

REPORT OF PESTICIDES PEER REVIEW TC 189 & TC 193

BOSCALID – AIR III

Rapporteur Member State: SK

5. Ecotoxicology

Date: 9 December 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS SK	NRL for pesticides UVLF Kosice
National Experts nominated by MS AT	Austrian Agency for Food and Health Safety (AGES) - AT
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Experts nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS LT	State Plant Service under the Ministry of Agriculture - LT
National Experts nominated by MS NL	Ctgb - NL
National Experts nominated by MS SE	Swedish Chemicals Agency (KEMI) - SE

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the experts at the beginning of this meeting.

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to decide the ecotoxicological relevant endpoint to use for the long-term risk assessment for mammals.	1. The experts considered all the available NOAEL from relevant studies and available position papers to agree on the ecotoxicologically relevant endpoint for wild mammals 2. All the experts agreed to use 113 mg/kg bw/d from the 2-gen study based on the following argumentation: - The endpoint from the rabbit developmental toxicity study (100 mg/kg bw/d) was not supported because the effect level was below 10% and thus not considered biologically relevant; - In the 2-gen study, the reduction in male pup body weight during lactation in the F2 generation at the intermediate dose were below 10% with no clear dose-response at post-natal day 4 and 7; - The effects on pup body weight (both sexes) during lactation in the DNT study were only observed at post-natal day 4 and were below 10%; - The estimated BMD supported the selected endpoint. Open point: - RMS to reflect the outcome of the discussion in the revised RAR. - RMS to update the revised RAR and LOEP by including the long-term risk assessment for mammals considering the agreed endpoint.
Experts' consultation 5.9 Experts to discuss if the available information is	Since no specific information was available to conclude on the ED criteria for non-target organisms other than mammals, all the experts agreed that further data are necessary as follows:



Subject	Conclusions Pesticide Peer Review Meeting
sufficient to conclude whether boscalid poses potential ED properties and if necessary, to agree on the testing strategy to be followed in line with ECHA/EFSA guidance.	-T-modality: Amphibian Metamorphosis Assay (AMA) in line with OECD TG 231 (OECD, 2009) is necessary; -EAS-modalities: Fish short-term reproduction assay (FSTRA)* in line with OECD TG 229 (OECD, 2012) including the histopathological investigation of potential effects on the gonads is necessary. If any of the above-mentioned assays resulted positive, the scenario 2a(i) applies and further data will be needed to support the mode of action (MoA) analysis, i.e., a level 4/5 study following OECD TG 241 (LAGDA, Larval Amphibian Growth and Development Assay) and/or OECD TG 240 (MEOGRT, Medaka Extended One Generation Reproduction Test) for T- and EAS-modalities respectively, would be necessary. * In case there are evidence that the substance has an Anti-Androgenic -MoA, the FSTRA may not be the most suitable test to detect such effects, therefore, the applicant might consider a different testing strategy more appropriate for the investigation of such MoA. For wild mammals as non-target organisms, the conclusions are considered pending on the outcome of the discussion related to the ED assessment for humans.

REPORT OF PESTICIDES PEER REVIEW TC 189

BIFENAZATE – Confirmatory data

Rapporteur Member State: SE

5. Ecotoxicology

Date: 25 November 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency (KEMI) - SE
National Experts nominated by MS AT	Austrian Agency for Food and Health Safety (AGES) - AT
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS NL	Ctgb - NL

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss the assessment for endocrine disruption in wild mammals pending on the conclusion reached for the assessment for humans for the EAS-modalities. See EFSA Technical Report, Appendix A, point 5(8)	The available 2 generation studies and its findings were discussed in the context of the ED assessment for humans and it was concluded that EAS-mediated parameters were sufficiently investigated, and a pattern of EAS-mediated adversity was not observed in the available dataset of studies. Similarly, the available limited data for the metabolite 4-4'-biphenol (D9569) were also discussed and it was concluded that although the potential for endocrine disruption of the metabolite could not be fully excluded based on the limited data, this potential property is unlikely to be expressed in studies on bifenazate as the toxicity of bifenazate would be a limiting factor. 1. Conclusion For wild mammals, the same conclusion drawn for humans applies for both bifenazate and the metabolite 4-4'-biphenol (D9569). Therefore, bifenazate is not an endocrine disruptor for wild mammals for EAS-modalities. It is noted that similar conclusion was reached for the T-modality in wild mammals and for non-mammalian species for EATS-modalities in the technical report https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2025.EN-9509 Open point RMS to report in the RAR the outcome of the discussion.

REPORT OF PESTICIDES PEER REVIEW TC 182

FLONICAMID – AIR IV

Rapporteur Member State: FI

5. Ecotoxicology

Date: 22 September 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff member	EFSA
National Expert nominated by RMS FI	Finnish Safety and Chemicals Agency (Tukes) - FI
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DK	Danish Environmental Protection Agency - DK
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS NL	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)- NL

All peer-review experts attending the meeting had an approved ADoI without a DoI waiver, and no interests were declared orally by any of the experts at the beginning of the meeting

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Discussion points/Outcome

5. Ecotoxicology

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Experts' consultation 5.15 Experts to discuss the available FSTRA and its findings.	1. A FSTRA with Japanese medaka was available to sufficiently investigate the endocrine activity through the EAS-modalities. The study was valid. The main uncertainties identified were related to the lack of proper validation of the protocol with this species (validation only for VTG and SSC) and the number of eggs/female/day which was considerably low compared to the recommendations of another test protocol only focusing on that species, i.e. OECD TG 240. 2. Overall, despite the uncertainties, the study was considered suitable to conclude on the ED properties of flonicamid and was considered negative based on the lack of effects in any of the assessed parameters. Open point RMS to update the RAR with the outcome of the discussion.
Experts' consultation 5.16 Experts to discuss the available AMA and its related findings.	1. An Amphibian Metamorphosis Assay was available. A number of drawbacks was noticed mainly pointing to a low performance and fitness of control animals, e.g., presence of thyroid gland hypertrophy and low values of all growth parameters.



Subject	Conclusions Pesticide Peer Review Meeting
	2. Based on the limitations identified, the experts agreed that a robust conclusion based on the available study cannot be drawn. The experts agreed, therefore, to request a new AMA, unless the applicant can provide robust and convincing evidence on the appropriateness and fitness of the control by re-analysing all control data.

REPORT OF PESTICIDES PEER REVIEW TC 188

BOSCALID – AIR III

Rapporteur Member State: SK

5. Ecotoxicology

Date: 9 October 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SK	National Reference Laboratory for Pesticides - SK
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection - DE
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS NL	Ctgb - NL
External expert	Emily McVey
Observer	BAFU - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.2 Experts to decide the suitability of the possible refinement provided by the applicant for addressing the risk assessment to mammals.	The experts discussed the available refined long-term risk assessment for smaller herbivorous mammals. The refined DT50 value in weeds was considered as sufficiently reliable. Furthermore, the experts agreed on the common vole to be a suitable focal species and for the PD values to be refined. The experts also agreed to refine the deposition value used for the exposure estimation in oilseed rape. Open point: RMS should complete the information in the revised RAR by including the missing information in the study summaries for the (i.e., distance among plots, [REDACTED] also included in the PPP, better explanation about the kinetics, exploration of outliers). Open point: RMS to update the refined risk assessment for small herbivorous mammals considering the agreed PD of 75/25 for the use in vineyards. General open points: RMS to reflect the outcome of the discussion in the revised RAR and LoEP.
Experts' consultation 5.3 Experts to decide on:	- <u>Acute endpoint to be used in the risk assessment for aquatic invertebrates:</u>



Subject	Conclusions Pesticides Peer Review Meeting
- Acute endpoint to be used in the risk assessment for aquatic invertebrates. - The reliability of the endpoint in the acute fish study where the limit of solubility was reached. - Experts to agree the endpoint based on the lemna gibba study. - Experts to agree on the use PECTWA for refined aquatic risk assessment pending on the data provided by the applicant. - Experts to decide if the available and potential new data covers the risk from aquatic metabolites. Give a consideration to QSAR analysis presented in the RAR.	The endpoint on shell deposition from the study with <i>C. virginica</i> eastern oyster is the lowest acute endpoint in the available dataset. All experts agreed that this endpoint shall be used in the tier 1 risk assessment. This is in line with current practices and what was done in previous similar cases. In addition, a new chronic study with aquatic invertebrates was available (life-cycle toxicity test with the saltwater mysid <i>Americamysis bahia</i>). Since this study was found valid and reliable by the RMS, all the experts agreed that the endpoints from this study shall be included in the LoEP (NOEC and EC10), and considered in the chronic risk assessment for invertebrate. Open point: -RMS to update the acute tier 1 risk assessment for aquatic invertebrate with the lowest available endpoint, 1.66 mg/L (mm) based on shell deposition from the study with <i>Crassostrea virginica</i>. This update shall be reflected in the revised RAR and LoEP. -RMS to update the chronic risk assessment by considering the lowest available endpoint with <i>Americamysis bahia</i>. - <u>Reliability of the endpoint in the acute fish study where the limit of solubility was reached:</u> • It was agreed that the study CA 8.2.1/1 on rainbow trout could be use in a way of evidence only, and without considering the additional top concentration performed 4 weeks after the start of the test. • It was agreed to consider the studies performed at concentration above the solubility limit of the active substance reliable provided that i)the validity criteria are met, ii) the concentrations are measured, iii) concentrations of filtered sample are taken into consideration as this could be considered as a worst-case. • It was agreed that the acute toxicity study on Rainbow trout (AIIA-8.2.1) should be reevaluated based on the latest version of the OECD TG 203 and the endpoint should be recalculated. If a discrete endpoint cannot be derived, the endpoint of >1.9 mg/L should be used.



Subject	Conclusions Pesticides Peer Review Meeting
	Open point: - RMS to reflect the outcome of the discussion on the fish acute toxicity studies in the revised RAR and LoEP if necessary. - RMS to recalculate the acute fish toxicity endpoint as indicated above for the study on rainbow trout (AIIA-8.2.1). <u>Endpoint based on the <i>Lemna gibba</i> study:</u> The missing information on validity criteria and endpoint calculation were submitted. However, it was noted that the endpoint descriptor is not precise and shall be clarified. Open point: RMS to clarify in the revised RAR the proper dose descriptors for the <i>Lemna gibba</i> study. <u>Use of PEC_{TWA} for refined aquatic risk assessment pending on the data provided by the applicant.</u> The assessment of reciprocity was discussed. It was agreed that reciprocity was not demonstrated based on the following: -In the case of sheepshead minnow, the analysis in the RAR seemed to be based on several concentrations, but a single time point. -For the rainbow trout, there was a high variability in the data and some lack of clarity on what data have been used. In addition, one of the criteria for using the PEC_{TWA} (the acute to chronic ratio), could not be checked since the available acute endpoint is recalculated (see above). Therefore, all experts agreed that PEC_{TWA} cannot be used for chronic risk assessment for fish. -New PEC_{SW} are available following the outcome of the e-fate discussion (peer-review meeting TC 186) and the current aquatic risk assessment shall be fully updated in the revised RAR and LoEP. -Endpoint to be used for the chronic risk assessment for fish: The reliability of the available endpoints was checked according to EFSA (2019), and all experts agreed that the LC_{10} of 0.209 mg a.s./L from the rainbow trout study, based on mortality, should be considered as reliable and used for the risk assessment.



Subject	Conclusions Pesticides Peer Review Meeting
	Open points: RMS to update the aquatic risk assessment reflecting the outcome of the discussion above (new PEC_{sw} from fate and use of the LC₁₀ from the rainbow trout study). The study summary for study AIIA-8.2.2.1 should be updated with the outcome of the discussion i.e. to include comparable LC20 values based on the same length of exposure. Both the RAR and the LOEP should be updated accordingly. <u>Available and potential new data covers the risk from aquatic metabolites.</u> - Based on the following uncertainties: -Only one QSAR model was used -Little information is given on the QSAR applicability domain and robustness -The use of a predicted log Kow create additional uncertainty -The loss of the toxophore was not demonstrated All experts agreed that the QSAR estimates cannot be used. - It was agreed that a screening chronic risk assessment for the metabolites should be performed: -M64 and M47: the parent's endpoint could be used without the factor of 10 since the data suggest that the toxophore has been lost. -For M49: there is no evidence that the toxophore was lost; this metabolite should be assumed to be 10 times more toxic than the parent for the chronic toxicity values. The possibility to use a WoE approach to conclude a low risk was considered however because of the uncertainties identified (assumption and lack of data on the exposure profile, persistence of M49 in surface water, and whether the toxophore was lost), experts agreed that a WoE approach could not be used. It was acknowledged that if the applicant was to provide additional information (e.g. data on persistence or a more refined exposure estimate) a WoE approach could be an option. - It was noted that no risk assessment for sediment dwelling organisms was available for M47 and M49 although these metabolites trigger an assessment due to their fate behaviour. Therefore, a screening chronic risk assessment for these metabolites should be performed. For M47 the same toxicity value of the parent may be used. For M49 the toxicity value should



Subject	Conclusions Pesticides Peer Review Meeting
	be the parent value with the additional factor of 10 applied. Open point -RMS to include a screening chronic risk assessment for fish and aquatic invertebrates for the metabolites, using, for M64 and M47 the endpoint for the parent (i.e. for aquatic invertebrates the endpoint for <i>Americamysis Bahia</i>: NOEC=0.21 and EC₁₀=0.22 mg a.s./L; for fish the chronic rainbow trout LC₁₀=0.209 mg/L). For M49, the endpoint should be the parent value divided by 10. However, it should be reflected that WoE may be considered if additional information was provided by the applicant in the future. -RMS to include a screening sediment dweller risk assessment for metabolites M47 and M49. For M47 the same toxicity value of the parent may be used. For M49 the toxicity value should be the parent value with the additional factor of 10.
Experts' consultation 5.4 The experts should discuss the risk assessment of boscalid to honeybee larvae development. In particular, the discussion should consider: ☐ The acceptability and use of the single dose laboratory study by [REDACTED] (2014), where large fraction of uneaten food were recorded at the end of the exposure period. ☐ The results of the two higher tier studies by [REDACTED] (2012) and [REDACTED] (2014), taking into account the limitation in terms of length and replication of these two studies. In addition, the experts should discuss the available residue trials on sunflower ([REDACTED], 2015) and oilseed	<u>Tier-1 risk assessment endpoints for larvae</u> Considering that single-dose exposure studies are no longer considered appropriate for addressing effects on brood at the lower tiers, and considering the specific deficiencies of study CA 8.3.1.3/1, all experts agreed not to use any endpoint from this study in the risk assessment. On the contrary, the newer repeated-dose study (CA 8.3.1.3/1) was considered appropriate. The tier-1 risk assessment should therefore be conducted using the endpoint from study CA 8.3.1.3/1, i.e. NOEC = 50 µg a.s./larva per dev. Period. <u>Higher tier studies</u> Important shortcomings were identified for both the available Oomen test (KCP 10.3.1.5/1) and tunnel test (CP 10.3.1.5/2). However, the experts agreed to use these studies in a weight of evidence supporting a potential concern related to honey bee development, in light of the higher termination rates observed in both studies for the treatment group with BAS 540 01 F. Concerning the available residues studies (KCA 8.3.1.4/1 and CA 8.3.1.4/2) agreed that this is additional information and does not change the outcome of the risk assessment, as the peak residues are in the range of those used by EFSA (2013) and the decline data cannot be used quantitatively. Open point: RMS to update the evaluation of the aforementioned studies in the revised RAR in line with the discussion at the meeting.



Subject	Conclusions Pesticides Peer Review Meeting
rape (██████, 2015), taking into consideration: - That sunflower is not part of the crops listed in the GAP - Any potential effect of the rainfall - The use of these studies for the risk assessment (qualitative as was done by the RMS or more quantitative use? Use of dissipation time or RUDs?)	
Experts' consultation 5.5 Experts to discuss the findings reported in Simon-Delso et al. (2018) and to assess their relevance for the risk assessment of boscalid under for its representative use.	In light of the findings of the literature study by Simon-Delso et al. (2018), the experts agreed that there are indications that boscalid has TRT properties (i.e. accumulative toxicity), which means that the standard chronic risk assessment does not cover the effects related to a longer exposure time at low doses. Open points for the RMS - RMS to reflect the outcome of the discussion at the revised RAR and include considerations related to the lack of a similar analysis for ██████ (2015), which would have helped in contextualizing the current discussion of Simon-Delso (2018). - RMS shall adjust the assessment of the study by dismissing the applicant's arguments that the tested doses are too high. Open point for EFSA - EFSA to highlight in the EFSA conclusion the above-described situation. Reference: Simon-Delso, N., San Martin, G., Bruneau, E. <i>et al.</i> Time-to-death approach to reveal chronic and cumulative toxicity of a fungicide for honeybees not revealed with the standard ten-day test. <i>Sci Rep</i> 8, 7241 (2018). https://doi.org/10.1038/s41598-018-24746-9
Experts' consultation 5.6 Experts to discuss the chronic toxicity of the	Study AIIIA-10.6.1.2/1 was performed with the formulation BAS 510 01 F sprayed on the soil surface rather than being incorporated into the soil as prescribed by Reg 284/2013. However, since this study is formally valid and provides the



Subject	Conclusions Pesticides Peer Review Meeting
formulation for earthworms (■■■■, 2000). In particular, the experts should discuss: - the validity/admissibility of the test (as the substance was not mixed in the soil); - the possibility to define a reliable endpoint (>20% effect on reproduction seen at the lowest dose); - in case of use for the risk assessment, the endpoint should be better recalculated considering the available information (areal rate and weight of soil in each vessel).	lowest available endpoints for earthworms, the experts agreed to derive an endpoint from the risk assessment. At the statistically-derived NOEC and below effects on reproduction were around 24-25%, which are considered biologically relevant. An EC10 was derived in the meeting. As the uncertainty around the median EC10 is very wide, it was agreed to retain the lower limit of the credible interval (0.281 g/ha, corresponding to 0.47 mg a.s./kg soil, to be further corrected for high boscalid lipophilicity to 0.23 mg a.s./kg soil) as the appropriate endpoint for the risk assessment. Open point: RMS to update the summary of study AIIIA-10.6.1.2/1 by including the information above. The tier-1 risk assessment for earthworms shall be updated as well. All changes shall be reflected in the pertinent volumes in the RAR and LoEP.
Experts' consultation 5.7 Experts to discuss the available multi-years studies with earthworms, and to decide whether they can be used to address the risk posed by the representative formulation. Experts should account for: – the sampling frequency – the sampling method – the taxonomic resolution offered – the representativeness for the different ecological groups (adults, juveniles, endogeic, anecic, epigeic) – the effects and the recovery time observed in the studies.	The experts carefully and closely considered multi-year trends for the main investigated species, morphological and ecological groups of earthworms. Among all monitored parameters, total juvenile biomass showed the most consistent findings across studies. An overall treatment-related decrease in juvenile biomass appears evident when considering all programmes and study years. Overall, the experts agreed that the data available from the field studies do not support a conclusion of low risk for the representative uses of BAS 510 01F. Open point: RMS to amend the study summaries by including the considerations made at the meeting concerning methodological limitations and study outcome. The RMS should also include in the RAR the final remarks on the whole data package. Open point: RMS to include in the revised RAR the table summarising all programmes, the sampling time and the application time.



Subject	Conclusions Pesticides Peer Review Meeting
– the measured concentrations vs. the predicted $PEC_{plateau}$.	
Experts' consultation 5.8 Experts are invited to select the most appropriate endpoint for <i>Folsomia candida</i>, taking into account the available studies, possibly with the aid of more detailed study summaries (see open point 5(261)). The experts should consider: - the validity of the studies, particularly the old ones; - the reliability of the observed effects on mortality and reproduction; - the new study that the applicant is planning to submit. In addition, the experts should assess the results of the available field study (██████████, 2001) in the context of the risk assessment.	Considering that validity criteria were not met, study CP 10.4.2.1/1 was confirmed to be invalid. On the contrary, study CP 10.6.2/1 should be considered formally valid, and the relevant endpoint is $NOEC_{corr} = 15.62$ mg a.s. /kg dry soil. However, the risk assessment should be based on the endpoint derived from study CP 10.4.2.1/2 ($NOEC_{corr} = 204.3$ mg a.s. /kg dry soil), in light of its higher reliability (i.e. better control performance, decreased variability, increased number of tested doses). Considering the serious methodological deficiencies, the available field study on collembolas species (Study AIIIA-10.6.2) should not be further considered for the risk assessment. Open point: RMS to reflect the outcome of this discussion in the RAR for <i>Folsomia</i> and update the RA accordingly. Endpoint should be expressed as concentration of boscalid and corrected for high logP.
New Experts' consultation proposed by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered,	The experts agreed that for one co-formulant, lack of chronic toxicity data meant that the safety of the formulation could not be confirmed. Open point: RMS to reflect the outcome of the consultation in the revised RAR.



Subject	Conclusions Pesticides Peer Review Meeting
MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	

REPORT OF PESTICIDES PEER REVIEW TC 188

FLUAZINAM – AIR IV after ED clock stop

Rapporteur Member State: AT

5. Ecotoxicology

Date: 9 October 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS NL	Ctgb - NL
External expert	Emily McVey
Observer	BAFU - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.15 - Follow up from the mammalian toxicology meeting: Implication on endpoints and RA for mammals to be discussed.	The experts discussed the impact of newly available studies submitted in the context of the assessment for endocrine disruptors and the re-evaluation of the DNT study on the ecotoxicological endpoint for the risk assessment of wild mammals selected at the Peer Review Experts' meeting TC 48 (NOAEL=7 mg/kg bw/d). Overall, based on the endpoints derived from the new studies and the DNT, the experts agreed that the previously selected endpoint is still relevant. Based on the outcome of the EFSA neurotoxicity WG which considered fluazinam as DNT, the experts discussed the implications for the selection of the endpoint for birds' risk assessment. Overall, the experts agreed that when considering (i) the neurotoxic Mode of Action do not seem to be a primary MoA, (ii) the DNT effects were observed at 10 mg a.s./kg bw per day which is higher than the developmental endpoint for mammals (7 mg a.s./kg bw per day), (iii) the endpoint for mammals is considered to cover neurotoxic effects, no additional assessment factor should be applied to the selected bird endpoint. Open point RMS to reflect the outcome of the discussion in the RAR for both the impact of the newly available data for the endpoint for wild mammals and for the impact of the DNT studies to the endpoint for birds.
New experts' consultation point	Experts agreed that a data gap was needed for a suitable study for soil micro-organisms with 'MCW 465 500 SC'.



Subject	Conclusions Pesticides Peer Review Meeting
proposed by EFSA for completeness: MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation 'MCW 465 500 SC' for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the available toxicity data with the formulation for representative uses, 'MCW 465 500 SC' and its co-formulants. Overall, all experts agreed RMS evaluation and agreed that the co-formulants will not impact on the safety of the representative formulation 'MCW 465 500 SC'. However, pending on the outcome on identified missing data for toxicology for one of the components in the formulation for representative uses, further consideration to non-target organisms may be necessary. Open point: RMS to reflect the outcome in the discussion in the revised RAR.
New experts' consultation point proposed by EFSA for completeness: MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation 'TIFC 500 SC' for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the available toxicity data with the formulation for representative uses, 'TIFC 500 SC' and its co-formulants. Overall, all experts agreed RMS evaluation and agreed that the co-formulants will not impact on the safety of the representative formulation 'TIFC 500 SC'. However, pending on the outcome on identified missing data for toxicology for one of the components in the formulation for representative uses, further consideration to non-target organisms may be necessary. Open point: RMS to reflect the outcome in the discussion in the revised RAR.
New experts' consultation point proposed by EFSA for completeness: MS experts to discuss whether the available	The experts discussed the available toxicity data with the formulation for representative uses, 'IKF-1216 500 SC' and its co-formulants. Overall, all experts agreed RMS evaluation and agreed that the co-formulants will not impact on the safety of the representative formulation IKF-1216 500 SC.



Subject	Conclusions Pesticides Peer Review Meeting
information is sufficient to characterise the full ecotoxicological profile of the formulation 'IKF-1216 500 SC' for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Open point: RMS to reflect the outcome in the discussion in the revised RAR.

REPORT OF PESTICIDES PEER REVIEW

TC 182 and TC 188

FENPYROXIMATE – AIR IV after ED clock stop

Rapporteur Member State: AT

5. Ecotoxicology

Date: 9 October 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Experts nominated by MS DK	Danish Environmental Protection Agency (DEPA) - DK
National Experts nominated by MS FI	Finnish Safety and Chemicals Agency (Tukes) - FI
National Experts nominated by MS NL	Ctgb - NL
External expert	Emily McVey
Observer	BAFU - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.8 Experts to discuss the AMA, its limitation, the effects observed (water control vs solvent control) and the absence of finding in the thyroid histopathology at the test termination.	Several uncertainties were identified in the available AMA: -temperature deviation, -high coefficient of variation of the measured concentration due to higher recovery on day 17 -several accidental mortality of the tadpole reported -solvent effect on all parameter on day 7 and on Hind-limb length and developmental stage on day 21 -reporting of the histopathological result not in line with the guidance. Overall, it was concluded that the study, of very low quality, should not be used to conclude for the T-modality as standalone. However, considering all available information including mammalian data in a weight of evidence, experts concluded that it is unlikely that fenpyroximate is an endocrine disruptor through the T-modality.
Experts' consultation 5.9 Experts to discuss the FSTRA and the outcome of the FSTRA more specifically: - the reliability of the study, also considering the control contamination	The effects observed in the available FSTRA were discussed (all non-statistically significant: increase in male VTG, decrease in female GSI, a decreased fertilisation success at the lowest and highest concentration). The only statistically significant finding (decrease in tubercle score in male at the highest tested concentration) was not treatment related since it was driven by one low value in one male fish. Despite some uncertainty related to the solvent control contamination, it was concluded that the observed effects do not suggest a pattern of EAS-mediated endocrine related activity or/and adversity in the available FSTRA. Considering all the available information, experts agreed that the ED criteria are not met for EAS-modalities for non-target organisms.



Subject	Conclusions Pesticides Peer Review Meeting
- the statistical analysis methodology (comparison with solvent control vs pooled control) - the increasing trend in male VTG - the effect on male tubercule score - the effect on GSI In addition, experts should discuss the ED assessment for the EAS modalities also considering the information from the other studies (mammalian dataset, in vitro assay).	
Experts' consultation 1 added by EFSA: MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the toxicity data with the formulation for representative uses together with the available toxicity data for the co-formulants. It was agreed that no concerns were identified related to the safety of the formulation for representative uses. Open point: RMS to reflect the outcome in the discussion in the revised RAR.

REPORT OF PESTICIDES PEER REVIEW TC 185

BACILLUS VELEZENSIS FZB42 – NAS 1107

Rapporteur Member State: NL

9. Microorganisms - Ecotoxicology

Date: 25 September 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS NL	Ctgb - NL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS EL	Benaki Phytopathological Institute (BPI) - EL
National Expert nominated by MS ES	National Institute for Agricultural and Food Research and Technology (INIA/CSIC) - ES
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS SE	Swedish Chemicals Agency (KEMI) - SE
National Expert nominated by MS SI	Agricultural institute of Slovenia - SI

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Discussion points/Outcome

9. Microorganisms - Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 0.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative use(s) with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	Formulation studies with aquatic organisms, soil organisms, bees and algae consistently showed low toxicity. One co-formulant is also approved for use in food, feed and pharmaceutical applications, presents no classification concerns under Regulation (EC) No 1272/2008, is readily biodegradable and is neither a PBT nor classified as hazardous. Despite the absence of chronic data for birds and mammals, the overall evidence supported a low risk for all non-target organisms. Experts concluded that this co-formulant did not increase the adversity of the microorganism to any non-target organism group and that the available dataset was sufficient to characterise the ecotoxicological profile of the preparation.

REPORT OF PESTICIDES PEER REVIEW TC 185

CANDIDA OLEOPHILA STRAIN O -AIR V

Rapporteur Member State: SI

9. Microorganisms - Ecotoxicology

Date: 25 September 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS SI	Agricultural institute of Slovenia - SI
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS EL	Benaki Phytopathological Institute (BPI) - EL
National Expert nominated by MS ES	National Institute for Agricultural and Food Research and Technology (INIA/CSIC) - ES
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS NL	Ctgb - NL
National Experts nominated by MS SE	Swedish Chemicals Agency (KEMI) - SE

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Discussion points/Outcome

9. Microorganisms - Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 0.1 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	It was confirmed by other sections involved in the peer-review that due to the production methods, <i>Candida oleophila</i> strain O [REDACTED]; thus [REDACTED] are added to Nexy Biomass. Open point: RMS to reflect the outcome of the discussion in the RAR.

REPORT OF PESTICIDES PEER REVIEW TC 185

TRICHODERMA HARZIANUM T78 – NAS 1107

Rapporteur Member State: NL

9. Microorganisms - Ecotoxicology

Date: 25 September 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS NL	Ctgb - NL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS EL	Benaki Phytopathological Institute (BPI) - EL
National Expert nominated by MS ES	National Institute for Agricultural and Food Research and Technology (INIA/CSIC) - ES
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS SE	Swedish Chemicals Agency (KEMI) - SE
National Expert nominated by MS SI	Agricultural institute of Slovenia - SI

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Discussion points/Outcome

9. Microorganisms - Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 9.1 Experts to discuss: - Whether the available studies can be considered appropriate to conclude on pathogenicity and infectivity. - Whether the available weight-of-evidence for honey bees is sufficient to exclude concerns. - The outcome of the risk assessment for honey bees.	Considering (i) the short duration of the study KMP 10.3/01 (48h), (ii) data from other <i>Trichoderma</i> spp. indicating mortality after 4 days, (iii) the lack of microscopic observations, and (iv) only water control was used in the study, the experts agreed that the available study is not sufficient to conclude the assessment for infectivity and pathogenicity. Nevertheless, the experts considered the following lines of evidence: (i) the available literature data indicating low adversity to bees, and (ii) exposure will be limited considering the application methods (i.e., drip irrigation and drenching). Overall, the experts agreed that the available weight-of-evidence is sufficient to conclude with low risk for honey bees. Open point: RMS to reflect the outcome of the discussion in the RAR.
Experts' consultation 9.2 Experts to discuss and agree on the risk assessment for soil macro-organisms.	During the peer-review, PED_{soil} were recalculated. Based on a 56-day laboratory study, a new margin of safety (145) was derived for earthworms. The experts at the meeting considered the laboratory study, the new derived margin of safety as well as literature data, and agreed a low risk can be concluded for earthworms. The experts at the meeting also discussed available studies with nematodes. Overall, no adverse effects to beneficial nematodes were indicated by the available information. Nevertheless, some effects on parasitic nematodes were noted.



Subject	Conclusions Pesticides Peer Review Meeting
	Open point: RMS to reflect the outcome of the discussion in the RAR.

REPORT OF PESTICIDES PEER REVIEW TC 185

TRICHODERMA ASPERELLUM T34 – AIR V

Rapporteur Member State: SE

9. Microorganisms - Ecotoxicology

Date: 25 September 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency (KEMI) - SE
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS EL	Benaki Phytopathological Institute (BPI) - EL
National Expert nominated by MS ES	National Institute for Agricultural and Food Research and Technology (INIA/CSIC) - ES
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS NL	Ctgb - NL
National Expert nominated by MS SI	Agricultural institute of Slovenia - SI

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Discussion points/Outcome

9. Microorganisms - Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Expert consultation 9.1 Experts to discuss whether adversity to fish has been sufficiently investigated in the study by Mikullas (2020) KMA 8.2.1-01, considering the effects on body weight and the limitations of the study design.	Considering that: (i) no NOEC can be established as the single tested concentration in KMA 8.2.1-01 showed biologically relevant effects, (ii) the concentration tested was higher than recommended in the test guidelines, (iii) no sterile filtrate was available, the experts at the meeting agreed that it is not possible to determine whether the observed effects are due to metabolites or to a physical effect of the spores in the study KMA 8.2.1-01. Nevertheless, it is agreed that the information available could be used in a weight-of-evidence approach for the risk assessment. Open point: RMS to reflect the outcome of the discussion in the RAR.
Expert consultation 9.2 Experts to agree on the conclusion for the acute and chronic risk assessment for adult bees and for bee larvae.	Based on the 12-day study, the experts at the meeting could not exclude a concern for field uses. A data requirement was set, but no additional information was provided by the applicant during the regulatory clock-stop. It should be noted that the product for field uses was discontinued. With regards to greenhouse use, it was agreed by the experts that the risk is low due to limited exposure. Open point: RMS to reflect the outcome of the discussion in the RAR.
Expert consultation 9.3 Experts to: agree whether the available information is	The experts at the meeting discussed the available data for the risk assessment of non-target arthropods. Considering that: (i) only product studies (T34 Biocontrol) were available, namely 48h and 7 day tests, (ii) the margin of safety of 23 established for <i>Typhlodromus pyri</i> was deemed relatively low considering the testing strategy with foliar dwellers, the experts agreed



Subject	Conclusions Pesticides Peer Review Meeting
sufficient to conclude on the risk assessment for non-target arthropods other than bees and other soil dwelling arthropods; • agree on the conclusion for the risk assessment.	that data is overall limited and it is not possible to conclude the risk assessment for field uses. A data requirement was set, but no additional information was provided by the applicant during the regulatory clock-stop. It should be noted that the product for field uses was discontinued. With regards to greenhouse use, it was agreed by the experts that the risk is low due to limited exposure. Open point: RMS to reflect the outcome of the discussion in the RAR.
Expert consultation 0.5 Experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation T34 Biocontrol with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	At the meeting, the experts agreed that, for all co-formulants present in the formulation, there is no indication that the co-formulant will potentially increase the toxicity of the formulated product. Open point: RMS to include the available information and the outcome of the discussion in the updated RAR Volume 4.
Expert consultation 0.6 Experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation Xilon with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS	A data requirement was set, but no additional information was provided by the applicant during the regulatory clock-stop. It should be noted that the product for field uses Xilon was discontinued. The data available do not allow to characterise the ecotoxicological profile of the formulation. Open point: RMS to reflect the outcome of the discussion in the RAR.



