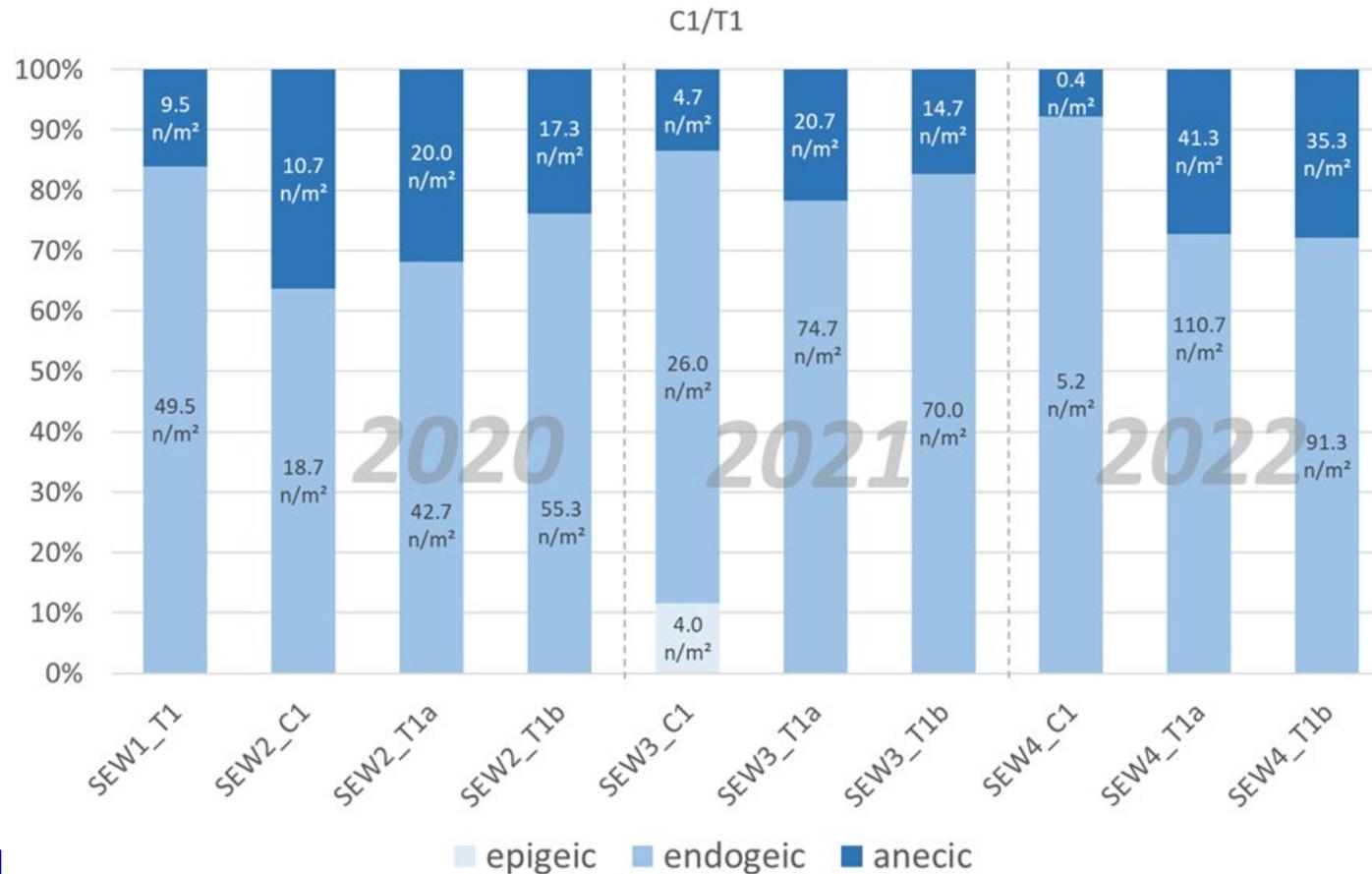
- 2 vineyards with flexible dose scheme for 3 years
  - Corresponding to 28 kg / 7 y with peak at 6 kg/ha
    - Conc Cu<sub>soil,0-20cm</sub>: 87 mg/kg (conventional) and 113 mg/kg (bio)



