

Environmental Risk Assessment (ERA) of Copper Compounds in the EU Active Substance Evaluation: State of Play

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EU Pesticides Database

EU Pesticides database - European Commission - Internet Explorer bereitgestellt von UBA - Umweltbundesamt Dessau

http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/pt

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Sustainable use of pesticides

Approval of active substances

Authorisation of Plant Protection Products

Maximum Residue levels

ALL TOPICS

Copper compounds Approved

Status under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC)

Legislation	2009/37/EC, Reg. (EU) 2015/232, Reg. (EU) No 540/2011		
Date of approval	01/12/2009	Expiration of approval	31/01/2018
RMS	FR	Risk Assessment	EFSA
Co-RMS	DE		
Category	BA, FU	Review Report	Confirmatory data 2015 Inclusion 2009
Type	Candidate for Substitution (CS)	Cfs - criteria	two PBT criteria

Authorisation at national level

Authorised in	In progress for
AT, BE, BG, CY, CZ, DE, EL, ES, FR, HR, HU, IT, LT, LU, LV, MT, PL, PT, RO, SI, SK, UK	

Classification Reg. 1272/2008

No classification

Toxicological information

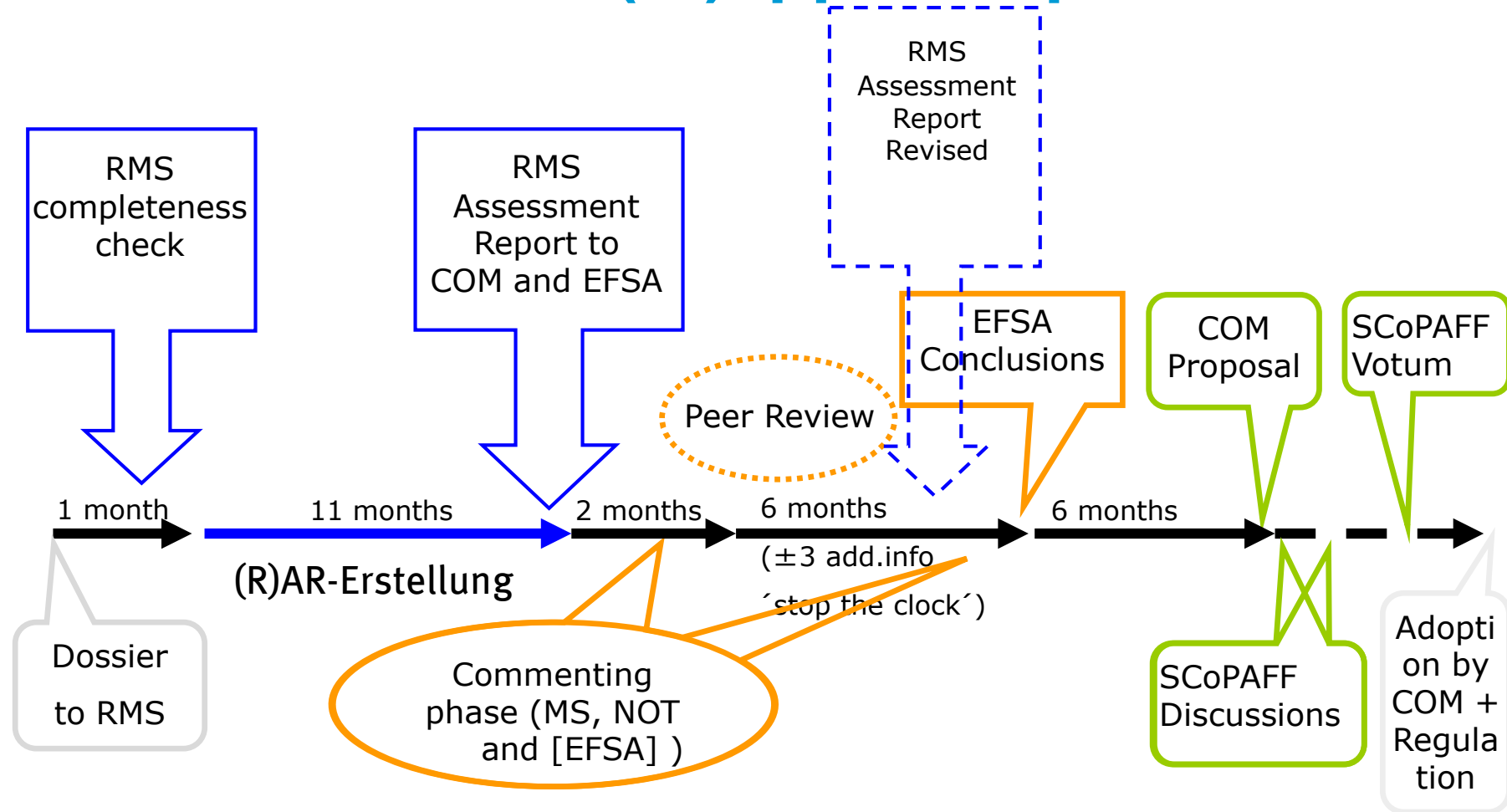
Reference values		Source	Remark
ADI	0.15	EFSA 08	
ARfD	Not applicable	EFSA 08	
AOEL	0.072	EFSA 08	

