CONVEGNO

«È possibile un'agricoltura biologica senza l'impiego del rame?»
La ricerca risponde e si confronta con il settore

Tenutosi presso l'Aula Magna «A. Quacquarelli»
Del Centro di ricerca Difesa e Certificazione (CREA-DC) Sede di Roma
il 14 giugno 2017

Progetto

Strategie per la riduzione e possibili alternative all'utilizzo del rame in agricoltura biologica (ALT.RAME*in*BIO)

III SESSIONE – IL FUTURO DEL RAME NELLA DIFESA FITOSANITARIA (Moderatore: Luca Colombo – FIRAB)

Il primo intervento di questa ultima sessione è stato tenuto da Carlo Bazzocchi (FIRAB) con la relazione dal titolo «*L'impiego del rame nei diversi Paesi europei*».

Strategie per la riduzione e possibili alternative all'utilizzo del rame in agricoltura biologica (ALT.RAME*in*BIO)

Roma, il 14 giugno 2017

L'IMPIEGO DEL RAME NEI DIVERSI PAESI EUROPEI

Carlo Bazzocchi

Reg. 834/2007

Reg. 889/2008

Allegato 1 – CONCIMI
Allegato 2 - FITOSANITARI

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IMPIEGO DEI CONCIMI - NORME GENERALI

Se le tecniche di lavorazione non consentono di soddisfare le esigenze nutrizionali, è consentito utilizzare solo i concimi e gli ammendanti inseriti in all'allegato I del Reg. CE 889/08 e solo nei limiti del necessario.

(Reg. CE 889/2008 – art. 3, punto 1)

Gli operatori conservano i documenti giustificativi che attestano la necessità di ricorrere a tali prodotti.

(Reg. CE 889/2008 – art. 3, punto 1)

Microelementi inorganici elencati nella parte E dell'allegato I del Reg. (CE) n. 2003/2003

(Reg. CE 889/2008 – Allegato 1)

FITOSANITARI - NORME GENERALI

Nei casi in cui le azioni di prevenzione non consentano di proteggere adeguatamente i vegetali contro i parassiti e le malattie, nell'ambito della produzione biologica è consentito utilizzare solo i prodotti di cui all'allegato II del reg. CE 889/08. (Reg. CE 889/2008 art. 5 , punto 1)

Gli operatori conservano i documenti giustificativi che attestano la necessità di ricorrere a tali prodotti.

(Reg. CE 889/2008 art. 5 , punto 1)

Rame … max kg/ha/anno 6 o per le perenni 30 kg in 5 anni

(Reg. CE 889/2008 Allegato 2)

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IL RAME NELLA NORMA DEL BIO

La s.a. autorizzata è lo <u>ione Cu</u> ed i suoi composti sono immessi sul mercato sotto la forma chimica di:

- **idrossido di rame**
- **ossicloruro di rame**
- **ossido di rame**
- **poltiglia bordolese**
- **solfato di rame tribasico**

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Consumi P.F. (PPP), s.a. rame

- P.F. (PPP): 136.055*
- fungicidi: 69.537*
- s.a. (p.a.) dei P.F. sono: 63.322*
- di cui fungicide: 38.887*

- **<u>Rame (s.a.) in Italia 5.894* (circa il 30% della UE)</u>**

(*: dati AGRI-ISTAT 2015 – in T)

AUTORIZZAZIONI NAZIONALI IN EU

AT, BE, BG, CY, CZ, DE, EL, ES, FR, HR, HU, IT, LT, LU, LV, MT, PL, PT, RO, SI, SK, UK (= 22/28 o 27)

Substance:	Authorised:
Bordeaux mixture	BE, CY, EL, HU, IT, MT, PT, RO, SI
Copper hydroxide	AT, BE, BG, CY, CZ, DE, EL, ES, HR, HU, IT, LT, LU, LV, MT, PL, PT, RO, SI, SK
Copper oxide	CY, EL, ES, HR, HU, IT, PT, SI
Copper oxychloride	AT, BE, BG, CY, CZ, DE, EL, ES, HR, HU, IT, LU, MT, PL, PT, RO, SI, SK, UK
Tribasic copper sulfate	AT, BG, CY, CZ, DE, EL, ES, FR, HR, HU, IT, LU, PT, RO, SI, SK

Non autorizzati in: DK, EE, FI, NL, SE - IE (?)