Subject	Conclusions Pesticides Peer Review Meeting
experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	

REPORT OF PESTICIDES PEER REVIEW TC 180

CLETHODIM – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 3 July 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS DE	German Environment Agency - DE
National Expert nominated by MS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS NL	Ctgb – NL
National Experts nominated by MS NO	Norwegian Food Safety Authority - NO
External Expert	Vanessa Mazerroles

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the long-term endpoint for mammals.	The RMS proposed a NOAEL=20.8 mg/kg bw/d from the rabbit developmental study based on maternal toxicity and in particular on decreased body weight gain and clinical signs Overall, when considering the type of effects, the experts did not consider the endpoint proposed by the RMS as ecotoxicologically relevant. Based on available studies and endpoints, all experts agreed to use the NOAEL=83.3 mg/kg bw/d based on developmental effects in rat and rabbit. Open point: RMS to reflect the outcome of the discussion and to update the RA accordingly both in the RAR and list of endpoints.
Experts' consultation 5.2 Experts to discuss the proposed approach for the aquatic risk assessment of metabolites (relevant for sediment): 1. the use of factor 43 to account for sensitivity difference between <i>Lemna gibba</i> and <i>Glyceria maxima</i>. 2. the use of aquatic macrophytes to cover the potential risk to algae and invertebrates.	Based on the fact that <i>Lemna gibba</i> is less sensitive to clethodim than <i>Glyceria maxima</i>, it was agreed to use the endpoint on <i>Glyceria maxima</i> from the parent, clethodim, to derive a surrogate endpoint for the metabolite. In addition, it was agreed that the usual factor of 10 should be applied to derive this endpoint for the metabolite without data on <i>Lemna</i> (3-chloropropenal) and for the metabolite showing a similar toxicity than the parent (CAA). For the other metabolite, showing a lower toxicity than the parent on <i>Lemna</i>, a factor of 1 should be applied. In addition, the factor agreed in the Fate meeting should be applied to the metabolite to address the uncertainty related to isomerization. All experts agreed that the risk assessment of aquatic macrophytes covers the potential risk to algae and aquatic invertebrates for the metabolites. Open point: RMS to reflect the discussion on uncertainty factors (5.2/1) in the revised RAR and to update the RA.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.3 Experts to discuss the risk assessment for aquatic macrophytes, including: - The most appropriate parameter for deriving an endpoint for risk assessment from the study CA 8.2.7/03 (2020) on <i>Glyceria maxima</i> with clethodim [see comment 5(45), 5(59), 5(82)] and how the endpoint should be expressed (geomean vs. TWA) [see comment 5(48)]. Additional data requested from the applicant under 5(36) should also be considered for the derivation of the endpoint. See also 5(73). - The endpoints derived from the available studies considering the effects on phytotoxicity. See comments 5(58), 5(60), 5(61). - The need for additional studies with <i>Glyceria</i> and the representative formulation and relevant metabolites. See 5(38). - The need for an overspray study.	<u>Endpoint for risk assessment from the study CA 8.2.7/03 (2020) on <i>Glyceria maxima</i>:</u> It was agreed to use the endpoint of 19 µg/L calculated across the range of concentrations showing a clear dose-response. When considering the confidence interval, this endpoint was not less reliable than the endpoint derived on fresh weight. This endpoint is more conservative and cover also the phytotoxicity effects observed in the low concentration range. Moreover, experts agreed to express the endpoint based on time-weight average concentration, given the semi-static test design and the differing sampling time intervals. <u>Endpoints derived from the available studies considering the effects on phytotoxicity.</u> Overall, it was agreed that the phytotoxicity is covered by the endpoint set for <i>Glyceria</i> at 19 µg/L. <u>The need for additional studies with <i>Glyceria</i> and the representative formulation and relevant metabolites.</u> <u>Metabolites</u> No additional studies with <i>Glyceria</i> are needed. See expert consultation 5.2 for the approach to be taken for metabolites risk assessment. <u>Need for a study with the formulation on <i>Glyceria</i>.</u> The data available show that for <i>Lemna</i>, the active is more toxic than the formulation. However, for other aquatic organism the formulation shows a higher toxicity than the active. Since the active substance is an herbicide for monocots, the toxicity difference between the formulation and active substance may not be concluded by the less sensitive species <i>Lemna</i>. Therefore, it was agreed that a study with the formulation on <i>Glyceria</i> should be requested. <u>Need for an overspray study.</u> There is no need for an overspray study with clethodim since <i>Glyceria</i> is clearly sensitive to the active substance, and there is no evidence that another route of exposure is more relevant, <i>Glyceria</i> being exposed both via the water column and the sediment. Open point: RMS to reflect the outcome of the discussion and to update the RA accordingly both in the RAR and list of endpoints.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 Experts to discuss the impact of pH-dependent ionisation of clethodim on toxicity, bioaccumulation and risk to aquatic and soil organisms.	Experts agreed to not apply any correction since there is no agreed consensus or agreed methodology to do so, and there is no evidence that the current methodology does not allow for a proper aquatic risk assessment for clethodim on macrophytes. Open point: RMS to reflect the discussion and to acknowledge the uncertainty in the revised RAR.
Experts' consultation 5.5 Experts to discuss the ecotoxicological equivalence between the different formulations used in the studies with the representative formulation Clethodim 120 EC / H1231bc.	The experts at the meeting reviewed the available information on the composition of the different tested formulations and toxicological data. The experts agreed that: • TM-20015 (H1231bc) can be considered equivalent with the formulation H1231cj. • TM-20015 (H1231bc) cannot be considered equivalent with the TM-5403 (Select 120) as the composition is different, and no systematic pattern was observed when comparing endpoints with the a.s. or representative formulation. • TM-20015 (H1231bc) cannot be considered equivalent with the TM-20006, TM-20004, and TM-20016 as the composition is different compared to the representative formulation. It is noted the RMS disagreed with the conclusion for TM-5403. Open Point: RMS to reflect the discussion in RAR.
Experts' consultation 5.6 Experts to discuss the endpoint from the chronic earthworm study CA 8.4.1/06 (2019b) with CAA.	<u>Chronic earthworm (<i>Eisenia andrei</i>) study CA 8.4.1/06 (2019b) with CAA.</u> The RMS proposed to revise the NOEC for earthworm (<i>Eisenia andrei</i>) reproduction following exposure to CAA from 6.4 mg/kg soil dry weight (dw) to 3.2 mg/kg soil dw. This proposal is based on the observation of a biologically relevant 13% reduction in reproduction at the highest tested concentration (6.4 mg/kg soil dw), despite the lack of statistical significance. The RMS considers the dose-dependent trend and magnitude of the effect to be indicative of biological relevance, consistent with the guidance provided in EFSA (2017, 2019). During the meeting, it was agreed that the study met all validity criteria, despite minor guidance deviations that were not considered to influence the outcome. Experts supported the RMS proposal to set the NOEC at 3.2 mg/kg soil dw, taking into



Subject	Conclusions Pesticide Peer Review Meeting
	account the dose-response trend and the biological relevance of the observed effects. No further action by the RMS is needed.
Experts' consultation 5.7 Experts to discuss appropriate assessment factors for extrapolation between parent compound and the various soil metabolites.	No reliable studies are available for the metabolites clethodim sulfoxide and clethodim sulfone concerning their effects on earthworms and soil microorganisms. While the applicant argued that the structural similarity to the parent compound and the low acute toxicity of clethodim sulfoxide justify a lower extrapolation factor, the RMS applied a precautionary assessment factor of 10 in the absence of adequate data. For collembola, some data are available for clethodim oxazole sulfoxide and clethodim sulfone. However, they do not cover all required endpoints. Experts agreed with the RMS approach, supporting the use of an extrapolation factor of 10 for risk assessment of these data-poor metabolites. No further action by the RMS is needed.
Ecotoxicity Experts' consultation 0.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts at the meeting discussed the available information on the composition of the formulation for representative uses. Overall, the majority of the experts agreed that the information is sufficient to characterise the full ecotoxicological profile of the formulation for representative uses with respect to the acute and chronic toxicity. Open point: RMS to reflect the outcome of the discussion in the confidential volume of the RAR.

REPORT OF PESTICIDES PEER REVIEW TC 175 AND TC 180

PENCONAZOLE – AIR IV

Rapporteur Member State: NO

5. Ecotoxicology

Date: 4 July 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS NO	Norwegian Food Safety Authority - NO
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) – AT
National Expert nominated by MS BE	Federal Public Service Health, Food Chain Safety, Environment - BE
National Expert nominated by MS CZ	The National Institute of Public Health - CZ
National Expert nominated by MS DE	German Federal Institute for Risk Assessment - DE
National Experts nominated by MS DE	German Environment Agency (UBA)
National Expert nominated by MS DE	Julius Kühn Institute (JKI) - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Experts nominated by MS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS NL	Ctgb – NL
National Expert nominated by MS SE	Swedish Chemicals Agency - SE
Observer	The Norwegian Food Safety Authority - NO

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the experts at the beginning of this meeting.

¹ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

² https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf



Discussion points/Outcome

5. Ecotoxicology

Please note that information part of this report may have been masked by EFSA in accordance with Article 63 of [Regulation \(EC\) No 1107/2009](#) as well as [EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation \(EC\) No 1107/2009](#), or [EFSA's Practical Arrangements concerning transparency and confidentiality](#) as a consequence of confidentiality requests submitted by the applicant on application dossiers for pesticides active substances or Maximum Residue Levels, respectively. Please note that information disclosed in this report is without prejudice to pre-existing intellectual property rights and data exclusivity clauses set out in Union law, and particularly in Article 62 of Regulation (EC) No 1107/2009.

Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the available data in the mammalian toxicology section that can be useful for setting the long-term ecotox relevant endpoint and the proposed new data to be submitted by the applicant (i.e., 2-gen study in line with the latest version of OECD TG 416).	Two generation studies were available but only considered supportive. The RMS selected the NOAEL=21.2 mg/kg bw/d based on reduced pup body weight (>10%) during lactation from one of those multigenerational studies. Considering the available 2 generation studies are only supportive owing to a number of deviations, overall, the experts agreed that the ecotoxicologically relevant NOAEL could be 21.2 mg/kg bw/d from available 2 gen studies. However, this endpoint is only provisional until the new 2 gen study (underway) is submitted. Open point: RMS to reflect the discussion in RAR.
Expert consultation 5.2 To finally decide on the reliability/acceptability of the bioconcentration in fish study (1988) for its use in risk assessment.	Study under discussion: Surprenant, 1988. Bioconcentration and elimination of ¹⁴C-residues by bluegill (<i>Lepomis macrochirus</i>) exposed to ¹⁴C-CGA 71818 (K-CA 8.2.2.3/01) During the meeting, experts discussed the bioconcentration study (1988). While the absence of TOC measurements was identified as the main issue impacting reliability, the applicant's justification, supported by historical TOC data and theoretical calculations, was considered acceptable. Experts agreed that other deviations identified (i.e., lack of lipid normalisation, growth dilution, temperature, fish size) could be considered minor and did not significantly impact the study's reliability. In addition, and given the large safety margins in the secondary poisoning assessment and the discussion on the potential need for a new vertebrate study, experts supported the RMS position to accept the study as reliable and suitable for risk assessment, with restrictions (as identified above).



Subject	Conclusions Pesticide Peer Review Meeting
	An Open point for the RMS to reflect this discussion in the RAR.
Expert consultation 5.3 Experts to discuss the following issues related to the aquatic risk assessment of penconazole: i) The acute risk assessment for fish including: - The reliability of the two acute fish studies with the formulated product - If acute toxicity study of CGA71818 to carp provides a suitable endpoint for risk assessment (96h, <i>Cyprinus carpio</i>, LC50 = 3.8 mg a.s./L with 95 % confidence limits of 2.5 to 5.2 mg/L) and if the justification from applicant is sufficient or the endpoint from the new study with <i>O. mykiss</i> should be used. ii) The chronic risk assessment for fish including: - To decide on the reliability of the Fish early life stage toxicity study (1984) for use in risk assessment as the small number of replicates was used and exposure of embryos was delayed. - Decide on more suitable endpoint for the risk assessment	1. Acute risk assessment for fish The rationale behind the decision on the endpoint to select for acute fish studies was the following: Experts evaluated the reliability and use of the two acute fish toxicity studies conducted with both the formulated product (TOPAS EC) and technical active substance for penconazole. <u>Study 1: Rainbow trout (K-CP 10.2.1/01) conducted with the formulation TOPAS EC</u> All experts agreed that the study is reliable and suitable for risk assessment, with restrictions and that the endpoint should be expressed using the geometric mean of available mean measured concentrations. Due to the lack of analytical confirmation for the 5.62 mg/L nominal concentration, the exposure level should be corrected using the average recovery rate from the highest tested concentration (recovery rate of 79%). <u>Study 2: Carp (K-CP 10.2.1/02) conducted with the formulation TOPAS EC</u> This study was also considered reliable and appropriate for risk assessment. Experts agreed to calculate endpoints using the geometric mean of the two tested concentrations (nominal 10 and 18 mg/L). Where analytical data is missing (i.e., for the replicate of 18 mg/L exposure concentration), the recovery rate from all replicates at time 0 will be used to estimate exposure concentrations. Although some experts would prefer using mean measured concentration over the whole duration of the test for the nominal concentration of 10 mg/L (as only 10% mortality was recorded for this concentration at the end of the study), the majority of experts were in favour of using the recovery observed at 0h for 10 mg/L and to use the average of all the concentrations of the 0h at 18 mg/L. <u>Study 3: Carp (K-CA 8.2.1/05) conducted with the active substance</u> All experts agreed that the endpoint of LC50 of 3.8 mg a.s./L from the study with carp (K-CA 8.2.1/05) conducted with the active substance could be used for the risk assessment. I was discussed if the study with the active substance (K-CA 8.2.1/01) may indicate a higher sensitivity to trout and should be considered further. Experts agreed it was not fully valid due to uncertainties in study conditions and differences in purity. Nonetheless, it was accepted as supportive. The potential supportive nature of the study (K-CA 8.2.1/04), was also mentioned, but experts agreed that it could not be used for the RA (in line with EFSA 2015).



Subject	Conclusions Pesticide Peer Review Meeting
between the Fish early life stage toxicity study (1984) and new full fish life cycle study. iii) The acute and chronic risk assessment for aquatic invertebrates including issues related to sediment dwellers: • Discussion on new acute toxicity study provided by applicant with Daphnia and technical penconazole to fulfil data requirement according to OECD TG 202 and consequent new endpoint and risk assessment. • discussion of potential new EC50 calculated by RMS for Acute toxicity to Daphnia magna, Wallace 2001 and consequent impact on risk assessment • Discussion on new chronic study with Daphnia magna and technical penconazole to fulfil data requirement and consequent new endpoint and risk assessment. • Discussion on the reliability/acceptability of the study on chronic toxicity and sediment dwelling organisms.	To conclude, all experts supported that the available data were sufficient, and no further fish studies were needed. For acute risk assessment, the endpoint from the trout study with the formulation (K-CP 10.2.1/01) was deemed appropriate for Tier 1. Open point: RMS to check the endpoint of the trout study with the active substance (Suprenant 1984, K-CA 8.2.1/01) and confirm whether it is 1.3 (or 1.2) mg/L, and update the RAR reflecting the overall discussion. RMS to reflect in the RAR if in view of the discussion had the study (K-CA 8.2.1/04) could be considered supportive. 2. Chronic risk assessment for fish The rationale behind the decision on the endpoint to select for chronic fish studies was the following: The discussion was focused on key deviations identified in the early life-stage (ELS, OECD 210) study (K-CA 8.2.2.1/01), specifically the low number of replicates and the delayed start of embryo exposure. These deviations were initially suggested to potentially impact the study's validity and use for the risk assessment. The applicant provided supporting arguments, including a power analysis indicating that the number of replicates was sufficient to detect dose-response effects. Experts also noted that despite the delayed exposure, embryos were still considered adequately exposed. Length and weight were identified as the most sensitive parameters. While these deviations were acknowledged, experts agreed that they did not significantly compromise the validity of the study. Furthermore, a full life-cycle (FFLC) study has been conducted (only a summary of results has been made available). A preliminary comparison with its summary results suggests that similar effects were observed at the similar concentrations. However, the full FFLC data set is still pending submission. To conclude, and despite noted deviations from OECD 210 requirements, the ELS study was considered to meet the necessary validity criteria and is therefore reliable for use in the risk assessment. The agreed endpoint (NOEC for length and weight = 0.36 mg a.s./L) is supported by all experts. The study can be used in the current risk assessment, with the understanding that the outcome may be revised if the full FFLC study, once submitted, provides a lower endpoint. Open point: RMS to update the RAR reflecting the outcome of this discussion. 3. Risk assessment to sediment dwelling organisms The rationale behind the decision on the endpoint to select for sediment dwelling organisms was the following:



Subject	Conclusions Pesticide Peer Review Meeting
Deviations in terms of temperature and pH were noted in the study. If new study is provided by the applicant or a justification is given, a further discussion on new endpoint and consequent risk assessment. iv) Issues related to the risk assessment for algae and aquatic macrophytes: • Discussion on new algal study provided by the applicant to fulfil data requirement for the metabolite CGA142856 according to OECD TG 201 (2006) and consequent new endpoint and risk assessment. • Discussion on risk assessment for aquatic macrophytes with new study provided by the applicant with <i>L. gibba</i> to clarify the possible effects to aquatic non-target plants. • General discussion on risk assessment for aquatic organisms once considered all available data newly submitted by the applicant.	The sediment-dwelling organism study (K-CA 8.2.5.3/01) was discussed by all experts focusing in particular with: deviations in pH, temperature, and the number of larvae introduced per vessel at the start of the study. Although minor variations in pH and temperature were considered acceptable by all experts, more critical concerns were raised regarding the study's validity. Specifically, the number of emerged larvae exceeded the number initially introduced, calling into question the accuracy and reliability of the data. Additionally, significant drops in oxygen saturation (approximately 35–51% in exposure scenario A) were observed in some replicates on day 0, further compromising test conditions. The exposure concentrations presented also showed minor discrepancies between geometric mean values and those reported in the study. Given the critical issues identified, particularly with larval counts and oxygen saturation, all experts agreed that the study does not meet validity criteria and should not be used in the risk assessment. A data gap remains for the sediment organism assessment. Data gap: Applicant to address the risk assessment to sediment organisms 4. Acute risk assessment for Daphnia No further discussion took place at the meeting, after RMS evaluation of new data submitted by the applicant (K-CA 8.2.4.1/07) and recalculation of EC50. To conclude, the new study was considered reliable and valid for the RA. 5. Chronic risk assessment of Daphnia New study provided (K-CA 8.2.5.1/03). During the expert discussion, it was highlighted that the use of a 4-parameter function for statistical evaluation of the data is preferred over the 3-parameter function, as it provides a better fit for the data in this study. An EC10 value of 0.01 mg a.s./L was previously used in the CLP classification for penconazole. However, this value was derived through a highly conservative approach and corresponded to only a 3% effect. Experts noted that the NOEC derived from the same study also reflected a 3% effect on mean body length. While the EC10 is a statistically derived value, it was considered overly conservative for use in the risk assessment because the actual biological effects were substantially below 10%. Based on the observed effects and statistical evaluation, the experts concluded that the NOEC of 0.015 mg a.s./L is a suitably conservative and scientifically justified endpoint for use in the risk assessment. The EC10 value of 0.01 mg a.s./L, while previously used for classification purposes, was considered too conservative



Subject	Conclusions Pesticide Peer Review Meeting
	for risk assessment, as the associated effects were well below the 10% threshold. An Open point for the RMS to reflect this discussion and update the RAR. 6. Risk assessment for algae No further discussion took place at the meeting, as algal study provided by the applicant (K-CA 8.2.6.1/15) to fulfil data requirement for the metabolite CGA142856 according to OECD TG 201 (2006) was considered reliable and valid for the risk assessment. 7. Risk assessment for aquatic plants The study evaluation of the newly submitted study (K-CA 8.2.7/02) and the updated risk assessment was considered as appropriate, therefore agreed by the experts.
Experts' consultation 5.4 Experts to decide on the risk assessment to bees in relation with: - Available information for the formulation to cover the a.s. risk assessment; - New available acute data in line with Data Requirement in 5(82) - New available chronic data. E.g., new chronic study has been requested (see 5(82)) including a new proposed by the Applicant 22-d study with larvae and the statistical re-evaluation of the study of 8-d (see 5(98). Please note that in line with the EU data requirements, the tests shall be conducted with the a.s. or the technical a.s. - Suitability of the refinement of the trigger values to achieve low risk for the active/metabolites (ECPA approach) (see 5(113)).	The study evaluation of the newly submitted studies and the updated risk assessment was considered as appropriate, therefore agreed by the experts. The rejection of the refinement options proposed by the Applicant were also agreed. Therefore, open points to reflect the pertinent discussions in the RAR were set. As regards the originally submitted chronic studies with the formulations, since they fulfil the validity criteria (and, overall, the methodological flows were not considered substantial), it was agreed that their endpoint should still be presented in the LoEP with pertinent footnote. Open point: The RMS to reflect the discussion in the RAR and report the chronic endpoints of the formulation studies in the LoEP.



Subject	Conclusions Pesticide Peer Review Meeting
- Any other information to address any potential risk to bees (e.g., further elaboration of the WoE for metabolite CGA132456 and any other information (e.g., report mentioned in 5(106), 5(124)). - Risk assessment in the treated weeds scenario and other scenarios for the a.s. and metabolites (see 5(123) for instance). If the new information highlights any other relevant scenario for bees, this EC subpoint would be extended to those scenarios. See 5(106) for information and data requirement related to this point. See furthermore other issues identified related to the bee risk assessment in 5(124-128).	
Experts' consultation 5.5 Experts to agree on the following aspects in the available studies with NTAS: - New endpoint for T.piry from a study to be submitted. - Endpoint derived in the study by K-CP 10.3.2.1/03; - Suitability of the study design in the study by 10.3.2.2/02 since only two replicates were available in the control; - Reliability of the study by K-CP 10.3.2.2/03 since one of the validity criteria is not fulfilled and other issues have been identified in 5(89-91).	<u>New endpoint for T. pyri from the extended laboratory study</u> Experts agree with the RMS assessment and with the endpoint derived (117 g a.s/ha). The high rate of toxic reference can be considered as a minor deviation. <u>Endpoint derived in the study K-CP 10.3.2.1/03</u> It was considered that this study gives usable and valid information about toxicity, therefore experts agreed to consider the study as supportive. It was agreed to include it in the LoEP with an explanatory footnote. <u>Suitability of the study design in the higher tier study (2019)</u> Because of the low number of replicates in the control, it was agreed to consider the study as supportive only, for the endpoint derived based on mortality. Regarding the reproduction, the endpoint should be considered as unreliable. Since more reliable endpoints are available, it was agreed not to report the endpoint in the LoEP. <u>Reliability of the study (1993a) (now K-CP 10.3.2.2/04)</u> Because of the limitation identified (i.e. the validity criteria for the amount of eggs/female not fulfilled; toxic reference, feeding regime, temperature, timeline and duration not in line with the



Subject	Conclusions Pesticide Peer Review Meeting
- Suitability and results of the available field study, 1999. See also 5(91), 5(105). - The endpoint to be derived from the study by Reber 2002. - Any new submitted experimental data or position paper shall be considered by the experts. - Experts to discuss the endpoint to be used in the risk assessment and obtain a final conclusion for the risk assessment in-field and off-field for NTAS.	guideline; testing of only one dose level; sparsely detailed study report) and because a new study, fully reliable, is available, experts agree to consider this study as not acceptable. <u>Suitability and results of the available field study (1999).</u> Several shortcomings were identified in this field study: - Lack of mites in the water control 1 week after the last application, and low mites density in all the treatment groups - Lack of information about study design - Application of other pesticides in some plots during the testing period In addition, the risk assessment demonstrates a low risk at tier 2 with a new study. Therefore, experts agreed that the study cannot be used in the risk assessment and should not be included in the LoEP. The endpoint to be derived from the semi-field study (2002). Several limitations were raised during the discussion: - The study design and its usefulness for risk assessment - The lack of details on the environmental conditions during the exposure phase - Mortality was not assessed, - There was limited or no control on the environmental conditions during the exposure phase and the temperature was noted to be quite variable - The study methodology does not comply with modern risk assessment standards Based on this, it was agreed to consider this study as supportive only, and to not include it in the LoEP. <u>Endpoint to be used in the risk assessment for T.pyri</u> Experts agreed with the RMS proposal to use the endpoint from the new study (2022), i.e 117 g a.s./ha. Taking this endpoint into consideration, the risk assessment demonstrated a low in-field and off-field risk to NTAs for all uses. A tier 2 off-field RA was not currently presented but could be useful considering that the tier 1 endpoint for T. pyri is only supportive. Open point: • RMS to reflect the outcome of the discussion in the RAR, specifically to update the study evaluations for the following studies: 10.3.2.1/03, 10.3.2.2/03, 10.3.2.2/04, the semi-field study (2002), the field study (1999). An explanatory footnote should be added in the LoED for the endpoint from the study (1999). • The endpoints from those studies which were not sufficiently reliable should be removed from the LoEP: - study 10.3.2.2/03 (2019)



Subject	Conclusions Pesticide Peer Review Meeting
	- study 10.3.2.2/04 (1993a) - semi-field study (2002) - field study (1999). • The RMS is also requested to provide a tier 2 off-field RA for NTA.
Experts' consultation 5.6 Experts to conclude on the risk to soil organism by: - Discussing the acceptability of the studies with soil organism and soil metabolites as they were not considering the proper indications of the OECD TGs for the experimental set-up. See also 5(133), 5(136). - Discussing the reliability of the Earthworms study (2002) as only 4 concentrations with dosing factors of 2, 2.5 and 4 were used and there was an absence of the GLP certificate - Any new data submitted (e.g., 5(140).	1. <u>Acceptability of the studies with soil organism and soil metabolites:</u> <u>Study (2000) on 1,2,4-triazole:</u> Considering the limitations reported, experts agreed to consider the study as supportive. It was agreed to include the study in the LoEP with an explanatory (i.e. the study is supportive because of the minor limitations observed). <u>Study (2004) on 1,2,4-triazole:</u> Experts agreed with the RMS to acknowledge the limitations but nevertheless considered that the study is sufficiently reliable to derive a NOEC to be used in the risk assessment. It was suggested to combine the two runs, however, given the difference observed in the control performance, and the lack of overlapping concentration, it was agreed to not combine the two runs. <u>Study (2002):</u> Despite some minor deviation from the test guideline, experts could not see added value in requesting another study with additional concentrations and it was agreed that the study was acceptable and that the NOEC derived from this study (10 mg a.s./kg dw soil) can be used in risk assessment. Therefore, no amendments are needed. 2 New data submitted: earthworm study with the metabolite CGA142856 (2018) Experts agreed that this study is reliable and can be used in the risk assessment. It was acknowledged that the endpoint from this study is much lower than the existing endpoint in the RAR for Penconazole, however no clear rational could be identified to explain the difference between the two endpoints. Therefore, it was agreed to use the lowest endpoint for the risk assessment. This endpoint indicates a low risk with a high margin of safety. Open point: RMS to: -update the RAR to reflect to outcome of the discussion on the studies 2000; 2004; 2002; 2018 - add an explanatory footnote in the LoEP to the endpoint from the (2000) and (2018) acknowledging the differences in the endpoints for the metabolite TAA, however, no rational was identified for the differences.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.7 Expert to agree on the new endpoints or NTPs and the pertinent risk assessment.	No considerable issues were identified with the newly submitted studies and the updated RA was also considered as appropriate. Open point: RMS to reflect the outcome of the discussion in the RAR
Experts' consultation 5.8 Experts to decide on the ED criteria for non-target organisms for both T and EAS-modalities. New information will be provided in the framework of the stop-of-the-clock period. E.g., 5(170), 5(169), 5(165). The new data would need to be included in the ED assessment, thus please see also 5(173).	T-modality Wild mammals All experts agreed that the same conclusions reached for humans in TCT 175 apply to wild mammals for the T-modality. NTOs other than mammals All experts agreed with the proposal of the applicant to perform an AMA according to OECD TG 231. EAS-modalities Wild mammals The EAS-adversity for human was considered not sufficiently investigated and additional information should be generated (see TC 175). Therefore, no conclusion could be reached for human. The same conclusions apply to wild mammals. All experts agreed. NTOs other than mammals An FFLCT is already performed but not evaluated. Experts agreed that performing an additional level 3 assay (FSTRA) i) is not in line with the testing strategy of the EFSA-ECHA guidance, ii) questioned whether this will be useful to dismiss the findings in the available level 4 (FSDT) and level 5 assay (FFLCT including all the endpoints foreseen to be investigated in the MEOGRT), iii) is going against the need of reducing vertebrates testing. Open points RMS to reflect the outcome of the discussion in the updated RAR. RMS to change the scenario for the T-modality to 2a(iii).
Experts' consultation (new) MS experts to discuss whether the available information is sufficient to characterise the full toxicological profile of the formulation(s) for representative use(s) with respect to the acute, genotoxicity, short- and long-term toxicity. If certain endpoints are not covered, MS experts to discuss the toxicological profile of each individual	The experts at the meeting discussed the available information on the composition of the representative formulation. Overall, the experts agreed that the available information is not sufficient to characterise the full ecotoxicological profile of the formulation. Open point: RMS to reflect the discussion in the confidential volume of the RAR. RMS to consider the conclusion for discussion point 5.4.



Subject	Conclusions Pesticide Peer Review Meeting
component other than the active substance.	
Experts' consultation (new) Experts to discuss and agree on the approach to the chronic risk assessment for aquatic organisms from surface water metabolites'	While the applicant assumed that metabolites had lost the toxophore and were therefore less toxic than the active substance, the RMS initially applied a conservative approach, assuming: the toxophore was retained for CGA91301 and CGA71019; equal toxicity to the a.s. for CGA142856 and CGA179944; and applied a 10x safety factor for CGA91305 and CGA71019. While this approach showed unacceptable risks for several uses following FOCUS Steps 1 and 2 modelling for chronic exposure, not all experts agreed that the available data supported the use of this approach and metabolite risk assessment. Regarding chronic risk assessment, several experts agreed that assuming the same toxicity as the parent compound is sufficiently conservative for all metabolites. Additional discussion focused on 1,2,4-triazole, given its classification as a reprotoxic category 1B substance, questioning whether this approach was adequate in that specific case. In conclusion, all experts agreed to consider all metabolites as toxic as the parent for the chronic risk assessment. An Open point for the RMS to update the metabolite risk assessment was set.

REPORT OF PESTICIDES PEER REVIEW TC 175 AND TC 180

CLODINAFOP – AIR III, MANDATED FOR ED RE-ASSESSMENT

Rapporteur Member State: EL

5. Ecotoxicology

Date: 4 July 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS CZ	The National Institute of Public Health - CZ
National Experts nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	German Federal Institute for Risk Assessment - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS NL	Ctgb – NL
National Experts nominated by MS NO	Norwegian Food Safety Authority - NO
National Expert nominated by MS SE	Swedish Chemicals Agency - SE
External Expert	Vanessa Mazerroles
Observer	Swiss Federal Office for the Environment – CH

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¹ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

² https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 identified after ED clock stop: Experts to consider the impact of the new 2-generation study on the ecotoxicological endpoint to be used in the risk assessment for mammals.	Following the 30-month clock stop granted to complete the dataset for the assessment of endocrine disrupting properties, a new two generation study was submitted. Therefore, the previously agreed ecotoxicologically relevant endpoint (Peer Review Experts' meeting 181, June 2018) was reconsidered in light of the new endpoints. The newly submitted Comparative Thyroid Assay (CTA) was also discussed. Based on the NOAEL derived from the 2-generation studies, the experts agreed to retain the previously agreed NOAEL=3.4 mg/kg bw per day. The endpoints derived from the CTA were not based on effects relevant for the selection of ecotoxicologically relevant endpoints. Open point: RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.3 identified after ED clock stop: Experts to discuss the effect observed in mammals. Pending on the conclusion of the Tox discussion on the T and EAS modalities (see experts' consultation 2.10), experts should discuss the effects observed and their population relevance, to conclude on the ED	The experts discussed the conclusion on the ED properties of clodinafop on wild mammals. All experts agreed that the same conclusions reached for humans apply for wild mammals for the EATS-modalities (i.e. ED criteria not met). Therefore, population relevance was not discussed. Open point RMS to reflect the outcome of the discussion in a revised RAR.



Subject	Conclusions Pesticide Peer Review Meeting
potential of clodinafop for wild mammals for both the T and the EAS modalities.	RMS to remove the population relevance tables in the revised RAR.
Experts' consultation 5.4 identified after ED clock stop: Expert to discuss the Amphibian Metamorphosis Assay (AMA) and more particularly: - the concentration setting and the concentration maintenance; - the effect observed and the outcome of the assay (i.e. if it should be considered negative or positive); - pending on the above, experts to discuss the T assessment for NTOs other than mammals and the proposed MoA analysis, as needed, also considering the other available information (in vitro, etc...).	All experts agreed that the testing concentrations in the AMA were appropriate. Since the effects on development observed at day 7 were not confirmed at day 21 and no histopathological findings were observed in thyroid, and taking into consideration the mammalian dataset and the absence of positive evidence of endocrine activity from the available in vitro data, all experts agreed that no pattern of T-mediated adversity was observed. Open point RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.5 identified after ED clock stop: Experts to discuss the 21-day screening assay and its reliability, considering: - the setting of the concentration; - the deviation and the validity criteria and the related uncertainties (i.e. concentration maintenance, age of the fish, active spawning).	Considering the following uncertainties: - A range-finder test was not carried out, and the testing concentrations could have been higher, -the absence of information on fecundity and fertility, -the lack of investigation on some parameters in the gonad histopathology, -vitellogenin (VTG) data were considered as reliable with restrictions. Together with the available evidence from the mammalian dataset and the in vitro dataset (i.e., evidence of endocrine activity), all experts agreed that the margin of uncertainty is too



Subject	Conclusions Pesticide Peer Review Meeting
	high to reach a robust conclusion for the assessment of the ED properties of clodinafop through the EAS-modalities. Open points RMS to reflect the outcome of the discussion in a revised RAR. RMS to provide an uncertainty table for the ED assessment of clodinafop through the EAS-modalities.

REPORT OF PESTICIDES PEER REVIEW TC 178

TRICHODERMA ATROVIRIDE 77B – NAS 1107

Rapporteur Member State: NL

9. Micro-organism – Ecotoxicology

Date: 24 June 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS NL	Ctgb - NL
National Expert nominated by RMS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Expert nominated by MS SE	Swedish Chemicals Agency – SE

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² https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf



Discussion points/Outcome

9. Micro-organism – Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 9.1 Experts to discuss: - the information for the aquatic risk assessment and the weight-of-evidence, - whether further studies are needed - the outcome of the risk assessment	The experts at the meeting noted the information submitted by the applicant to support the aquatic risk assessment is scarce. Some lines of evidence that could support a conclusion of low risk through a weight of evidence were identified and agreed by experts, i.e.: - the strain's MoA and habitat (soil, decaying wood) - some studies show that exposure to terrestrial plants is beneficial <i>T. atroviride</i> is not related to fish or <i>Daphnia</i> pathogens <i>T. atroviride</i> is not currently considered a plant pathogen or herbicide (however, it should be noted that some literature studies became available during the peer-review on potential pathogenicity of some <i>Trichoderma</i> species). It was also noted that information might be available for other recently peer-reviewed <i>Trichoderma</i> species and strains. Nevertheless, the experts at the meeting considered the information currently available in the DAR is not sufficient to adequately support the aquatic risk assessment, which is considered not finalised. Data gap: Applicant to update the literature search to support the aquatic risk assessment and, if necessary, submit additional effect data.
Experts' consultation 1.1 MS experts to discuss whether the available information is sufficient to	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s).



Subject	Conclusions Pesticide Peer Review Meeting
characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	It is noted at least one co-formulant is an active substance. The experts at the meeting could not conclude on the potential long-term effects of the mixture. The experts agreed that the required product data according to EU Regulation 284/2013 have not been provided and therefore data gaps are identified. Furthermore, owing to this data gaps, no further considerations could be given to impact of the co-formulants on the long-term toxicity.

REPORT OF PESTICIDES PEER REVIEW TC 178

BEAUVERIA BASSIANA R444 – NAS 1107

Rapporteur Member State: DK

9. Micro-organism – Ecotoxicology

Date: 24 June 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS DK	Danish Environmental Protection Agency - DK
National Expert nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Expert nominated by MS NL	Ctgb - NL
National Expert nominated by MS SE	Swedish Chemicals Agency – SE

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Discussion points/Outcome

9. Micro-organism – Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 9.1 To discuss the (need of) risk assessment for metabolites of concern for all relevant groups of non-target organisms	The RMS presented a literature search and relevant data on secondary metabolites potentially produced by the microbial strain in the product. The search approach was considered adequate, and no toxicological concerns were identified for secondary metabolites except for one metabolite, which was determined not to be genotoxic and of low toxicity. Experimental ecotoxicology data with the representative formulation showed no effects attributable to secondary metabolites, although some mortality at high doses was observed in one species. Experts generally agreed that the information from strain-specific studies and literature indicated no unacceptable risk from secondary metabolites under the proposed uses. However, concerns were raised regarding the absence of chemical analyses of several identified metabolites in the formulation, which limited the ability to fully assess exposure and potential effects. While one metabolite was concluded not to pose an ecotoxicological risk based on available data and low exposure, the presence and concentration of other metabolites remained unknown. Most experts supported a data gap for chemical analyses of key metabolites in the product to better understand potential exposure, although the RMS did not consider this necessary given the current evidence. Additionally, some metabolites potentially produced by the strain could not be addressed due to incomplete genomic information. Experts considered analyses of these additional metabolites desirable but not essential at this stage. The final conclusion was that, despite the current evidence indicating no unacceptable risk from secondary metabolites, a data gap for chemical analysis of certain metabolites in the formulation was warranted to reduce remaining uncertainties.



