

Member States' comments on the draft EFSA Conclusion on Copper compounds (RMS: FR) (co-RMS: DE)(24.11.2017) 1/9
Pesticides Peer Review Written Procedure: November 2017

Background			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
1	Conclusion text (general)	<p>DE: This is a general comment on the draft EFSA conclusion and the whole renewal procedure (so far) from our view as co-RMS. We do strongly recommend to include in the conclusion text a prominent and clear description of the special characteristics of the active substance copper (compounds) since these are rather unique among the (typically synthetic) active substances under review in the EU approval procedure. Copper is a non-degradable (heavy) metal, which is – for sure, in tiny amounts – essential for all live forms but toxic at higher doses. As a consequence, no degradation of the active substance following application as a pesticide neither in environmental matrices nor in the harvested crops occurs, but still, exposure of non-target organisms is modulated by the specific properties of (environmental) matrices (i.e. bioavailability varies). Moreover, homeostatic and adaptive physiological processes take place if non-target organism are exposed to (excess) copper. Within his dossier, the notifier provided a comprehensive review of the huge amount of data and knowledge available on the fate and behaviour, toxicity and bioavailability of copper which was thoroughly considered by the RMS in his RAR (indeed, the RAR is of clearly higher scientific quality compared to the last renewal). However, the final outcome of the assessment and peer-review being now summarised in the draft EFSA-conclusion is severely hampered by the lack of metal-specific scientific guidance under 1107/2009/EC within all relevant assessment areas. Clearly, the basic risk assessment paradigm, exposure models, risk</p>	

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		<p>indicators and uncertainty factors as established in existing KOM/EFSA guidance documents have been derived and validated for synthetic chemicals but not for metals. The lack of metal-specific guidance is thus mirrored in the overall outcome as presented in the RAR, making this non-standard risk assessment for copper compounds inherently more complex and uncertain than it is the case for synthetic chemicals. We do strongly recommend to clearly highlight this general uncertainty to the risk managers. Furthermore: The above described special characteristics of the active substance copper compounds (especially non-degradability) advocate a more precautionary-based approach (according to recital clause No. 8 in REGULATION (EC) No 1107/2009) in decision making and risk management, respectively. Decision making on and risk management of copper pesticides should be in coherence to other pieces of environmental EU legislation which generally do intend to avoid/minimize the widespread and diffuse contamination by heavy metals such as copper. This intention was backed by the existing COMMISSION IMPLEMENTING REGULATION (EU) 2015/232 (of 13 February 2015) with specific conditions for approval of copper compounds, i.e. implementation of a general and clear requirement for minimization of copper use, implementation to efficiently reduce copper input into adjacent non-target areas by risk management (e.g. prescription of maximum economically reasonable techniques for the reduction of spray-drift), requirement for monitoring of copper accumulation in target- and non-target areas. As a consequence of the last mentioned specific conditions, monitoring programs have been launched</p>	

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		in several member states with resulting monitoring data on copper contamination being reported in the actual RAR. We do strongly recommend that the EFSA conclusion does more explicitly inform the risk managers on the latter aspect in order to enable them to take a decision as informed as possible (for the EU, for their respective member states).	
2	Conclusion text (general)	DE: There is (yet) no final conclusion of EFSA with regard to the renewal of copper compounds in the draft conclusion? What is the position of EFSA?	

Environmental fate and behaviour			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
1	Conclusion text, Chapter 4, page 14	DE: It is mentioned, that 160 mg Cu/kg soil (90th percentile) for grape and 26 mg Cu/kg soil (90th percentile) for tomatoes and cucurbits were used in the present assessment, both values from European monitoring programs. We do agree that considering background values in soil is appropriate to estimate meaningful PEC values. Considering the 90th percentile from EU monitoring data (RMS approach) can be a simple way forward to demonstrate the influence of certain background values of copper in soils in vine or vegetable growing areas in the EU.	

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Environmental fate and behaviour			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		<p>However, more information about varying background values of copper in different crop growing areas in Europe (member states), especially in vine growing areas, where copper has been used since a long time, should be provided in the EFSA conclusion. This information is an important outcome from assessing the large monitoring data set in the RAR, which should be discussed in more detail. To further consider varying background values of copper in soils in the risk assessment and for risk management decision will be a need and a challenge for national product registrations. It would be helpful to address that issue in more detail in the EFSA conclusion (see also general comment on this issue).</p>	
2	Conclusion text, Chapter 4, page 14	<p>DE: The PECsoil calculation considering background values and a 10 years application is mentioned in paragraph 6 of the chapter. We do generally agree with this approach. However, the co-RMS suggests that varying background values in different crop growing areas, especially in vine growing areas, would need to be considered for PECsoil calculation and risk assessment/management at member state level for product registrations (see comment above). It should be further mentioned in the EFSA conclusion that considering a 10 year application period for PECsoil calculation has still shortcomings in relation to typical application periods, especially in permanent crops (e.g. vines). Member states should be aware of, that the copper concentrations in soil could be still higher after a use of copper more than 10 years.</p>	
3	Conclusion text, Chapter 4,	DE: There is no critical discussion in the EFSA conclusion about	