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LIMITAZIONI del Cu in UE e in ITALIA

EUROPA:
Austria
Rep. Ceca
Germania

ITALIA:
-Emilia-Romagna
-Toscana
-Altre

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E DOMANI?

FITOSANITARIO:
limitazione al 2018

FERTILIZZANTE:
limitazione nei formulati commerciali
limitazione nella dose d'impiego
apporto secondo il calcolo degli asporti

E IL CONTROLLO

Strategie per la riduzione e possibili alternative all'utilizzo del rame in agricoltura biologica (ALT.RAME*in*BIO)

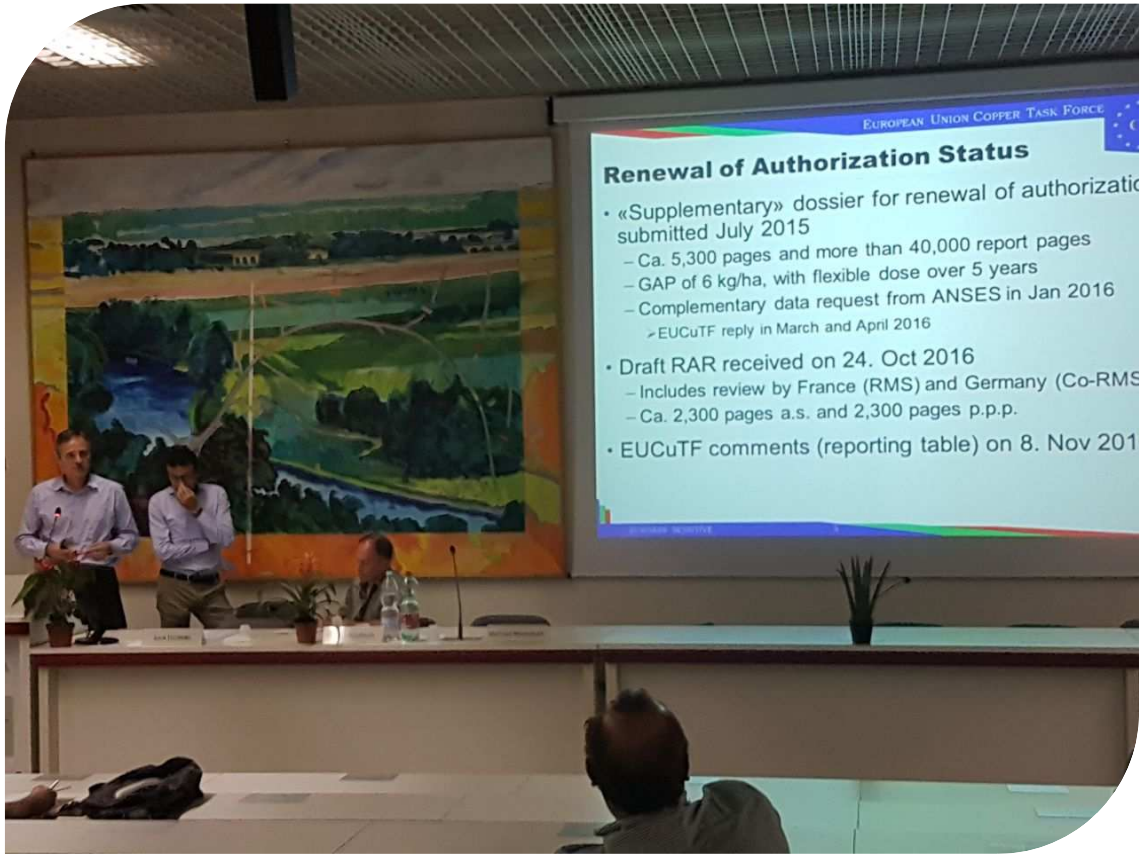
GRAZIE PER L'ATTENZIONE

Carlo Bazzocchi

FIRAB
Fondazione Italiana per la Ricerca in Agricoltura Biologica e Biodinamica

III SESSIONE – IL FUTURO DEL RAME NELLA DIFESA FITOSANITARIA (Moderatore: Luca Colombo – FIRAB)

La sessione si è chiusa con la relazione dal titolo «*Situazione attuale e prospettive sull'uso del rame*» tenuta dal dott. Matthias Weidenauer (Chairman European Task Force Copper).