Site 1:  
Neckarwestheim

Applications Cu  
2020: 3 kg/ha;  
2021: 6 kg/ha,  
2022: 3 kg/ha

Additional plot  
with phyto-  
extraction seeds

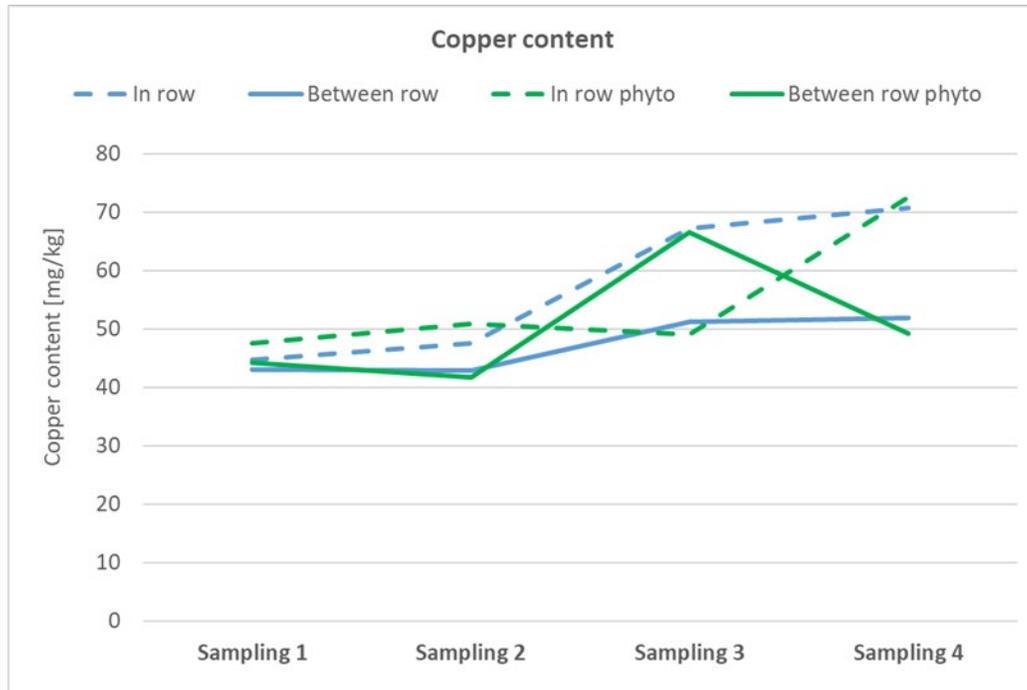




# Results soil location T1 Neckarwestheim

Soil horizon: 0 – 5 cm

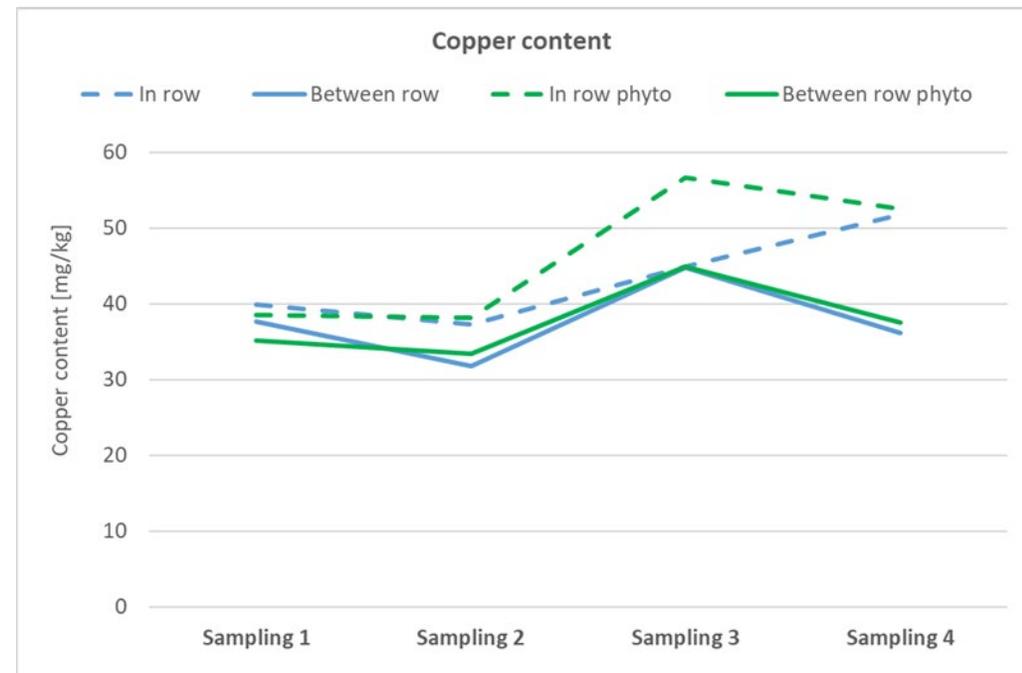
T1	In row	Between row	In row phyto	Between row phyto
Sampling 1	45	43	48	44
Sampling 2	48	43	51	42
Sampling 3	67	51	49	67
Sampling 4	71	52	73	49



Observed average increase; 13 mg/kg and 10 mg/kg (phyto)  
 Expected average increase: 19 mg/kg