Subject	Conclusions Pesticide Peer Review Meeting
	The RMS was requested to update the assessment report accordingly.
Experts' consultation 9.2 Experts to discuss the risk assessment for non-target arthropods. The experts should consider: The selection of the species for the hazard assessment. All relevant routes of exposure. All relevant peer-reviewed literature publications. All relevant peer-reviewed literature publications.	Based on the available data and expert discussion, a low risk to non-target arthropods via oral exposure could not be conclusively demonstrated for the formulation Bb-Protec. Tier-1 laboratory studies on selected beneficial arthropods (ladybird beetle, lacewing, and parasitic wasp) were limited to oral exposure. Experts acknowledged that the selected species are ecologically relevant and representative of natural enemies associated with the proposed uses. However, it was agreed that additional contact exposure studies are needed, especially considering the potential for physical effects from co-formulants. The literature review supports a generally low toxicity profile for <i>Beauveria bassiana</i> across various arthropod species, although strain-specific data are lacking. While the product's low persistence may mitigate repeated exposure risks, the high number of allowed applications (up to 20) was considered in the overall assessment. In conclusion, due to the absence of standard contact studies and uncertainty related to co-formulants, a data gap was identified. Further information is needed to complete the risk assessment for NTAs, particularly regarding contact exposure.
Experts' consultation 1.2 (ecotoxicity section) Pending the outcome of the request for additional information on the status of [REDACTED] and [REDACTED] in the MPCA as manufactured, MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component	Experts agreed that a potential concern could not be excluded for one of the major co-formulants present at high concentration in the formulation due to its possible physical mode of action affecting non-target arthropods. Despite its [REDACTED] classification from toxicological perspective, it may still cause adverse effects through physical mechanisms. The absence of contact exposure studies with the full formulation confirmed a previously identified data gap. Conversely, for the other co-formulant present at a much lower concentration, experts considered that no unacceptable risk is expected. This was supported by available toxicological and environmental information, including regulatory approvals and risk assessments of similar substances. The RMS will be requested to reflect these conclusions and the identified data gap in the updated assessment report.



Subject	Conclusions Pesticide Peer Review Meeting
other than the active substance considering also their short- and long-term toxicity.	

REPORT OF PESTICIDES PEER REVIEW TC 178

METARHIZIUM BRUNNEUM CB15III – NAS 1107

Rapporteur Member State: DE

9. Micro-organism – Ecotoxicology

Date: 24 June 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Expert nominated by MS SE	Swedish Chemicals Agency – SE
National Expert nominated by MS NL	Ctgb - NL

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Discussion points/Outcome

9. Micro-organism - Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 9.1 Experts to discuss the available lines of evidence for birds and mammals and agree whether the weight of evidence (WoE) is regarded as conclusive or more assessment/information may be needed. Experts to consider also, whether an assessment for secondary poisoning is triggered.	All experts agreed that considering the existing information about the ecology/biology of the microorganism, and the WoE as presented by the RMS, low risk is identified for birds and mammals. Open point: RMS to reflect the discussion in the DAR.
Experts' consultation 9.2 Experts to discuss the available data and information to non-target arthropods other than bees and put them in the context of the risk assessment.	The experts agreed that in view of the data presented, including contradictory results found in literature studies and effects in reproduction in collembolan reported in the study from the dossier (Document No 4351980), adverse effects to non-target arthropods from exposure to <i>M. brunneum</i> Cb15-III cannot be excluded. Open point: RMS to reflect the outcome of the discussion in the DAR.
Experts' consultation 9.3 Experts to discuss the data and the risk assessment for soil macro- and microorganisms .	Based on the lines of evidence presented, the experts considered that a low risk to soil macro- and microorganisms is sufficiently supported. Open point:



Subject	Conclusions Pesticide Peer Review Meeting
	RMS to consider additional literature publications on earthworms to support the WoE approach, as discussed and agreed during the meeting.
Experts' consultation (Ecotoxicology) 1.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	Based on the data available for each individual co-formulant, and considering the nature and concentration of the components in the formulation, no significant concerns for non-target organisms or the environment were identified. In conclusion, it is not expected that effects from the formulated product will be more adverse than those posed by the active microorganism. Open point: RMS to reflect the outcome of the discussion in the DAR.

REPORT OF PESTICIDES PEER REVIEW TC 175

FLUAZINAM – AIR IV AFTER ED CLOCK-STOP

Rapporteur Member State: AT

5. Ecotoxicology

Date: 17 June 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS BE	Federal Public Service Health, Food Chain Safety, Environment - BE
National Expert nominated by MS CZ	The National Institute of Public Health - CZ
National Expert nominated by MS DE	German Federal Institute for Risk Assessment - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Experts nominated by MS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS NL	Ctgb - NL
National Experts nominated by MS NO	Norwegian Food Safety Authority - NO
Observer	Norwegian Food Safety Authority - NO

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.12 Experts to discuss the available Amphibian Metamorphosis Assay (AMA) including its deviations and its findings.	Following the long-term clock stop an Amphibian Metamorphosis Assay (AMA) was submitted. Although a range finding test was conducted, in the definitive test, at the highest tested concentration, 70% mortality was observed. At the low and mid concentration, no effects in any parameter were observed. Although the highest treatment level is compromised, in line with the OECD test guideline stating that at least two uncompromised concentrations should be available, the assay could still be used to draw a conclusion on the ED properties. Overall, also considering the outcome of ED assessment for humans, it was concluded that, despite the limitations reported above, no clear pattern of T-mediated effects is observed and the substance does not meet the ED criteria for the T-modality. Open point RMS to reflect the outcome of the discussion in the updated RAR.
Experts' consultation 5.13 Experts to discuss the conclusion reached for humans and agree on the population relevance of any identified ED-mediated adversity.	Some changes compared to the control were observed in some studies with mammals related to the T-modality. Overall, no clear pattern was identified in mammals and therefore fluazinam was concluded not to meet the ED criteria for humans. Based on the conclusion of the ED assessment for humans, fluazinam was also considered not to meet the ED criteria for wild mammals.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.14 Experts to discuss the available Fish Short-Term Reproduction Assay (FSTRA) and its findings.	Following the long-term clock stop a Fish Short-Term Reproduction Assay (FSTRA) with fathead minnow was submitted. A statistically significant decrease in Secondary Sex Characteristics in males and a decrease in fecundity, although not statistically significant, at the highest tested concentration were noticed. It is noted that based on the ToxCast AR model being positive for anti-androgenicity (AA), the applicant during the Peer Review TC 51 (April 2021) was requested to first clear off the potential concern for AA since the FSTRA may not be the most suitable test to conduct in that case. However, only a FSTRA was submitted. Regarding the interpretation of the findings, for Secondary Sex Characteristics (SSC), it was noted that there was one individual with a very high score in the control. When doing the statistical analysis without this value, the effect was not statistically significant anymore. This raises the question if the effect observed on SSC, although statistically significant, can be considered as treatment related. A non-statistically significant decrease in fecundity was observed. The decrease in fecundity in isolation is not enough to trigger a concern for ED since fecundity may also be affected by non-ED mode of actions (MoAs). Considering that the anti-androgenic potential of fluazinam was not confirmed in the newly submitted test according to OECD TG 458, the experts agreed that although an OECD 229 was not recommended in the previous TC 51, and the applicant didn't further justify the choice of the OECD 229, in light of all the available data, the FSTRA can be now considered appropriate to conclude. Overall, considering the outcome of the assessment for humans, the lack of positive evidence in in-vitro standard study, there was a general agreement that there was no clear pattern of EAS-mediated effects and endocrine activity and the substance does not meet the ED criteria for the EAS-modalities. Open point RMS to reflect the outcome of the discussion in the updated RAR.

REPORT OF PESTICIDES PEER REVIEW TC 172 AND TC 173

PROPAMOCARB – AIR III AFTER ED CLOCK-STOP

Rapporteur Member State: PT

5. Ecotoxicology

Date: 23 May 2025

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS PT	DGAV (General Directorate for Food and Veterinary) - PT
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS BE	Federal Public Service Health, Food Chain Safety and Environment - BE
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Experts nominated by MS DE	German Environment Agency - UBA
National Experts nominated by MS DK	Danish EPA - DK
National Experts nominated by MS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS NL	Ctgb - NL
National Experts nominated by MS SE	Swedish Chemicals Agency - SE
Observer	Austrian Agency for Health and Food Safety (AGES) - AT
Observers	Federal Public Service Health, Food Chain Safety and Environment - BE
Observers	Norwegian Food Safety Authority - NO
Observers	Swedish Chemicals Agency - SE



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¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

²

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.9 Experts to decide on the suitability of the experimental design of the Xenopus Eleutheroembryonic Thyroid Assay (XETA) and its results.	The reliability and findings of the available XETA (OECD TG 248) were discussed among the experts in the context of the ED assessment for non-target organisms (NTOs) of propamocarb for the T-modality. The experts questioned that the maximum tolerated dose (MTC) was reached considering the inconsistency and the magnitude of the (sub)lethal effects observed in both the range-finding test and the definitive test, together with the lack of analytical verification in the range-finder and the variable recovery results across the three runs in the definitive test. Overall, all experts agreed that, according to the decision logic in OECD TG 248, the results of the XETA are indicative of thyroidal activity, although some uncertainties, as reported above, were identified. Open point RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.10 Experts to draw a conclusion for the ED properties of propamocarb for the T-modality for non-target non-mammalian species based on the available information. The results of the available EAMA shall be considered and contextualized also in line with the outcome of the	The reliability and findings of the available Extended Amphibian Metamorphosis Assay (EAMA) were discussed among the experts in the context of the ED assessment of propamocarb for NTOs for the T-modality. Overall, all experts agreed that based on the absence of statistically significant effects on growth and developmental parameters, the results of the thyroid histopathology, the range of testing concentrations (up to 100 mg/L) and dose-spacing factor applied, no pattern of effects that could be related to perturbation of the hypothalamic–pituitary–thyroid (HPT) axis was observed in the available EAMA. All experts at the meeting concluded that based on a weight-of-evidence approach, considering the mammalian dataset, the



Subject	Conclusions Pesticide Peer Review Meeting
available XETA, as discussed previously	results of both the XETA and the EAMA, propamocarb is not considered to meet the ED criteria through the T-modality. Open point RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.11 Experts to discuss the available dataset for the EAS-modalities for non-target organisms.	The reliability and findings of the available Fish Short Term Reproduction Assay (FSTRA) (OECD TG 229) were discussed among the experts in the context of the ED assessment of propamocarb for NTOs for the EAS-modalities. Overall, based on the results, the range of testing concentrations (up to 10 mg/L) and the dose spacing, considering also the mammalian data package, the experts agreed that no pattern of effects potentially indicating a perturbation on the hypothalamus-pituitary-gonadal (HPG) axis can be observed in the available FSTRA. Open point RMS to reflect the outcome of the discussion in the revised RAR.
Additional experts' consultation 5.12 identified following the Applicant's arguments on the derivation of the toxicological reference values and mammalian endpoint: Experts to discuss the derivation of the endpoint for wild mammal reproductive risk assessment.	The experts discussed the previously selected endpoint (Peer Review Experts' meeting PREV 03, April 2019) and all the available and relevant studies with mammals. Overall, the experts agreed that the applicant's suggested endpoint of 200 mg a.s./kg bw per day was not appropriate. It was agreed that, if the two 2-generational studies can be merged, the endpoints from the 2 generational studies would be NOAEL of 200 mg a.s./kg bw per day and therefore the ecotoxicologically relevant endpoint would be 140 mg a.s./kg bw per day, as suggested by the RMS, from the rabbit developmental toxicity study. If it is agreed not to be appropriate to merge the data, then the endpoint is 57.6 mg kg bw per day and would be the ecotoxicologically relevant endpoint. Post-meeting note: After checking and discussing the available multigenerational studies with the mammalian toxicologist at EFSA, it was agreed that since the 2 studies are not fully comparable in terms of study designs (one is a dietary and the other a gavage study), it is not appropriate to derive an 'overall' NOAEL from the 2 studies. Therefore, following the agreement at the meeting, the ecotoxicologically relevant endpoint for mammals will be NOAEL=57.6 mg/kg bw per day. Open point



Subject	Conclusions Pesticide Peer Review Meeting
	RMS to update the risk assessment for wild mammals using the agreed endpoint NOAEL=57.6 mg/kg bw per day. The LoEP will need to be updated. The RMS should also update the RAR with the outcome of the meeting related to the selection of the end point for wild mammals.
Additional experts' consultation 5.13 identified: Experts to discuss the combined assessments for the 2nd active substance fluopicolide in the PPP Infinito/Volare.	Please refer to the discussion on the full ecotoxicological profile of the formulation for representative uses Infinito/Volare below.
Additional experts' consultation (ecotoxicology) included for completeness: MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative use(s) Proplant with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts at the meeting agreed with the assessment of the RMS that the characterisation of the formulation for representative uses 'Proplant' was sufficient. No concerns related to the PPP or co-formulant(s) were raised.
Additional experts' consultation (ecotoxicology) included for completeness: MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative uses Infinito / Volare with	Data and risk assessment were available for non-target arthropods (NTA), soil organisms and non-target terrestrial plants (NTTP) and therefore the experts agreed that these groups of NTOs were sufficiently addressed. The data retrieval exercise performed by the applicant was not considered to be sufficiently thorough. Therefore, the experts agreed that a data gap for a thorough data retrieval exercise for the co-formulants was needed. For birds and mammals, no formulation data are available and no additive/mixture risk assessment is presented in the RAR. Therefore, a data gap is identified for the additive / mixture



Subject	Conclusions Pesticide Peer Review Meeting
respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	risk assessment. The experts also agreed that no additional vertebrate studies should be performed. As no additive/mixture risk assessment for aquatic organisms (acute and chronic) is available, a data gap is identified. For honey bees, the experts agreed that chronic toxicity data (adult and larvae) were required for mixed active PPP according to Regulation (EU) No 284/2013. Therefore, a data gap is identified. In addressing the above data gaps, the experts agreed that no additional vertebrate testing should be performed. Open point RMS to remove the endpoint from KCP 10.2.1/05 from the LoEP. Open point RMS to reflect the outcome of the discussion on the co-formulants in the Volume 4 of the RAR (confidential section). The RMS should reflect in the B.9 of the RAR the outcome of the discussion on the need for an additive/mixture assessment. Open point identified by EFSA post meeting The RMS is requested to discuss the assessment of the formulation toxicity data and the additive/mixture risk assessment with the RMS for fluopicolide (Austria) and harmonise the assessment where possible. This is needed since the RMS for fluopicolide (Austria) indicated that the same formulation for representative uses is included in the renewal dossier for fluopicolide.

REPORT OF PESTICIDES PEER REVIEW TC 172

CLETHODIM – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 22 May 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Expert nominated by RMS SE	Umweltbundesamt (UBA) - German Environment Agency -SE
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS BE	Federal Public Service Health, Food Chain Safety and Environment - BE
National Experts nominated by MS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS NL	Ctgb - NL
National Expert nominated by MS PT	Division of Management and Authorization of Plant Protection Products - PT
Observer	Austrian Agency for Health and Food Safety (AGES) - AT
Observers	FPS Health, Food Chain Safety and Environment - BE
Observers	Norwegian Food Safety Authority - NO
Observer	Swedish Chemicals Agency - SE



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¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.8 Experts to discuss: - the findings in the AMA and the overall conclusion of the AMA - the assessment for the T-modality for NTOs. Also considering any additional data that might have been submitted.	Wild mammals The same conclusions drawn for humans applies to wild mammals for the T-modality: ED criteria not met. NTOs other than mammals The AMA is considered valid. It was agreed that the effects observed were mainly related to the fact that the tadpoles were smaller at the highest concentrations (weight, length) and at an earlier developmental stage (histopathology). In line with the RMS conclusion and the advice of the ED WG advice, the majority of experts agreed that there is no distinct pattern of effects indicative of a perturbation of the HPT. This was also corroborated by the mammalian dataset and the available in vitro data, including ToxCast. Open point The RMS to reflect the outcome of the discussion and to add an uncertainty analysis in the revised RAR. The RMS may also consider to present a MoA analysis.

Pesticides Peer Review TC 172 & TC 173
Part B Fatty acids - caprylic acid (C-8)

REPORT OF PESTICIDES PEER REVIEW TC 172 & TC 173

PART B FATTY ACIDS - CAPRYLIC ACID (C-8)

Rapporteur Member State: EL

5. Ecotoxicology

Date: 23 May 2023

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS NL	CTGB - NL

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 Pending new PEC calculation, experts to discuss the refinement of the risk assessment for aquatic organisms.	Considering the available and accepted endpoints, along with the additional PECsw calculations, a low risk can be concluded for all representative uses, provided that mitigation measures (buffer zones of 20 or 15 meters) are implemented. Therefore, no further refinement is necessary.
Experts' consultation 5.3 Expert to agree on the acceptability of the endpoint EC50 derived from KCA 4.1.2/07, 2012e, taken into account the information available with respect to the recovery rate in old media as commented under 5(27) in column 3.	Although some limitations related to the analytical verification of the test item were noted, it was agreed to use the currently selected endpoint, also considering that no effects were observed in the limit test and the behaviour (degradation) of the substance in water (as reported by in the environmental fate section). Open point: The RMS to reflect the outcome of the discussion in the updated RAR.
Experts' consultation 5.6 Expert to discuss on the reliability of KCA 8.4.1.2/01 (2017) and of the endpoint derived and agree on the risk assessment.	Although some uncertainties were noted in relation to the analytical verification of the test item, the experts at the meeting agreed that the study can be used in the risk assessment. Based on the results of the study, the experts at the meeting agreed to set the endpoint based on the effects observed for reproduction. For soil organisms other than earthworms, no bridging was accepted between the representative formulation and formulation Decanoic acid + Octanoic acid EC 250 (see also peer review meeting report from TC167), therefore the endpoints from studies conducted with Decanoic acid + Octanoic acid EC 250 will not be used for the risk assessment of caprylic acid. A data gap is identified.



Subject	Conclusions Pesticide Peer Review Meeting
	Open point: The RMS to reflect the outcome of the discussion when updating the RAR.
Experts' consultation 5.8 Experts to discuss the proposed justifications for waiving a full ED assessment for non-target organisms.	Overall, based on a WoE approach considering: - The literature studies showed no effects that could be related to a pattern of EATS-mediated activity, - the knowledge on toxicological properties on fatty acids, - the conclusions drawn in the mammalian toxicology area, - their properties of being natural body constituents present in all living organisms, - the ubiquitous presence of fatty acid in the environment - the previous conclusion on pelargonic acid, another fatty acid used as a food additive and for which a waiver was also agreed, all experts agree with the waiver. Further testing for ED assessment is not needed and fatty acids/caprylic acid are considered as unlikely to have endocrine disrupting properties. Open point The RMS to reflect the outcome of the discussion in a revised RAR.
Expert consultation 1.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative uses with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	At the meeting it was agreed that for no co-formulant present in the representative formulation there is any indication of potential to increase the toxicity of the formulated product, except for [REDACTED] co-formulant for which it is not possible to conclude for its long-term effects, also in accordance with the mammalian toxicology peer review meeting (TC 164). Open point: RMS to include the available information and the outcome of the discussion in the updated Volume 4.

REPORT OF PESTICIDES PEER REVIEW TC 172 AND TC 173

PART B FATTY ACIDS - CAPRIC ACID (C-10)

Rapporteur Member State: EL

5. Ecotoxicology

Date: 23 May 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS BE	Federal Public Service Health, Food Chain Safety and Environment - BE
National Expert nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 Experts to: • Agree on the use of toxicity data from test carried out with fatty acids other than capric acid to perform the risk assessment for aquatic organisms. • Agree on the use of B.9.2.6.1/01, B.9.3.1.2/01 and B.9.3.1.3/02 for the risk assessment • Agree on the use of B.9.3.1.3/01 2005, and B.9.3.1.4/01 2005b in the risk assessment • Discuss the risk assessment approach for aquatic organisms and agree on the conclusion.	<u>Agree on the use of toxicity data from test carried out with fatty acids other than capric acid to perform the risk assessment for aquatic organisms.</u> Overall, the experts agreed that - the conclusions drawn from the toxicity tests conducted with Herbiclean SL 300 are equally applicable to HERBICLEAN AL for ecotox. - The formulations HERBICLEAN AL and Decanoic acid + Octanoic acid EC 250 cannot be considered comparable and therefore, bridging is not possible between these two formulations. - chronic endpoints for fish and aquatic invertebrates derived from studies with pelargonic acid could be used for the risk assessment for fatty acids. The uncertainties should be nevertheless indicated in the aquatic risk assessment and the agreements should only apply to the risk assessment for the current representative uses as reflected in the GAP. Open point: RMS to reflect the outcome of the discussion in the RAR. <u>Experts to agree on the use of KCA 8.2.6.1/04, KCA 8.2.4.1/01 (KCP 10.2.1.2/01) and KCA 8.2.6.2/01 (10.2.1.3/02) for the risk assessment</u> - For the study KCA 8.2.6.1/04, it was agreed that the study presents some analytical restrictions, nevertheless the endpoint derived from this study can be used based on the clear dose/response observed, the reliability of the three highest concentrations and the theoretical value calculated by the applicant. - For the study KCA



Subject	Conclusions Pesticide Peer Review Meeting
	8.2.4.1/01 (KCP 10.2.1.2/01), based on the conclusion on the DT50 from the environmental fate section, the study can be used correcting the nominal concentration considering the degradation of the substance. - For the study KCA 8.2.6.2/01 (10.2.1.3/02), the currently agreed endpoint can be used in the risk assessment Open point: The RMS should reflect the outcome of the discussion when updating the RAR. The RMS should also correct the endpoint for capric acid from the Daphnia study considering the degradation of caprylic acid. <u>Experts to agree on the use of KCA 8.2.6.1/01 (KCP 10.2.1.3/01) and KCA 8.2.7/01 (KCP 10.2.1.4/01) in the risk assessment</u> - For the studies KCA 8.2.6.1/01 (KCP 10.2.1.3/01) and KCA 8.2.7/01 (KCP 10.2.1.4/01), given the conclusion from the environmental fate section regarding the degradation of C8 and C10, it was agreed that the studies are considered to be valid to be used in the risk assessment. Experts to discuss the risk assessment approach for aquatic organisms and agree on the conclusion To ensure consistency it was agreed: - If the endpoint is for capric acid only, the PEC_{sw} for capric acid should be used - If the endpoint is for the mixture, the PEC_{sw} for the mixture should be used - If the endpoint is for pelargonic acid, the PEC_{sw} values for capric acid should be used - No mixture risk assessment is needed for the blend - To present separate risk assessments for capric acid, and for the blend capric and caprylic acid Open point: RMS to reflect the discussion in the RAR, and to update the aquatic risk assessment accordingly.
Experts' consultation 5.5 Experts to: discuss the risk assessment for soil organisms other than earthworms and agree on the approach, also considering background exposure and risk envelope approach; discuss and agree on the weight of evidence for soil	Overall, considering (i) the high application rate (when expressed per hectare) is a significant factor in the quantitative risk assessment, (ii) the very conservative PEC_{soil} where no interception was considered, (iii) the available endpoint for soil organisms do not indicate a high toxicity profile, (iv) the spot application will reduce the likelihood of effects at population level, (v) the limited volume of the ready-to-use formulation, and (vi) the rapid degradation (DT50 less than two days) allows for recolonization of treated spots, the majority of the experts agreed a low risk can be concluded for soil organisms other than earthworms based on the weight of evidence approach. Open point: RMS to refine qualitatively the Tier 1 risk assessment for soil organisms applying the weight of evidence agreed by the experts.



Subject	Conclusions Pesticide Peer Review Meeting
organisms other than earthworms, as presented by the Co-RMS in 5(63).	
Experts' consultation 5.6 Expert to: discuss on the validity and reliability of KCA 4.1.2/12 (2020) and of the endpoint derived, and agree on the risk assessment for earthworms. discuss and agree on the risk assessment approach for earthworms, as suggested by the Co-RMS under 5(61).	<u>Discuss on the validity and reliability of KCA 4.1.2/12 (2020) and of the endpoint derived and agree on the risk assessment for earthworms.</u> The main limitation of the study was the lack of analytical verification of the test item, given the properties of the substance. It was agreed that, notwithstanding the limitation, the study should still be accepted and the endpoint used in the Tier 1 risk assessment. This approach would be consistent with similar cases. Open point: RMS to reflect the outcome of the discussion in the updated RAR. <u>Discuss and agree on the risk assessment approach for earthworms, as suggested by the Co-RMS under 5(61).</u> Overall, considering (i) the high application rate (when expressed per hectare) is a significant factor in the quantitative risk assessment, (ii) the very conservative PECsoil where no interception was considered, (iii) the available endpoint for earthworms do not indicate a high toxicity profile, (iv) the spot application will reduce the likelihood of effects at population level, (v) the limited volume of the ready-to-use formulation, and (vi) the rapid degradation (DT50 less than two days) allows for recolonization of treated spots, the majority of the experts agreed a low risk can be concluded for earthworms based on the weight of evidence approach. Open point: RMS to refine qualitatively the Tier 1 risk assessment for earthworms applying the weight of evidence agreed by the experts.
Experts' consultation 5.7 Experts to discuss the proposed justifications for waiving a full ED assessment for non-target organisms.	Overall, based on a WoE approach considering: - The literature studies showed no effects that could be related to a pattern of EATS-mediated activity, - the knowledge on toxicological properties on fatty acids, - the conclusions drawn in the mammalian toxicology area, - their properties of being natural body constituents present in all living organisms, - the ubiquitous presence of fatty acid in the environment - the previous conclusion on pelargonic acid, another fatty acid used as a food additive and for which a waiver was also agreed, all experts agree with the waiver.



Subject	Conclusions Pesticide Peer Review Meeting
	Further testing for ED assessment is not needed and fatty acids/capric acid are considered as unlikely have endocrine disrupting properties. Open point The RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 0.1 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative uses with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	At the meeting, the majority of the experts agreed that none of the single components of the formulated product is expected to increase the toxicity of the formulated product. Open points: RMS to reflect the outcome of the discussion in the revised RAR (vol 4).

Pesticides Peer Review TC 172 AND TC 173
Part B Fatty acids - potassium salts (Fatty acids from hydrolysed vegetable oils)

REPORT OF PESTICIDES PEER REVIEW TC 172 AND TC 173

PART B FATTY ACIDS - POTASSIUM SALTS (FATTY ACIDS FROM HYDROLYSED VEGETABLE OILS)
– AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 23 May 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated RMS EL	Benaki Phytopathological Institute – EL
National Expert nominated MS AT	AGES (Austrian Agency for Health and Food Safety) – AT
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**Discussion points/Outcome****5. Ecotoxicology**

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 Experts to discuss how to express the endpoints for those studies where concentration only refers to some components.	The experts agreed that, since oleic acid, linoleic acid and palmitoleic acid are the main components of fatty acids C14–C20 from hydrolysed oils, using toxicity endpoints based on these components is representative of the full mixture. The PEC _{sw} assessment conservatively assumes the entire application rate is based on oleic acid. It was considered acceptable to assume that all components share the same fate properties as oleic acid, consistent with the approach taken for rapeseed oil. The RMS will reflect this outcome in the RAR.
Experts' consultation 5.3 Experts to: • Discuss and agree on the plausibility of bioaccumulation of fatty acids in fish studies; • Discuss the role of Van Egmond et al. (1999) for the current assessment and on its relevance and acceptability.	The bioaccumulation study was deemed suitable for a weight-of-evidence approach. A similar rationale had been accepted for pelargonic acid. The experts concluded that there was no concern for bioaccumulation, and the lauric acid study could be used to support the assessment. The RMS was tasked to reflect this in the RAR.
Experts' consultation 5.4 Experts to: • Agree on the comparability of the ecotoxicological equivalence of the formulations NEU 1128 ISL and ABP-617, and whether the studies	<i>Ecotoxicological equivalence of the formulations NEU 1128 ISL and ABP-617</i> Considering the composition of the formulations, the experts agreed to extrapolate from NEU 1128 I to ABP-617 but not vice versa. The experts acknowledged that there would be some uncertainty arising from the presence of a co-formulant and its combined effect with the active substance.



Subject	Conclusions Pesticide Peer Review Meeting
conducted with the formulations can be used interchangeably in the risk assessments; • Agree on the reliability and use in the risk assessment of the early-life stage study (Document No.D92953) considering the information reported by the RMS regarding the LOQ.	<i>Reliability and use in the risk assessment of the early-life stage study (document No. D92953)</i> The experts agreed that the early-life stage study (document No. D92953) is valid for use in risk assessment despite analytical limitations. While the method's Limit of Quantification (LOQ) of 35.9 µg oleic acid/L doesn't meet SANCO/3029/99 rev. 4 requirements for the lowest test concentration, this limitation doesn't affect the study's overall reliability since no effects were observed even at the highest concentration tested. All experts concurred with the RMS assessment that a new validation of the analytical method would not alter the study outcome, therefore allowing the study to be used in the risk assessment. The RMS will incorporate these conclusions in the RAR.
Experts' consultation 5.5 Experts to agree on the approach and on the risk assessment for aquatic organisms with the new set of PECsw/sed values.	The experts concluded that the risk assessment for aquatic organisms is acceptable based on the lead component (oleic acid) approach, which represents the worst-case scenario with higher PECsw values than other fatty acids. The RMS verified compliance of the new PECsw values dataset and updated assessments accordingly. The risk assessment for non-professional use on pome and stone fruit is not covered since the calculations provided by the applicant and presented in Section 8 (Environmental fate) had not been accepted by the RMS. The long-term risk assessment for aquatic invertebrates remains incomplete due to lack of relevant studies. The RMS was tasked to update the RAR to reflect these conclusions.
Experts' consultation 5.7 Experts to discuss the safety of the formulation(s), if there is any controversy on whether it's adequately addressed by the available studies and risk assessment.	It was noted that this discussion point was covered in both under the Pesticides Peer Review Experts' Teleconferences 167 (Fatty acids part A; discussion point 5.1) and 173 (Fatty acids part B; discussion point 5.4). Considering the composition of the formulations, the experts agreed to extrapolate from NEU 1128 I to ABP-617 (and not vice versa), while acknowledging that there would be some uncertainty arising from the presence of a co-formulant and its combined effect with the active substance. No additional open point was identified.
Experts' consultation 5.8 Experts to agree on the suitability of the provided tests for soil organisms, considering the degradability of the substance and whether it	The experts reviewed the relevance of existing soil studies for fatty acids of hydrolysed vegetable oils, noting that current OECD guidelines (updated in 2016) require analytical verification for degradable substances. While most older studies lack such data, the earthworm study with ABP-617 (Document number 83842022) did include analytical measurements, confirming rapid degradation of oleic acid over time.



Subject	Conclusions Pesticide Peer Review Meeting
can be assumed that sufficient exposure was ensured. Experts should consider if the conclusion needs to be harmonised with the discussion for Caprylic acid.	Despite concerns about the absence of analytical verification in earlier studies, the experts agreed that these studies could still be used in the risk assessment, provided the associated uncertainties are clearly acknowledged. It was agreed to retain the current risk assessment based on nominal endpoints and to include an illustrative risk assessment using the geometric mean concentration from the earthworm study, acknowledging that this is not yet an EU-wide approach but based on a Central Zone agreement. The lack of analytical data and use of nominal values should be clearly highlighted for both formulations. The RMS is tasked to update the RAR accordingly and include the illustrative risk assessment.
Experts' consultation 5.10 Experts to discuss the proposed justifications/studies for waiving a full ED assessment for non-target organisms.	Overall, based on a WoE approach considering: - The literature studies showed no effects that could be related to a pattern of EATS-mediated activity, - the knowledge on toxicological properties on fatty acids, - the conclusions drawn in the mammalian toxicology area, - their properties of being natural body constituents present in all living organisms, - the ubiquitous presence of fatty acids in the environment, - the previous conclusion on pelargonic acid, another fatty acid used as a food additive and for which a waiver was also agreed, all experts agreed with the waiver. Further testing for ED assessment is not needed and fatty acids from hydrolysed vegetable oils are considered as unlikely to have endocrine disrupting properties. Open point RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 1.1 from the confidential Evaluation table (Neudorff): MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual	The experts concluded that the co-formulants in the formulation for the representative uses NEU 1128 I SL presents no significant ecotoxicological concerns based on: the minimal concentration of co-formulants; no concerns identified of [REDACTED] from previous regulatory assessments; and absence of mammalian toxicology concerns for [REDACTED] co-formulants. The meeting determined that the formulation's ecotoxicological profile is sufficiently characterized for risk assessment purposes, with the sole exception of chronic effects on aquatic invertebrates. The RMS was tasked to reflect the outcome of the discussion in the RAR and to update the table in Vol. 4 specifying the source for the endpoints proposed as surrogate for the active substance.

MEETING MINUTES – 23 May 2025

Pesticides Peer Review TC 172 AND TC 173

Part B Fatty acids - potassium salts (Fatty acids from hydrolysed vegetable oils)



Subject	Conclusions Pesticide Peer Review Meeting
component other than the active substance.	
Experts' consultation 1.2 from the confidential Evaluation table (Alpha BioPesticides): MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative uses with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts agreed that the co-formulants present in the formulation for the representative uses ABP-617 are not expected to increase the toxicity of the formulation considering their low content and the available information. The RMS was tasked to reflect the outcome of the discussion in Volume 4 of the RAR.

