



CDG Wine

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Copper in plant protection products: state of play under Regulation (EC) 1107/2009

Eric LIEGEOIS
Unit E4 Pesticides and Biocides
DG Health and Food Safety

*Health and
Food Safety*

Contents

- Copper as active substance: state of play and next steps
- Background slides - brief reminders of main provisions of Regulation (EC) No 1107/2009 on placing on the market of plant protection products



Copper under Directive 91/414/EEC

- *included in the review programme under Directive 91/414/EC as Copper compounds (copper hydroxide, oxychloride, oxide, tribasic copper sulphate , Bordeaux mixture) approved for uses as fungicide and bactericide*
- *Approved by COM Directive 2009/37/EC (EFSA peer review 2008)*

Conditions of first approval

- *Approval period : 7 years (until 30 November 2016)*
- *MS to apply risk mitigation measures where appropriate*
- *Amount of active substance in terms of rates and number of applications minimum necessary to achieve the desired effects*
- *Notifier to submit confirmatory data on several areas of assessment*
- *MS to initiate monitoring programme in vulnerable areas where contamination is of concern to set limitations such as max application rate*

Amended conditions in 2015

➤ *COM Reg.2015/232:*

- MS to set a minimum rate that is effective and does not cause any unacceptable effect on the environment taking into account background levels of copper at the application site
- Notifiers to submit monitoring programme and results for areas where contamination of soil and water (including sediments) is a concern or may become of concern - to verify whether further limitations of use are necessary to prevent any unacceptable environmental effect – results by end of 2017

Copper as candidate for substitution

- Copper included in the list of candidates for substitution - Reg.2015/408
- MS to perform a Comparative assessment:
 - ◆ A safer alternative exists (also non chemical or prevention method) with significant differences in risk
 - ◆ No significant economic or practical disadvantages
 - ◆ Alternative adequate to minimise occurrence of resistance
 - ◆ Consequences for minor uses must be taken into account

Renewal assessment ongoing

- First approval expired on 30 November 2016 - renewal assessment to apply three years in advance
- Under Renewal Programme Reg. 626/2012 : FR as RMS and DE as Co-RMS for copper compounds
- Prolongation of approval period – Reg.2014/85 (expires on 31 January 2019)
- EFSA conclusions on the peer review adopted in December 2017
- EFSA technical report on monitoring programme for contamination of vulnerable areas - August 2018

Renewal assessment ongoing (2)

- EFSA conclusions:
 - **issues of concern for non-target terrestrial vertebrates and soil organisms with current GAPs**
 - **need to adapt current methodology for exposure assessment of copper compounds**
 - **potential concerns regarding non-dietary exposure**
 - **potential concerns regarding dietary exposure if all critical GAPs and background level in all commodities are considered**



Renewal assessment ongoing (3)

- Commission proposal for renewal :
 - issues of concern for non-target terrestrial vertebrates and soil organisms with current GAPs:
 - **Maximum total application rate with some flexibility for MS** (SANTE to discuss with AGRI about alignment of organic farming Regulation)
 - need to adapt current methodology for exposure assessment of copper compounds
 - **Mandate to EFSA to develop new guidance**
 - potential concerns regarding non-dietary exposure → **PPE + mitigation for bystanders**
 - potential concerns regarding dietary exposure
 - **revision of MRLs + suggested human biomonitoring**



Renewal assessment ongoing

- Next steps:
 - **Legislative decision making (Article 20 of PPP Regulation (EC) No 1107/2009) November 2018 (?)**
 - **MS re-authorisations (>2019)**
 - **Alignment Organic Farming Regulation (?)**
 - **EFSA guidance environmental exposure assessment (2019-2020)**
 - **Revision MRLs (>2019)**
 - **New application for renewal due in 2022**



Background slides

Reminders about PPP Regulation

For up-to-date information DG SANTE website:
https://ec.europa.eu/food/plant/pesticides_en



Objectives of the Regulation (EC) No 1107/2009

- Ensure a high level of protection for human and animal health and the environment and
- Improve the functioning of internal market through harmonisation of rules for marketing of plant protection products while improving agricultural production

Main provisions

- Stricter approval criteria
“cut-off criteria” - Substitution principle
and criteria to list candidates actives
- Work sharing
EU active substances - products at national
level - zonal system and mutual recognition -
parallel trade permit
- Incentives for low-risk, basic substances, minor
uses
- Proper use: sustainable use and integrated pest
management under Directive 2009/128/EC



Approval vs. Authorisation



Active substances



**EU
approval**



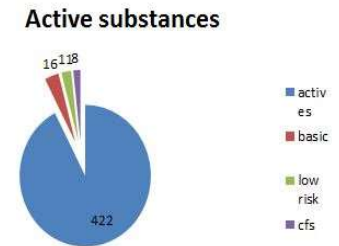
**Plant protection
products**



**National
authorisation**

Substances at EU level

- Application for approval with dossier of studies
 - **Data requirements**
- Evaluation shared for each substance => one Rapporteur MS
 - **Uniform principles of evaluation**
- Peer review by the European Food Safety Authority
- Legislative decision making
- List of approved substances
 - <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>
- Total length of the procedure = 2,5 to 3 years
- Approval for 10 years/renewal for 15 years (+ shorter cases)



Plant protection products at national level

➤ **Zonal evaluation:**

- One evaluation per zone (ZRMS)
- Zonal peer review
 - Member States grant authorisations on the basis of the zonal evaluation
- For greenhouse, seed treatment and post-harvest:
 - One evaluation for whole EU
- Total length of the procedure = 12 to 18 months

➤ **Mutual recognition:** 120 days



PLANTS

European Commission > Food Safety > Plants > Pesticides > REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues



HEALTH

FOOD

ANIMALS

PLANTS

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PESTICIDES

EU Pesticides database

Sustainable use of pesticides

Approval of active substances

Authorisation of Plant Protection Products

Maximum Residue Levels

REFIT Evaluation

ALL TOPICS

REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues

Plant protection products (PPPs) and their residues are regulated in the EU by Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. As announced in the **2016 Commission Work Programme** of 27 October 2015, the Commission is now carrying out a REFIT evaluation of the EU pesticide legislation in order to assess if the regulations meet the needs of citizens, businesses and public institutions in an efficient manner.

Plant protection products (PPPs) are used to protect plants against pests or diseases. The Commission approves active substances, i.e., the agent used to achieve the protective effect, for the use in PPPs. In order to protect consumers, the Commission also sets maximum residue levels (MRLs) for pesticides, i.e. the highest levels of pesticide residues that are legally tolerated in or on food or feed, including imported products. The evaluation aims to perform an evidence-based assessment of the implementation of the PPP and MRL regulations and address synergies, gaps, inefficiencies and administrative burdens.

Evaluations and Fitness Checks are tools that are used to implement the **Regulatory Fitness and Performance programme (REFIT)**. REFIT is a rolling programme to keep the entire stock of EU legislation under review and ensure that it is 'fit for purpose'; that regulatory burdens are minimised and that all simplification options are identified and applied.

The evaluation process is constituted of different steps, of which the initial ones are outlined below. The evaluation is foreseen to be finalised in the second half of 2018.

The Roadmap

The Commission published on 17 November 2016, a **Roadmap** on the REFIT



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GMO register



EU Pesticides database



Procedure to apply for authorisation of a PPP



Plant variety database



Community Plant Variety Office (CPVO)



Health and food audits and analysis



European Food Safety Authority (EFSA)



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