EUROPEAN UNION COPPER TASK FORCE

crea / mipaaf Convegno

Situazione attuale e prospettive sull'uso del rame

Matthias Weidenauer

European Union Copper Task Force (EUCuTF)

Roma, 14. giugno 2017

Battelle
The Business of Innovation

European Union Copper Task Force

- 13 member companies

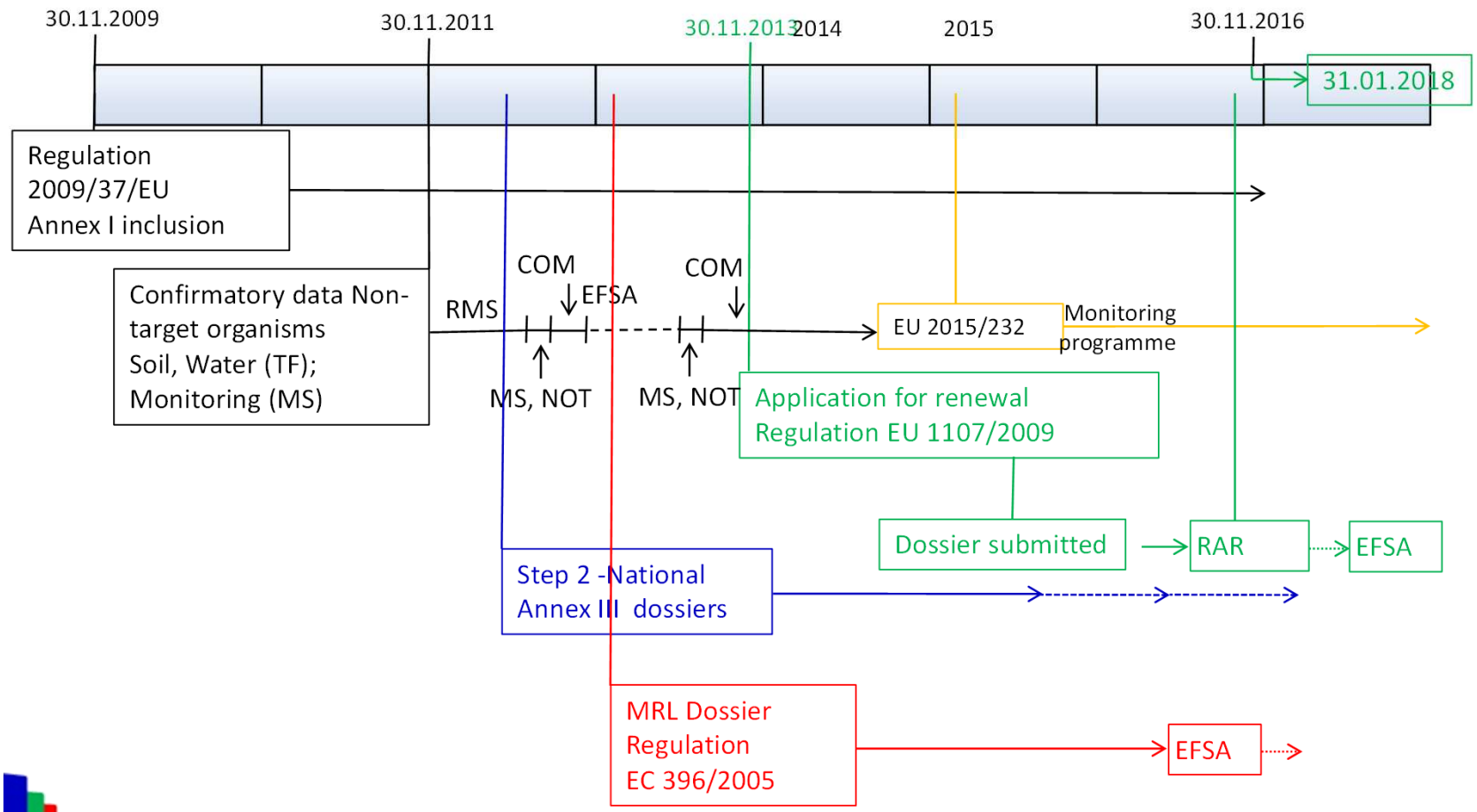
  Albaugh Europe SARL
  Cinkarna - Metallurgical & Chemical Industry Celje, INC.
  Erachem Comilog SPRL
  Industrias Quimicas Del Valles, S.A.
  Isagro S.p.A.
  Kocide LLC
  Manica SpA
  Montanwerke Brixlegg AG
  Nordox AS
  Nufarm GmbH & Co KG
  Sales y Derivados de Cobre S.A.
  Spiess-Urania Chemicals GmbH
  UPL Europe Ltd.