17-21 March 2025

MINUTES

Pesticides Peer Review TC 167 Part A Fatty acids - capric acid (C-10)

REPORT OF PESTICIDES PEER REVIEW TC 167

PART A FATTY ACIDS - CAPRIC ACID (C-10) – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 21 March 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency (DEPA) - DK
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by RMS EL	Benaki Phytopathological Institute (BPI) - EL
National Expert nominated by MS NL	Ctgb - NL

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Expert to agree on the approach for the risk assessment for birds and mammals and on the weight-of-evidence provided by the applicant both for acute and long-term scenarios.	Regarding the <u>bridging</u>, all experts agreed that the concentrated formulation (SL300) is a worst-case scenario for ecotoxicology, making bridging possible between SL300 and Herbiclean AL (the formulation for representative uses). Decanoic acid + octanoic acid EC 250 can also be considered worst case and therefore endpoints from this worst-case formulation be used in the risk assessment of HERBICLEAN AL. Open point: RMS to reflect the outcome of the discussion in the RAR. <u>Birds & mammals</u> Based on the available data, including the new acute toxicity data on mammals with capric acid and with the formulation HERBICLEAN AL, experts agreed that it could be concluded that capric acid is of low acute toxicity. No long-term toxicity data are available; however, a weight of evidence approach could be used to finalise the risk assessment for birds and mammals: - considering the low toxicity of capric acid, its use as a food additive, combined with its readily biodegradable nature, the natural exposure of birds and mammals to fatty acids through their diet and the fact that the amount of capric acid ingested by birds and mammals due to the uses as PPP is expected to be only a small fraction of their natural diet. - Considering that prolonged exposure of avian and mammalian species to sprayed green vegetation is not considered relevant based on the proposed home and garden uses, the application on post-emerged weeds only and the Mode of action of fatty acid (by contact)



Subject	Conclusions Pesticide Peer Review Meeting
	Experts agreed and concluded a low acute and long-term risk to birds and mammals from exposure to capric acid considering all available lines of evidence presented at the meeting. Open point: RMS to reflect the outcome of the discussion in the RAR. Any calculations for the birds and mammals risk assessment should be removed from the List of Endpoints, both for capric and caprylic acid.
Experts' consultation 5.3 Expert to: - Discuss the selection of the endpoint from [REDACTED] 2019c (KCA 8.3.1.3/01), as commented under 5(42) - Discuss and agree on the risk assessment approach presented and on the conclusion of the risk assessment for honey bees, as commented under 5(43). See reporting table 5(42)	Endpoint from the [REDACTED] 2019c All experts agreed to set the NOED at 362 µg a.s./larva. Open point: The RMS is tasked with reflecting the outcome of the discussion in the RAR. <u>Risk assessment for bees:</u> <i>Chronic endpoint for bees:</i> Based on the following: -The available data does not show interaction between capric and caprylic acid, -No mortality was observed at the highest rate on day 10 in the study with HERBICLEAN AL, Experts agreed using the LDD50 of 28.8 ug a.s./bee/day from the study with the formulation Capric acid 280 g/kg. <i>Larvae:</i> A bee larvae study using the representative formulation (a mixture of capric and caprylic acid), is not available, and the current endpoint for capric acid alone may not be sufficiently protective. Most experts agreed to consider the current risk assessment as illustrative only and considered that the risk could be addressed in a weight of evidence approach. Overall, the experts considered that low risk to bees could be concluded based on a weight of evidence approach for the non-professional uses with capric acid. The lines of evidence are: Non-selective burn-down effect: As an herbicide, capric acid causes a rapid and non-selective burn-down of green tissues. After



Subject	Conclusions Pesticide Peer Review Meeting
	a short period of time, application of capric acid renders all flowering weeds/treated crops unattractive to bees <i>Limited target area:</i> Only a small portion of the garden is typically treated with the herbicide in the context of "non-professional use". <i>Localized application:</i> Herbicide application is usually confined to specific spots, such as areas around trees, in addition for non-professional home and garden use on paths, most weeds might not be flowering at the time of application. Practical limitations of ready-to-use (RTU) formulations: RTU formulations are impractical for overall spraying operations Open point: The RMS should reflect the outcome of the discussion in the RAR and update the risk assessment to bees using a weight of evidence approach for the non-professional uses.
Experts' consultation 5.4 Expert to discuss the approach to the risk assessment for non-target arthropods and agree on the suitability of the studies provided by the applicant on and the evidence available.	Most experts agreed on using the available aged-residue studies with the caprylic acid-based formulation. Using this endpoint, the risk assessment indicates high in-field risk for all uses at Tier 2. Overall, experts agreed that the available data could be used to further refine the risk assessment and to conclude low risk to non-target arthropods for the representative uses with capric acid based on the following line of evidence: Limited target area. Localised application. Practical limitations of RTU formulations. Rapid degradation in soil (max DT50 of 3 days in soil, relevant for soil-dwelling arthropods) and low persistence expected in plants. Non-selective burn-down effect. Open point: The RMS is tasked with reflecting the outcome of the discussion in the RAR and with updating the risk assessment to non-target arthropods.

REPORT OF PESTICIDES PEER REVIEW TC 167

PART A FATTY ACIDS - CAPRYLIC ACID (C-8) – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 21 March 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency (DEPA) - DK
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by RMS EL	Benaki Phytopathological Institute (BPI) - EL
National Expert nominated by MS NL	Ctgb - NL

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to: discuss and agree on the acceptability of using endpoints from different formulation of fatty acids for the current assessment for all non-target organisms agree on the approach for the risk assessment for birds and mammals and on the weight-of-evidence provided by the applicant both for acute and long-term scenarios.	<u>Acceptability of using endpoints from different formulation of fatty acids:</u> Overall, the experts agreed and concluded that -bridging between 11ELM-AC-3 and 11ELM-AC-4 is possible for ecotox. -The formulations Dés herb'nat® (11ELM-AC-4) and Decanoic acid + Octanoic acid EC 250 cannot be considered comparable and therefore, bridging is not possible between these two formulations.). Open point: RMS to reflect the outcome of the discussion in the RAR. <u>Birds & mammals</u> Experts agreed and concluded a low acute and long-term risk to birds and mammals from exposure to caprylic acid based on the following weight of evidence: -The low toxicity of caprylic acid, its use as a food additive, combined with its readily biodegradable nature, the natural exposure of birds and mammals to fatty acids through their diet and the fact that the amount of capric acid ingested by birds and mammals due to the uses as PPP is expected to be only a small fraction of their natural diet. -Prolonged exposure of avian and mammalian species to sprayed green vegetation is not considered relevant based on the proposed home and garden uses, the application on post-emerged weeds only and the Mode of action of fatty acid (by contact).



Subject	Conclusions Pesticide Peer Review Meeting
	Overall, all experts agreed and concluded a low acute and long-term risk to birds and mammals from exposure to capric and caprylic acid considering all available lines of evidence. Open point: RMS to reflect the outcome of the discussion in the RAR. Any calculations for the birds and mammals risk assessment should be removed from the List of Endpoints, both for capric and caprylic acid.
Experts' consultation 5.4 Expert to discuss the refined risk assessment for NTAs; any possible new information provided by the applicant; the weight of evidence including the proposed mitigation	Experts acknowledged that the data requirements were not fully met, however experts agreed that enough toxicity data would be available to address the in-field risk, considering the available aged-residue study. Using these studies, a low in-field risk is concluded. The low in-field risk conclusion is further supported by several qualitative arguments such as the rapid degradation in soil (DT50 in soil is < 2 days), and the non-selective burn-down effect, eliminating the need for repeated applications on the same spot in quick succession. Regarding the off-field, it was concluded that the dataset was not sufficient to refine the off-field risk indicated at Tier 1 for the representative uses with caprylic acid. (lack of extended lab studies with the standard species and two additional species) and that a low off-field risk could not be demonstrated. Therefore, the off-field risk for NTAs cannot be finalised. Open point: The RMS was tasked with reflecting the outcome of the discussion in the RAR. The Tier 1 risk assessment using endpoints from glass plate studies should be presented in the RAR.
Experts' consultation 5.5 Experts to discuss and agree on the risk assessment for bees foraging on weeds in the treated field.	Most experts agreed with the RMS conclusion regarding the high risk identified at Tier 1 from contact exposure ("flowering weeds in the treated field" scenario). Regarding the risk from oral exposure, although the conservativeness of the assumptions used in the Tier 1 risk assessment was acknowledged, in the absence of additional studies or to refine the Tier 1 risk assessment, most experts concluded that there was also a high acute oral risk. Regarding chronic risk, most experts considered that there is insufficient evidence to conclude a low chronic risk.



Subject	Conclusions Pesticide Peer Review Meeting
	For both acute and chronic risk, risk mitigation measures could be proposed by Member States at the national level for product authorisation. In addition, the experts agreed that the chronic risk to larvae could not be finalised (data gap). Open point: The RMS was tasked with reflecting the outcome of the discussion in the RAR.
Experts' consultation 5.7 Expert to discuss the selection of the most appropriate endpoint from the study under CA 8.6.2.1/01.	Considering that several types of phytotoxicity effects were observed at application rates ≥ 2.96 L/ha that rate, and acknowledging the subjectivity on how visual effects are recorded, overall, the experts agreed to use a fixed value of 2.96 L/ha in the risk assessment for non-target terrestrial plants based on the visual phytotoxic effects observed in the vegetative vigour study CA 8.6.2.1/01. This surrogate endpoint would address the uncertainties arising from the initial endpoint of 6.83 L/ha, based on shoot fresh weight. It was noted that different mitigation measures may be proposed at the Member State level (spray shields, drift-reducing nozzles, buffer zone, etc...). Open point: The RMS was tasked with incorporating the outcome of the discussion into the RAR and with updating the risk assessment for non-target terrestrial plants. Specifically: A footnote should be added in the List of Endpoints, clarifying that the endpoint is based on phytotoxic effects. The RAR should indicate that different mitigation measures may be proposed at the Member State level. The risk assessment considering drift values from spray shields could be included in the RAR for illustrative purposes although it should not be included in the List of Endpoints.

17-21 March 2025

MINUTES

Pesticides Peer Review TC 167

Part A Fatty acids – potassium salts (Fatty acids from hydrolysed vegetable oils)

REPORT OF PESTICIDES PEER REVIEW TC 167

PART A FATTY ACIDS – POTASSIUM SALTS (FATTY ACIDS FROM HYDROLYSED VEGETABLE OILS)
– AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 21 March 2025

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency (Miljøstyrelsen) - DK
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS NL	Ctgb - NL

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to consider all the available information, discuss and agree on the approach to address the risk for birds and mammals.	<u>Equivalence of the formulations NEU 1128 I and ABP-617</u> Considering the composition of the formulations, the experts agreed to extrapolate from NEU 1128 I to ABP-617 (and not vice versa), while acknowledging that there would be some uncertainty arising from the presence of [REDACTED] and its combined effect with the active substance. The RMS was tasked with reflecting the outcome of the discussion in the RAR and, with conducting the risk assessment with endpoints derived from NEU 1128 I when data are not available with the formulation ABP-617. <u>Risk assessment for birds and mammals</u> The experts agreed that the qualitative arguments provided by the applicant were sufficiently robust to support the conclusion that the acute and long-term risks to birds and mammals from fatty acids derived from hydrolysed vegetable oils are acceptable. The experts also noted that the argumentation provided for NEU 1128 I was more extensive than that for ABP-617. However, they agreed that a low risk could also be established for ABP-617. The RMS was tasked with (i) incorporating the outcome of the discussion into the updated RAR and (ii) removing the endpoints and the quantitative risk assessment for birds and mammals from the List of Endpoints.
Experts' consultation 5.6 Experts to: - Agree on the acceptability of the approach for the risk assessment for bees based on the available	<u>Acute studies with NEU 1128 I – Endpoints selection</u> The experts evaluated two bee toxicity studies for risk assessment purposes. They determined that the study 99270/01-BLEU (KCA 8.3.1.1.1/02)] though classified as "reliable with major restrictions," should not be used for risk assessment due to methodology limitations with the toxic standard dimethoate. Instead, they agreed to use the endpoints from the study 111121035 (KCA 8.3.1.1.1/01) for risk assessment of the

MEETING MINUTES – 21 March 2025

Pesticides Peer Review TC 167

Part A Fatty acids – potassium salts (Fatty acids from hydrolysed vegetable oils)



Subject	Conclusions Pesticide Peer Review Meeting
laboratory and higher-tier studies; - Discuss the selection of the most appropriate endpoints for the risk assessment of bees between the acute studies 99270/01-BLEU (KCA 8.3.1.1.1/02) and 111121035 (KCA 8.3.1.1.1/01) with Neudosan Neu and the risk assessment; - Discuss the acceptability and use of the new studies KCA 8.3.1.2/04; - Agree on the acceptability and use in the risk assessment of the study KCA 8.3.1.3/02, pending phys-chem discussion on potassium salts of fatty acids composition; - Agree on the acceptability and use in the risk assessment of the study KCA 8.3.1.3/01, pending phys-chem discussion on potassium salts of fatty acids composition; - Discuss and agree on the selection of the endpoints from the new available studies; - Agree on the validity of semi-field bee study 111121037 with formulation NEU 1128 I and its use in the risk assessment; - Discuss and agree on whether the study design of the tier 1 acute contact studies with bees and whether the acute risk via contact exposure is properly addressed by the standard studies.	representative uses with formulation NEU 1128 I, as this newer study had no identified issues. <u>Chronic studies with ABP-617</u> The RMS evaluated two bee toxicity studies. Study APIS-ABIO-002 was deemed unreliable due to extremely low recovery rates for key fatty acids (<0.37% for oleic acid, <1.07% for linolenic acid, <6% for palmitoleic acid) and significant variations in test item consumption between cages at higher dose levels. Study APIS-009-009 met all OECD guideline criteria but required corrections for low recovery rates (49.4-58.6%). The RMS proposed a worst-case correction using the lowest recovery rate of 49.4%, yielding a revised NOED of 73.75 µg a.s./bee/d and a 10-d LDD50 of 104.4 µg a.s./bee/d. This study used the representative formulation ABP-617. The experts agreed to reject the APIS-ABIO-002 study and to use the corrected endpoints from APIS-009-009 for risk assessment. <u>Bee larvae studies and endpoint selection</u> It was not possible to estimate a NOED from study AB-18-GLP-01 due to mortality at the lowest tested rate and unsuitable design for detecting emergence effects. While the fatty acids mixture study (BT049/19) yielded a lower endpoint than the NEU 1128 I formulation study (S16-00158), the experts noted that oleic acid (77.8%) is the main component in both the test mixture and representative formulations. The experts concluded that risk assessments should be presented using both endpoints (representative formulation and fatty acids mixture), while acknowledging uncertainties about the representativeness of the fatty acids mixture test. <u>Semi-field (tunnel) study 111121037 with formulation NEU 1128 I</u> The study presented several limitations: insufficient replication (3 vs. recommended 4), monitoring period too short to cover a complete brood cycle, lack of residue analyses in nectar and pollen, reduced foraging due to poor weather, and unreliable colony strength assessment. These limitations restricted the study's ability to detect anything beyond immediate effects. The majority of experts agreed that the study should only be used to support the acute contact risk assessment for worst-case GAP in terms of application rate, and for both representative formulations (where NEU 1128 I is considered worst-case compared to ABP-617, as discussed under expert consultation 5.1). <u>New acute study CH-0226/2021 (KCP 10.3.1.1.1/02) with fatty acids C14-C20 mixture</u>



Subject	Conclusions Pesticide Peer Review Meeting
	The experts agreed with the RMS's evaluation and confirmed that the study can be used in the risk assessment. <u>Semi-field (tunnel) study S21-05878 (KCP 10.3.1.5/02) using formulation NEU 1128 I</u> The semi-field study S21-05878 (2023) using NEU 1128 I at 20.4 kg a.s./ha was discussed. The study was considered reliable with limitations, primarily due to the absence of an adulticidal reference item. No statistical effects were found on worker bee mortality or brood, though flight activity temporarily decreased on day 0. The experts disagreed on whether the study could adequately assess brood effects due to the limited statistical power of semi-field studies. The majority of the experts considered that the study could be used to assess effects on bee broods only. EFSA and some experts disagreed on the use of the study to assess effects on bee brood. Considering that no toxic reference item was used, the majority of the experts agreed that it is not possible to conclude for the effects on foragers and contact toxicity. <u>Bee risk assessment</u> For the representative uses with ABP-617, most experts and the RMS concluded that chronic risk to bees could be refined using multiple lines of evidence (semi-field studies, physical mode of action, low persistence) and noting that some ETR values were close to triggers. However, EFSA and some experts disagreed with using semi-field studies for this refinement, arguing that low chronic risk couldn't be demonstrated, especially with multiple applications. The experts agreed that the semi-field study 111121037 adequately addressed effects due to direct overspray caused by fatty acids as bees were actively foraging during application, and therefore a data gap is not necessary for any of the representative uses. For the representative uses with NEU 1128 I, the experts discussed that the succeeding crop scenario may not be relevant for certain crops if DT50 is confirmed to be maximum three days. Regarding acute oral risk, the experts concluded that a low acute oral risk to adult bees could not be demonstrated. For chronic risk, the majority of experts concluded that the risk to adult bees and brood could be refined using weight-of-evidence (semi-field studies, physical mode of action, low persistence) for non-flowering stages, despite ETR values being 10 times higher than triggers. EFSA and some experts disagreed, maintaining that high risk remains.

MEETING MINUTES – 21 March 2025

Pesticides Peer Review TC 167

Part A Fatty acids – potassium salts (Fatty acids from hydrolysed vegetable oils)



Subject	Conclusions Pesticide Peer Review Meeting
	Open point: The RMS was tasked with incorporating the discussion outcomes into the RAR and updating both the risk assessment and the LoEP. Additionally, the RMS needs to verify the DT50 value for soil that triggers the succeeding crop scenario, as well as check the environmental fate conclusion from the Pesticides Peer Review meeting TC 166.
Experts' consultation 5.9 Experts to: - Agree on the suitability of the seedling emergence study with formulation ABP-811 and its use in the current risk assessment; - Agree on the suitability of the risk assessment approach for the formulation ABP 617 for non-target terrestrial plants and the selection of endpoints from studies carried out with NEU 1128 I.	The discussion centred on whether data from a new seedling emergence study using a different formulation (ABP-811) could be used in the risk assessment for ABP-617. Pelargonic acid, the active substance in ABP-811, has a herbicidal mode of action and was considered a worst-case scenario for non-target terrestrial plants compared to the potassium salts of fatty acids in ABP-617, which primarily have insecticidal properties. The experts noted that pelargonic acid had more severe effects in the vegetative vigor test than in the seedling emergence test. The existing risk assessment for ABP-617 was based on an endpoint from a vegetative vigor study with the formulation NEU 1128 I, which indicated a low risk with a high margin of safety. While some experts considered the new study with ABP-811 as supportive but not directly relevant for inclusion in the List of Endpoints, one expert argued that the study should be used in the quantitative risk assessment since it represented a worst-case scenario. This expert also suggested that bridging between formulations was justified due to the shared herbicidal properties of pelargonic acid and other fatty acids. After discussion, the experts agreed to include the endpoints from the studies with formulations NEU 1128 I and ABP-811 in the List of Endpoints. A footnote was added to indicate that the seedling emergence study with ABP-811 involved a different substance but was still considered a worst-case scenario. The quantitative risk assessment would be based on the lowest endpoint, which already demonstrated a low risk with a high margin of safety. Additionally, the risk assessment would account for the effects observed in the seedling emergence study. The experts agreed that the inclusion of both endpoints, with appropriate clarification, was justified. The quantitative risk assessment should be based on the lowest endpoint, ensuring a conservative approach that maintains a high margin of safety. Open point: The RMS was tasked with reflecting the outcome of the discussion in the RAR and updating the List of Endpoints accordingly.

REPORT OF PESTICIDES PEER REVIEW TC 168

BACILLUS SUBTILIS STRAIN FMCH002 – NAS 1107

Rapporteur Member State: NL

5. Microorganism - Ecotoxicology

Date: 18 March 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS NL	Ctgb - NL
National Expert nominated by MS DE	Julius Kühn-Institut (JKI), Federal Research Centre for Cultivated Plants - DE
National Expert nominated by MS DE	UBA - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food - HR

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¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Microorganism - Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 9.1 Experts to agree on the risk assessment approach and on the outcome of the risk assessment for aquatic invertebrates.	The studies available in the DAR were discussed by the experts at the meeting. Based on the available valid data and the risk assessment approach followed by the RMS, the experts agreed that a low risk to aquatic invertebrates can be concluded. Open point: RMS is tasked to - reflect the outcome of the discussion in a revised DAR; - confirm the endpoint based on surviving adults in the MP 10.2-03 study; - correct the mistakes noted in the DAR.
Experts' consultation 9.2 Experts to agree on the waiver presented by the applicant to address the risk assessment for algae and aquatic plants other than algae	No study was available for algae. Nevertheless, the available lines of evidence were discussed to address the risk assessment for algae and macrophytes. The experts agreed that a low risk can be concluded for algae and macrophytes. Open point: RMS is tasked with reflecting the outcome of the discussion in a revised DAR.
Experts' consultation 9.3 Experts to agree on the risk assessment approach and on the outcome presented to address the risk assessment for bees.	The experts at the meeting discussed the available data for honey bees. Based on the available information and on a weight of evidence approach, the experts agreed that a low risk can be concluded for honey bees for contact and oral exposure. Open point: The RMS was tasked with - explaining better the outcome of the bee studies and removing LD50 < values;



Subject	Conclusions Pesticide Peer Review Meeting
	- performing calculations based on EFSA (2013)³ guidance document to quantify exposure from seed treatment; - update the ecotoxicology section considering the information provided in the environmental fate part regarding exposure from drift; - reflecting the outcome of the discussion in a revised DAR.
Experts' consultation 9.4 Experts to discuss the toxicity data available for NTAs from the studies with the active substance and with the formulation for representative uses. Experts to agree on the approach and on the outcome of the risk assessment.	The experts at the meeting discussed the available data for non-target arthropods. Based on a weight of evidence approach, the expert agreed that a low risk can be concluded for non-target arthropods. Open point: RMS to consider preliminary comments sent by experts from MS and reflect the outcome of the discussion in a revised DAR.
Experts' consultation 0.2 Experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	At the meeting, the experts agreed that that none of the component of the formulation is expected to impact the toxicity of the MPCA-AM. Open point: The RMS was tasked with updating Volume 4 of the DAR to reflect the outcome of the discussion.

³ European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). *EFSA Journal* 2013; 11(7):3295, 268 pp., doi:[10.2903/j.efsa.2013.3295](https://doi.org/10.2903/j.efsa.2013.3295)

Pesticides Peer Review TC 168
Bacillus paralicheniformis strain FMCH001

REPORT OF PESTICIDES PEER REVIEW TC 168

BACILLUS PARALICHENIFORMIS STRAIN FMCH001 – NAS 1107

Rapporteur Member State: NL

5. Microorganism - Ecotoxicology

Date: 18 March 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS NL	Ctgb - NL
National Expert nominated by MS DE	Julius Kühn-Institut (JKI), Federal Research Centre for Cultivated Plants - DE
National Expert nominated by MS DE	UBA - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food - HR

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Discussion points/Outcome

5. Microorganism - Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 9.1 Experts to agree on the risk assessment approach and on the outcome of the risk assessment for aquatic invertebrates.	The studies available in the DAR were discussed by the experts at the meeting. Based on the available valid data and the risk assessment approach followed by the RMS, the experts agreed that a low risk to aquatic invertebrates was concluded. Open point: RMS is tasked to - reflect the outcome of the discussion in the DAR; - confirm the endpoint based on surviving adults in the MP 10.2-03 study; - correct the mistakes noted in the DAR (check preliminary comments sent by MS).
Experts' consultation 9.2 Experts to agree on the waiver presented by the applicant to address the risk assessment for algae and aquatic plants other than algae	No study was available for algae. Nevertheless, the available lines of evidence were discussed to address the risk assessment for algae and macrophytes. The experts agreed that a low risk is concluded for algae and macrophytes. Open point: RMS is tasked with reflecting the outcome of the discussion in the DAR.
Experts' consultation 9.3 Experts to agree on the risk assessment approach and on the outcome presented to address the risk assessment for bees.	The experts at the meeting discussed the available data for honeybees. Based on the available information and on a weight of evidence approach, the experts agreed that a low risk is concluded for honeybees for contact and oral exposure. Open point: The RMS was tasked with:



Subject	Conclusions Pesticide Peer Review Meeting
	- explaining better the outcome of the bee studies and removing LD50 < values; - performing calculations based on EFSA (2013) guidance document to quantify exposure from seed treatment; - update the ecotoxicology section considering the information provided in the environmental fate part regarding exposure from drift; - reflecting the outcome of the discussion in the DAR.
Experts' consultation 9.4 Experts to discuss the toxicity data available for NTAs from the studies with the active substance and with the formulation for representative uses. Experts to agree on the approach and on the outcome of the risk assessment	The experts at the meeting discussed the available data for non-target arthropods. Based on a weight of evidence approach, the expert agreed that a low risk is concluded for non-target arthropods. Open point: RMS to consider preliminary comments sent by experts from MS and to reflect the outcome of the discussion in the DAR.
Experts' consultation 0.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	At the meeting, the experts agreed that that none of the component of the formulation is expected to increase the toxicity of the MPCA-AM. Open point: The RMS was tasked with updating Volume 4 of the DAR to reflect the outcome of the discussion.

REPORT OF PESTICIDES PEER REVIEW TC 163 AND TC 167

ZIRAM – AIR III AFTER ED CLOCKSTOP

Rapporteur Member State: IT

5. Ecotoxicology

Date: 21 March 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
EU statutory staff representing EU Institutions, agencies or other bodies (other than EFSA)	ECHA
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by RMS IT	International Centre for Pesticides and Health Risk Prevention – ICPS - IT
National Expert nominated by MS CZ	The National Institute of Public Health - CZ
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DK	Danish Environmental Protection Agency (DEPA) - DK
National Experts nominated by MS EL	Benaki Phytopathological Institute (BPI) - EL
National Experts nominated by MS ES	Ministerio de Sanidad - ES
National Experts nominated by MS FI	Finnish Safety and Chemicals Agency (Tukes) - FI
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS IE	Pesticide Registration and Controls Division / Department of Agriculture, Food and the Marine - IE
National Experts nominated by MS NL	Ctgb - NL
National Expert nominated by MS PL	Merit Mark Polska Sp.z o.o. on behalf the Ministry of the Agriculture and Rural Development - PL



Status	Name of institution/attendee
External expert	Andrea Terron
External expert	Emily McVey
Observers	Austrian Agency for Health and Food Safety (AGES) - AT
Observer	Danish Environmental Protection Agency (DEPA) - DK
Observers	International Centre for Pesticides and Health Risk Prevention – ICPS - IT

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Expert's consultation 5.7 The experts should discuss the available FSTRA with regard to: • Choice of the tested concentration • Any effect observed • Conclusion on the ED properties of ziram for EAS-modalities	1.A Fish Short-Term reproduction Assay (FSTRA) was available. At the highest tested concentration, a statistically significant increase in male GSI. In addition, although not statistically significant, at the same concentration, a decrease in fecundity, in male SSC, in female VTG were noted. Moreover, at the 2 highest treatments, a flat increase in the testicular score was also noted. 2.Conclusion Considering the results of the range-finder, the effects observed in some parameters, the selection of the testing concentration could be considered as appropriate for the investigation of the ED properties of ziram, although higher concentrations could have been tested. Considering the observed effects on fecundity, GSI in males, VTG in females and on testicular stage score, together with the indications of endocrine activity for anti-androgenicity and aromatase inhibition, in agreement with the opinion of the ED WG, experts raised a concern on the observed effects however it is not possible to discern a clear pattern of EAS-mediated effect in the current study. Open point The RMS to please reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.8 The experts should discuss the available AMA with regard to:	An Amphibian Metamorphosis Assay (AMA) was available. No effects were observed in any of the measured parameters with the exception of a decrease in the prevalence of follicular cell hyperplasia at the 2 highest tested concentrations.



Subject	Conclusions Pesticide Peer Review Meeting
- Choice of the tested concentration - Any effect observed - Conclusion on the ED properties of ziram for T-modalities - All available data on mammals related to the T-modality, 9	However, the concentrations tested were too low when considering the available acute and chronic studies with fish and the contradictory results of the two range finding tests. Moreover it was noted that although the performance criteria were met, there was a spread in the developmental stages of 7 in the negative control and 6 stages in the solvent control and this variability was considered to have an impact on the power of the test to detect an effect on that parameter. 2. The experts agreed that the level of uncertainties is too high to draw a conclusion on the ED properties in non-target organisms through the T-modality based on the available AMA Open point The RMS to please reflect the outcome of the discussions in the revised RAR.
Experts' consultation 5.9 Based on the outcome of the experts' consultation in 1, the experts should discuss the conclusion of wild mammals and in case ziram is considered to meet the ED criteria for humans, the population relevance of the effects observed in mammals should be discussed.	- The impact of the newly submitted Extended One Generation Study (EOGRT) on the previously agreed endpoint for the risk assessment of wild mammals was discussed. Moreover, the previously agreed endpoint was reconsidered based on the agreed endpoint of the mammalian toxicologists in the Peer Review experts' meeting Prev 01 and TC 163 and 164. - The experts agreed to select a NOAEL=8 mg/kg bw/d from the rat developmental toxicity studies based on increase in diaphragmatic thinning since that effect was observed in 2 studies, with a dose response and it's not only a variation. Open point RMS to revise the risk assessment for mammals using the agreed NOAEL. The LoEP should be also updated.
New experts' consultation point 5.10 proposed by EFSA for completeness of discussion MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain	Based on the discussion, the experts agreed that there are sufficient ecotoxicity data available with the formulation for representative uses and the outcome of the data retrieval exercise did not result in any concerns related to the impact of co-formulants on safety of the formulation for representative uses to non-target organisms. Open point RMS to reflect the outcome of the experts' consultation point in volume 4 of the RAR.



Subject	Conclusions Pesticide Peer Review Meeting
endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	

REPORT OF PESTICIDES PEER REVIEW

TC 163 AND TC 167

CINMETHYLIN – NAS 1107

Rapporteur Member State: NL

5. Ecotoxicology

Date: 21 March 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS NL	Ctgb - NL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS CZ	The National Institute of Public Health - CZ
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Experts nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DK	Danish Environmental Protection Agency (DEPA) Miljøstyrelsen - DK
National Experts nominated by MS ES	Ministerio De Sanidad - ES
National Expert nominated by MS FI	Finnish Safety and Chemicals Agency (Tukes) - FI
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS IE	Pesticide Registration and Controls Division / Department of Agriculture, Food and the Marine - IE
External expert	Andrea Terron
External expert	Emily McVey
Observers	Austrian Agency for Health and Food Safety (AGES) - AT
Technical hearing (Applicant)	BASF



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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts' to discuss the bioaccumulation factor of BAS 684 H in earthworms from the study 2021/2018467 (data point KCA 8.1.3/1).	The discussion focused on the rationale for correcting the bioaccumulation factor (BAF) from the study 2021/2018467(data point KCA 8.1.3/1) using a factor of 2.6, based on predicted degradation in soil according to the laboratory DT50 study. The applicant had argued that detected radioactivity was primarily from the parent compound rather than its metabolites. The RMS maintained the correction was necessary, highlighting inconsistencies in the extraction methods between the fate study and the earthworm BAF study. The RMS noted that combustion-only extraction in the earthworm study led to higher measured concentrations than would be bioavailable. Key concerns included whether using the worst-case DT50 (18.5 days) was overly conservative and whether non-extractable residues (NER) should be considered bioavailable. Experts agreed that NER should be excluded from the BAF calculation due to their composition and lack of bioaccumulative potential. The RMS cited the absence of clear guidance in OECD TG 317 but concluded that NER exclusion would result in a more accurate BAF value. A proposal to use a geometric mean DT50 (34.6 days) as a more balanced alternative was discussed, but experts ultimately supported the worst-case DT50 approach. Justifications included: - The DT50 used for the PEC calculation was already refined (not overly conservative). - The radioactivity behavior in the earthworm study was unexpected. - A margin of safety of 6 was obtained in the risk assessment.



Subject	Conclusions Pesticide Peer Review Meeting
	It was also noted that accounting for the time to reach a steady state in the bioaccumulation study could improve PEC value selection. However, inconsistencies in concentration levels complicated this approach. Experts also reflected on the soil PEC's use of a DT50 value of 53.9 days, derived from field studies, which may not be appropriate for earthworm BAF correction. In conclusion, the experts agreed to correct the BAF for DT50 and supported the RMS's conservative approach. The final decision was justified by refinements in PEC calculations, unexpected radioactivity behavior, and the established margin of safety. The RMS was tasked with incorporating these conclusions into the updated RAR.
Experts' consultation 5.2 Experts to discuss whether and, if so, how the phytotoxic effects observed in the available aquatic macrophyte studies should be considered for deriving the endpoints for the risk assessment.	The discussion focused on Visual Phytotoxic Effects (VPE) in risk assessment studies, evaluating whether observed VPE impacts standard toxicity endpoints. The RMS reviewed several studies and found that VPE did not change any endpoints since either no effects were observed or they were already covered by existing endpoints (e.g., frond number, length, and weight). However, RMS acknowledged a flaw in current OECD guidelines, as they lack clear instructions for rating and scoring VPE. It was noted that standard biomass endpoints do not always account for clear and consistent VPE. To address this, the RMS proposed an interim solution comparing qualitative VPE data with standard growth data. If the default ErC50 (growth-based endpoint) is not protective for VPE, a correction factor of 3 would be applied to lower the endpoint. However, there was no consensus among experts on implementing this approach at the EU level due to the lack of harmonized guidance. A specific case with cinmethylin demonstrated that phytotoxicity was not covered by standard endpoints, but the issue was deemed non-critical as lower endpoints were selected for the risk assessment. The experts acknowledged that phytotoxic effects should be considered in risk assessments, but implementing an additional assessment factor remains challenging without a standardized framework. The RMS proposed including footnotes in the List of Endpoints (LoEP) to document VPE observations, ensuring these effects are recognized even if not quantitatively incorporated into risk assessments. This was particularly relevant for Glyceria study 2017/1000861 (CP 10.2.1/6), which showed severe root development effects at concentrations lower than the standard endpoint. The experts agreed with the RMS assessment and the inclusion of footnotes.