Soil horizon: 0 – 20 cm

T1	In row	Between row	In row phyto	Between row phyto
Sampling 1	40	38	39	35
Sampling 2	37	32	38	33
Sampling 3	45	45	57	45
Sampling 4	52	36	53	38



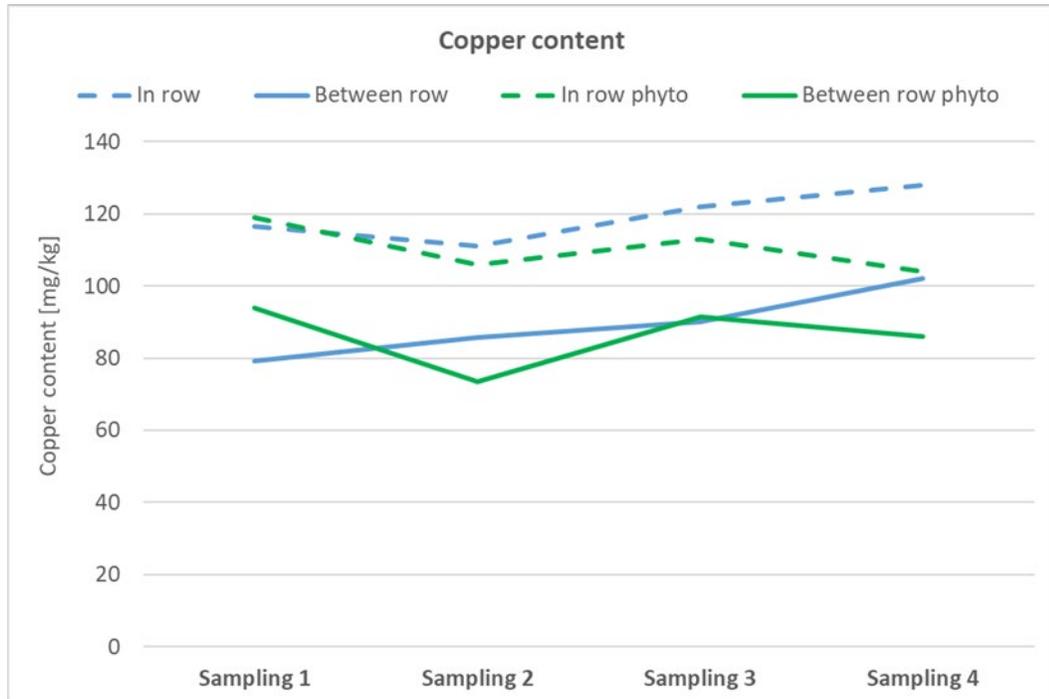
1.2 mg/kg and 5.5 mg/kg (phyto)  
 4.7 mg/kg



# Results soil location T2 Winnenden

Soil horizon: 0 – 5 cm

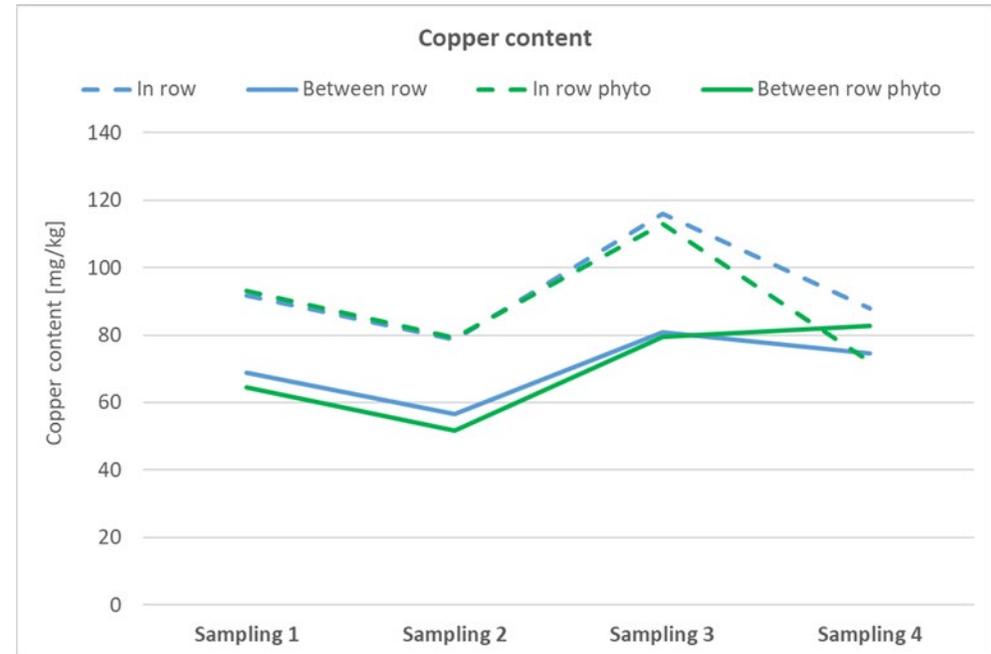
T2	In row	Between row	In row phyto	Between row phyto
Sampling 1	117	79	119	94
Sampling 2	111	86	106	74
Sampling 3	122	90	113	92
Sampling 4	128	102	104	86