Other

0,5 JECFA 1982

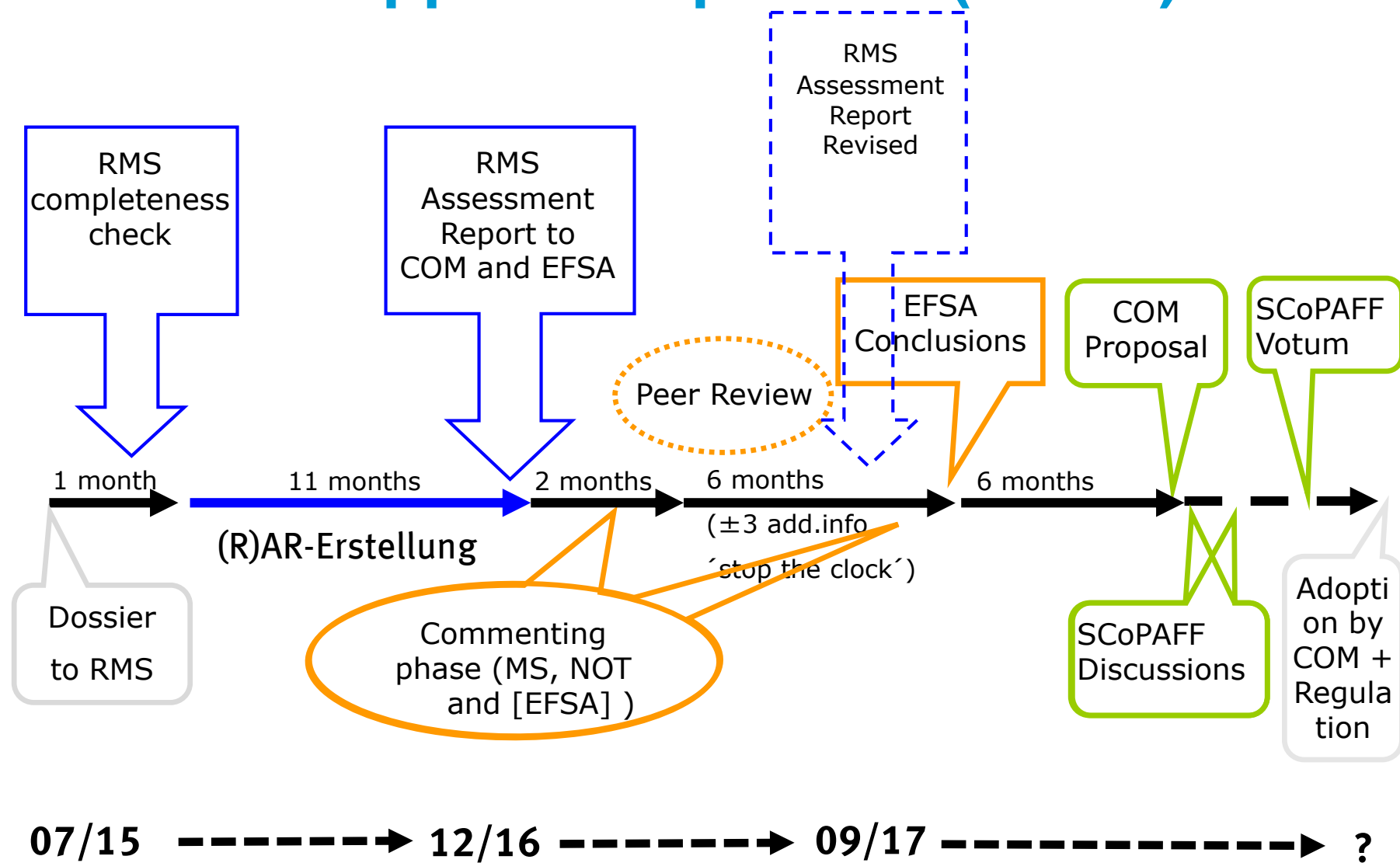
Where no units are shown, the ADI and AOEL are expressed in mg/kg bw per day.