Subject	Conclusions Pesticide Peer Review Meeting
	The experts agreed that: - VPE is a relevant issue in risk assessment but lacks clear evaluation guidelines. - Standard biomass endpoints may not fully cover VPE. - The RMS proposed an interim solution using a correction factor, but it lacks EU-wide agreement. - Experts agreed that phytotoxic effects should be reflected in study evaluations and the LoEP through footnotes. - For the current assessment, Lemna-driven endpoints cover the observed phytotoxic effects. The RMS was tasked with including footnotes in the LoEP reflecting where visual phytotoxic effects were observed in the aquatic plants studies and not covered by the derived standard endpoints. If a reliable endpoint for such effects was available, this could be included in the footnote. This is needed for the Glyceria study 2017/1000861 (CP 10.2.1/6).
Experts' consultation 5.3 Experts to discuss the geometric mean approach proposed by the applicant to refine the risk to aquatic macrophytes considering the available studies.	The applicant proposed using a geometric mean approach for aquatic plant toxicity assessment, deriving a Geomean-RAC of 17.0 µg a.s./L. While the RMS initially found it acceptable to combine Glyceria, Lemna, and Myriophyllum, concerns were raised regarding differences in study design sediment presence, and EFSA (2019) guidance, which discourages using a geometric mean for chronic studies. As a result, the RMS decided against applying the geometric mean approach. The experts agreed with the RMS that a geometric mean should not be used for risk assessment due to study design inconsistencies and sediment influence. Instead, the Tier 1 endpoint for Lemna should be applied. Additionally, the entire aquatic risk assessment should be updated with refined exposure estimates to ensure the most accurate PEC values are used in higher-tier assessments if needed. The RMS was tasked with - Removing the risk assessment using the geometric mean; - Updating the risk assessment using the Tier 1 endpoint for Lemna and updated exposure estimates (see fate experts' meeting);



Subject	Conclusions Pesticide Peer Review Meeting
	Ensuring that the PEC values with the most refined exposure estimate are used in the case a high risk is indicated at Tier 1 (if FOCUS Step 4 PECsw values are available).
Experts' consultation 5.4 Experts to discuss the risk assessment for non-target terrestrial plants, including: - The relevance and reliability of the vegetative vigour and seedling emergence studies with the representative formulation. - The endpoints to be used for the risk assessment. - The probabilistic risk assessment based on species sensitivity distribution.	<u>Relevance and reliability of the vegetative vigour and seedling emergence studies with the representative formulation</u> The RMS questioned the relevance and reliability of the vegetative vigour and seedling emergence studies due to concerns about species selection and study methodology. Most tested species were not representative of non-target species, and bottom-only irrigation may have reduced exposure, especially given the volatility of BAS 684 H. While the applicant argued that the studies followed OECD guidelines and cited literature for support, the RMS maintained that uncertainties remained. Despite these concerns, the RMS concluded that the studies were sufficiently reliable for tier 1 risk assessment but emphasized that uncertainties should be considered. Experts agreed with the RMS's assessment, and it was clarified that volatilisation was accounted for in the exposure calculation. The RMS deemed the studies reliable for tier 1 risk assessment but highlighted uncertainties related to species selection and exposure. Experts agreed, and it was confirmed that volatilisation was accounted for in the exposure calculation. <u>Probabilistic risk assessment</u> The RMS rejected the applicant's probabilistic risk assessment (HR5 value of 41 mL/ha) due to uncertainties in species sensitivity distribution (SSD). Key concerns included the use of unbound ER50 values, questionable species relevance, and inconsistencies in SSD, particularly between monocots and dicots. A recalculation confirmed the applicant's findings but highlighted a large confidence interval, reinforcing the RMS's preference for the lowest deterministic endpoint (ER50 for ryegrass). Regarding exposure, experts agreed that volatilisation (0.82% contribution) must be accounted for, but there was no EU-wide approach for its mitigation. Some experts questioned the 90% reduction factor applied to both drift and volatilisation, as it might not be achievable in practice. The RMS concluded that risk assessment should rely on the lowest ryegrass ER50 value and that volatilisation considerations should be explicitly included. The RAR will be updated to reflect these concerns. The experts agreed that the refined HR5 value should not be used for risk assessment due to uncertainties in the dataset and species sensitivity distribution. Instead, the lowest deterministic endpoint (ER50 for ryegrass) was preferred. Additionally,



Subject	Conclusions Pesticide Peer Review Meeting
	volatilisation must be accounted for in exposure assessments, but there is no EU-wide agreed approach for its mitigation. The RMS will update the RAR to reflect these concerns and clarify the appropriate application of risk mitigation measures. <u>Vegetation vigour phytotoxicity endpoint</u> The RMS identified significant phytotoxic damage (48%–80%) at the lowest ER50 from the vegetative vigour test (709.8 mL/ha) and proposed a surrogate ER50 of 350 mL/ha based on 46% phytotoxicity in barley. The applicant, however, suggested a higher surrogate ER50 (700 mL/ha) based on observed effects. Since ER50 values based on phytotoxicity are not typically used in risk assessment due to the lack of standardized methods, and the seedling emergence study was the primary driver of the risk assessment, it was agreed that the phytotoxic effects should be documented as a footnote in the LoEP rather than directly influencing the assessment. The RMS was tasked with updating the LoEP accordingly. Phytotoxic effects from the vegetative vigour test will be documented as a footnote in the LoEP, as ER50 values based on phytotoxicity are not typically used in risk assessment. The RMS will update the LoEP to reflect this.
Experts' consultation 5.5 Experts to discuss the ED potential of cinmethylin for NTOs. In particular, discussion will be on the following points: The available information to assess the ED potential of cinmethylin for the T-modality (i.e., findings of the available AMA study, including the additional information provided by the applicant e.g., raw data from tadpoles, supplementary	The ED potential of cinmethylin for the EATS-modalities was discussed among the experts. Wild mammals, T-modality Based on the conclusions drawn in the area of mammalian toxicology, the population relevance in wild mammals was discussed among the experts. Effects on nasal olfactory epithelium were observed in several studies on rat at similar or higher doses where effects on the thyroid were identified. Since effects on the olfactory epithelium is considered population relevant, a discussion was held on its potential relation to a T-MoA. Several MoAs could lead to the degeneration of the nasal olfactory epithelium e.g., hypothyroidism, although some histopathological evidence points to local cytotoxicity related to biotransformation as a likely MoA, and not to impaired genesis of olfactory neurons. Overall, based on the available evidence and related uncertainties on the MoAs potentially contributing to the observed effects on the nasal epithelium, all experts agreed that a robust conclusion on the population relevance of the thyroid adverse effects cannot be drawn.



Subject	Conclusions Pesticide Peer Review Meeting
histopathology report); The appropriateness of the selection of the testing concentrations and the findings of the available FSTRA study, to assess the ED potential of cinmethylin for the EAS-modalities. Please note that in case of positive findings, the applicant should submit additional information according to 283/2014, following the indications of the ECHA/EFSA ED Guidance (2018). Please also note that, pending on the outcome of the discussions from the toxicology section, the population relevance of the effects on humans may need to be discussed for wild mammals among the experts for the T- and/or EAS-modalities.	Wild mammals, EAS-modalities For the EAS-modalities, experts agreed that the same conclusions reached for humans (scenario 1a) are applied. Other NTOs, T-modalities The reliability and the findings of the available AMA were discussed among the experts. All experts agreed that: - although the study showed some limitations, it could be used in the ED assessment of cinmethylin; - the pattern of effects presented in the considered AOPs do not match with the one observed in the available study and that the effects observed are more likely related to a non-ED MoA. The conclusions were in line with the advice of the ED WG (appendix 2). Other NTOs, EAS-modalities The reliability and the findings of the available FSTRA were discussed among the experts. All experts agreed that that: - higher concentrations could have been selected, however, the study is still relevant and can be used in the ED assessment also considering that at the highest tested concentration in the test no effects were observed and the highest concentration in the FSTRA is likely close to the MTC. - no pattern of effects was observed in the available FSTRA; - VTG method was in this case considered appropriate. Open point RMS to amend the RAR in line to the discussion for wild mammals and other NTOs. The RMS should amend the table with the developmental stage in the AMA. RMS to add an uncertainty analysis in relation to the conclusion for EAS-modalities.
Summary discussion with technical hearing (applicant) experts under Experts' consultation 5.5	Please see High-Level Report of Pesticides Peer Review TC 163 and TC 164, under Experts' consultation 2.7.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 1.1 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The formulation BAS 684 03H was evaluated using various toxicity studies, including acute oral toxicity in birds and mammals, aquatic toxicity, effects on non-target arthropods, soil organisms, and plants. Chronic oral toxicity studies on honey bees and bumble bees were conducted with a different formulation. Experts agreed that chronic toxicity endpoints from the available studies could be used to support the assessment of the representative product. A toxicity data search on co-formulants was also conducted. Acute toxicity studies showed no increased risk compared to the active substance, and experts concluded that there were no chronic safety concerns for birds and wild mammals, though they recommended verifying the toxicology meeting outcome. For chronic toxicity in fish and Daphnia, experts did not see the lack of formulation-specific data as a concern since the aquatic risk assessment was driven by toxicity to aquatic macrophytes, for which formulation data are available. Open point: RMS to reflect the outcome of the discussion for the co-formulants in the Volume 4 of the RAR.

REPORT OF PESTICIDES PEER REVIEW TC 163

PHENMEDIPHAM – AIR III, re-assessment of ED following mandate

Rapporteur Member State: FI

5. Ecotoxicology

Date: 12 March 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS FI	Finnish Safety and Chemicals Agency (Tukes) - FI
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS CZ	The National Institute of Public Health - CZ
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DK	Danish Environmental Protection Agency (DEPA) - DK
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS IE	Pesticide Registration and Controls Division / Department of Agriculture, Food and the Marine - IE
National Experts nominated by MS IT	International Centre for Pesticides and Health Risk Prevention – ICPS - IT
National Expert nominated by MS NL	Ctgb - NL
External Expert	Andrea Terron
External Expert	Emily McVey
Observers	Austrian Agency for Health and Food Safety (AGES) - AT
Observer	Danish Environmental Protection Agency - DK



Observer	Department of Agriculture, Food and the Marine; Pesticide Control and Registration Division - IE
Observers	International Centre for Pesticides and Health Risk Prevention – ICPS - IT

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Follow-up of Experts' consultation 5.4 Experts to decide if based on the re-evaluation of the available data for the T-modality, a conclusion on whether the substance meets the ED criteria for the T-modality for non-mammalian species can be drawn. See previous experts' consultation, the advice from the ED WG and the background document provided by EFSA prior the meeting	The available Extended Amphibian metamorphosis Assay (EAMA), the in vitro data and the weight of evidence for the ED assessment through the T-modality were discussed by the experts. 1. The experts considered that in the EAMA no clear signs of overt toxicity were observed. The delay in time to reach the metamorphosis was considered adverse when also looking at the distribution of days the animals needed for reaching the metamorphic climax. The changes in thyroid histopathology were considered a clear indication of proliferation in the thyroid attributable to an increase in the TSH and decrease in the THs. In vitro, phenmedipham is positive for TPO inhibition. 2. Overall, the experts concluded that considering the positive evidence in vitro and in vivo and the biological plausible link between the endocrine activity and the adversity, it cannot be excluded that phenmedipham is an ED through the T-modality. Although the relevance at the level of population of 1-d delay in the time to reach metamorphosis may be questioned, no other evidence was submitted to demonstrate that the effect was not relevant, in line with Regulation 2018/605. The experts also agreed that it cannot be excluded that under field conditions and less iodide input the effects may be exacerbated. Open point The RMS to please update the ED assessment for wild mammals and NTOs other than mammals considering the outcome of the discussions.

REPORT OF PESTICIDES PEER REVIEW TC 161

TRICHODERMA AFROHARZIANUM (FORMERLY *T. HARZIANUM*) T-22 - AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Expert nominated by MS IE	Department of Agriculture Food and the Marine - IE
National Experts nominated by MS NL	CTGB - NL
External Experts	Annette Aldrich
Observer	Agroscope - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation point identified by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed that the formulated product was sufficiently characterised and no concerns were raised.

REPORT OF PESTICIDES PEER REVIEW TC 161

TRICHODERMA ASPERELLUM T25 – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Expert nominated by MS IE	Department of Agriculture Food and the Marine - IE
National Experts nominated by MS NL	CTGB - NL
External Experts	Annette Aldrich
Observer	Agroscope - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation point identified by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed that the formulated product was sufficiently characterised and no concerns were raised for the drench and drip irrigation uses. For the spray uses, a concern cannot be excluded for non-target arthropods.

REPORT OF PESTICIDES PEER REVIEW TC 161

TRICHODERMA ASPERELLUM TV1 – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Expert nominated by MS IE	Department of Agriculture Food and the Marine - IE
National Experts nominated by MS NL	CTGB - NL
External Experts	Annette Aldrich
Observer	Agroscope - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation point identified by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long- term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long- term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed that the formulated product was sufficiently characterised and no concerns were raised.

Pesticides Peer Review TC 161
Trichoderma atrobrunneum (formerly *T. harzanium*) strain
ITEM908

REPORT OF PESTICIDES PEER REVIEW TC 161

TRICHODERMA ATROBRUNNEUM (formerly *T. harzanium*) STRAIN ITEM908 - AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Expert nominated by MS IE	Department of Agriculture Food and the Marine - IE
National Experts nominated by MS NL	CTGB - NL
External Experts	Annette Aldrich
Observer	Agroscope - CH

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**Discussion points/Outcome****5. Ecotoxicology**

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation point identified by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed that the formulated product was sufficiently characterised, and no concerns were raised.

REPORT OF PESTICIDES PEER REVIEW TC 161

TRICHODERMA ATROVIRIDE T11 – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Expert nominated by MS IE	Department of Agriculture Food and the Marine - IE
National Experts nominated by MS NL	CTGB - NL
External Experts	Annette Aldrich
Observer	Agroscope - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation point identified by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed that the formulated product was sufficiently characterised and no concerns were raised for the drench and drip irrigation uses. For the spray uses, a concern cannot be excluded for non-target arthropods.

REPORT OF PESTICIDES PEER REVIEW TC 161

TRICHODERMA GAMSII ICC080 – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
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External Experts	Annette Aldrich
Observer	Agroscope - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
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REPORT OF PESTICIDES PEER REVIEW TC 161

TRICHODERMA ASPERELLUM ICC012 – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS SE	Swedish Chemicals Agency - SE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
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External Experts	Annette Aldrich
Observer	Agroscope - CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation point identified by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long- term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long- term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed that the formulated product was sufficiently characterised, and no concerns were raised.

REPORT OF PESTICIDES PEER REVIEW TC 161

DICHLORPROP-P – amendment of approval conditions

Rapporteur Member State: IE

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS IE	Department of Agriculture Food and the Marine - IE
National Experts nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) – FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Experts nominated by MS NL	CTGB - NL
National Experts nominated by MS SE	Swedish Chemicals Agency - SE
External Experts	Annette Aldrich
Observer	Agroscope - CH

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REPORT OF PESTICIDES PEER REVIEW TC 161

PENDIMETHALIN – mandate, confirmatory data assessment

Rapporteur Member State: NL

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
EU statutory staff representing EU Institutions, agencies or other bodies (other than EFSA)	ECHA
National Expert nominated by RMS NL	Ctgb - NL
National Expert nominated by MS DE	German Environment Agency (Umweltbundesamt, UBA) - DE
National Expert nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Expert nominated by MS IE	Dept of Agriculture food and the marine - IE
National Expert nominated by MS SE	Swedish Chemicals Agency - SE
External Expert	Annette Aldrich
Applicants	BASF

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
1. Summary discussion with the hearing experts	Upon request from RMS, the applicant was given the opportunity to provide clarifications on the agreed-upon questions with the NL as RMS and the other experts. 1. The fish in the BCF laboratory study by [REDACTED] (2003a) Study CA 8.2.2.3/08 ([REDACTED] DocID 2003/1033759) were not fed during the uptake phase. The experts during TC 123 (22 October 2015) indicated that, for this reason and the lack of growth correction, they considered this deviation sufficient not to consider the BCF reliable. However, in the commenting for the confirmatory data assessment, the applicant indicated that they did not consider that the deviations should result in the study endpoint not to be considered reliable. Please could you elaborate on the reasons for that together with the uncertainties for the derived BCF value from this study. 2. Given the range of BCF values observed in the laboratory studies, please provide a rationale to explain the difference in the observed values (361 to 3587 L/kg in the tested species). 3. Could you please provide an explanation for the lower bioaccumulation to fish observed in the two mesocosm studies (CA 8.2.2.3/02, [REDACTED] (2001) and CA 8.2.2.3/09 [REDACTED] (2010a)) relative to that observed in the available bioconcentration studies performed under laboratory conditions. 4. Currently, the risk assessment for fish-eating birds and mammals has used both the highest and lowest BCF value that were available at the time of peer review of the RAR and EFSA conclusion (2016). Since, then three new BCF studies were provided as confirmatory data which confirmed a range of values. What is your proposal for how the risk assessment for fish-eating



Subject	Conclusions Pesticide Peer Review Meeting
	birds and mammals should account for the variability in the BCF values. The replies provided by the applicant's experts were considered during the experts' discussion on the available assessment.
2. Experts to agree on the reliability of the BCF value for zebrafish (██████ DocID2003/1033759).	Owing to the deviations compared to the test guideline, the experts agreed that the BCF for the zebrafish study (██████ DocID2003/1033759) of 1179 is 'reliable with restrictions' and may be considered in the WoE with an acknowledgment of the associated uncertainties. Open point: RMS to reflect on the discussion about the use of the lipid content values and effect this might have in the BCF value for this study and update RAR accordingly. Also to highlight that sub-lethal effects were not included in detail in the study report.
3. Experts to agree on whether the BCF values should be corrected to be in terms only of the parent substance. For this it is important that it is clear that the metabolites are properly characterised.	Overall, experts agreed on using BCF corrected by the parent compound only, when considering the bioaccumulation potential of the active substance. Also, experts agreed to keep all values in the table for the WoE discussion. Open point: RMS to check the BCF calculation for rainbow trout study considering the proportion of parent and metabolites in water and in fish.
4. Experts to agree on the BCF value to be used for the secondary poisoning risk assessment for birds and mammals. Following this agreement, the risk assessment will need to be update.	The experts considered that the approach taken to use the highest and lowest BCF values in the quantitative risk assessment, for fish-eating birds and mammals, was reasonable. However, the risk assessment needs to be updated using the newly available (reliable) BCF value for the bluegill sunfish (3311) and the rainbow trout (361). Open point for the RMS to update the secondary poisoning risk assessment for fish-eating birds and mammals using the newly available (reliable) BCF value for the bluegill sunfish (3311) and BCF value for the rainbow trout without metabolites (361).
5. Experts to agree on the BCF value for pendimethalin making use of all available information. Such consideration should account all relevant regulatory guidance documents, including the ongoing work on the update to ECHA Guidance on the application of the CLP criteria: PBT/vPvB and	The experts discussed the available data to be considered in the WoE assessment of bioaccumulation. The experts agreed on their relative weight in the assessment. The data submitted for the confirmatory data assessment confirmed that one of the BCF values is above the trigger of 2000 for bioaccumulation given in Regulation 1107/2009. Overall, the majority of experts agreed that the data are indicative of meeting the B criteria but cannot be confirmed. However, the minority of experts considered that the data set was inconclusive due to the fact that the SANCO working document does not provide an interpretation of the application of a weight of evidence approach in cases of studies giving differing results. Furthermore, the ECHA, 2024 guidance suggests a WoE



Subject	Conclusions Pesticide Peer Review Meeting
PMT/vPvM. Consideration and any uncertainties used to reach the outcome should be documented.	should be followed but the outcome of the integration of the evidence would need to be consider by the RAC (ECHA Risk Assessment Committee). Open point for the RMS to include the WoE assessment in the RAR for the bioaccumulation assessment on the basis of the above discussions. Open point: RMS to check the conversion from BMF to BCF and include the evaluation (for the feeding fish studies) in the updated RAR. Open point RMS to check whether dry-weight data is available for the study of Study CA 8.1.3/01. If available, the BAF value should be recalculated and the implications considered in the WoE. Open point: RMS to reflect in the RAR a short summary of the bioaccumulation observed in the ADME studies (from the toxicology section of the RAR). The RMS should also include the argumentation in the WoE. Open point: RMS to confirm the evidence for adsorption on to the skin of the fish in the available BCF studies (i.e. to check the value of 77%); this should be reported in the updated RAR under the discussion on bioaccumulation. DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides", Brussels, 25.09.2012 – rev. 3. https://food.ec.europa.eu/document/download/56e2ab25-ea6c-4695-8e00-5115fdb0bdc9_en?filename=pesticides_ppp_app_proc_guide_fate_evidence_identify-pop-pbt-vpvpb-props.pdf Guidance on the Application of CLP Criteria, ECHA-24-G-05-EN, ED-01-24-015-EN-N, ISBN: 978-92-9468-411-0, DOI: 10.2823/4895485, Nov 2024. https://echa.europa.eu/documents/10162/2324906/clp_parts4-5_en.pdf/56ed0738-f7e9-6a6f-e9ca-c13af265ec6b?t=1730718888268



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 1.2 CONFIDENTIAL (NUFARM) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Considering the data available for the formulation for representative uses and the data retrieval exercise performed by the applicant, data gaps were identified: 1) Data/information to address the toxicity of the formulated product should be available for acute data for birds and mammals; aquatic organisms; honey bees; macro-soil organisms; micro-soil organisms; and non-target plants. 2) A more robust data retrieval exercise for the co-formulants is needed, and to fully characterise the safety of the formulation. Open point: RMS to reflect the outcome of the discussion in the volume 4 of the RAR.

REPORT OF PESTICIDES PEER REVIEW

TC 157 AND TC 161

BENZOBICYCLON – NAS 1107

Rapporteur Member State: MT

5. Ecotoxicology

Date: 6 February 2025

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS MT	ICPS – IT on behalf of MT
National Expert nominated by RMS MT	Malta Competition and Consumer Affairs Authority (MCCAA) - MT
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS BE	Federal Public Service Health Food Chain Safety and Environment - BE
National Experts nominated by MS DE	German Environment Agency - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency (DEPA) - DK
National Experts nominated by MS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS ES	Ministerio de Sanidad - ES
National Expert nominated by MS FR	French agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS HU	National Food Chain Safety Office - HU
National Expert nominated by MS HR	Center for Plant Protection - HR
National Expert nominated by MS IE	Department of Agriculture Food and the Marine - IE
National Expert nominated by MS NL	Ctgb - NL
External Expert	Annet Aldrich
Observer	Federal Food Safety and Veterinary Office (FSVO) - CH



Status	Name of institution/attendee
Observer	Swiss Federal Office for the Environment - CH
Observer	Malta Competition and Consumer Affairs Authority (MCCAA) - MT

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the suitability of the risk assessment for birds and mammals proposed by the applicant to cover all the potential feeding guilds occurring in rice fields. The experts should particularly discuss the selected focal species and the parameters used by the applicant, taking into account the limitations listed by the RMS regarding the literature review (2018) and the uncertainties related to the fact that such assessment does not follow a standard scheme. Experts could also considered the discussion held at the Pesticides Peer Review meeting 181 (EFSA, 2018).	The applicant's screening-level risk assessment, using cereals as a surrogate for rice, indicated acceptable acute risk but unacceptable long-term risk for both birds (TERLT = 1.75) and mammals (TERLT = 3.68). Experts agreed that cereals can be used at the screening level, but further refinement is needed for high-risk scenarios. The RMS was asked to conduct this assessment for completeness and include it in the List of Endpoints (LoEP). Experts reviewed and adjusted focal species selection for Tier 1 long-term risk assessment, ensuring better representation across feeding guilds. Higher-tier assessments for herbivorous and insectivorous species will be conducted at the Member State level, while carnivorous and piscivorous mammals will only be assessed where necessary. For piscivorous species, secondary poisoning assessment was agreed as the appropriate approach. Experts also approved worst-case RUD values for aquatic plants and invertebrates. The applicant's risk assessment was considered illustrative, as some proposed refinements lacked full support. Experts emphasized the need for specific guidance on birds, mammals, and other vertebrates in rice paddy environments. Open points: - Include a Tier 1 risk assessment using cereals as a surrogate, while highlighting uncertainties. - Revise the Renewal Assessment Report (RAR) to incorporate discussion outcomes.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 Experts' to agree on the long-term endpoint for mammals.	During the commenting phase, experts discussed and agreed on the long-term endpoint for the risk assessment of benzobicyclon in wild mammals. The lowest NOAEL for benzobicyclon (1.13 mg/kg bw/day) was based on male rat-specific renal effects. However, experts agreed to disregard these effects, as they were not severe enough to impact population maintenance. The relevance of these effects to other wild mammals was debated, but experts concluded that rats are an ecologically relevant species, making the findings applicable. When renal effects were excluded, benzobicyclon did not show significant effects in relevant studies (NOAEL: 1000 mg/kg bw/day). The metabolite 1315P-070, which forms after benzobicyclon hydrolysis, showed significant vision-related effects in rats at 1.345 mg/kg bw/day. Experts agreed that this toxicity is relevant for terrestrial vertebrates (birds and wild mammals). Uncertainty remains due to the lack of a long-term study with birds. Experts agreed on a NOAEL of 1000 mg/kg bw/day for benzobicyclon and 1.345 mg/kg bw/day for 1315P-070 for wild mammals. No long-term study exists for the metabolite in birds, raising concerns (data gap). Open point: RMS to conduct a risk assessment for mammals, taking into account: - The agreed NOAELS for benzobicyclon and metabolite 1315P-070. - The occurrence rate of the metabolite in plants (12.5%). - The need to combine the risk assessment for the metabolite and the active substance, in line with the updated Birds and Mammals Guidance (EFSA, 2023).
Experts' consultation 5.3 Experts' to discuss the risk assessment to aquatic macrophytes considering all available data.	<u>Consideration of and additional macrophyte study</u> The experts agreed that the available studies with non-target terrestrial plants cannot be used to conclude that dicot species are more sensitive than monocots. However, the experts acknowledged the relevance of the new <i>Mirophyllum spicatum</i> study in assessing root uptake. This study could serve to evaluate potential effects associated with root uptake of the active substance. <u>Uncertainty factor for Benzobicyclon</u> The experts agreed that the additional uncertainty factor of 2, which accounts for the composition of benzobicyclon as a



Subject	Conclusions Pesticide Peer Review Meeting
	racemate, should not be applied in the risk assessment for aquatic organisms. This decision was based on the study 134393240 (347-001), which demonstrates that the two enantiomers of benzobicyclon and the racemate exhibit comparable toxicity to the most sensitive species, <i>Lemna gibba</i> Open point: RMS should update the Renewal Assessment Report (RAR) to incorporate the outcomes of this discussion. The aquatic risk assessment should be updated with the agreed PEC values. Further evaluation of the new <i>Myriophyllum spicatum</i> study is required to refine the risk assessment for rooted macrophytes.
Experts' consultation 5.4 Experts to discuss the risk assessment for bees. In particular, the experts' should discuss: (i) The risk to honey bee larvae considering the outcome of the quantitative risk assessment according to the EFSA bee guidance (2013) and all lines of evidence presented by the applicant (to be used in a weight of evidence approach). (ii) The risk from exposure to relevant metabolites. Any additional data submitted by the applicant should also be considered.	The experts concluded that bee exposure to benzobicyclon is expected to be low due to the low occurrence of weeds at the time of application, as demonstrated by efficacy trials. An acceptable acute risk was identified for both metabolites 1315P-570 and 1315P-966, based on both risk assessment approaches (EC, 2002; EFSA, 2013) applied in the evaluation. Regarding the "next crop" scenario, the experts agreed to exclude it from further consideration for the risk assessment of metabolite 1315P-570, as it was deemed not relevant. This decision was based on rotational crop studies indicating that no measurable residues of metabolite 1315P-570 were detected in the succeeding crop. For the "weeds" scenario, the experts did not rule out the possibility of exposure to the relevant plant metabolites of benzobicyclon. Based on the available data, an unacceptable risk cannot be definitively excluded. As a result, the experts agreed on setting a data gap to further assess the risk posed by metabolites 1315P-570 and 1315P-966 in the weeds scenario. The experts also agreed on using the maximum %TRR of 41.1% for metabolite 1315P-966, ensuring a conservative approach in the risk assessment. Open points: - The RMS should update the Renewal Assessment Report (RAR) to reflect the outcome of the discussions. - The RMS should update the risk assessment for metabolite 1315P-966, using the maximum %TRR of 41.1% as agreed. - The RMS should revise the risk assessment for the "next crop" scenario, as it is no longer considered relevant. - The RMS should set a data gap to further assess the chronic risk posed by metabolites 1315P-570 and 1315P-966 in the weeds scenario.
Experts' consultation 5.5 Experts to discuss the validity of the seedling emergence (CP 10.6.2/01)	The majority of experts considered that the duration of the seedling emergence study (14 days instead of the maximum duration recommended by OECD test guideline 208) was a major shortcoming. Some additional limitations were also indicated.



Subject	Conclusions Pesticide Peer Review Meeting
and vegetative vigour (KCP 10.6.2/02) studies, the endpoints to be derived from such studies in case they are considered valid, and the risk assessment to non-target terrestrial plants. The experts should take into account the preliminary limitations identified by the RMS in the DAR as well as the arguments put forward by the applicant to consider both studies valid. Any additional data/justifications submitted by the applicant should also be considered by the experts.	Considering all limitations, it was agreed that a new seedling emergence study with an observation period of 21 days, should be provided by the applicant. In contrast, the limitations of the vegetative vigour study were considered minor. Open point The RMS should update the Renewal Assessment Report, taking into account the outcome of the discussion. The risk assessment for non-target terrestrial plants could not be finalised. A data gap was identified, requiring the applicant to submit a new seedling emergence study.
Experts' consultation 5.6 Experts to discuss the results of the available FSTRA study. The following points will be further discussed: • The appropriateness of the selected testing concentrations, considering the relatively low solubility of benzobicyclon in water, the precipitation observed, and the absence of effects among all the investigated parameters. • The impact of the observed low fecundity values in some replicates of both the negative and solvent controls on the overall reliability of the study; • The impact of the high CV values for fecundity (i.e., eggs/female/day) in the negative control, on the statistical power of the study; • The results from the statistical analysis carried	Wild mammals The ED criteria were considered as not met in humans for the EAS-modalities. The same conclusion applies for wild mammals. NTOs other than mammals The findings from the available FSTRA (OECD TG 229) were discussed among the experts. Based on the available information, the experts considered that, although a number of drawbacks/uncertainties was observed i.e., no sufficient information justifying the selection of the testing concentrations in the definitive test, fecundity and VTG measurements considered as reliable with restrictions, the available FSTRA can be used to conclude on the EAS- modalities for NTOs other than mammals. Open points: • RMS to check the study authors and report correctly in the RAR. • RMS to reflect the outcome of the discussion in the revised RAR and to add an uncertainty analysis.



Subject	Conclusions Pesticide Peer Review Meeting
out on VTG values (i.e., normalized and not normalized). Conclusion on ED properties for the EAS-modalities of benzobicyclon on wild mammals will be discussed, also based on the outcome of endocrine assessment for humans.	
Experts' consultation 5.7 Experts to discuss the findings of the available AMA study. In particular, the following point will be further discussed during the consultation: • Performance criteria based on the calculated 10th and 90th percentile values of the developmental stage; Conclusion on ED properties for the T-modality of benzobicyclon on wild mammals will be discussed, also based on the outcome of endocrine assessment for humans.	Wild mammals The ED criteria were considered as not met in humans for the T-modality. The same conclusion applies for wild mammals. Non-target organisms other than mammals The findings from the available AMA (OECD TG 231) were discussed among the experts. Overall, based on the drawbacks identified in the study, and reported below: - Presence of compromised replicates both in the solvent control and the highest treatment questioning whether the study met the validity and performance criteria; - Missing animals in control and treatment likely due to a human error; - Although a range finder was conducted, the selection of the highest test concentration for the definitive test was even lower than the one tested in the FSTRA with no clear justification. The experts agreed that the level of uncertainties is too high to use the study to draw a conclusion on the ED assessment for the T modality. Open points: - RMS to reflect the outcome of the discussion in the revised RAR. - RMS to check the study authors and report correctly in the RAR.
Experts' consultation (ecotoxicity section) 1.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed on the data gaps for GWN-10235, as suggested by the RMS, regarding the chronic toxicity study on earthworms, the nitrogen transformation study, and the seedling emergence study. A data requirement has already been established in the reporting table to provide an acute bee toxicity study with the formulation. The experts considered it unlikely that any of the co-formulants present would increase the toxicity of the formulation for the



Subject	Conclusions Pesticide Peer Review Meeting
endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	representative uses of GWN-10235, given the known low toxicity of the co-formulants and/or their low concentrations in the formulation. Open point: RMS to reflect the discussion in the updated volume 4 of the RAR.
Expert consultation (ecotoxicity section) 1.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance considering also their short- and long-term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed on the data gaps for GWN-10235, as suggested by the RMS, regarding the chronic toxicity study on earthworms, the nitrogen transformation study, and the seedling emergence study. A data requirement has already been established in the reporting table to provide an acute bee toxicity study with the formulation. The experts considered it unlikely that any of the co-formulants present would increase the toxicity of the formulation for the representative uses of GWN-10235, given the known low toxicity of the co-formulants and/or their low concentrations in the formulation. Open point: RMS to reflect the discussion in the updated volume 4 of the RAR.

REPORT OF PESTICIDES PEER REVIEW TC 155

METALAXYL-M - MANDATE, UPDATED PEER REVIEW

Rapporteur Member State: BE

5. Ecotoxicology

Date: 9 December 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff member	EFSA
National Experts nominated by RM BE	Federal Public Service Health, Food Chain Safety and Environment, DG Animals, Plants and Food, Service Plant Protection Products and Fertilisers - BE
National Expert nominated by MS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Expert nominated by MS DE	Federal Environment Agency (UBA) - DE
National Expert nominated by MS DK	Danish EPA – DK
National Experts nominated by MS FR	ANSES (French Agency for Food, Environmental and Occupational Health & Safety) – FR
National Experts nominated by MS NL	Ctgb - NL
National Expert nominated by MS SE	Swedish Chemicals Agency (Kemikalieinspektionen) - SE
External Experts	Emily Mcvey
Observer	BAFU - CH
Observer	Swedish Chemicals Agency - SE

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the representative uses: a. Reporting of the representative uses in GAP, considering the response by the applicant to the commission mandate, b. Efficacy aspects such as whether the minimum effective dose per hectare is justified considering the lower number of seeds per hectare, based on the available data.	Under this revised assessment the RMS considered sowing densities of 1-12 million seeds per hectare. A reduction from 12 to 1 million seeds leads to a proportional reduction of the rate per hectare. Consequently, the RMS and MSs were requested to report the views of their efficacy experts on whether the efficacy is still supported. Considering the MoA and systemic translocation, the efficacy (to protect the growing plant) is likely driven by the concentration on the seed. Overall, no concern was raised on the EU-level efficacy assessment of Metalaxyl-m considering the representative use as seed treatment in spinach (lower rate) considering a range of 1-12 million seeds per hectare.
Experts' consultation 5.2 Use in spinach in SEU: Experts to acknowledge the risk assessment conclusion and WoE reported in the EFSA conclusion. Experts to discuss the revised higher-tier (WoE) risk assessment for SEU based on the consideration that sowing rates per hectare range from 1-12 mil. seeds per hectare. a. Assuming spinach is sown via standard drilling	Experts were presented with the available higher tier risk assessment for SEU, considering the outcome of the evaluation reported in the EFSA conclusion. Key aspects of the previous assessment of the available higher tier data were discussed and no disagreement was identified. Concerning the risk assessment for SEU for the acute risk to mammals consuming seeds on the soil surface all experts agreed that a low acute risk could be concluded for mammals consuming seeds in SEU after precision drilling based on the refined TER, qualitative consideration of the PD and WoE/uncertainty analysis. Concerning the overall outcome of the risk assessment for SEU considering the WoE and uncertainty analysis, please refer to the conclusion reported below, under "note for all points".



Subject	Conclusions Pesticide Peer Review Meeting
techniques at the highest sowing rate per hectare, experts to characterise the (acute and chronic) risk for birds and mammals. Hence, to identify - where relevant and possible - sowing rates below which a low risk for birds and mammals may be identified. The available lines of evidence and uncertainties should be adequately weighted to draw a risk assessment conclusion for each use scenario. b. Assuming spinach is sown via precision drilling techniques at the highest sowing rate per hectare, experts to characterise the (acute and chronic) risk for birds and mammals. Hence, to identify - where relevant and possible - sowing rates below which a low risk for birds and mammals may be identified. The available lines of evidence and uncertainties should be adequately weighted to draw a risk assessment conclusion for each use scenario.	
Experts' consultation 5.3 Use in spinach in CEU: Experts to acknowledge the risk assessment conclusion and WoE reported in the EFSA conclusion. Experts to discuss the revised higher-tier (WoE) risk assessment for CEU based on the consideration that sowing rates per	Experts were presented with the available higher tier risk assessment for CEU, considering the outcome of the evaluation reported in the EFSA conclusion. Key aspects of the previous assessment of the available higher tier data were discussed and no additional concern or disagreement was identified. The experts considered that the focal species selection for CEU originally included rook, wood pigeon, red-legged partridge and skylark. However, uncertainty was identified on whether smaller species would be covered. Therefore, to address the risks for granivorous birds in this zone, the updated WoE (foraging area approach) would need consider smaller species than the skylark (i.e. a tier 1 generic focal species with bodyweight of 15.3 g).