- Objective: Renewal of authorization of Copper compounds according to regulation (EU) 1107/2009
  - Copper hydroxide - Bordeaux mixture
  - Copper oxychloride - Tribasic copper sulphate
  - Copper(I)oxide

European Union Copper Task Force

- Formed in July 2000 by 11 companies
- Objective: Re-registration of Copper compounds under Directive 91/414
  - GAP of 8 kg/ha, safe use vine and tomato
- Battelle took over EUCuTF chair in 2009/2010
- Amended objective:
  - Renewal of authorization of Copper compounds according to regulation (EU) 1107/2009
  - GAP of 6 kg/ha, flexible dose (30 kg/ha in 5 years)
- Further agreed scope:
  - MRL submission, general Step 2 support

Status of Authorization in the EU



Renewal of Authorization Status

- «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

Renewal of Authorization Status (2)

- RAR received on 16. Dec 2016
  - corrections made on formal issues
  - some changes to content
  - forwarded by RMS to EFSA
- EFSA requested sanitized RAR on 3. Jan 2017
  - uploaded 17. Jan 2017
  - published 2. Feb 2017
- EFSA invitation to comment on 3.Feb 2017
  - 60d period for applicant, EFSA, MS
- EUCuTF comments (reporting table) on 5. Apr 2017

Renewal of Authorization Status (3)

- RMS invitation to comment on EFSA and MS comments on 20. Apr 2017
  - consolidated reporting table of 230 pages
  - Comments from EFSA, PL, DK, SI, NL, DE, UK
  - Comments from FNAB, AVC (Assoc. Vet. Cons.)
- EUCuTF comments (reporting table) on 4. May 2017
- RMS compiled their final reply to EFSA
  - Call RMS / EFSA on 1st June 2017
- Request for additional data received last week
  - Due 10 July 2017
- Will now start EFSA peer review (4-6 months)

RAR Summary

- Proposed decision: Copper compounds can be approved under regulation EC 1107/2009
  - However, risk not acceptable for uses >4 kg/ha
  - EUCuTF disagrees with this
- Assessments often read like
  - The study is acceptable, however…
- 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…

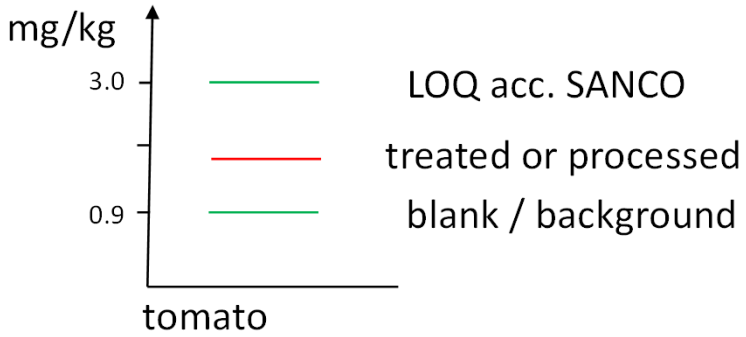
Copper – A Different Pesticide

- 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!

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 Regulations do not apply PBT for inorganics
  - omitted in pesticide guidance

➢ EUCuTF requested COM to harmonize approach for all chemicals

Copper: CfS (2)

- List published on 12.Mar. 2015
  - Commission Implementing Regulation (EU) 2015/408
  - Letter of complaint 19. May 2015
    - Rejected, procedure only open to Member States
  - Appeal filed on 5. Jun 2015 (updated in July, published on 7 Sep 15)
    - Appeal inadmissible on 29. Oct 2015

➢ Case likely to be to dismissed by the Court of Justice: no impact, not directly concerned