Active substance (re)approval procedure



BLUE = (R)AR | ORANGE = PEER REVIEW | GREEN = SCOPAFF (STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED, SECTION PHYTOPHARMACEUTICALS, LEGISLATION)

Renewal Copper Compounds (AIR III)



Representative PPPs and intended uses

FUNGURAN OH 50 WP (Copper hydroxide), NORDOX 75 WG (copper oxide),
 CURENOX 50 WG (copper oxychloride), CUPROXAT SC (tribasic copper sulfate)
 POLTIGLIA CAFFARO 20 DF NEW (Bordeaux mixture)

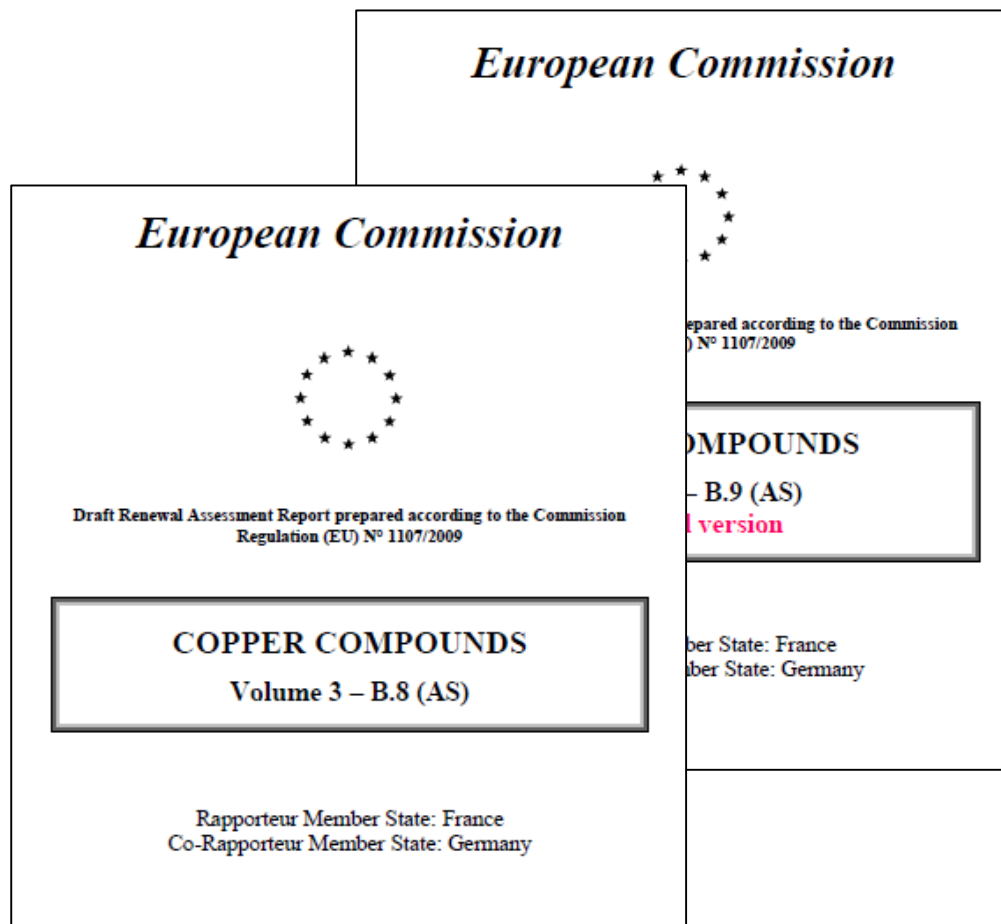
Crop/ crop group	Application method	Spray volume [L/ha]	Maximum individual application rate [kg a.s./ha]	Number of applications	Application timing (growth stage)
Vineyards	Airblast sprayer	400-1000	1.25	8 (7-d interval)	BBCH 12-89
Vineyards	Airblast sprayer	400-1000	1.25	3 (21-d interval)	BBCH 91-11
Tomato	Foliar spraying	200-1000	0.85	8 (7-d interval)	BBCH 10-89
Cucurbits	Foliar spraying	200-1500	0.85	8 (7-d interval)	BBCH 10-89