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Environmental fate and behaviour			
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	page 14 and List of Endpoints	the use of the standard FOCUS models for the metal copper. A discussion would be helpful, what processes are covered in a suitable way and what would be sources for systematic errors. For example, for PEC surface water calculations (in the LoEP), it becomes not very clear, if the used water solubility value for copper is related to the solubility of the different copper salts and how those PECsw are related to ecotoxicological endpoints.	

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
1	Conclusion text, Chapter 5, page 15	DE: In the first paragraph it is stated: "The risk assessment was based on the following documents: European Commission (2002a, b), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013b)." There is urgent need of clarification to be included in the final EFSA conclusion in this respect (in the following, we do repeat our general comment on this issue): We do strongly recommend to include in the conclusion text a prominent and clear description of the special characteristics of the active substance copper (compounds) since these are rather unique among the (typically synthetic) active substances under review in the EU approval procedure.	

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Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		<p>Copper is a non-degradable (heavy) metal, which is – for sure, in tiny amounts – essential for all live forms but toxic at higher doses. As a consequence, no degradation of the active substance following application as a pesticide neither in environmental matrices nor in the harvested crops occurs, but still, exposure of non-target organisms is modulated by the specific properties of (environmental) matrices (i.e. bioavailability varies). Moreover, homeostatic and adaptive physiological processes take place if non-target organism are exposed to (excess) copper. Within his dossier, the notifier provided a comprehensive review of the huge amount of data and knowledge available on the fate and behaviour, toxicity and bioavailability of copper which was thoroughly considered by the RMS in his RAR (indeed, the RAR is of clearly higher scientific quality compared to the last renewal). However, the final outcome of the assessment and peer-review being now summarised in the draft EFSA-conclusion is severely hampered by the lack of metal-specific scientific guidance under 1107/2009/EC within all relevant assessment areas. Clearly, the basic risk assessment paradigm, exposure models, risk indicators and uncertainty factors as established in existing KOM/EFSA guidance documents have been derived and validated for synthetic chemicals but not for metals. The lack of metal-specific guidance is thus mirrored in the overall outcome as presented in the RAR, making this non-standard risk assessment for copper compounds inherently more complex and uncertain than it is the case for synthetic chemicals. We do strongly recommend to clearly highlight this general uncertainty to the risk managers.</p>	

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Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
2	Conclusion text, Chapter 5, page 15 and List of Endpoints	<p>DE: It is stated “The Tier I acute and long-term risk assessment to birds and mammals was indicated as high for all the representative uses.” This outcome of the risk assessment is connected to high uncertainties due to the following reasons:</p> <ul style="list-style-type: none"> - risk indicators (TER-values) and critical TER-values are according to the existing EFSA guidance (2009) which however was developed for synthetic chemicals and not metals, - acute risk indicated, but in (nearly) all short-term toxicity studies there was indication of avoidance of copper-contaminated food items, - calculating exposure by assuming the application of the overall yearly intended amount in one single application is clearly more conservative than the typically implemented “realistic worst-case”. 	
3	Conclusion text, Chapter 5, page 16 and List of Endpoints	<p>DE: It is stated “At Tier 1 level a high risk to aquatic organisms was concluded for all the representative uses.” Further refinement steps do still indicate a risk for aquatic organism (fish, algae and aquatic invertebrates, sediment dwellers). This outcome of the risk assessment is connected to high uncertainties since (i) the critical TER-values included in the assessment are following the existing EFSA guidance (2013) which however was developed for synthetic chemicals and not metals, and (ii) bioavailability was not considered explicitly in the risk assessment due to the lack of specific guidance in the existing EFSA guidance (2013). The significance of the risk</p>	

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		assessment outcome for differing environmental conditions across Europe therefore remains obscure (realistic worst-case for all situations/scenarios?). See also our general comment on this issue.	
4	Conclusion text, Chapter 5, page 16	DE: It is stated “Consequently, low risk was only concluded for the use on grapes up to an application rate of 3.75 kg/ha/year for all the assessed copper compounds (data gap).” It is not addressed in the draft conclusion how risk managers at member state level should generally conduct a risk assessment in view of the outcome of the risk assessment presented in the RAR: Generally speaking, only a site-specific risk assessment – taken the bioavailability-determining factors as well as the natural copper background and/ or the already elevated copper content from historical copper use into account – would be necessary. See also general comments on this issue before.	

Other			
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		<MS comments>	

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