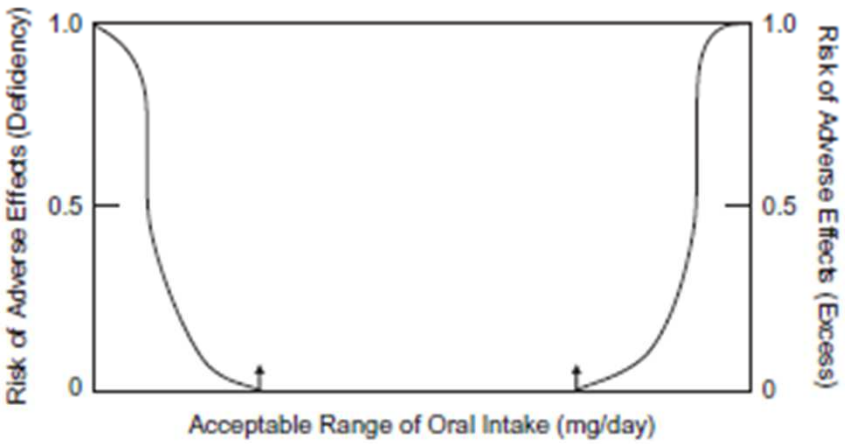
  ➢ Subject of appeal not assessed; EUCuTF will pursue case once a comparative risk assessment has been performed

➢ ECJ notified the EUCuTF of a hearing 6 Jun 2017

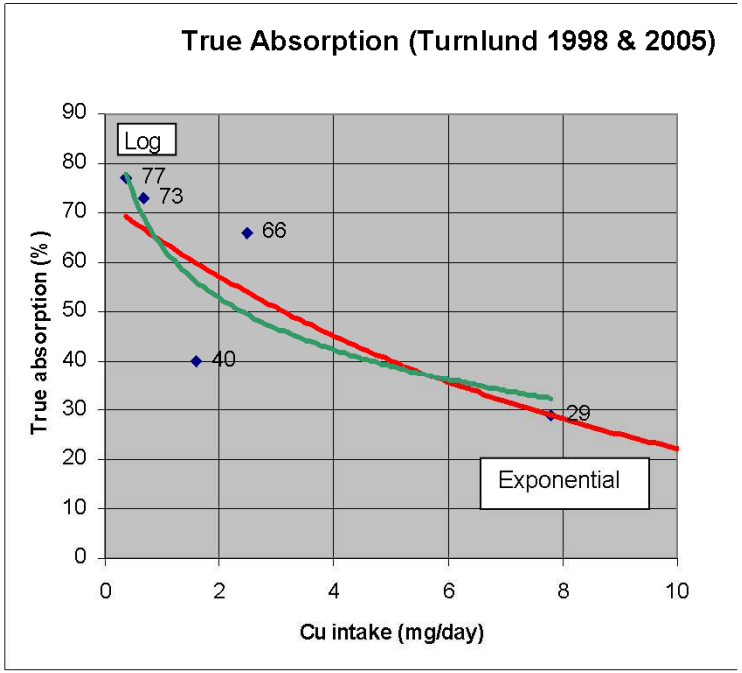
  ➢ Outcome will be received in Sep. 2017

Risk assessment for Cu

- Essential micronutrient
- Ubiquitous
- Metal
- Homeostatic control



Source: J Tox Env Health A, 73:114-127 2010



Source: VRAR

Copper in the human body

- Healthy adult contains 70-90 mg Cu
- Daily intake 1 – 4 mg / d
  - Daily excretion estimated to 2 – 2.5 mg/d (feces, urine, skin, sweat, saliva, menses)
- Copper in organs
  - Liver 5 mg/kg for adults, 19 mg/kg for infants
  - Brain 6 mg/kg for adults, 4 mg/kg for infants
  - Heart, kidney 2-3 mg/kg
- Copper in blood and fluids
  - 1 to 1.5 mg/L in blood, mainly bound to ceruloplasmin
    - Double during pregnancy
  - All fluids of the body (incl. sweat) contain Cu complexes

AOEL and Exposure to Operator, Worker and Resident

- AOEL is currently set at 0.072 mg/kg bw/d (2009)
  - This is at the lower end of the normal blood plasma content
    - AOEL could be >0.116 mg/kg/day
  - EUCuTF has proposed 0.1 mg/kg bw/d

- Exposure: AOEL must not be exceeded
  - Exposure of operator and worker through inhalation and skin
  - Dermale Absorption
    - Extensive in-vitro Studies with Cu available
    - ➢ New studies with enriched stable Cu-65 isotope submitted

AOEL and Exposure to Operator, Worker and Resident

- Worker exposure
  - New AOEM model to be used soon under 1107/2009 with high TF for vine
    - Creates general issue, not only for Cu
    - Dermal penetration 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 dil.