Maximum total rate per year (kg Cu/ha/year)

- **Grapes: 6.0 (8.0)** = flexible dosing regime: max. 30 kg Cu/ha/year in any rolling 5 year period and 8 kg Cu/ha/year in any single year
- **Tomato/Cucurbits: 6.0**

Risk Assessment Report (12/16)

- Extensive report
- Huge amount of data (including a lot of published literature)
- E-Fate (a.s. and PPP): 833 pages
- Ecotox (a.s. and PPP): 1650 pages



Risk Assessment Report (12/16)

*Attention! Preliminary!
(since peer-review
not finalized yet)*

Proposed decision (RMS):

“Copper compounds can be renewed and authorizations of PPP can be granted in at least one member state. However, considering the outcomes of the evaluation, risk is not acceptable for uses with annual application exceeding 4 kg Cu/ha.”

E-Fate – discussions and decisions

Fate and behaviour of copper:

- **No degradation in soil, no half-life estimated**
- **Cu background values (geo- and anthropogenic) derived from soil monitoring data**
- **New adsorption endpoint ($K_{d_{OC}}$) to be derived from literature data for > 400 soils, pH-dependency of Cu considered (RMS work on-going)**
- **Correction factor to estimate dissolved from total copper content in water proposed by the Notifier was not accepted**

E-Fate – discussions and decisions

How are fate properties considered in the exposure assessment?

- **PEC_{soil}: long-term accumulation (10 & 20 y) + background values**
- **PEC_{surface water/sediment} (RMS work on-going):**
 - **Standard FOCUS models (Step1+2) + risk mitigation: spray-drift, run-off, drainage considered as entry routes**
 - **DissT₅₀ in water not considered: instead DegT₅₀ of 1000 days (whole water/sediment-system); the Kd_{OC} value in FOCUS modeling already accounts for partitioning of Cu from the water to sediment (avoid double counting)**
 - **IDMM-model proposed by Notifier not accepted**
- **PEC_{groundwater} (RMS work on-going):**
 - **Standard FOCUS modeling with PEARL and PELMO: use DT₅₀ = 1.000.000 days, Kd_{OC} value, background concentration in soil**

Ecotox – discussions and decisions

Birds & Mammals

- **EFSA Guidance (2009) not applicable, Weight-of-Evidence mainly based on literature data**
- **Acute risk assessment not finalized (data gap)**
- **Long-term risk acceptable (except: see below) if restricted to 5 kg Cu/ha during bird breeding season**
- **Long-term risk assessment not finalized for omnivorous and frugivorous birds, large herbivorous and frugivorous mammals (data gap)**
- **Risk from secondary poisoning acceptable (earthworm and fish eating birds/ mammals)**