Subject	Conclusions Pesticide Peer Review Meeting
hectare range from 1 to 12 mil. seeds per hectare. c. Assuming spinach is sown via standard drilling techniques at the highest sowing rate per hectare, experts to characterise the (acute and chronic) risk for birds and mammals. Hence, to identify - where relevant and possible - sowing rates below which a low risk for birds and mammals may be identified. The available lines of evidence and uncertainties should be adequately weighted to draw a risk assessment conclusion for each use scenario. d. Assuming spinach is sown via precision drilling techniques at the highest sowing rate per hectare, experts to characterise the (acute and chronic) risk for birds and mammals. Hence, to identify - where relevant and possible - sowing rates below which a low risk for birds and mammals may be identified. The available lines of evidence and uncertainties should be adequately weighted to draw a risk assessment conclusion for each use scenario.	Concerning the overall outcome of the risk assessment for CEU considering the WoE and uncertainty analysis, please refer to the conclusion reported below, under "note for all points".
Experts' consultation 5.4 Use in spinach in NEU: Experts to acknowledge the risk assessment conclusion and WoE reported in the EFSA conclusion. Experts to discuss whether a risk assessment conclusion for birds and mammals can be drawn based on the limited available data (under the	It was noted that the EFSA conclusion (EFSA 2023) reported that risks in NEU were not considered covered by the previous experts' meeting (2022), partially owing the fact that NEU MSs did were not present. Therefore, the experts during TC 155 further discussed whether the available data could be used to support a risk assessment conclusion in the Northern EU Zone. <u>RA for birds consuming seeds after precision drilling:</u> - Focal species: according to the NEU Guidance document skylark would be considered a suitable small granivorous bird species. Therefore,



Subject	Conclusions Pesticide Peer Review Meeting
assumption that drilling is either done via standard or precision techniques and that sowing is done at increasing rates of 1-12 million per hectare). Hence to identify - where relevant and possible - sowing rates below which a low risk for birds and mammals may be identified	experts agreed that the small granivorous bird species for NEU is skylark. - Ecological refinements: Extrapolations of ecological data should be considered on a case-by-case basis. However, in this specific instance the PD for the skylark in CEU was considered in line with the PD estimate reported in the guidance of the Northern EU zone. Therefore, all experts agreed to extrapolate the ecological refinement for skylark from CEU to NEU. - Residue dissipation (also relevant for the reproductive risk assessment for wild mammals): The experts agreed that the available CEU residue data cannot be applied to the refined assessment for the NZEU. However, the experts agreed that an fTWA value of the 0.53 for seeds on the soil surface maybe be used in the overall WoE together with the uncertainty analysis (both for birds and mammals). <u>RA for mammals consuming seeds after precision drilling:</u> - Focal species: Experts agreed with the selection of the woodmouse (and its FIR/bw) as focal species for NEU - Ecological refinements: PT study for the wood mouse obtained in CEU was sufficiently relevant for the refined assessment for the NZ. The experts agreed the PT value of 0.170 for the wood mouse can be used for the refined assessment in NEU. Open point RMS to update the refined risk assessment (TER values) for both birds and mammals taking account of the agreements made during the meeting for the refinement for the Northern Zone conditions: - Birds: skylark was selected as focal species, considering the same FIR/bw and PD refinements used for CEU. Furthermore, a 21d fTWA = 0.53 for seeds on the soil surface was agreed by the experts. Mammals: woodmouse was selected as focal species with a refinement of its FIR/bw as in CEU. For the acute risk, the PD was qualitatively considered to be likely lower than 1. For the reproductive risk the PT of 0.170 from the study in Germany was also considered suitable for NEU. As for birds, a 21d fTWA = 0.53 for seeds on the soil surface was agreed by the experts. Concerning the overall outcome of the risk assessment for NEU considering the WoE and uncertainty analysis, please refer to the conclusion reported below, under "note for all points".
Note for all points:	A WoE assessment considering the foraging area required to reach toxicity was submitted by the applicant, considering the



Subject	Conclusions Pesticide Peer Review Meeting
While addressing the points above, the experts should consider the following aspects: - The updated WoE approach by the applicant based on the foraging area approach and the thresholds provisionally used by the RMS. - The assumption that some species of birds and mammals may dig up the seeds (and the influence of this potential source of uncertainty on the risk assessment under the assumption of precision drilling)	influence of precision and standard sowing techniques at sowing rates ranging from 1 to 12 million seeds/ha. The foraging area approach is included in EFSA (2023) which refers to is as 'maximum searching area to reach the RAD'. Furthermore, this approach is considered in the Northern Zone Guidance Document. Therefore, the experts discussed the following aspects of the applicant's proposal. 1. Seed availability on the soil surface (based on the study submitted by the applicant) The use of this study in the foraging area approach was considered uncertain for several reasons. These included issues related to i) the study reliability, ii) the variability of data within and across seed availability studies; iii) the proposed extrapolations; and iii) the lack of raw data. Overall, all experts agreed that the WoE, foraging area approach should assume 2.135% spinach seeds to be left on the soil surface upon sowing (a higher estimate than the one suggested by the applicant to deal with the abovementioned uncertainty). 2. Consideration of spillages Spillages observed the seed availability study were not quantitatively considered in the foraging area approach. For the quantitative RA based on the foraging area calculation the majority of experts agreed that the spillages should not be accounted for. 3. Species selection experts agreed that the foraging area approach should cover the focal species for which a high risk is identified based on the Tier-1 and refined TER calculations. In addition, for CEU a generic small granivorous bird species with a body weight of 15.3 g was considered, as explained in 5.3. 4. Risk thresholds for the foraging area approach All experts agreed with the following thresholds for use in the WoE, foraging area approach: - For the acute risk assessment of small birds and mammals: 70 m2 - For the chronic risk assessment of small birds and mammals: 35 m2 - These values should be doubled for larger focal species. 5. Further considerations related to the reduced availability of seeds It was remarked that the revised EFSA guidance for birds and mammals (EFSA 2023) reports that for seeds which are buried within the top 3 cm of soil it is not appropriate to consider reduction in exposure to mammals based on reduced seed availability on the soil surface, due to their ability to dig up seeds. However, as explained in 5.3, experts agreed that a WoE/uncertainty analysis for Algerian mouse may not require explicit consideration of the foraging area approach.



Subject	Conclusions Pesticide Peer Review Meeting
	6. Consideration of seed residue dissipation in the foraging area approach the experts agreed that the foraging area calculation for the chronic risk assessment of Metalaxyl-m should use the fTWA. 7. Additional calculation by the experts on the foraging area to reach toxicity A shiny app was developed in R programming environment with the purpose of providing dynamic data visualisation of the foraging area approach at changing input values (i.e., species, exposure durations, % of seeds on the soil surface, seed residue dissipations, spillage values and risk thresholds). This tool was used at the meeting to explore further scenarios than the one provided by the applicant. Specifically, the meeting considered the seed residue dissipation (i.e., including fTWA), additional species (i.e., a generic bird species with body weight of 15.3 g) and different assumptions for the % of seeds on the soil surface (see above). The outcome of this exercise was assessed together with the following uncertainty analysis: Uncertainty related to the focal species selection was considered at the meeting. However, the directionality of such an uncertainty could not be assessed. The experts agreed to base the foraging area conclusion on the worst-case % of seeds in the headland of 2.135 for precision drilling. However, the experts considered medium uncertainties related to how the diversity of equipment used for precision drilling may affect seed availability on the soil surface. On a similar note, experts quantified as high the uncertainty related to the variability of literature data on the % of seeds on the soil surface upon sowing. These sources of uncertainty could either lead to an overestimation or an underestimation of exposure. Despite experts acknowledging that it is likely that birds would be exposed to lower amounts of contaminated seeds due to lower sowing rates and reduced surface availability of seeds, uncertainty remains on its quantification due to the potential of small birds digging up contaminated seeds. It was considered that this aspect leads to an underestimation of real risks, if small birds are confirmed to dig up spinach seeds. The chronic risk assessment based on the foraging area approach assumed residue dissipations with fTWAs in line with those used for the TER calculations. However, experts acknowledged that there is medium-high uncertainty due to the absence of a quantification of the residue decline in buried seeds, leading to a potentially underprotective assessment. Uncertainty related to the derivation of ecological data was also considered at the meeting. The directionality of such an uncertainty could not be assessed, except for the acute risk assessment for mammals in SEU, where the PD was considered



Subject	Conclusions Pesticide Peer Review Meeting
	likely to be lower than 1, meaning that the real risk is likely lower than what indicated by the TER calculation. Some evidence for (un)palatability, avoidance or de-husking of seeds was available. However, these were only considered qualitatively (with low weight) since the evince was insufficiently robust. Overall, all experts agreed that, based on the refined TER values (i.e., the consideration that certain refinements did not explicitly cover for precision drilling) and foraging area approach (additional calculations by the experts), a low risk is not demonstrated when Metalaxyl-M is used at the lowest seed treatment rate in spinach via standard drilling at sowing rates of 1 to 12 million seeds in any of the EU zones. All experts agreed that a low risk for birds and mammals in the EU can be concluded when Metalaxyl-M is used at the lowest seed treatment rate in spinach via precision drilling at sowing rates below 2 million seeds across all zones. Open point RMS to update the risk assessment according to the agreements made during the experts meeting.

REPORT OF PESTICIDES PEER REVIEW

TC 152 and TC 155

PARAFFIN OILS (CAS 72623-86-0) – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 9 December 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DK	Danish EPA - DK
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS IT	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS NL	Ctgb - NL
Observer	Austrian Agency for Health and Food Safety (AGES) - AT
Observer	BAFU - CH



In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

Please note that information part of this report may have been masked by EFSA in accordance with Article 63 of [Regulation \(EC\) No 1107/2009](#) as well as [EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation \(EC\) No 1107/2009](#), or [EFSA's Practical Arrangements concerning transparency and confidentiality](#) as a consequence of confidentiality requests submitted by the applicant on application dossiers for pesticides active substances or Maximum Residue Levels, respectively. Please note that information disclosed in this report is without prejudice to pre-existing intellectual property rights and data exclusivity clauses set out in Union law, and particularly in Article 62 of Regulation (EC) No 1107/2009.

Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.1 Experts to: - Agree on validity and the endpoints derived from the tier 1 aquatic toxicity studies with the active substance and the formulated product considering the analytical measurements and the water solubility of paraffin oil CAS 72623-86-0. - Discuss the relevance of the tier 1 studies (including those where a water accommodated fraction was tested) for the aquatic risk assessment considering the physicochemical properties and behaviour of oils in water (whether the exposure in the aquatic tier 1 studies and the tested species can be considered as a representative worst case) and for classification purposes.	<u>Endpoints from studies with a water accommodated fraction (WAF)</u> Based on the information presented by the RMS, all experts agreed to not consider the endpoints obtained via WAF in classic quantitative risk assessment. It was agreed that such endpoints can be used qualitative as a supportive in a weight of evidence approach. <u><i>Daphnia magna</i> reproduction study with Finavestan EMA, Study ID : [REDACTED]</u> No measurements prior to day 9 were available. Quantifiable concentrations were only observed for the highest concentration at most time points, with limited data for lower concentrations. Experts disagreed with the RMS's proposed NOEC value due to uncertainties related to the physico-chemical properties of paraffin oils and limitations in the data. While a dissipation pattern using DT₅₀ was suggested, it was acknowledged that significant uncertainties would remain. Consequently, no endpoint could be established for quantitative risk assessment, and a data gap was identified. <u>Outdoor microcosm study (Volume 3CP_OLIE-H, B.9.3.3/01)</u> The study used a specific design to simulate overspray exposure, resulting in an ER₅₀ for daphnids estimated as higher than the highest tested concentration (>16 L/ha). Although an endpoint based on 2D exposure (mg/m²) was proposed, this approach was deemed uncertain because <i>Daphnia magna</i> is not representative of this exposure scenario. Additionally, the study was not considered a microcosm due to testing only one species, and there was no clear exposure pattern in the water column or measurement of the active substance on the water surface. Given the lack of species and exposure representativeness (<i>D. magna</i> does not inhabit the water surface and no surface oil



Subject	Conclusions Pesticides Peer Review Meeting
If provided, the experts should consider the updated PEC values [refer to data requirement in 4(62)] and revised endpoints [refer to data requirement in 5(10)]. The experts should also consider the experts' discussion for paraffin oil 8042 46 5 at the Pesticide Peer Review Teleconference 102 (April, 2023).	layer was observed), the study was not suitable for risk assessment. It was agreed the study could only provide limited supportive information. Open Point: The RMS was tasked with removing endpoints from the LoEP and updating the revised RAR to reflect these discussions. <u>Outdoor prolonged acute test (Study ID: [REDACTED]) with Olie-H and <i>Culex</i> sp.</u> The endpoint was recalculated by using Bayesian Benchmark Dose (BMD), which confirmed that the proposed ED₅₀ might be not fully reliable to be used in a quantitative risk assessment. However, it was considered that based on the mode of action of the substance, an attempt to make the most use of the endpoint could be done. Based on the outcome of the re-analysis, a proposal was made to set the endpoint at the lower limit of the CL (135.7 mg/m²). All experts agreed with this proposal. <u>Outdoor prolonged acute test (Study ID: [REDACTED]) with Olie-H and <i>Notonecta</i> sp.</u> Based on the outcome of the re-analysis using Bayesian BMD, and on the approach used with the study with <i>Culex</i> sp. a proposal was made to set the endpoint at the lower limit of the CL (122.827 mg/m²). However, it was also considered that similar effects were observed at 32.5 mg/m² and where the ED₅₀ was identified with BMD (303.68 mg/m²). It was also checked that the mortality at 32.50 was not driven by a single replicate. Therefore, based on the above-mentioned uncertainties over the dose response, experts agreed to set the endpoint at > 32.5 mg/m². The selection of the endpoint was considered as a worst-case scenario. All experts agreed. Open points: The RMS to reflect the outcome of the discussion in the revised RAR. The RMS to please report in the footnote that the selection of the endpoints from modified exposure studies on <i>Culex</i> and <i>Notonecta</i> was based on the different approaches (lower limit of BMD, and concrete dose effect), respectively. <u>2D vs. 3D approach</u> For aquatic invertebrates of the water column, experts agreed that the risk assessment should be conducted by following both the 3D and the 2D risk assessment. For all the other organisms (for which endpoints were available), only 3D approach is required. A concern was raised over the exposure to aquatic plants (e.g., <i>Lemna</i>), considering the physical MoA of the a.s. (forming surface film after over spraying). However, it was further clarified that there is no concern over the toxicity of the a.s. from the available studies on terrestrial plants (lowest



Subject	Conclusions Pesticides Peer Review Meeting
	endpoint 10.42 L/ha from seedling emergence study with Polithiol formulation). Therefore, based on the available data, no further concern was raised by the experts. Open point: The RMS to reflect the outcome of the discussion in a revised RAR, that is: For aquatic invertebrates of the water column, the risk assessment should be conducted by following both the 3D and the 2D risk assessment. For all the other organisms (for which endpoints were available), only 3D approach is required.
Experts' consultation 5.2 Experts to discuss the mesocosm study (Reference: [REDACTED]) with Citrole. - Validity of the study (reliability and relevance, considering the it was conducted with a formulation different than the representative one) and how it could be used in the risk assessment for the different representative uses of paraffin oil CAS 72623-86-0. Refer to most specific comments regarding the study design, exposure and data analysis in 5(35). - The relevance of the species tested (i.e., whether the most sensitive species were tested). - The endpoints derived from the study (ETO-RAC, ERO-RAC) and the corresponding assessment factor.	<u>Assessment of relevance and reliability of the mesocosm study (Reference: [REDACTED])</u> Based on the available information and the evaluation performed by the experts, many drawbacks were identified in the mesocosm study. It was further noted that the concentration of the positive control used was considerably high resulting in obvious effects <u>Representativeness of the study</u> It was agreed that, since the formulation was injected in the stream, it does not represent a typical exposure from paraffin oils (over spray). It was also added that the mesocosm test design (flow-through in artificial streams) does not allow to understand the real effect of paraffin oils on most sensitive species to the MoA of the substance (living at the surface in pond systems, e.g., culex and notonecta). It was also remarked that the exposure time is questionable for assessing potential effects on growing communities (issue when evaluating direct effects). The number and interval of applications might not cover all uses identified in the GAP table; no comparison with the FOCUS profile was carried out. <u>Other discussion points</u> It was noted that the alleged recovery mentioned by the applicant for the abundance of benthic invertebrates at 5 mg/L was not agreed upon. No trend of recovery was observed but simply a larger variability among control replicates. For what concern inhibition of feeding in caged <i>Gammarus</i> sp., statistically significant effects with a clear dose-response were observed for both tested concentrations (differently to what was reported in the original study report). <u>Conclusions</u> Overall, all experts agreed that based on the identified limitations and drawbacks hindering the relevance, reliability and representativeness of the study, the mesocosm could not be used in a quantitative risk assessment and no regulatory endpoints can be derived. Open point The RMS to update the risk assessment and the LoEP based on the discussions of the meeting.
Experts' consultation 5.3	The RMS considered that the applicant's proposal to reduce the default assessment factors used in the aquatic risk assessment



Subject	Conclusions Pesticides Peer Review Meeting
Experts to discuss the proposal to reduce the assessment factors used in the aquatic risk assessment considering the potential overconservative estimation of endpoints and exposure.	was not justified. The experts agreed that there was not EU agreement and supported the RMS's view. Open point The RMS to report the outcome of the discussions in a revised RAR.
Experts' consultation 5.4 Experts to discuss the risk assessment to fish considering the available toxicity data and the physico-chemical properties.	Fish ELS study with Finavestan EMA (Document No: [REDACTED]) The analytical findings and semi-static test designs were noted to be similar to those in the <i>Daphnia magna</i> reproduction study. Based on these discussions, all experts agreed that no endpoint could be derived for quantitative risk assessment. Due to discrepancies between the water solubility reported in the LoEP (<2.5 µg/L at pH 7.5 and 20°C) and the LOQ (10 µg/L), the use of the solubility limit to establish an endpoint was deemed inappropriate, and the risk assessment based on water solubility was agreed to be removed. This conclusion applied to all groups of aquatic organisms. Open points The RMS to (i) delete the risk assessment performed with the solubility limit from the LoEP, and (ii) reflect the outcome of the discussions in the revised RAR. <u>Weight of evidence (WoE) approach to assess the acute and chronic risk to fish</u> All the available endpoints for fish (which were all conducted with a water accommodated fraction) were not considered suitable to be used in the risk assessment. The available fish studies did not show toxic effects and it is likely that fish won't be sensitive to the mode of action (MoA) of paraffin oil (physical MoA from film surface). Experts also considered studies from previous conclusions on paraffin oils, which did not raise concerns over toxicity of paraffin oils towards fish. Therefore, also in view of reducing vertebrate testing, all experts agreed to accept the proposed WoE approach and that additional fish studies are not required. Open points The RMS to (i) reflect the outcome of the discussion in a revised RAR and (ii) revise the LoEP based on the outcome of the discussions.
Experts' consultation 5.5 Experts to discuss the risk assessment for bees. In particular: - The relevance of standard contact studies considering the physical mode of action of paraffin oil.	Semi-field (tunnel) study with Olie-H (Report No.: [REDACTED]) The study was assessed more in detail. The data showed substantial flight activity on the same day of the application, both before and 30 minutes after treatment. Based on this, experts agreed that indications of overspray were present in the study. The study was not specifically designed to assess effects on adult bee mortality, especially as fenoxycarb (an insect growth



Subject	Conclusions Pesticides Peer Review Meeting
- Any new studies/evidence submitted by the applicant to address the chronic risk to bee adults and larvae or to refine the high acute risk identified for the representative uses with paraffin oil CAS 72623-86-0. - The updated risk assessment for bees.	regulator) was used as the toxic reference. Despite this limitation, the results were considered informative. While the study design was not deemed suitable for assessing adult mortality, its findings, combined with those of the semi-field study No. [REDACTED] with paraffin oil CAS 64742-46-7, supported the conclusion that overspray is unlikely to cause high acute mortality. Regarding the brood assessments, most experts agreed that the patterns of effects and variability across treatments made the biological significance of the observed effects debatable. However, the majority concluded that the study results were insufficient to rule out a high risk to larvae from paraffin oil application. <u>Risk assessment</u> - The acute Tier 1 risk and the risk due to overspray were considered addressed. - Tier 1 chronic data for adult and larvae were not available. Therefore, a data gap was identified. <u>Open points</u> RMS to (i) reflect the outcome of the discussion on the bee studies and risk assessment in a revised RAR/LoEP, and (ii) revise the risk assessment accordingly.
Experts' consultation 5.6 Experts to discuss the risk assessment to non-target arthropods. - The possibility for extrapolation of results between formulations. Refer to 0(2). - The relevance of the aged-residue study with <i>Typhlodromus pyri</i> and OLIE-H. - To discuss any additional high tier studies or to propose any risk mitigation measures that can be used for refining the risk to non-target arthropods other than bees for the representative uses with Finavestam EMA and OLIE H.	<u>Extrapolation between formulations</u> Please refer to experts' consultation 5.7. <u>Relevance of the available studies considering the physical mode of action of paraffin oil</u> All experts agreed that an overspray study would be required to address the off-field risk, given that the glass plate and aged-residue studies, due to their exposure regime, were not considered suitable to capture the mode of action of substances like paraffin oil, which has a (primarily) physical mode of action. The experts agreed that the standard risk assessment based on the SANCO terrestrial guidance (EC, 2002) should be kept in the RAR and reported in the EFSA conclusion. The experts also agreed that the uncertainties related to the special mode of action of paraffin oil should be highlighted and that, ideally, an overspray study should be available to address that route of exposure. <u>Relevance of the aged-residue study (Report No. [REDACTED]) with <i>Typhlodromus pyri</i> and OLIE-H</u> The experts agreed that the study is unsuitable to cover the worst-case GAP (12 × 5 kg/ha with 3–7-day intervals). However, the study could support a use scenario involving 2 × 5 kg/ha with a 3–7-day interval. For this scenario, the available study would represent a worst-case exposure. <u>Field study (Document No: [REDACTED]) with DEV 2008-13 on predatory mites</u>



Subject	Conclusions Pesticides Peer Review Meeting
	Given the uncertainty around the low mite counts in the control, the limited timing of assessments immediately after applications, and the absence of extended study duration (a minimum assessment one month after the final application is typically required), the study was deemed insufficient for assessing recovery. <u>Overall conclusion on recovery based on the aged residue and field studies</u> Based on the outcome of the aged-residue study with the predatory mite <i>Typhlodromus pyri</i>, all experts agreed that potential for recovery was demonstrated for paraffin oil use at 2 × 5 kg/ha with a 3–7-day interval in potatoes. <u>Open point</u> The RMS to (i) reflect the meeting discussion on the assessment of non-target arthropod studies in a revised RAR, and (ii) include the standard off field risk assessment in a revised RAR and the List of Endpoints. The risk assessment should explicitly consider the worst-case GAP use, as well as the ones resulting in lower exposure (e.g., 2 × 5 kg/ha in potato).
Experts' consultation 5.7 Experts to discuss the ecotoxicological equivalence of the formulations used in the toxicity studies with paraffin oil CAS 7263-86-0. If provided, the experts should consider the additional information provided by the applicants.	It was noted that the three paraffin oils (i.e., CAS 64742-46-7, CAS 72623-86-0 and CAS 97862-82-3) are saturated hydrocarbons, and that the main difference is in carbon chain length. It was also pointed out the variability observed within individual CAS numbers is larger compared to the variability observed across different CAS numbers. Therefore, all experts agreed to consider the three paraffin oils as comparable. Based on the composition of the formulations, all experts agreed to consider Citrole, Olie-H, Ovispray and Finavestan EMA as comparable. <u>Open point</u> The RMS to reflect the outcome of the discussions in the revised RAR.
Experts' consultation 5.8 Expert to discuss the waiver of the ED assessment for NTOs submitted for paraffin oil (CAS_72623-86-0).	The waiver of the ED assessment submitted for paraffin oil (CAS 72623-86-0) was discussed and all the experts agreed on the following: -The waiver presented for mammalian toxicology also applies to wild mammals. -The waiver proposed for non-target organisms other than mammals was agreed based on the following: - Main constituents of paraffin oils are alkanes, i.e., mainly straight and branched hydrocarbon chains with no aromatics, - Paraffin oils are ubiquitously present in the environment, including in food items; and are known components of plant and arthropod cuticle wax;



Subject	Conclusions Pesticides Peer Review Meeting
	- No concern related to the ED properties of paraffin oils has been identified in the available systematic literature review; - No alert was reported in the available QSAR studies related to endocrine activity; - Paraffin oils have been used as adjuvant for veterinary vaccines/in pharmacological products; - The substance has a potential physical MoA. Open point RMS to align the information in the revised RAR with the discussion at the meeting.
Experts' consultation 2.2 (ecotoxicity) Confidential_total energies MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	It was raised whether sufficient information are available to assess the ecotoxicological profile of each individual component other than the active substance. The risk assessment for all non-target organisms is covered by the formulation, except chronic data for bees (which are not available also for the a.s.), and for birds. Open point The RMS to complement the exercise for the assessment of the ecotoxicological profile of each individual components other than the active substance in Volume 4 of the revised RAR.
Experts' consultation 2.2 (Ecotoxicity) Confidential_Certis MS experts to discuss whether the available information is sufficient to characterize the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	It was raised whether sufficient information are available to assess the ecotoxicological profile of each individual component other than the active substance. For CAS (72623-86-0) (Olie-H): the applicant provided an assessment based on several EU Legal frameworks, with evidence of that the two co-formulants did not have toxic effects higher than the a.s. However, the comparison of the data between the co-formulants and the a.s. was not conducted. Open point The RMS to complement the exercise for the assessment of the ecotoxicological profile of each individual components other than the active substance for Olie-H and Polithiol in Volume 4 of the revised RAR.

REPORT OF PESTICIDES PEER REVIEW

TC 152 and TC 155

PARAFFIN OILS (CAS 64742-46-7) – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 9 December 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DK	Danish EPA - DK
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS IT	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS NL	Ctgb - NL
Observer	Austrian Agency for Health and Food Safety (AGES) - AT
Observer	BAFU - CH

MEETING MINUTES – 9 December 2024
Pesticides Peer Review TC 152 and TC 155
Paraffin oils (CAS 64742-46-7)



In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.1 Experts to: - Agree on validity and the endpoints derived from the tier 1 aquatic toxicity studies with the active substance and the formulated product considering the analytical measurements and the water solubility of paraffin oil CAS 64742-46-7. - Discuss the relevance of the tier 1 studies (including those where a water accommodated fraction was tested) for the aquatic risk assessment considering the physicochemical properties and behaviour of oils in water (whether the exposure in the aquatic tier 1 studies and the tested species can be considered as a representative worst case) and for classification purposes. - If provided, the experts should consider the updated PEC values [refer to data requirement in 4(63)] and revised endpoints [refer to data requirement in 5(49)]. - The experts should also consider the experts'	<u>Endpoints from studies with a water accommodated fraction (WAF)</u> Based on the information presented by the RMS, all experts agreed to not consider the endpoints obtained via WAF in classic quantitative risk assessment. It was agreed that such endpoints can be used qualitative as a supportive in a weight of evidence approach. <u>2D vs. 3D approach</u> For aquatic invertebrates of the water column, experts agreed that the risk assessment should be conducted by following both the 3D and the 2D risk assessment. For all the other organisms (for which endpoints were available), only 3D approach is required. A concern was raised over the exposure to aquatic plants (e.g., <i>Lemna</i>), considering the physical mode of action of the active substance (forming surface film after over sparging). However, it was further clarified that there is no concern over the toxicity of the a.s. from the available studies on terrestrial plants (lowest endpoint 10.42 L/ha from seedling emergence study with Polithiol formulation). Therefore, based on the available data, no further concern was raised by the experts. <u>Open point</u> The RMS to reflect the outcome of the discussion in a revised RAR, that is: For aquatic invertebrates of the water column, the risk assessment should be conducted by following both the 3D and the 2D risk assessment. For all the other organisms (for which endpoints were available), only 3D approach is required.



Subject	Conclusions Pesticides Peer Review Meeting
discussion for paraffin oil 8042-46-5 at the Pesticide Peer Review Teleconference 102 (April, 2023).	
Experts' consultation 5.2 Experts to discuss the mesocosm study (Reference: [REDACTED]) with Citrole. - Validity of the study (reliability and relevance). - The relevance of the species tested (i.e., whether the most sensitive species were tested). - The endpoints derived from the study (ETO-RAC, ERO-RAC) and the corresponding assessment factor.	<u>Assessment of relevance and reliability of the mesocosm (outdoor aquatic artificial open streams) study (Reference: [REDACTED])</u> Based on the available information and the evaluation performed by the experts, many drawbacks were identified in the mesocosm study. It was further noted that the concentration of the positive control used was considerably high resulting in obvious effects. <u>Representativeness of the study</u> It was agreed that, since the formulation was injected in the stream, it does not represent a typical exposure from paraffin oils (over spray). It was also added that the mesocosm test design (flow-through in artificial streams) does not allow to understand the real effect of paraffin oils on most sensitive species to the MoA of the substance (living at the surface in pond systems, e.g., culex and notonecta). It was also remarked that the exposure time is questionable for assessing potential effects on growing communities (issue when evaluating direct effects). No comparison with the FOCUS profile was carried out. <u>Other discussion points</u> It was noted that the alleged recovery mentioned by the applicant for the abundance of benthic invertebrates at 5 mg/L was not agreed upon. No trend of recovery was observed but simply a larger variability among control replicates. For what concern inhibition of feeding in caged <i>Gammarus</i> sp., statistically significant effects with a clear dose-response were observed for both tested concentrations (differently to what was reported in the original study report). <u>Conclusions</u> Overall, all experts agreed that based on the identified limitations and drawbacks hindering the relevance, reliability and representativeness of the study, the mesocosm could not be used in a quantitative risk assessment and no regulatory endpoints can be derived. <u>Open point</u> The RMS to update the risk assessment and the LoEP based on the discussions of the meeting.



Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.3 Experts to discuss the proposal to reduce the assessment factors used in the aquatic risk assessment considering the potential overconservative estimation of endpoints and exposure.	The RMS considered that the applicant's proposal to reduce the default assessment factors used in the aquatic risk assessment was not justified. The experts agreed that there was not EU agreement and supported the RMS's view. Open point The RMS to report the outcome of the discussions in a revised RAR.
Experts' consultation 5.4 Experts to discuss the risk assessment to fish considering the available toxicity data and the physico-chemical properties.	<u>Weight of evidence (WoE) approach to assess the acute and chronic risk to fish</u> All the available endpoints for fish (which were all conducted with a water accommodated fraction) were not considered suitable to be used in the risk assessment. The available fish studies did not show toxic effects and it is likely that fish won't be sensitive to the mode of action of paraffin oil (physical mode of action from film surface). Experts also considered studies from previous conclusions on paraffin oils, which did not raise concerns over toxicity of paraffin oils towards fish. Therefore, also in view of reducing vertebrate testing, all experts agreed to accept the proposed WoE approach and that additional fish studies are not required. Open point The RMS to (i) reflect the outcome of the discussion in a revised RAR and (ii) revise the LoEP based on the outcome of the discussions.
Experts' consultation 5.5 Experts to discuss the risk assessment to non-target arthropods other than bees. In particular: - The relevance of the available studies for the in-field and off-field risk assessment considering the mode of action of paraffin oil. The experts should consider the outcome of the discussion at the Teleconference 101 for paraffin oil CAS 8042-47-5 (April, 2023). Refer to comments 5(68), 5(96), 5(100). - The reliability of the fresh and aged residue laboratory study [REDACTED] (2018) with <i>Typhlodromus pyri</i> and whether additional	<u>Relevance of the available studies</u> All experts agreed that an overspray study would be required to address the off-field risk, given that the glass plate and aged-residue studies, due to their exposure regime, were not considered suitable to capture the mode of action of substances like paraffin oil, which has a (primarily) physical mode of action. The experts agreed that the standard risk assessment based on the SANCO terrestrial guidance (EC, 2002) should be kept in the RAR and reported in the EFSA conclusion. The experts also agreed that the uncertainties related to the special mode of action of paraffin oil should be highlighted and that, ideally, an overspray study should be available to address that route of exposure. <u>Reliability of the fresh and aged-residue laboratory study</u> Report No. [REDACTED] The experts considered the study on <i>Typhlodromus pyri</i> (Report No. [REDACTED]) was valid but highlighted the uncertainty due to the mortality observed immediately upon exposure on day 0. Additionally, a mean effect of 30%, accompanied by high variability across replicates, was reported.



Subject	Conclusions Pesticides Peer Review Meeting
studies on predatory mites are needed considering the available dataset. - Any additional high tier studies or risk mitigation measures to refine the risk [refer to the data requirement in 5(74)]. - Refined MAF value for the off-field exposure assessment. Refer to 5(99).	Most experts agreed to retain the study in the LoEP, with a footnote to emphasize the uncertainty related to the endpoint derivation (LR₅₀ is >12 kg a.s./ha). <u>Additional high tier studies</u> An aged-residue study with <i>T. pyri</i> was available, providing indicative data on in-field recovery after 1–3 applications. A field study (Project: [REDACTED]) was also available, monitoring the population development of <i>T. pyri</i> following four applications of paraffin oil at 30 L/ha in vineyards. In comparison, the uses in citrus involve four applications at 40 L/ha. Thus, the application regime in the study was not considered worst-case relative to the GAP. Despite this best-case application regime, clear effects on <i>T. pyri</i> populations were observed. Clear treatment effects were observed, with no recovery proven within one year. All experts agreed on this conclusion. Based on the field study findings, all experts agreed that recovery in the field could not be concluded. The possibility of recovery following a single application was also questioned. <u>Open points</u> RMS to reflect the meeting discussion in a refined RAR and to include the standard risk assessment in the RAR and List of Endpoints (considering the critical GAP and all uses resulting in lower exposure, including the single application).
Experts' consultation 5.6 Experts to discuss the risk assessment for bees. In particular, the experts should discuss: - The relevance of standard contact studies considering the physical mode of action of paraffin oil CAS 64742-46-7. - Any new studies/evidence submitted by the applicant to address the chronic risk to bee adults and larvae or to refine the high acute risk from oral exposure identified for the representative uses with paraffin oil CAS 64742-46-7 [refer to the data requirement in 5(73)].	<u>Semi field (tunnel) study number [REDACTED]</u> The experts considered that the study presented several limitations regarding the brood assessment but that it could be used to assess contact toxicity. The majority of experts agreed that the study did not show clear treatment-related effects on mortality upon overspray, although some numerical differences between the treatment and the control were observed. Some experts expressed reservation that the study results are not sufficiently robust to rule out effects. Overall, the study was considered to cover the overspray route of exposure. Although uncertainty was highlighted as to whether mortality due to overspray can be completely ruled out, the study results were taken together with additional evidence (e.g., supportive use of Tier 1 contact study) to conclude low acute risk from contact (overspray) exposure <u>Risk assessment</u> The possibility of using the extrapolation factors of EFSA (2023) allowing to estimate a surrogate LD₅₀ in the case of limit tests showing no effect was discussed. All experts



Subject	Conclusions Pesticides Peer Review Meeting
- The updated risk assessment for bees [refer to the data requirement in 5(73)].	agreed that this would not be acceptable given that the EFSA (2023) guidance document has not yet been noted. The additional uncertainty concerning the overspray route of exposure was considered addressed by the semi-field study. experts agreed that a low acute risk from oral exposure could be concluded using a WoE approach, considering that: - The tier 1 endpoint is a right censored value. - The higher tier study did not show clear effects. - The substance is expected to have primarily a physical MoA. Chronic data from the formulation for the representative uses or from comparable formulations were not available and the available higher tier studies were considered not suitable to address the chronic risk. Therefore, the majority of experts agreed that no low risk conclusion could be drawn for the chronic adult and larval risk assessment for bees, due to the absence of data. Open point The RMS to reflect the outcome of the discussion in a revised RAR/LoEP and to update the risk assessment accordingly.
Experts' consultation 5.7 Experts to discuss the risk assessment for Collembola. The experts should discuss: - The validity of the study (2018). - The endpoint to be used for the risk assessment considering the available dataset. - Any additional information submitted by the applicant.	Validity of the Collembola study [redacted] <i>Validity of the study:</i> The experts agreed not to invalidate the study based on the observed high mortality and variability at the three lowest tested concentrations. However, the study was classified as reliable with restrictions, with the caveat that the proposed endpoint is associated with some uncertainty. This conclusion should be clearly reflected in the evaluation. <i>Study design:</i> The exposure regime, where the test substance is mixed into the soil, was considered consistent with the recommended approach for substances with non-physical mode of action. Consequently, experts agreed that this exposure regime is appropriate for evaluating paraffin oil in lower-tier studies. <i>Endpoint selection:</i> The experts closely examined the reproductive data and observed no apparent correlation between mortality and reproduction at the two lowest concentrations. They agreed to adopt a NOEC of 171 mg a.s./kg based on reproductive effects, considering it a more conservative approach than relying on the EC₁₀. However, they recommended adding a footnote to the LoEP to acknowledge the uncertainty regarding whether this endpoint adequately accounts for potential mortality effects. Use of the Collembola study [redacted] <u>with natural soil</u> Experts agreed that the results of the study conducted with natural soil ([redacted] 2021) should not override those of the [redacted] (2018) study, which was performed with artificial



Subject	Conclusions Pesticides Peer Review Meeting
	soil. While the validity of the [REDACTED] (2021) study was not questioned, its use in the risk assessment was not recommended. Nonetheless, the endpoint derived from this study should be retained in the LoEP. Open point The RMS is tasked with reflecting the outcome of the discussion in a revised RAR.
Experts' consultation 5.8 Expert to discuss the waiver of the ED assessment for NTOs submitted for paraffin oil (CAS_64742-46-7)	The waiver of the ED assessment submitted for paraffin oil (CAS 64742-46-7) was discussed and all the experts agreed on the following: -The waiver presented for mammalian toxicology also applies to wild mammals. -The waiver proposed for non-target organisms other than mammals was agreed based on the following justifications: - Main constituents of paraffin oils are alkanes, i.e., mainly straight and branched hydrocarbon chains with no aromatics, - Paraffin oils are ubiquitously present in the environment, including in food items; and are known components of plant and arthropod cuticle wax; - No concern related to the ED properties of paraffin oils has been identified in the available systematic literature review; - No alert was reported in the available QSAR studies related to endocrine activity; - Paraffin oils have been used as adjuvant for veterinary vaccines/in pharmacological products; - The substance has a potential physical MoA. Open point RMS to align the information in the revised RAR with the discussion at the meeting.
Experts' consultation 5.9 Experts to discuss the ecotoxicological equivalence of the different formulations used in the toxicity tests with non-target organisms. The experts should consider the requested data on the composition of the formulations.	It was noted that the three paraffin oils (i.e., CAS 64742-46-7, CAS 72623-86-0 and CAS 97862-82-3) are saturated hydrocarbons, and that the main difference is in carbon chain length. It was also pointed out the variability observed within individual CAS numbers is larger compared to the variability observed across different CAS numbers. Therefore, all experts agreed to considered the three paraffin oils as comparable. Based on the composition of the formulations, all experts agreed to consider Citrole, Olie-H, Ovispray and Finavestan EMA as comparable. Open point The RMS to reflect the outcome of the discussions in the revised RAR.