* for concentrated product / spray dilution

➢ RMS used "potentially absorbed Cu"

➢ A study is underway to show that this is not appropriate

➢ Copper is safe for humans (consumer, operator, residents & bystander)

Ecotox risk assessment for Cu

- Risk defined as quotient toxicity over exposition:

$$\mathrm{TER} = \frac{NOEC}{PEC}$$

  - NOEC: no observed effect concentration
  - PEC: predicet environmental concentration in the compartment
  - acceptable TER usually includes an assessment factor

➢ Standard PEC modelle not applicable for Cu

➢ Toxicity of Cu strongly dependent on speciation

  ➢ Lab studies need to be assessed with caution

➢ Assessment factor for essential element?

Non target organisms: birds

- Estimated theoretical exposure:

  ETE = (FIR/bw) * C * AV * PT * PD [mg/kg bw/d]

  FIR = Food intake rate; bw = Body weight

  C = Cu concentration in diet(mg/kg); AV = Avoidance factor

  PT = Diet part from treated area; PD = Part of diet

- Risk assessment using defaults Risk

$$TER = \frac{NOEL}{ETE} = \frac{5.05}{0.4 * 10 * 1 * 1 * 1} = \frac{5.05}{4} = 1.26\ (>5)$$

- Refinement of model:
  - Residue studies conducted to measure Cu in different food items (grass, insects, etc..)
  - Conc = 15-20 mg/kg in insects **before** Cu application

Non target organisms: birds

- Refinement of model:
  - Model indicates risk even at Cu concentrations in food items of the untreated control plot!
    - Standard model not applicable for Cu!
- Literature study and expert judgement
  - « weight of evidence » approach
- No adverse effect on reproduction success and bird population
  - as long as 5 kg/ha are not exceeded during reproduction phase

➢Not a «real world» issue, but again model driven

Aquatic 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

Aquatic Organisms

- Exposure
  - PECsw submitted up to ca. 4 µg/L (5 m)
- Toxcicity endpoint (RAC)
  - Derived from mesocosm: 4.8 µg/L diss. Cu
    - SSDs show fish is not most sensitive species
- RAR:
  - Different endpoint derived from fish SSD plus Assessment factors RAC <1 µg/L to 2 µg/L
  - This is below natural 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

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 eventual restrictions for sites with high Cu co and unfavorable soil type
- Combination of dose rate and soil content matters

Non Target Terrestrial Organisms

- Earthworms GLP field study completed by the EUCuTF after 10 years and submitted
  - ➢ No statistically significant effects at 4 kg/ha/y and 8 kg/ha/y
  - ➢ Confirmed by an Expert panel opinion
- The RMS position (RAC 4 kg/ha) does not do justice to the complexity of the system with annual application, decrease in bio-availability and aged soil Cu

➢ EUCuTF will re-convene an expert panel and further generate and evaluate data (incl. biomonitoring data)

Copper as 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 a dose rate that is not efficacious
  - ➢ 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

Thank you very much !

I lavori del Convegno sono stati chiusi dalla dott.ssa Anna La Torre, coordinatore del progetto, che, dopo aver ringraziato relatori e partecipanti, ha tirato le conclusioni della giornata.

crea
Consiglio per la ricerca in agricoltura e l'analisi dell'economia agraria

UNIVERSITÀ DEGLI STUDI DELLA Tuscia

LAIMBURG

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Fondazione Italiana per la Ricerca in Agricoltura Biologica e Biodinamica

Strategie per la riduzione e possibili alternative all'utilizzo del rame in agricoltura biologica ALT.RAME*in*BIO

Con il patrocinio dell'Associazione Italiana per la Protezione delle Piante (AIPP)

Associazione Italiana per la Protezione delle Piante

mipaaf
ministero delle politiche agricole alimentari e forestali

Progetto di ricerca ALT.RAME*in*BIO finanziato dall'Ufficio PQAI I - Agricoltura Biologica e Sistemi di qualità alimentare nazionale e affari generali del Ministero delle Politiche Agricole Alimentari e Forestali con D.M. 92705/2014

Grafica di Valerio Battaglia CREA-DC Roma