Ecotox – discussions and decisions

Aquatic organism

- **EFSA Guidance (2013) not metal-specific (e.g. no consideration of bioavailability)**
- **Extensive set of acute and chronic toxicity data (lab testing and micro-/mesocosm)**
- **Biotic Ligand Model (BLM) proposed by Notifier not accepted**
- **Refined acute and long-term risk assessment by HC₅-SSD (species sensitivity distribution), Assessment factor: 3**
- **Refined risk assessment by microcosm (NOEC = 12 µg Cu/L total), Assessment factor: 2**
- **Can acceptable (refined) risk be shown for all scenario-organism combinations? (recalculation by RMS pending)**

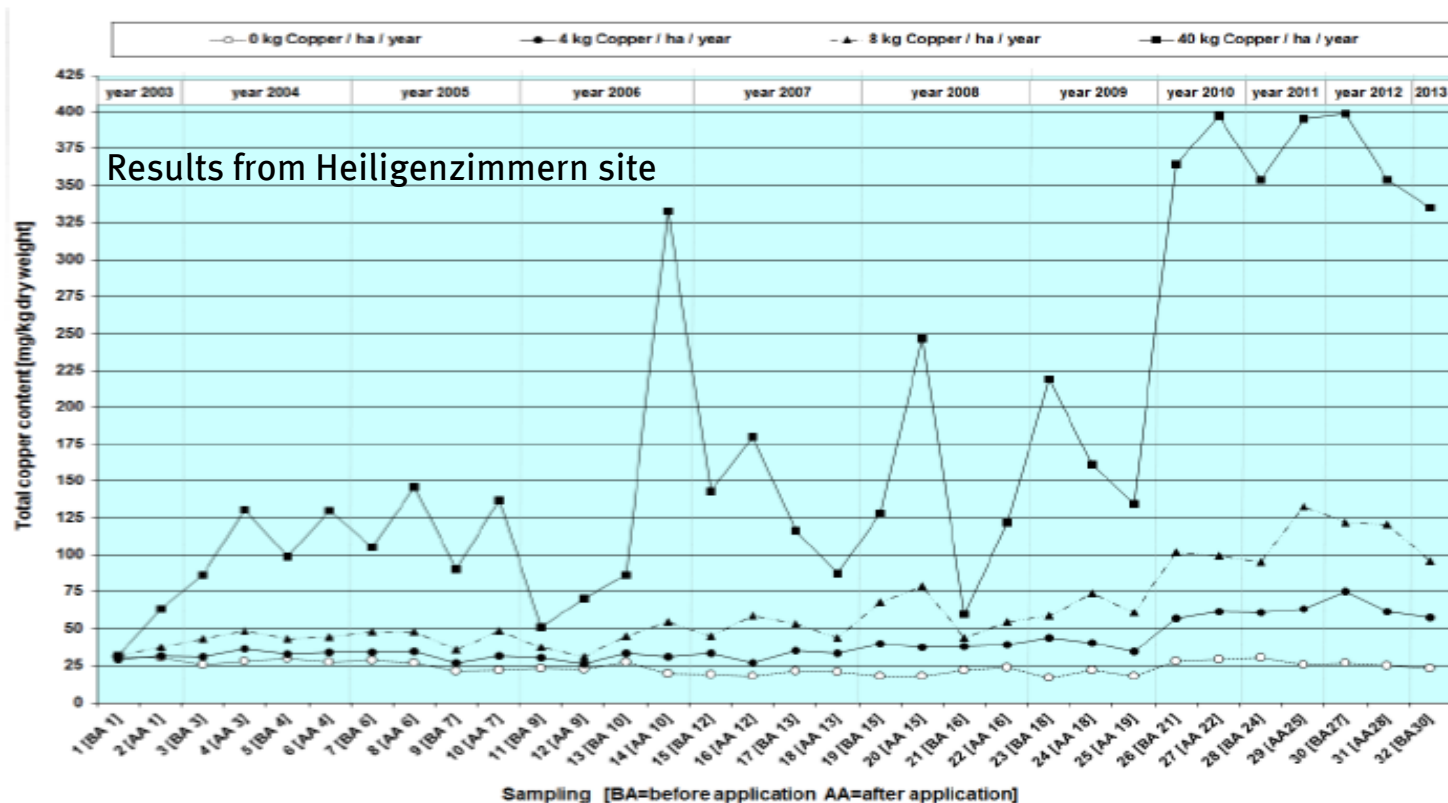
Ecotox – discussions and decisions

Soil organism (earthworms and soil arthropods)