Observed average increase; 21 mg/kg and -10 mg/kg (phyto)  
 Expected average increase: 17 mg/kg

Soil horizon: 0 – 20 cm

T2	In row	Between row	In row phyto	Between row phyto
Sampling 1	92	69	93	64
Sampling 2	79	57	79	52
Sampling 3	116	81	113	79
Sampling 4	88	75	72	83



3.9 mg/kg and 10.6 mg/kg (phyto)  
 4.3 mg/kg



# Earthworm vineyard studies DE and FR

- While earthworm populations are healthy and diverse, results for soil accumulation is not conclusive
  - Similar situation on the 2 trials running in FR
- There are surprisingly little reliable data on soil copper concentration increase at an average of 4 kg/ha
  - What is the true long-term accumulation at that dose?
- Phyto-extraction plant concentrations is yet disappointing
  - Maximum removal of 108 g/ha
  - But still potential for optimization
- EUCuTF decided to extend study in DE and is likely to do so for FR
  - Improved and extended soil sampling and improved phyto-remediation seeds



# Conclusion

- Renewal will not be completed before 2027
  - Risk assessments improved
    - Expect adequate scientific evaluation if transition metal statement is implemented
- Addressing accumulation is crucial for improving image of Cu
  - Monitoring data collection and interpretation incl. Biomonitoring
- Socio-economic study shows negative impact if Cu is lost as ppp
  - Effects on farm economics, organic farming and resistance management
- EUCuTF has the ambition to defend the use of copper sustainably
  - Extraordinary tool deserving consideration for conventional and organic farming
  - Would like to encourage dedicating part of the research funds spent on preserving copper as ppp



Thank you for your attention !



# Backup slides



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. M.

Kostas Koutsoumanis, Claude Lam.

Josef R. Schlatter, D.

Gordon A.A. F.

Agnès de

### Abstract

Copper is a... farming pes... effects. In th... guidance values... resolve the divergen... manifestation in the shor... copper homeostasis and its tes... 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 contribution 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 cop... important contribute... oral source... adult...

**Keywords:** copper,

**Requestor:** European Commission

**Question number:** EFSA-Q-2020-00399

**Correspondence:** MESE@efsa.europa.eu

# Consumer Risk Assessment

- EFSA draft opinion



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.

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.



# Consumer Risk Assessment

- EFSA reasoned opinion

Although residues in other small fruits and berries are minor contributors to the overall consumer exposure, a risk management decision has to be taken on whether it is appropriate to increase the existing MRLs for these crops, given that a potential consumer intake concern could not be excluded.



- Contradicting messages regarding the contribution of Cu fungicides to consumer intake!

Modification of the existing MRLs for copper compounds in other small fruits and berries

Giulio

In a decision of the European Food Safety Authority (EFSA) on 8 July 2022, the maximum residue levels (MRLs) for copper compounds in other small fruits and berries were reviewed. The purpose of the review was to derive MRL proposals for copper compounds in other small fruits and berries, taking into account the methods for enforcement of MRLs and the available data on the matrices under consideration at the time of the review. The indicative risk assessment results, EFSA concluded that the MRLs resulting from the intended and existing uses of copper compounds present a risk to consumer health. Although residues in other small fruits and berries are minor contributors to the overall consumer exposure, a risk management decision has to be taken on whether it is appropriate to increase the existing MRLs for these crops, given that a potential consumer intake concern could not be excluded.

© 2022 Wiley-VCH Verlag GmbH & Co. KGaA on behalf of the European Food Safety Authority.

**Keywords:** copper compounds, copper hydroxide, other small fruits and berries, pesticide, MRL, consumer risk assessment

**Requestor:** European Commission

**Question number:** EFSA-Q-2021-00463

**Correspondence:** pesticides.mrl@efsa.europa.eu



# Consumer Risk Assessment

- Not really an issue, but...
  - EFSA opinion resulted in an HBGV (ADI) of 0.07 mg/kg bw significantly lower than the current 0.15 mg/kg bw
    - Although EFSA opinion declares PRIMo not appropriate for Cu it will be used for renewal
  - Significant discrepancy between
    - PRIMo outcome resulting in daily uptake between 1.4 und 8 mg
    - Studies determining actual uptake to 1-2 mg per day
- Renewal should use the ADI of 0.15 mg/kg bw while new mandate to review MRLs should use the HBGV of 0.07 mg/kg bw
  - Inconsistencies are programmed if conducted in this way
- With new HBGV high percentages of allowance will result, which may trigger raising concerns although in a perfectly healthy situation