MEETING MINUTES – 9 December 2024
Pesticides Peer Review TC 152 and TC 155
Paraffin oils (CAS 64742-46-7)



Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 2.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	For paraffin oil CAS 64742-46-7, the risk assessment for all non-target organisms is covered by the formulation for the representative uses (Citrole) or by a comparable formulation (Ovispray), except chronic data for bees (which are not available also for the a.s.), and for birds. Open point The RMS to complement the exercise for the assessment of the ecotoxicological profile of each individual components other than the active substance for Olie-H and Polithiol in Volume 4 of the revised RAR.

REPORT OF PESTICIDES PEER REVIEW

TC 152 and TC 155

PARAFFIN OILS (CAS 97862-82-3) – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 9 December 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	Julius Kühn Institute (JKI), Federal Research Centre for Cultivated Plants - Institute for Bee Protection
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS DK	Danish EPA - DK
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Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the ecotoxicological equivalence of the different paraffin oils and paraffin oil-containing formulations used in the ecotoxicity studies. The experts should consider the information submitted by the applicant under the relevant data requirement.	It was noted that for Citrole vs. Polithiol, there are many concerning differences such as low % of a.s. in the latter formulation, presence of a second active substance. Therefore, based on these differences, all experts agreed that the two formulations Citrole and Polithiol could not be considered comparable, and extrapolation from studies conducted with Polithiol will not be considered for risk assessment. Open point The RMS to reflect the outcome of the discussions in the revised RAR.
Experts' consultation 5.2 Experts to discuss the proposal to reduce the assessment factors used in the aquatic risk assessment considering the potential overconservative estimation of endpoints and exposure.	The RMS considered that the applicant's proposal to reduce the default assessment factors used in the aquatic risk assessment was not justified. The experts agreed that there was no EU agreement and supported the RMS's view. Open point The RMS to report the outcome of the discussions in a revised RAR.
Experts' consultation 5.3 Experts to: - Agree on the validity and the endpoints derived from the tier 1 aquatic toxicity studies with the active substance and the formulated product considering the analytical measurements and the water solubility of paraffin oil CAS 97862-82-3.	<u>Endpoints from studies with a water accommodated fraction (WAF)</u> Based on the information presented by the RMS, all experts agreed to not consider the endpoints obtained via WAF in classic quantitative risk assessment. It was agreed that such endpoints can be used qualitatively as supportive in a weight of evidence approach. <u>2D vs. 3D approach</u> For aquatic invertebrates of the water column, the experts agreed that the risk assessment should be conducted by following both the 3D and the 2D risk assessments. For all the



Subject	Conclusions Pesticides Peer Review Meeting
- Discuss the relevance of the tier 1 studies (including those where a water accommodated fraction was tested) for the aquatic risk assessment considering the physico-chemical properties and behaviour of oils in water (whether the exposure in the aquatic tier 1 studies and the tested species can be considered as a representative worst case) and for classification purposes. If provided, the experts should consider the updated PEC values and revised endpoints. The experts should also consider the experts' discussion for paraffin oil 8042-46-5 at the Pesticide Peer Review Experts' Teleconference 102 (April, 2023).	other organisms (for which endpoints were available), only 3D approach is required. A concern was raised over the exposure to aquatic plants (e.g., <i>Lemna</i>), considering the physical MoA of the active substance (forming surface film after over spraying). However, it was further clarified that there is no concern over the toxicity of the active substance from the available studies on terrestrial plants (lowest endpoint 10.42 L/ha from seedling emergence study with Polithiol formulation). Therefore, based on the available data, no further concern was raised by the experts. Open point The RMS to reflect the outcome of the discussion in a revised RAR, that is: For aquatic invertebrates of the water column, the risk assessment should be conducted by following both the 3D and the 2D risk assessments. For all the other organisms (for which endpoints were available), only 3D approach is required.
Experts' consultation 5.4 Experts to discuss the risk assessment to fish considering the available toxicity data and the physico-chemical properties. The experts should also discuss the fish chronic study conducted on a formulation containing CAS 64742-46-7.	<u>Weight of evidence (WoE) approach to assess the acute and chronic risk to fish</u> All the available endpoints for fish (which were all conducted with a water accommodated fraction) were not considered suitable to be used in the risk assessment. The available fish studies did not show toxic effects and it is likely that fish won't be sensitive to the mode of action (MoA) of paraffin oil (physical MoA from film surface). The experts also considered studies from previous conclusions on paraffin oils, which did not raise concerns over toxicity of paraffin oils towards fish. Therefore, also in view of reducing vertebrate testing, all experts agreed to accept the proposed WoE approach and that additional fish studies are not required. Open point The RMS to (i) reflect the outcome of the discussion in a revised RAR and (ii) revise the LoEP based on the outcome of the discussions.
Experts' consultation 5.5	<u>Assessment of relevance and reliability of the mesocosm study</u>



Subject	Conclusions Pesticides Peer Review Meeting
Experts to discuss the mesocosm study with Citrole. Specifically, the experts should discuss: - Validity of the study (reliability and relevance, considering that it was conducted with a formulation different than the representative one) and how it could be used in the risk assessment for the different representative uses of paraffin oil CAS 97862-82-3. - The relevance of the species tested (i.e., whether the most sensitive species were tested). - The endpoints derived from the study (ETO-RAC, ERO-RAC) and the corresponding assessment factor.	Based on the available information and the evaluation performed by the experts, many drawbacks were identified in the mesocosm study. It was further noted that the concentration of the positive control used was considerably high resulting in obvious effects. <u>Representativeness of the study</u> It was agreed that, since the formulation was injected in the stream, it does not represent a typical exposure from paraffin oils (over spray). It was also added that the mesocosm test design (flow-through in artificial streams) does not allow to understand the real effect of paraffin oils on most sensitive species to the MoA of the substance (living at the surface in pond systems, e.g., <i>Culex</i> and <i>Notonecta</i>). It was also remarked that the exposure time is questionable for assessing potential effects on growing communities (issue when evaluating direct effects). No comparison with the FOCUS profile was carried out. <u>Other discussion points</u> It was noted that the alleged recovery mentioned by the applicant for the abundance of benthic invertebrates at 5 mg/L was not agreed upon. No trend of recovery was observed but simply a larger variability among control replicates. For what concern inhibition of feeding in caged <i>Gammarus</i> sp., statistically significant effects with a clear dose-response were observed for both tested concentrations (differently to what was reported in the original study report). <u>Conclusions</u> Overall, all experts agreed that based on the identified limitations and drawbacks hindering the relevance, reliability and representativeness of the study, the mesocosm study could not be used in a quantitative risk assessment and no regulatory endpoints can be derived. Open point RMS to update the risk assessment and the LoEP based on the discussions of the meeting.
Experts' consultation 5.6 Experts to discuss the risk assessment for non-target arthropods. In particular, the experts should discuss: - Any new studies submitted by the applicant. - The use of the high tier (field) study with DEV 2008-13 to further refine the risk. The relevance and reliability of the study	<u>Relevance of the available studies</u> All experts agreed that an overspray study would be required to address the off-field risk, given that the glass plate and aged-residue studies, due to their exposure regime, were not considered suitable to capture the mode of action of substances like paraffin oil, which has a (primarily) physical mode of action. The experts agreed that the standard risk assessment based on the SANCO terrestrial guidance (European Commission, 2002) should be kept in the RAR and reported in the EFSA conclusion. The experts also agreed that the uncertainties related to the special mode of action of paraffin oil should be highlighted and that, ideally, an overspray study should be available to address that route of exposure.



Subject	Conclusions Pesticides Peer Review Meeting
should be discussed by the experts. - The updated in-field and off-field risk assessment. The experts should consider the mode of action of paraffin oil (refer also to the experts' meeting report for Paraffin oil CAS 8042-47-5 (Teleconference 101 Ecotoxicology, April 2023)).	<u>Aged-residue study with <i>Typhlodromus pyri</i></u> One aged-residue study with Polithiol on apple leaves (3D) with one application at 75 L/ha was made available and discussed at the meeting. This study suggests that there is potential for recovery within one year from application. All experts agreed that the study can be used to demonstrate potential for recovery for the representative uses. <u><i>Pardosa</i> sp. study</u> The extended laboratory study with <i>Pardosa</i> sp. was also discussed. The experts agreed with the RMS's evaluation and the proposed endpoint. <u>Field study with paraffin oil with DEV 2008-13</u> The experts also concluded that the field study with DEV 2008-13 (paraffin oil CAS-72623-86-0) cannot be used for the risk assessment of this active substance (CAS 97862-82-3) because the composition of the two formulations for representative uses is different. Open point RMS to reflect the meeting discussion and to update the risk assessment in-field in a revised version of the RAR. Additionally, to include the off-field risk assessment in the revised RAR and in the List of Endpoints.
Experts' consultation 5.7 Experts to discuss the risk assessment for bees. In particular, the experts should discuss: - The relevance of standard contact studies considering the physical mode of action of paraffin oil CAS 97862-82-3; - Any new studies/evidence submitted by the applicant to address the chronic risk to bee adults and larvae or to refine the high acute risk from oral and contact exposure identified for the representative uses with paraffin oil CAS 97862-82-3. - The updated risk assessment for bees. The relevance of the scenarios (e.g., treated crop, flowering weeds in the field) should be assessed	<u>Newly submitted studies (chronic bee studies and acute bumble bee studies)</u> The acute studies with bumblebees were considered valid and reliable. Both endpoints resulted in right-censored values. In the chronic study with honey bees, minor deviations were noted, e.g. modification of the sucrose solution to improve homogeneity. However, these were not considered to have an impact on the study results and, thus, the study was considered valid and reliable. The larval study was also considered valid and reliable. All experts agreed with the RMS' evaluation done for the newly submitted studies and the derived endpoints. <u>Semi-field (tunnel) study with bees</u> Based on the lack of effects in the tunnel test, the experts agreed that low contact acute risk for the weed can be concluded based on the fact that the study represents a worst-case scenario (highly attractive crop). All experts agreed that the semi-field study is not suitable to address potential effects on bee brood since those were not assessed in the study. The majority of experts agreed that the tunnel study is not enough to refine the chronic risk to adult bees in absence of other evidence supporting the conclusion that high risk to adult bees is excluded. The experts agreed that low acute oral risk can be concluded for the weed scenario since the ETR are very close to the trigger.



Subject	Conclusions Pesticides Peer Review Meeting
considering the proposed application time of paraffin oil (CAS 97862-82-3).	Moreover, also according to the SANCO guidance the oral HQ is very close to the trigger and the LD₅₀ is an unbound value and therefore low risk can be concluded. <u>Risk assessment</u> Overall, based on the available evidence a high chronic risk to bees and bee larvae cannot be excluded. The available tunnel test was considered sufficient to refine the acute risk to bees. Open point RMS to revise the risk assessment in the RAR and LoEP in line with the discussions.
Experts' consultation 5.8 Experts to discuss the waiver of the ED assessment for non-target organisms submitted for paraffin oil (CAS 97862-82-3).	The waiver of the ED assessment submitted for paraffin oil (CAS 97862-82-3) was discussed and all the experts agreed on the following: -The waiver presented for mammalian toxicology also applies to wild mammals. -The waiver proposed for non-target organisms other than mammals was agreed based on the following: - Main constituents of paraffin oils are alkanes, i.e., mainly straight and branched hydrocarbon chains with no aromatics, - Paraffin oils are ubiquitously present in the environment, including in food items; and are known components of plant and arthropod cuticle wax; - No concern related to the ED properties of paraffin oils has been identified in the available systematic literature review; - No alert was reported in the available QSAR studies related to endocrine activity; - Paraffin oils have been used as adjuvant for veterinary vaccines/in pharmacological products. - The substance has a potential physical MoA. Open point RMS to align the information in the revised RAR with the discussion at the meeting.
New experts' consultation 5.9 following RMS request after clock stop: Experts to discuss: - the relevant endpoint for risk assessment from the earthworm study with Polithiol, together with the acceptability of EC10 and the historical data and new statistical evaluation provided by the applicant;	<u>Earthworm reproduction study with Polithiol</u> All experts agreed to set the NOEC to 125 mg/kg. The historical control data and the re-analysis of the study using the Dunnett's test was discussed. - The experts considered more appropriate to use the real control as baseline for comparison. - The suitability of the Dunnett's test was questioned, given that it assumes normal distribution (n. of juveniles is a count data and Poisson like distributions may be more appropriate). Open point RMS to reflect the meeting discussion on the endpoint selection for earthworms in a revised RAR.



Subject	Conclusions Pesticides Peer Review Meeting
- the endpoints from the new <i>Folsomia</i> and <i>Hypoaspis</i> studies as well as the relevant endpoint for <i>Folsomia</i> risk assessment; - the endpoints from the new nitrogen transformation study.	<u>Collembolan reproductive study</u> The experts agreed with the endpoint selection by the RMS (EC_{10} = 314 mg product/kg based on reproduction) and considered the use of studies with artificial substrate more appropriate in the context of the risk assessment. Open point The RMS to (i) reflect the outcome of the discussion on the study in a revised RAR, and (ii) remove from the List of Endpoints the risk assessment carried out with the endpoint derived from the study with natural soil. <u><i>Hypoaspis aculeifer</i> study with Polithiol</u> The RMS considered the EC_{10} unreliable (confidence interval around the EC_{10}.) and proposed a NOEC of 952.8 mg ppp/kg to be used in the risk assessment. All experts agreed with the endpoint selection by the RMS. Open point RMS to reflect the discussion on the study in a revised RAR. <u>Soil nitrogen transformation study with Polithiol</u> No concern was raised at the meeting on the study assessment. The experts recommended that soil transformation rates are also reported at each time interval to confirm the risk assessment outcome. Open point RMS to recalculate the nitrogen transformation rates for each time interval and to report them in a revised RAR.
New experts' consultation 5.10 following RMS request after clock stop: Experts to discuss the endpoints from the new seedling emergence and vegetative vigour study.	<u>Vegetative vigour test</u> The experts agreed with the RMS' evaluation of the study (i.e. valid study) and with the proposed endpoint. <u>Seedling test</u> The experts agreed with the RMS' evaluation of the study (i.e. valid study) and with the proposed endpoint. <u>Risk assessment</u> Low risk was indicated only when considering risk mitigation measures (different combinations). Open point RMS to reflect the outcome of the studies' evaluation by the experts in a revised RAR.
Expert consultation point from the Confidential Evaluation Tables	
Experts' consultation (ecotoxicology) 2.1	For paraffin oil CAS 97862-82-3, an assessment of the individual co-formulants in the formulation for the representative uses



Subject	Conclusions Pesticides Peer Review Meeting
MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Polithiol was presented. However, the comparison of the data between the co-formulants and the paraffin oil was not conducted. Open point RMS to complement the exercise for the assessment of the ecotoxicological profile of each individual components other than the active substance for Polithiol.

REPORT OF PESTICIDES PEER REVIEW TC 155

PELARGONIC ACID – ART 31 (AD HOC MANDATE)

Rapporteur Member State: EL

5. Ecotoxicology

Date: 9 December 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Expert nominated by MS DE	Federal Environment Agency (UBA) - DE
National Expert nominated by MS DK	Danish EPA - DK
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS NL	Ctgb - NL

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¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.10: Experts to discuss the in-field risk assessment for non-target arthropods (NTAs) for the home and garden uses. In particular, the different use scenarios within the representative uses of the plant protection product 'MON 74134' should be evaluated individually. If needed, the following scenarios should be assessed in particular: i) 4-8 applications, ready-to-use product, no pack size limitation; ii) Single application, ready-to-use product with a pack size limited to a treatment area <50 m²; iii) 4-8 applications, ready-to-use product with a pack size limited to a treatment area <50 m²; iv) 4-8 applications, overall spray with hand-held pump, no pack size limitation.	To address the in-field risk to non-target arthropods (NTAs) for the uses with 'MON 74134', the experts (i) considered the approach of the Netherlands as described in Chapter 7 of the Evaluation Manual for the authorisation of plant protection products according to Regulation (EC) No 1107/2009, and (ii) conducted a weight of evidence approach for the four scenarios indicated in the mandate: i) 4-8 applications, ready-to-use (RTU) product, spot treatment, with no limitation on pack size; ii) Single application, RTU product, spot treatment, with a pack size limited to a treatment area less than 50 m²; iii) 4-8 applications, RTU product, spot treatment with a pack size limited to a treatment area less than 50 m²; iv) 4-8 applications, RTU product, overall spray with hand-held pump, with no limitation on pack size. Regarding the approach of the Netherlands, the experts concluded that a limited treated area cannot be considered to show a low risk with the quantitative risk assessment. The outcome of the weight of evidence approach for scenarios i to iii is summarised: Scenario i The RMS concluded that a "low risk" could not be demonstrated for this scenario, as it does not involve a limited exposure scenario. All experts agreed with the RMS' assessment. Scenario ii Given the short persistence of the active substance and the limitation to a single application, all experts agreed with the RMS' qualitative risk assessment, concluding that the risk is low.



Subject	Conclusions Pesticides Peer Review Meeting
The experts should consider, as an illustrative risk assessment, the approach of the Netherlands for non-professional uses as described in Chapter 7 of the Evaluation Manual for the Authorisation of Plant protection products according to Regulation (EC) No 1107/2009¹. Furthermore, experts to consider the fast degradation of pelargonic acid (mean DT₅₀ in soils 1.22 days; DT₅₀ in air 1.1 days) and the potential for in-field recolonisation/recovery of non-target arthropods in ecologically relevant timescale(s) to be accounted for in the qualitative argumentation, in particular as regards the duration of any potentially unacceptable effect. ¹Available at: https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2022/10/01/7.-ecotox-non-professional-uses-nl-part-em1.0	Scenario iii There was discussion about whether the same conclusion as Scenario ii could be applied to multiple applications. Some experts expressed concern that multiple applications might target the same spots, potentially extending the period during which NTAs are affected and reducing the opportunity for recovery of the NTA population. However, it was suggested that the short persistence and specific characteristics of the active substance may mitigate this risk, even with repeated applications. The experts also debated whether the localized, spot-treatment nature of the applications should be considered. It was noted that this scenario involves spot application to a limited treatment area, and that treating 50 m² using a RTU hand-held trigger sprayer would be logistically challenging for users. Recovery was deemed more likely with small-scale spot treatments. However, some experts pointed out that source-sink dynamics could influence population recovery. Ultimately, the majority of experts agreed with the RMS' proposal, concluding that this scenario can also be considered of low risk to in-field NTAs. Scenario iv (Full exposure scenario) The RMS stated that the previous assessment remains applicable. This earlier evaluation did not conclude a low risk to in-field NTAs for the representative home and garden uses of 'MON 74134'. No additional WoE was possible with the information available. Consequently, a low risk was not demonstrated. All experts agreed with the RMS' assessment. Open points • RMS to update the RAR considering the discussions of the experts' meeting for the four scenarios. • EFSA to update their conclusion considering the discussions of the experts' meeting for the four scenarios.

REPORT OF PESTICIDES PEER REVIEW

TC 152 AND TC 155

METYL TETRAPROLE – NAS 1107

Rapporteur Member State: FR

5. Ecotoxicology

Date: 9 December 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS BE	Federal Public Service Health, Food Chain Safety and Environment, DG Animals, Plants and Food, Service Plant Protection Products and Fertilisers - BE
National Expert nominated by MS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Experts nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Experts nominated by MS DK	Danish Environmental Protection Agency - DK
National Expert nominated by MS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS IT	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS NL	Ctgb - NL
National Expert nominated by MS SE	Swedish Chemicals Agency (Kemikalieinspektionen) - SE
External Expert	Emily Mcvey
Observer	Austrian Agency for Health and Food Safety (AGES) - AT



Status	Name of institution/attendee
Observer	Federal Food Safety and Veterinary Office - CH
Observer	BAFU - CH
Observer	National Institute of Public Health - CZ
Observer	Ctgb - NL
Observer	Swedish Chemicals Agency (Kemikalieinspektionen) - SE

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¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Expert consultation 5.1 Experts to discuss and agree on the appropriate ecotoxicologically relevant endpoint for the assessment of wild mammals.	Based on the considerations by the RMS and experts, it was agreed that the most appropriate endpoint for long-term risk assessment for wild mammals was 100 mg a.s./kg bw per day. Open point: RMS to reflect in the updated DAR the outcome of the meeting discussion and the additional considerations noted by the experts (e.g. palatability and food consumption).
Expert consultation 5.2 Experts to discuss whether it is reasonable to express endpoints from aquatic toxicity studies as time-weighted average concentrations even when it is not specifically recommended in the corresponding test guideline. The applicant is correct to indicate that some test guidelines (including OECD 23, 2019), where renewal of the test media, is done it is recommended to use time-weighted average concentrations. However, it would be useful to reach agreement whether this approach can be used for	Overall, all experts agreed with the proposal from the RMS to maintain the TWA concentrations approach for expressing the endpoints in all aquatic toxicity studies. No open point is identified for this aspect.



Subject	Conclusions Pesticide Peer Review Meeting
all types of aquatic toxicity studies. Please note that, if agreed, then such agreement will also be applicable to other substances should the applicant propose to express endpoints in terms of time-weighted average concentrations.	
Expert consultation 5.3 Experts to discuss the information provided by the applicant and the need for a risk assessment for mysid shrimps.	Overall, all experts agreed with the RMS on the need for an acute toxicity study with mysids. The rationale for this was based on the toxicity of the substance to non-target arthropods and knowledge that other substances with a similar MoA where the mysid shrimp was more sensitive than other aquatic invertebrates. Open point: RMS to reflect the outcome of the discussion in the DAR and indicate the need for toxicity data with Mysid shrimp.
Expert consultation 5.4 Experts to discuss the refined acute risk assessment for fish. In particular, the SSD should be discussed including whether LC₁₀ values should be used and what AF should be applied. The inclusion of unbounded values in the SSD should also be discussed.	Several comments were received regarding the refined acute risk assessment for fish using the SSD. Therefore, the experts discussed the RMS's assessment. Overall, the experts agreed with the RMS's assessment and using the LC₁₀ endpoints and one unbounded value for the plotting of the SSD. However, it was agreed also to use the highest of the available unbounded values. Open point: RMS to update the DAR and SSD using the highest unbounded value to build the SSD for fish. RMS to present a reliability assessment for the LC₁₀ endpoints used in SSD. Pending the outcome of the updated SSD, the risk assessment may need to be updated.
Expert consultation 5.5 Experts to discuss the reliability of the endpoints from study 'CA 8.2.6.1/01 K.A, TSW-0017' (2016), TSW-0017'. Specifically, consideration should be given to the low concentrations at the start of the test and how the endpoints have been expressed.	During the commenting on the DAR the reliability of the endpoints from study 'CA 8.2.6.1/01 K.A, TSW-0017' was questioned. Therefore, the experts discussed the RMS' evaluation of the study. The RMS concluded that the study was reliable and that an error was made in the previous evaluation. The experts agreed on the conclusion proposed by the RMS. No open point is required.



Subject	Conclusions Pesticide Peer Review Meeting
Expert consultation 5.6 Experts to discuss the available data for metabolite 4-chlorophenol and whether a reliable endpoint is available for risk assessment.	The risk assessment for metabolite 4-chlorophenol proposed by the Applicant was not considered sufficient as the toxicity data used were not included in the dossier and evaluated by the RMS. Open point: For the RMS to reflect the outcome of the discussion in DAR and to indicate that, pending the outcome of the identified data gap for the aquatic exposure assessment for metabolite 4-chlorophenol, an aquatic risk assessment is needed.
Expert consultation 5.7 Experts to discuss the results from the available AMA study to evaluate the ED potential (T-modality) of metytltetraprole on NTOs. In particular, experts will discuss: • The effects observed on nHLL at day 7 and day 21. • The absence of thyroid histopathology at the negative control and the first two concentrations levels. • The results from the other available AMA conducted with the major metabolite ISS7.	For wild mammals, the same conclusion reached for humans applies (ED criteria not met) for the T-modality. All experts agreed. The available Amphibian Metamorphosis Assay with the a.s. was further discussed among the experts. All experts agreed that, although some limitations/uncertainties were identified, no pattern of endocrine effect was observed. The AMA performed with the metabolite was presented for completeness. The RMS clarified that data with the metabolite were asked before the implementation of the criteria, which do not apply to degradation products. All experts agreed that no pattern of endocrine effect was observed. Open point: RMS to reflect the outcome of the discussion in the revised DAR.
Expert consultation 5.8 Experts to discuss the results from the available FSTRA study to evaluate the ED potential of metytltetraprole (EAS-modalities). In particular, experts will discuss: • The appropriateness of the selected testing concentrations.	For wild mammals, the same conclusion reached for humans applies (ED criteria not met) for the EAS-modalities. All experts agreed. The available Fish Short Term Reproductive Assay (FSTRA, OECD TG 229) was further discussed among the experts. In view of the results from the range-finding test, and of the pattern of the mortality data in the control and treatments, the majority of the experts agreed that the highest treatment should not be excluded from the ED assessment. The pattern of effect observed on fecundity (decrease), SSC (increase in males) and GSI (increase in males with no effects on body weight) may suggest an Androgenic MoA (agonist). Gonad histopathology was not available. The submission of gonad histopathological data after the clock stop was acknowledged. These data are formally not eligible, nevertheless, since after a preliminary assessment they seem to



Subject	Conclusions Pesticide Peer Review Meeting
• The use of the results at highest testing concentration in the context of the ED assessment, considering the observed mortality. • The reliability of the VTG measurements, considering the protocol deviation for the VTG analysis. • The effects observed on SSC and GSI in males, and on fecundity and fertility in females. • The uncertainties introduced by the absence of gonad histopathology.	strengthen the already identified concern, the experts agreed that they need to be carefully assessed and considered in a follow-up peer review meeting. Open point: RMS to assess the newly submitted data.
Expert consultation 1.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts agreed with the assessment of the RMS regarding the characterisation of the product for representative uses except for the fact that chronic toxicity data were also lacking. The experts agreed with the conclusion of the RMS that the data retrieval done by the applicant for the co-formulants was insufficient. Therefore, the following data gaps were identified: Data gap: Formulation toxicity data for soil macro and soil micro-organisms. Data gap: A proper assessment of the co-formulants focussing on where the product was not fully characterised (terrestrial vertebrates, aquatic organisms (chronic) and soil organisms). Open point: RMS to reflect the outcome of the discussion in the DAR (Vol. 4) and B.9 including the data gaps identified.

REPORT OF PESTICIDES PEER REVIEW

TC 152 AND TC 155

DIFLUFENICAN – AIR III after ED clock stop

Rapporteur Member State: CZ

5. Ecotoxicology

Date: 9 December 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Experts nominated by RMS CZ	National Institute of Public Health - CZ
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS BE	Federal Public Service Health, Food Chain Safety and Environment, DG Animals, Plants and Food, Service Plant Protection Products and Fertilisers - BE
National Experts nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Experts nominated by MS DK	Danish EPA - DK
National Experts nominated by MS EL	Benaki Phytopathological Institute - EL
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS IE	Pesticide Registration Division, Dept. of Agriculture, Food & the Marine Laboratories - IE
National Experts nominated by MS IT	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS NL	Ctgb - NL
National Expert nominated by MS SE	Swedish Chemicals Agency (Kemikalieinspektionen) - SE



Status	Name of institution/attendee
External Expert	Emily Mcvey
Observer	BAFU
Observer	Austrian Agency for Health and Food Safety (AGES) - AT
Observer	Federal Food Safety and Veterinary Office - CH
Observer	Swedish Chemicals Agency (Kemikalieinspektionen) - SE

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.7 If the substance is identified as having ED properties for humans, a discussion on whether the adversity identified could be relevant at population level is necessary.	For mammals as non-target organisms, the same conclusion as the one reached for human health applies for the EATS-modalities. See for further information report of the mammalian toxicology PREV TC 152. Open point: RMS to revise the conclusion for wild mammals in line with the agreement reached for human health.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.8 Experts to discuss and agreed the ecotoxicological relevant endpoint for wild mammals in light of the newly submitted extended One-Generation Reproductive Toxicity Study (OECD TG 443). This experts' consultation will need to consider the outcome of the discussion in the mammalian toxicology section as set in point 27.	Following the submission of a new extended one generation study with rats, the experts discussed whether this study may challenge the previously selected endpoint for the risk assessment of wild mammals (NOAEL=35.5 mg/kg bw/d based on reduction in body weight of the parental generation and decreased food consumption) The experts agreed that the offspring NOAEL=30 mg/kg bw/d is the relevant ecotoxicological endpoint from the newly submitted extended one generation study in rat. The endpoint is based on a reduction of offspring body weight (>10%) in offspring of the F1A and F1B generation. Open point RMS to update the risk assessment and agreed endpoint in the RAR and LoEP using the newly agreed endpoint of 30 mg a.s./kg bw per day. The RMS should also update the RAR with the justification for the endpoint as discussed at the experts' meeting.
Experts' consultation 5.9 Experts to agree in the endpoints to be derived from the newly submitted reproductive toxicity studies with birds. If a change of the endpoint to be used in the long-term risk assessment is triggered, the risk assessment would need to be revised.	Two new studies with mallard duck were submitted in the context of the ED assessment. Therefore, the previously agreed sub-chronic endpoint with bird was reconsider in light of the new studies. The experts agreed that the available endpoint with bobwhite quail was still the lowest endpoint to be used in risk assessment. The 2 studies with mallard duck were combined, considering that the same species and study design was followed and a combined NOAEL=181 mg/kg bw/d was overall derived. The experts noted that in one of the 2 studies, the number of eggs laid per hen in the control was much higher than the normal range as reported in the relevant OECD guideline. Therefore, when also considering the result of the other available study with the same species, the experts did not consider the reduction in egg production per hen, observed at all tested doses in that study, as treatment related. Open point RMS to provide the combined endpoint for the two studies with the mallard duck studies in the LoEP.
Experts' consultation 5.10 Experts to discuss the results of the available XETA. Experts must be aware that the study is not GLP for the biological part.	The available Xenopus Eleutheroembryonic Thyroid Assay (XETA) in line with OECD TG 248 was considered appropriate to draw a conclusion on the ED properties of diflufenican for the T-modality of non-mammalian species. EFSA will include in the EFSA conclusion that a part of this test was conducted in a non-GLP test facility as it was done in previous cases. Open points: - RMS to reflect the outcome of the discussion in the revised RAR.



Subject	Conclusions Pesticide Peer Review Meeting
	- RMS to include an assessment on the selection of the tested concentration in the revised RAR.
Experts' consultation 5.11 Experts to discuss the available information for the EAS-modality for non-mammalian sp. The results of the FSTRA on reproductive parameters will need to be contextualized taking into account the potential disruption on the oestradiol synthesis as indicated in the mammalian toxicology package if finally positive. Additional lines of evidence (e.g., reproduction effects) in other species could also be used in the WoE approach (see point 65).	The available Fish Short-Term Reproduction Assay (FSTRA) in line with OECD TG 229 was considered appropriate in the overall weight-of-evidence considered to draw a conclusion on the ED properties of diflufenican for the EAS-modalities for non-mammalian species. Open points - RMS to reflect the outcome of the discussion in a revised RAR. - RMS to update the uncertainty table by including the issues identified for the VTG assessment.
Experts' consultation ECOTOX proposed by EFSA (UPL) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts considered the data on ecotoxicological tests available with formulation HCO01. No increase in toxicity was reported compared to the active substance diflufenican. The formulation comprises several co-formulants, the majority of which were present at less than 1%. The experts suggested those co-formulants at <1%, considering the relative toxicity to the toxicity of the a.s., individually are not likely to have an impact on the toxicity of the formulated product. Consequently, the discussion focussed on the co-formulants present above 1% and no concerns were raised based on the available information. Overall, the experts agreed that a low impact of co-formulants on the safety of formulation HCO01 is expected. Nonetheless, a consideration of the outcome of the toxicology assessment would be needed regarding the chronic toxicity to mammals. Open point RMS to reflect the outcome of the meeting discussion for ecotoxicology (including the consideration of the implications of the toxicology assessment) in the Volume 4.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation ECOTOX proposed by EFSA (Sapec) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts considered the data on ecotoxicological tests available with formulation Diflufenican 500 SC. No increase in toxicity was reported compared to the active substance diflufenican, with the exception of earthworms, in which case the toxicity of the formulation is considerably enhanced compared to the active ingredient. Nonetheless, the risk assessment for earthworms has been carried out using the endpoint based on the formulation and a low risk was demonstrated with the sufficient margin of safety. The formulation comprises several co-formulants, the majority of which were present at less than 1%. The experts suggested those co-formulants at <1%, considering the relative toxicity to the toxicity of the a.s., individually are not likely to have an impact on the toxicity of the formulated product. Consequently, the discussion focussed on the co-formulants present above 1% and no concerns were raised based on the available information. Overall, the experts agreed that a low impact of co-formulants on the safety of formulation Diflufenican 500 SC is expected. Nonetheless, a consideration of the outcome of the toxicology assessment would be needed regarding the chronic toxicity to mammals. Open point RMS to reflect the outcome of the meeting discussion for ecotoxicology (including the consideration of the implications of the toxicology assessment) in the Volume 4.
Experts' consultation ECOTOX proposed by EFSA (Rotam) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts considered the data on ecotoxicological tests available with formulation FH-020. No increase in toxicity was reported compared to the active substance diflufenican, with the exception of <i>Folsomia</i> and <i>Hypoaspis</i>, in which case the toxicity of the formulation is considerably enhanced compared to the active ingredient. Nonetheless, the risk assessment for those soil macro-organisms has been carried out using the endpoint based on the formulation and a low risk was demonstrated with the sufficient margin of safety. The formulation comprises several co-formulants, the majority of which were present at less than 1%. The experts suggested those co-formulants at <1%, considering the relative toxicity to the toxicity of the a.s., individually are not likely to have an impact on the toxicity of the formulated product. Consequently, the discussion focussed on the co-formulants present above 1% and no concerns were raised based on the available information. Overall, the experts agreed that a low impact of co-formulants on the safety of formulation FH-020 is expected. Nonetheless, a consideration of the outcome of the toxicology assessment would be needed regarding the chronic toxicity to mammals. Open point



Subject	Conclusions Pesticide Peer Review Meeting
	RMS to reflect the outcome of the meeting discussion for ecotoxicology (including the consideration of the implications of the toxicology assessment) in the Volume 4.
Experts' consultation ECOTOX proposed by EFSA (FMC) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	See following point (the two applicants belong to the same task force with a single formulation for the representative uses).
Experts' consultation ECOTOX proposed by EFSA (Bayer) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts considered the data on ecotoxicological tests available with formulation AG-D1-500SC. No increase in toxicity was reported compared to the active substance diflufenican. The formulation comprises several co-formulants, the majority of which were present at less than 1%. The experts suggested those co-formulants at <1%, considering the relative toxicity to the toxicity of the a.s., individually are not likely to have an impact on the toxicity of the formulated product. Consequently, the discussion focussed on the co-formulants present above 1% and no concerns were raised based on the available information. Overall, the experts agreed that a low impact of co-formulants on the safety of formulation AG-D1-500SC is expected. Nonetheless, a consideration of the outcome of the toxicology assessment would be needed regarding the chronic toxicity to mammals. Open point RMS to reflect the outcome of the meeting discussion for ecotoxicology (including the consideration of the implications of the toxicology assessment) in the Volume 4.