- **EFSA Guidance (2002) not metal-specific (e.g. no consideration of bioavailability)**
- **Extensive set of acute and chronic toxicity data (lab testing, field studies, monitoring data)**
- **Lab-to-field correction factor (4) and normalization to reference soil (regression model) proposed by Notifier not accepted**
- **Refinement by HC₅-SSD (species sensitivity distribution) proposed by Notifier not accepted (no guidance available)**
- **Available data indicate earthworms as most sensitive group**
- **Earthworm monitoring data from JKI, etc. only “informative”**

Ecotox – discussions and decisions

Earthworm long-term field study: Cu accumulation in soil (0-5 cm)

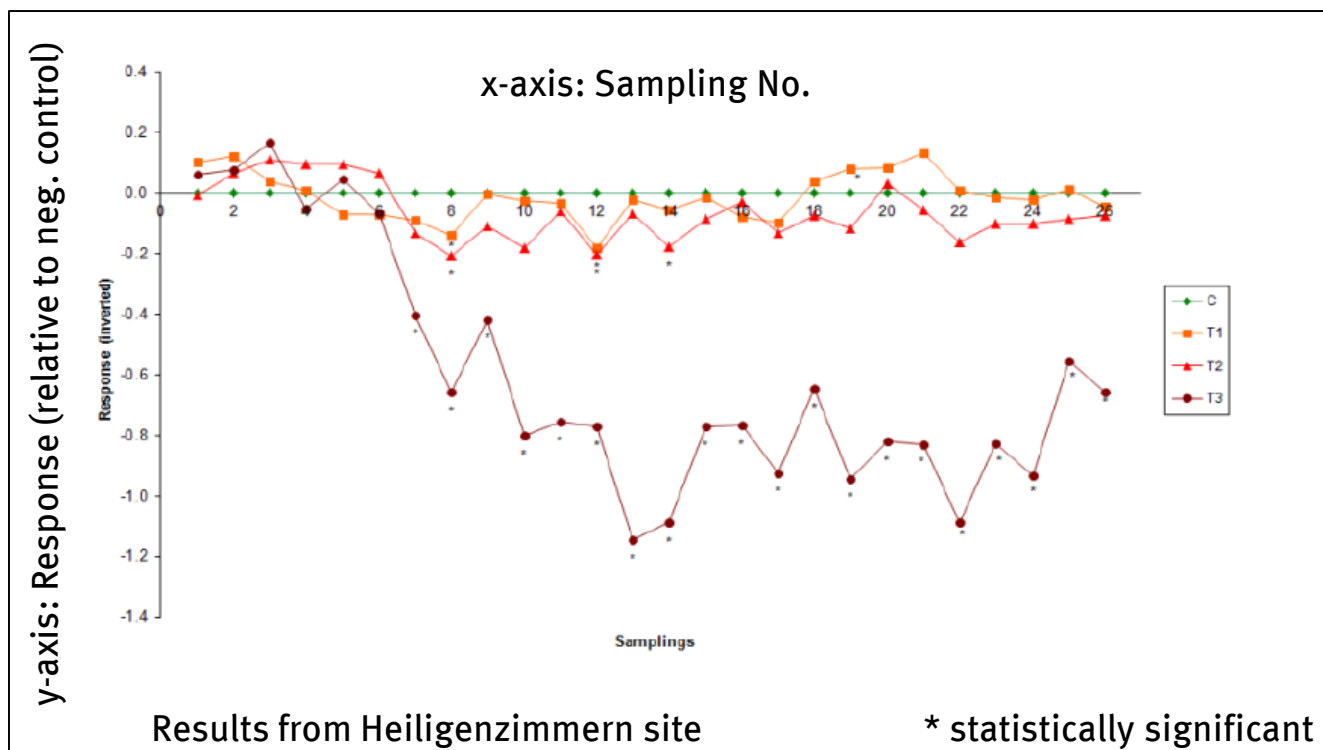


0 = Water (negative control)

T1 = 4 kg Cu/ha/year; T2 = 8 kg Cu/ha/year; T3 = 40 kg Cu/ha/year (positive control)

Ecotox – discussions and decisions

Earthworm long-term field study: Community analysis (PRC)

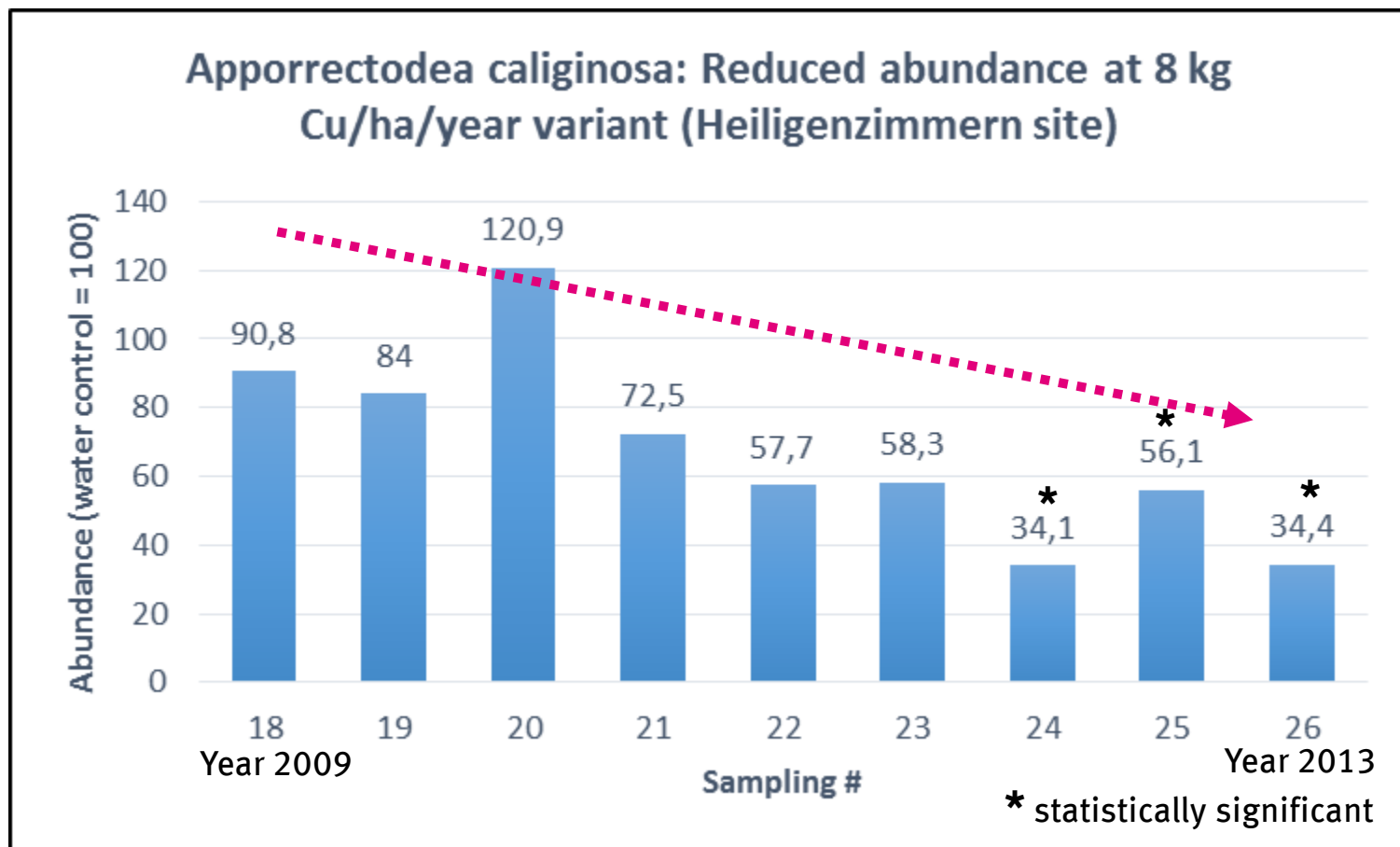


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Ecotox – discussions and decisions

Earthworm long-term field study: Analysis of individual species



Ecotox – discussions and decisions

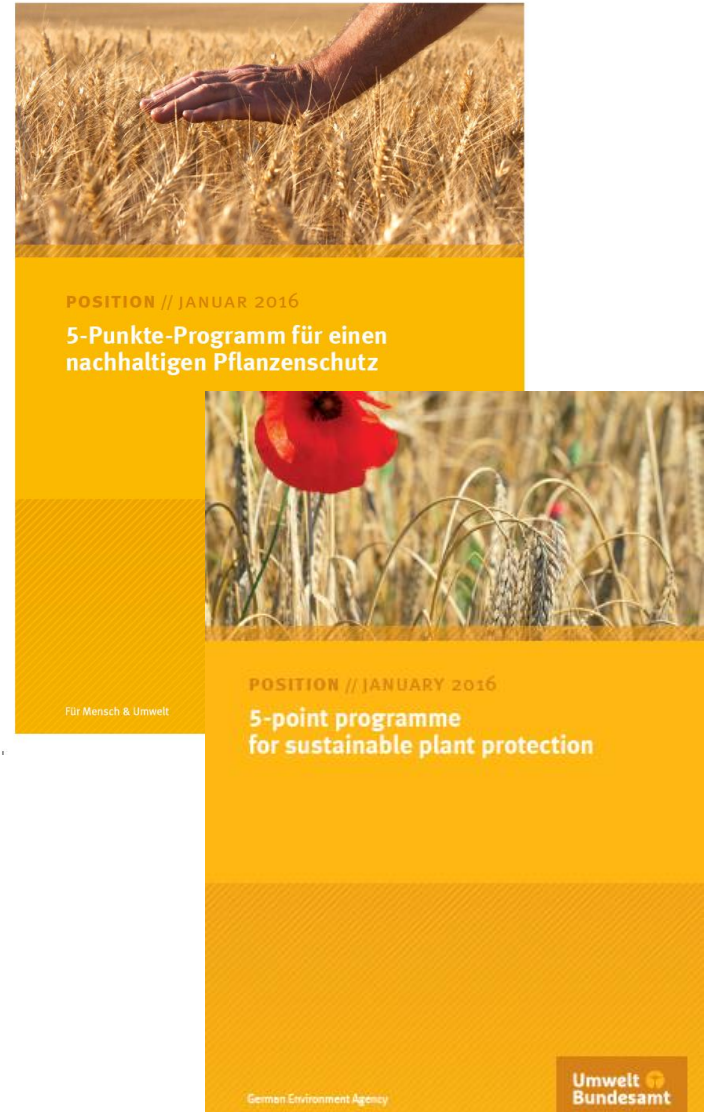
Earthworm Risk Assessment

– Conclusion:

“As an overall conclusion, it is of RMS opinion that taking into account all the effects observed: i – in the monitoring studies (with clear indication of an effect of copper content in soil on species abundance and diversity especially for endogeic species like *Aporrectodea caliginosa* for soils with total copper higher than 100 mg Cu/kg d.w.); ii – in the Klein (2015) field study at 8 and 40 kg/ha/y, and the slight effects observed at 4 kg/ha/y, a no observed adverse effect concentration (NOAEC) of 4 kg Cu/ha/y should be set for earthworms.”

5-point programme for sustainable plant protection

- published in 2016
- fact sheet and position paper for general public, stakeholders and policy makers
- strategic approach of UBA section plant protection products
- available via:
www.umweltbundesamt.de



Thank you.

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