REPORT OF PESTICIDES PEER REVIEW TC 152

ETOXAZOLE – CONFIRMATORY INFORMATION

Rapporteur Member State: EL

5. Ecotoxicology

Date: 19 November 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS EL	Benaki Phytopathological Institute - EL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS CZ	Central Institute for Supervising and Testing in Agriculture - CZ
National Expert nominated by MS CZ	National Institute of Public Health - CZ
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS DE	German Federal Institute for Risk Assessment (BfR) - DE
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS IT	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Expert nominated by MS NL	Ctgb - NL
Observer	Austrian Agency for Health and Food Safety (AGES) - AT

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the endocrine disruption (ED) assessment of etoxazole for non-target organisms (NTOs) for the T-modality in view of the uncertainties / limitations and effects observed in the available Amphibian Metamorphosis Assay (AMA). In particular: • Deviation from the OECD 231 TG validity criteria (spread > 4 stages in both negative (5) and solvent control (6)); • Statistical analysis for the developmental stage were not performed using the recommended method (multi quantal step down Jonckheere Terpstra 20th–80th percentile); • Consideration for tadpoles NF>60 (if >20% different	The uncertainties/limitations identified in the available Amphibian Metamorphosis Assay (AMA) were discussed among the experts. The spread of the developmental stage in both negative and solvent control groups exceeding the limit set in the performance criteria of OECD TG 231 was considered as negatively impacting the overall reliability of the study. Therefore, also in view of the positive <i>in vitro</i> evidence for NIS-inhibition, the majority of experts agreed to consider the study as not sufficiently reliable to address the ED assessment of etoxazole for non-target organisms (T-modality). Open point: RMS to include in the revised confirmatory data addendum an uncertainty analysis and report the outcome of the discussion, and to delete the results of the AMA from the ED assessment (line of evidence).



Subject	Conclusions Pesticide Peer Review Meeting
statistical analysis should be performed) is not reported; Methodology for selection of tadpoles for thyroid histopathology is unclear.	
Experts' consultation 5.2 Experts to discuss the ED assessment of etoxazole for non-target organisms (NTOs) for the EAS-modalities in view of the drawbacks identified in the available Fish Short-Term Reproduction Assay (FSTRA). In particular: The appropriateness of the testing concentrations can be questioned, since i) no range-finding test was carried out to accurately set the appropriate testing concentrations, ii) the solubility limit was set at 0.3 mg/L considering a non-GLP solubility / stability trial conducted using different testing conditions compared to the ones applied in the definitive study (9 vs. 12 times vessel volume turnover/day), iii) different solvents could have been tested to increase the solubility of the test item and allow testing at higher concentrations, iv) no effects on any of the investigated parameters were observed up to highest tested concentration (0.22 mg/L twa);	The drawbacks identified in the available Fish Short-Term Reproductive Assay (FSTRA) were discussed among the experts. The majority of the experts identified limitations in the study, i.e. selection of testing concentrations according to practical solubility, absence of gonad histopathology assessment, vitellogenin (VTG) measurements reliable with restrictions. However, considering the absence of <i>in vitro</i> evidence in ToxCast data and the outcome of the ED assessment in humans, all experts agreed that the study was sufficiently reliable to be used in the ED assessment of etoxazole for NTOs (EAS-modalities). Open point: RMS to reflect the outcome of the discussion in the revised confirmatory data addendum.



Subject	Conclusions Pesticide Peer Review Meeting
• Gonad histopathology assessment was not available while it should be carried out to maximize the available information (it is acknowledged that it is defined as optional according to OECD TG 229); • Vitellogenin (VTG) analytical method is poorly reported and does not allow to check if the recommendations from the OECD TG 229/230 for VTG analysis were met (e.g. no calibration curve, correlation coefficient R² available and confirmed as ≥ 0.99, LOQ/LOD not specified, quantification range established as 2-100 ng/mL according to kit manual and calibration curve, however no information on the number/%recovery of concentrations tested for either standard/spiked samples, no information on the % non-specific binding).	

REPORT OF PESTICIDES PEER REVIEW

TC 147 and TC 150

FLUAZAINDOLIZINE – NAS 1107

Rapporteur Member State: MT

5. Ecotoxicology

Date: 07 October 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS MT	Malta Competition and Consumer Affairs Authority (MCCAA) - MT
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DE	German Federal Institute for Risk Assessment - DE
National Experts nominated by MS DE	Julius Kühn Institute – DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS NL	Ctgb - NL
Observers	Malta Competition and Consumer Affairs Authority (MCCAA) - MT
Observer	Ctgb - NL



Observer	Swiss Agricultural Research
Observer	Swiss Federal Office for the Environment

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¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

²

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss and agree on the selection of the most relevant ecotoxicological endpoint for mammals. Experts to also consider implication and agree on the risk assessment.	The experts at the meeting agreed to set the ecotoxicological relevant NOAEL based on the rabbit developmental toxicity study at 30 mg/kg/day Open point: RMS to reflect to outcome of the meeting discussion and to update the risk assessment with the agreed endpoint.
Experts' consultation 5.2 Experts to discuss the pH in aquatic studies and its potential impact on the outcome of the aquatic toxicity studies.	The available data on algae, gives some indications that toxicity might vary with pH but there are uncertainties (different species, not the most sensitive group of species, the pH range is not wide enough). In addition, the risk is driven by invertebrate (i.e. chronic daphnia study). The daphnia study could be considered carried out at the higher range of environmentally relevant pH. Since the active substance is a weak acid, the dissociation at lower environmentally relevant pH (i.e. 7) is not expected to be high and the non-dissociated fraction (the most toxic form) is expected to be low. However, the logD approach, presented during the meeting, suggests that the endpoint could be significantly lower. Even though this approach is not routinely used in aquatic risk assessment, this adds uncertainty to the current risk assessment outcome. Overall, it was concluded that this uncertainty related to the pH range used in the aquatic studies should be highlighted, and that these uncertainties could be addressed by further studies on lower pH range (i.e chronic studies with D. magna.)



Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to update the DAR reflecting the discussion.
Expert's consultation 5.3 Experts to discuss the chronic toxicity endpoint for sheepshead minnow (i.e. NOEC of 0.75 mg/L vs 1.5 mg/L).	The RMS presented the outcome of the available ELS. Based on the uncertainty related to the statistical test used and the non-normality of the data, and the biological relevance of the effect observed at 1.5 all experts agreed to set the NOEC at 0.75 mg/L. This does not impact the risk assessment since it has already been performed with a NOEC of 0.75 mg/L Open point: RMS to reflect the discussion in the DAR Open point: RMS to update the DAR and the risk assessment using the most recent available PECs from the efate section, which will be recalculated.
Experts' consultation 5.4 Experts to discuss the aquatic risk assessment for the IN-REG72 metabolite and the approach used, more specifically, if the metabolite can be considered of comparable toxicity of the parents or 10 times more toxic.	The comparison between the toxicity of the parent and the toxicity of the metabolite suggests that the metabolite might not be more toxic than the parent to aquatic organisms, in general, and the analysis of the efficacy trail suggests that the metabolite has lost its efficacy against the target organisms. This however cannot guarantee that the toxicity is lost against non-target organisms, such as fish and sediment-dwellers. Therefore, the presented weight of evidence was not considered as convincing. Therefore, the majority of the experts agreed that the risk assessment should be carried out considering the metabolite as 10-times more toxic than the parent. Open point: RMS to update the DAR based on the discussion. RMS to present in the LoEP only the approach considering the metabolite as 10-times more toxic than the parent.
Expert's consultation 5.5 Experts to discuss the studies by [REDACTED] 2017 (KCA 8.3.1.3/02), by [REDACTED] 2017b (KCA 8.3.1.3/03) and [REDACTED] 2017a (KCA 8.3.1.3/04) and agree in the endpoints to be derived from these studies.	Study KCA 8.3.1.3/02: Due to considerable differences from the negative control, biologically relevant effects were not excluded at lower doses compared to the originally proposed NOED. Therefore, the NOED was lowered to 3.42 ug a.s./larvae/developmental period. RMS to update the DAR and the risk assessment accordingly. KCA 8.3.1.3/03: Due to unclear dose- response, some uncertainties were identified in relation to the proposed NOED which was, therefore, considered as reliable with restrictions. RMS to update the DAR indicating the uncertainties. KCA 8.3.1.3/04: Due to flat dose response, some uncertainties were identified in relation to the proposed NOED. RMS to update the DAR indicating the uncertainties.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.6 Experts do discuss the available risk assessments for bees and conclude the risks for the two representative uses. As part of this discussion, experts to agree on the endpoint for the a.s. for larva to be used for the RA.	Considering that high exposure is not expected from the proposed application methods, that indeed no residues of fluazaindolizine and relevant metabolites were identified in the available residue studies for pollen and nectar, and that no apparent adverse effects on honey bee colonies were seen in the higher tier studies, low risk to bees (for both the parent and the metabolites) was concluded using a WoE approach.
Experts' consultation 5.7 Experts to agree on the selection of the most appropriate endpoint for <i>E. fetida</i>, and on the outcome of the risk assessment.	The experts at the meeting agreed to use the endpoint from the a.s. KCA 8.4.1/02 study for risk assessment purposes. Open point: • RMS to reflect the outcome of the discussion in the revised RAR. • RMS to update the risk assessment considering the new calculated PECs in soil.
Experts' consultation 5.8 Experts to agree on the selection of the most appropriate endpoint for the metabolites IN-REG72, and on the outcome of the risk assessment for <i>E. fetida</i>. Accounting for the assessment provided by the applicant and discussion in the residues and fate sections, for the metabolite TFA experts to agree on the selection of the most appropriate endpoint for all relevant non-target organisms, and to agree on the risk assessment.	The experts at the meeting agreed to use the endpoint from the study KCA 8.4.1/05 study for risk assessment purposes of metabolite ON-REG72. For the metabolite TFA, at the meeting it was acknowledged that TFA could be a metabolite potentially occurring in environmental compartments (see report of the peer-review meeting TC 149) but no confirmation is currently available from the environmental fate section. Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.9 Experts to discuss the ED assessment for non-target organisms. The discussion shall take into account the following aspects:	Although uncertainties were noted, no evidence of EATS-mediated endocrine activity or adversity could be observed in the available Fish Short-term Reproduction Assay (FSTRA) and Amphibian Metamorphosis Assay (AMA). For wild mammals as non-target organisms, the same conclusion as the one reached for the humans is applicable. All the experts agreed so.



Subject	Conclusions Pesticide Peer Review Meeting
- The outcome of the ED assessment for humans and its applicability for wild mammals as non-target organisms (see 5(83) and 2(77)); - The available information to draw a conclusion for the T-modality for non-target organisms. An AMA is available. Particular attention shall be given to i) the validity of the test, ii) the appropriateness of the tested concentrations based on the results of the range finding test (see data requirement also in 5(84)) and iii) the biological findings (5(85-86). - The available information to draw a conclusion for the EAS-modalities for non-target organisms. An FSTRA is available. Particular attention shall be given to i) the reproductive performance in the test, ii) suitability of the tested concentrations, iii) the biological findings in the assay.	Open points - RMS to highlight the uncertainties identified in the two available studies for the ED assessment of non-mammalian species: • AMA: the uncertainties on the selection of testing concentrations (MTC), the control animals being smaller compared to the ones in the treatments. • FSTRA: issues in the raw data (study report) in the reporting of fertility/fecundity data (% non-viable eggs), missing information related to the VTG analysis. - RMS to update the ED assessment and the study evaluation by including the identified uncertainties where pertinent (e.g., Vol 1 if needed and in the pertinent study summaries and/or in the RMS commenting box in the Vol 3 CA). - RMS to remove the NOEC resulted from those studies (as from screening assays, this is not necessary).
Experts' consultation 0.3 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with	At the meeting, the majority of the experts agreed that that none of the single components of the formulated product is expected to increase the toxicity of the formulated product. Open points: • RMS to reflect the outcome of the discussion in the revised RAR (vol 4).



Subject	Conclusions Pesticide Peer Review Meeting
respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	• RMS to check the predefined list of databases from which data could be retrieved for this exercise (see follow the indications of the Technical Report on the Data collection on co-formulants https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2022.EN-7547). • RMS to check the list of banned co-formulants from Commission Regulation 2023/574.

REPORT OF PESTICIDES PEER REVIEW

TC 147 and TC 150

FLUROCHLORIDONE – AIR IV

Rapporteur Member State: AT

5. Ecotoxicology

Date: 4 October 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Experts nominated by MS DE	German Federal Institute for Risk Assessment - DE
National Expert nominated by MS DK	Danish Environmental Protection Agency - DK
National Experts nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS MT	Malta Competition and Consumer Affairs Authority (MCCAA) - MT
National Experts nominated by MS NL	Ctgb - NL
Observer	Agroscope - CH
Observer	Federal Office for the Environment, FOEN – CH
Observers	Ctgb - NL
Observer	Finnish Safety and Chemicals Agency (Tukes) - FI
Observers	Malta Competition and Consumer Affairs Authority (MCCAA) - MT



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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the appropriate endpoint for the long-term assessment for mammals.	The experts considered all the available endpoint for mammals. Effects on male reproductive organs and sperm quality were consistently observed across the different available studies. Those effects were considered ecotoxicologically relevant. The experts agreed to set the ecotoxicologically relevant endpoint (NOAEL) at 5 mg/kg bw/day. This was selected considering that a dose spacing of 10 was used in the available multi-generation test and the information from all available studies where the effects on male reproduction were observed. Open point: The RMS should reflect the outcome of the discussion in the RAR and update the long-term risk for wild mammals for all uses with the agreed endpoint of 5 mg a.s. kg bw/day.
Experts' consultation 5.2 Experts to discuss the refined assessment for mammals.	The applicant did not submit any data to refine the long-term risk assessment for mammals for bare soil applications. No open point was set for the RMS.
Experts' consultation 5.3 Experts to discuss and agree on the	The validity and reliability of the ELS study was discussed among the experts. The deviations from the validity criteria of temperature and post-hatching success in the negative control were considered minor. Therefore, based on the available

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Subject	Conclusions Pesticide Peer Review Meeting
reliability/validity and the endpoints from the fish ELS study [REDACTED], 2018a; Document No. 90020526. Any new information provided by the applicant should be considered.	information, all experts agreed that the fish study is valid, sufficiently reliable (reliable with minor restrictions) and suitable for use in risk assessment. A NOEC of 16 µg /L was identified (based on significant effects on mean length), as agreed upon by the RMS and the experts. Open points: - The RMS should update the RAR to reflect the outcome of the discussion. - The RMS to please update the aquatic risk assessment in the RAR with the updated PEC values, following the discussions in the fate section (TC 149).
Expert consultation 5.4 Provided the applicant submits additional higher tier data and assessment, then the experts should discuss its reliability.	No additional higher tier data and assessment were made available.
Expert consultation 5.5 Experts to discuss the higher tier assessment to algae.	The experts discussed the two pulse exposure studies conducted with flurochloridone trans-isomer on <i>Desmodesmus subsipcatus</i>, presented to refine the risk assessment for algae (Tier 2C). Several uncertainties/limitations were identified, such as e.g. questionable selection of testing species, inappropriate selection of testing concentrations not allowing the identification of a No Observed Adverse Exposure Pattern (NOAEP), confounding effects likely induced by algal nutrient limitations (specific for KCA 8.2.8_12), among others. All experts agreed that, due to the identified uncertainties and limitations, the data from the two pulsed exposure studies on algae should not be used in a higher-tier risk assessment. Open points: - The RMS should update the RAR to reflect the outcome of the discussion and clarify that the refined risk assessment cannot be used due to the limitations identified in both studies. - The RMS to please update the aquatic risk assessment in the RAR with the updated PEC values, following the discussions in the fate section (TC 149).
Expert consultation 5.6 Experts to discuss the higher tier risk assessment to aquatic plant.	The experts discussed the two pulse exposure studies conducted with flurochloridone trans-isomer on <i>Lemna minor</i> and <i>Myriophyllum spicatum</i>, presented to refine the risk assessment for aquatic macrophytes (Tier 2C). Several uncertainties/limitations were identified, such as e.g. the delayed/absence of intermediate biological measurements during



Subject	Conclusions Pesticide Peer Review Meeting
	the exposure period not allowing an identification of the NOAEP and consequently of the ETC, among others. Overall, all experts agreed that, due to the identified uncertainties and limitations, the data from the two pulsed exposure studies on aquatic macrophytes should not be used in a higher-tier risk assessment. Open points: - The RMS should update the RAR to reflect the outcome of the discussion and clarify that the refined risk assessment cannot be used due to the limitations identified in both studies. - The RMS to please update the aquatic risk assessment in the RAR with the updated PEC values, following the discussions in the fate section (TC 149).
Expert consultation 5.7 Experts to consider the new information and to draw a conclusion on the risk to bees based on the available evidence. A consideration to pertinent metabolites shall be considered.	Experts at the meeting discussed and agreed on the following aspects related to the risk assessment to honey bees associated to the representative uses of flurochloridone: - The risk assessment of relevant metabolites will need to be updated based on the information in the residue section and the pertinent discussion in the peer-review meeting. - There is enough information to conclude low risk for those scenarios where high risk was identified at tier 1 for the uses of Flurochloridone 250 EC. - The lack of chronic data with the active substance shall be reflected in the revised RAR. Open points: - RMS should consider the discussion at the residues experts' meeting and update the risk assessment for metabolites accordingly. - RMS should also provide a consideration on the potential exposure of bees to TFA based on the available residue and fate data if this metabolite becomes relevant for any environmental matrix (e.g., whether TFA is formed in plants in rotational crops). - RMS should incorporate the outcomes of the discussion in the RAR and update the chronic risk assessment in relation to the uses of Flurochloridone 250 EC, reflecting the conclusion of low risk to adult bees and bee larvae considering the above-mentioned arguments. - RMS should also verify and provide 95% confidence intervals for the chronic endpoints, wherever possible.



Subject	Conclusions Pesticide Peer Review Meeting
	- RMS should reflect the uncertainty linked to the lack of chronic data with the a.s. and honey bees and whether a conclusion could be obtained on the expected toxicity of the a.s. based on the available information. - RMS should revise in the RAR any risk assessment related to uses that are not included in the definitive GAP table (e.g., cotton 1 x 0.25 kg a.s./ha), as indicated in the post-meeting note included at the beginning of the present report. - RMS to reflect the outcome of the discussion point in the revised RAR, including the update of the risk assessment if needed in the pertinent volumes and LoEP.
Expert consultation 5.8 Experts to decide whether the available information is sufficient to address the risk to non-target terrestrial plants. Particular attention shall be given to potential phytotoxicity effects and whether the risk assessment proposed is enough conservative to those effects.	Experts at the meeting agreed the endpoints derived from each of the studies available with the formulated products for the representative uses of flurochloridone. In line with previous assessments, the experts agreed to flag the issues encountered regarding the consideration of phytotoxicity and the noted deviations of the test guidelines. All the uncertainties and evidence were considered for reaching a conclusion for non-target terrestrial plants. Mitigation measures are needed. Open points: - RMS should incorporate the outcome of the discussion in the updated RAR. - RMS should clarify in the RAR the specific risk mitigation measures required to conclude a low risk. - RMS should also revise in the RAR any risk assessments for uses that are not included in the definitive GAP table (e.g., cotton at 1 x 0.25 kg a.s./ha), in line with the post-meeting note included at the top of this report. - EFSA should ensure that the conclusion reflects the uncertainty in the risk assessment for non-target terrestrial plants, which stems from the use of an endpoint that does not account for phytotoxic effect. - RMS should incorporate the conclusions of this discussion in the RAR, updating the risk assessment for the uses of Flurochloridone 250 CS. Specifically, it should be noted that the probabilistic risk assessment was not accepted by the experts, and it should be removed from the LoEP, if present. Additionally, the LoEP should reflect the uncertainties related to the endpoints used in the risk assessment (RMS can include footnote(s) for flagging these issues).



Subject	Conclusions Pesticide Peer Review Meeting
Expert consultation 5.9 (Pending on the outcome of the mammalian toxicology part) If the substance meets the ED criteria for humans, ecotoxicology experts shall discuss the relevance of the identified adversity to draw a conclusion for wild mammals as non-target organisms.	For flurochloridone, all the experts agreed that the pattern of EAS-mediated adversity leading to an impairment relevant at the level of population is identified. Open points: - RMS to reflect the outcome of the discussion in the revised RAR. - RMS to include a summary table of all the effects identified as adversity in the overall conclusion in the updated RAR, including the magnitude of effects and its relevance at the level of population.
Expert consultation 5.10 Experts to discuss and agree on the proper testing strategy for this substance in line with the ECHA/EFSA ED guidance (2018) and the information in the toxicological data package. The potential concern raised for antiandrogenic activity and the information available for the T-modality shall be considered for this purpose. In the context of this decision, experts shall consider the biological results (e.g., reliability of VTG and gonad histopathology reporting) as well as other more technical aspects such as the appropriateness of the tested concentration for the purpose of the ED assessment as well as the concern highlighted above.	All the experts, including the RMS, agreed that the study has major reliability issues and that the study could not be used to conclude on the ED properties for the EAS-modalities for non-target organisms. Open point: RMS to reflect the outcome of the discussion in the revised RAR and in the LoEP.
Expert consultation 1.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and	Based on the data retrieved from the individual co-formulants and the available ecotoxicity dataset, the experts agreed with the evaluation performed by the RMS and considered that these co-formulants will not contribute to increase the overall toxicity of the formulation Flurochloridone 250 CS for non-target organisms. Open point: The RMS should include an updated information of the individual co-formulants present in the two representative formulations in Vol. 4 of the RAR. The RMS should check with tox that the latest

MEETING MINUTES – 4 October 2024
Pesticides Peer Review TC 147 and TC 150
Flurochloridone



Subject	Conclusions Pesticide Peer Review Meeting
chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	information for the individual co-formulants in both formulations is presented.

REPORT OF PESTICIDES PEER REVIEW TC 147

FOSETYL – AIR III, mandated for re-assessment of ED Rapporteur Member State: FR

5. Ecotoxicology

Date: 24 September 2024

List of participants:

Status	Name of institution/attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS DE	German Federal Institute for Risk Assessment - DE
National Expert nominated by MS DE	German Environment Agency (UBA) - DE
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS NL	Ctgb - NL

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.6 Experts to discuss: - the Extended Amphibian Metamorphosis Assay (EAMA) submitted, its relevance and reliability (also considering the mortality observed, the relevant validity criteria of the LAGDA, the data reported, time to reach NF62, etc...) - the biological results - the ED assessment for the T-modality.	The Extended Amphibian Metamorphosis Assay (EAMA) submitted was discussed. The experts agreed that the 26% mortality observed at the highest tested concentration should not invalidate the study since the mortality was mainly observed in only one replicate. The validity criterion from the LAGDA related to the mean weight was not fulfilled; however, since the animals showed a similar weight in all replicates, this was only considered as a minor deviation. The experts also agreed that higher concentrations could have been tested, since no mortality was observed in the range finding test up to 5 mg/L. This should be reported as an additional uncertainty. Overall, it was concluded that the biological findings observed in the available EAMA do not show any pattern of T-mediated endocrine activity and adversity. Open point: RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.7 Expert to discuss the Fish Short-Term Reproduction Assay (FSTRA): - the effects observed, in particular the decreased	The available Fish Short-Term Reproduction Assay (FSTRA) was discussed. The effects (gonadosomatic index (GSI), fecundity) are not observed in a consistent dose-response manner and can be partly explained by the low performance of one replicate at the lowest concentration. Therefore, they were not considered as treatment related. In addition, the vitellogenin (VTG) measurements could not be considered fully reliable since the



Subject	Conclusions Pesticides Peer Review Meeting
fecundity and histopathological finding, - the interpretation of the results.	reporting of the methodology is incomplete (e.g. no calibration curve). Overall, it was agreed that despite these uncertainties (low performance of one replicate, VTG measurement not fully reliable), the study can be considered as valid, and that the effects observed do not show a plausible pattern of endocrine activity through the EAS-modalities. Open point: RMS to update the RAR by reflecting the outcome of the discussion.

4-12 July 2024

MINUTES

Pesticides Peer Review TC 146 Proquinazid

REPORT OF PESTICIDES PEER REVIEW TC 146

PROQUINAZID – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 12 July 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by RMS Sweden	Swedish Chemicals Agency - SE
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS Germany	German Environment Agency (UBA) - DE
National Expert nominated by MS Hungary	National Food Chain Safety Office - HU
National Expert nominated by MS Ireland	Department of Agriculture food and the Marine Ireland - IE
National Expert nominated by MS Netherlands	Ctgb - NL
Observer	BAFU - CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.5 Experts to discuss the need for a fish full life cycle study to address the data requirements. The experts should consider the bioaccumulation potential of proquinazid, the available studies with fish and the new irradiated water-sediment study.	1. The need for a fish full life cycle test (FFLCT) study to address the data requirements for proquinazid was discussed at the Peer Review Experts' Meeting TC 134 (March 2024). Since the trigger value related to the bioconcentration factor (>1000) was not fulfilled for proquinazid, the experts agreed that FFLC study should not be required for this substance. However, potential reproductive effects observed in the available Fish Short term Reproduction Assay (FSTRA) were not discussed. Moreover, experts raised the need for clarification on criteria for triggering a FFLCT. 2. The experts agreed on the general criteria for triggering a FFLCT. For proquinazid, it was confirmed that a FFLCT is not triggered since effects on reproduction in the available FSTRA were observed at a concentration more than 10 times higher than the chronic NOEC proposed to be used for risk assessment and the substance does not bioaccumulate, i.e., $BCF < 1000$. Open point RMS to reflect the outcome of the discussion in the updated RAR.

REPORT OF PESTICIDES PEER REVIEW TC 141 AND TC 146

MALTODEXTRIN - AIR V

Rapporteur Member State: IE

5. Ecotoxicology

Date: 12 July 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS Ireland	Department of Agriculture food and the Marine Ireland - IE
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS Czechia	The National Institute of Public Health - CZ
National Experts nominated by MS France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS Germany	German Federal Institute for Risk Assessment (BfR); German Environment Agency (UBA) ; Julius Kühn-Institut - DE
National Expert nominated by MS Hungary	National Food Chain Safety Office - HU
National Experts nominated by MS Netherlands	Ctgb - NL
National Experts nominated by MS Poland	EVA - PL
National Expert nominated by MS Sweden	Swedish Chemicals Agency - SE
Observer	BAFU - CH
Observers	PRCD, Department of Agriculture, Food and the Marine - IE

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the ED assessment of Maltodextrin on non-target organisms.	The potential waiver for the ED assessment of Maltodextrin was discussed among the experts. Although some uncertainties were identified in the information provided by the applicant as support to the ED waiver, and more effort is expected especially in the area of ecotoxicology, based on the available information on maltodextrin (including the available info on toxicological profile and the ones provided in the mammalian section), all the experts agreed that a potential concern related to the ED assessment for NTOs is not identified. Open point The RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.2 Experts to: • agree on the suitability of the new information provided by the applicant to address the risk for aquatic organisms • discuss and agree on the approach for the aquatic risk assessment.	Considering the nature of the a.s., the available toxicity data for invertebrates and the mode of action, it is agreed that a fish acute and chronic study, an invertebrate chronic study, and an algae study are not needed with the a.s.. Considering the information available on the composition of the formulation and lack of toxicity data with the formulation for representative uses, it is agreed that an acute invertebrate study with the representative formulation should be requested. Pending the results of the study, chronic toxicity data with the formulation on aquatic invertebrates might be needed, as well as data for sediment-dwelling organisms. Based on the lack of toxicity from the available study with <i>D. magna</i>, and the nature of maltodextrin, a low acute and chronic risk can be concluded for aquatic organisms for the a.s..
Experts' consultation 5.3	It was agreed that the acute contact toxicity study based on OECD TG might not be suitable to address potential effects of the a.s. given its mode of action.



Subject	Conclusions Pesticide Peer Review Meeting
Experts to: • Discuss the suitability of the studies used in the risk assessment considering the MoA and characteristics of the substance • Discuss and agree on the approach to the risk assessment for bees. The experts should particularly consider the exposure conditions and MoA of the substance.	It was agreed the available larvae chronic toxicity data with Eradicoat Max study should not be used to carry out the risk assessment for the formulation for representative uses. It was agreed that no chronic effects on adults are expected due to the mode of action of the a.s.. It was agreed the available semi-field study on phacelia can provide information on potential adverse effects due to the physical mode of action for application less than 7.5 kg a.s./ha. Overall, up to 20 x 7.5 kg a.s./ha applications to all crops, a low acute and chronic risk for honey bees and larvae could be concluded. For higher application, a low risk can be concluded only in non-attractive crops for the treated and succeeding crop scenarios. A low risk can be concluded for all the uses in permanent structures based on minimal exposure.
Experts' consultation 5.4 Experts to: • Discuss the suitability of the studies used in the risk assessment considering the MoA and characteristics of the substance • discuss and agree on the approach to the risk assessment for non-target arthropods. The experts should particularly consider the exposure conditions and MoA of the substance.	At the meeting, some uncertainties regarding the test system relevance and suitability, and potential effects on reproduction were highlighted. However, based on a tier 1 risk assessment, a low risk can be concluded for the field uses and uses in permanent protected structures. For uses in non-permanent structures (e.g. walk-in tunnels), a risk assessment was not presented. If HQ values exceed the trigger value of 2, then low risk for NTAs will not be able to be concluded and further refinements would be needed.
Experts' consultation 5.5 Experts to discuss and agree on the approach and on the risk assessment for <i>F. candida</i> and <i>H. aculeifer</i>.	It was agreed that, considering the fate properties of the a.s., its mode of action, its insecticidal properties, and the risk assessment for non-target arthropods, a toxicity study with soil macro-organisms other than earthworms is needed. It was agreed the chronic toxicity study for earthworms can be waived. It was agreed the risk assessment for soil macro-organisms other than earthworms cannot be finalised.
Experts' consultation 5.6	Given the nature of the substance, the expected low persistence of maltodextrin and mode of action, a low risk to maltodextrin is expected for earthworms (see EC 5.5) and for soil microorganisms.



Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss and agree on the approach and on the risk assessment for earthworms and soil micro-organisms.	
Experts' consultation 1.1 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Considering the available data package, the experts at the meeting could not conclude on the overall safety of the formulation for representative uses, owing to the lack of acute tox data for aquatic invertebrates (see EC 5.2).

REPORT OF PESTICIDES PEER REVIEW TC 141 and TC 146

MCPB - AIR III

Rapporteur Member State: PL

5. Ecotoxicology

Date: 12 July 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS Poland	EVA - PL
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS Czechia	The National Institute of Public Health - CZ
National Experts nominated by MS France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS Germany	German Federal Institute for Risk Assessment (BfR) ; German Environment Agency (UBA) - DE
National Expert nominated by MS Hungary	National Food Chain Safety Office - HU
National Expert nominated by MS Ireland	Department of Agriculture food and the Marine Ireland - IE
National Experts nominated by MS Netherlands	Ctgb - NL
National Expert nominated by MS Sweden	Swedish Chemicals Agency - SE
Observer	BAFU - CH
Observers	PRCD, Department of Agriculture, Food and the Marine - IE

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Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the acute avian endpoint selection for MCPB and MCPA. Experts should agree on: - The validity and use of the available dietary studies - The endpoint selection for risk assessment purpose Particular consideration should be given to: - Any relevant approach/discussion on MCPB in the area of mammalian toxicology - The assessment of MCPA (which is under review as active substance) in the area of ecotoxicology and mammalian toxicology, including potentially relevant experts' consultations - any additional information by the	The validity and use of avian short-term dietary toxicity studies in risk assessment was discussed. Particularly the assessment done by the RMS on the study validity was discussed. Additionally, the available evidence that phenoxy herbicides in general, and MCPB/ A in particular may cause gastro-intestinal (GI) tract damage during gavage (or bolus), high dosage was reviewed. All the experts agreed with the assessment of the avian short-term dietary studies done by the RMS and considered experiments conducted with MCPA, but not MCPB, as acceptable. Specifically, in the case of MCPB, the preliminary stability was not considered fully confirmed (an apparent decline was observed). Additionally, the experts considered that there may be indication that the substances (MCPA and MCPB) might cause GI damage when dosed at very high levels. However, evidence of GI damage was neither consistently observed nor confirmed at the microscopic level. Therefore, a clear causality could not be established. Based on the available data, the use of LD50s from gavage/bolus dosing studies could not be dismissed for use in risk assessment (and could not be superseded by the available short-term dietary studies). Overall, based on the available information, all experts agreed that only acute studies based on gavage/bolus administration should be used in the risk assessment for birds and mammals. Open point RMS to reflect the outcome of the discussion in the revised RAR and to revise the risk assessment in the MCPB RAR accordingly (i.e., by deleting the refinement based on dietary studies for MCPA as a metabolite).



Subject	Conclusions Pesticide Peer Review Meeting
applicant which may include additional data on i) exposure and metabolism (plant and animal) of MCPB and MCPA ii) the effects of MCPB, MCPA and other phenoxy-carboxylates when ingested via gavage vs. dietary route	
Experts' consultation 5.2 Experts to agree on the long-term mammalian endpoint for MCPB and MCPA. Experts should discuss the use of data on MCPA as surrogate for the hazard assessment of MCPB. Additionally, they should select the endpoint for the long-term risk assessment for wild mammals for both substances. Particular consideration should be given to: - Any parallel discussion on MCPB in the area of mammalian toxicology - The assessment of MCPA (which is under review as active substance) in the area of ecotoxicology and mammalian toxicology, including potentially relevant experts' consultations - any additional information by the applicant which may include additional	The experts discussed the applicant's proposal to consider toxicity data with MCPA as surrogate for the risk assessment of MCPB (i.e., read across) considering the available evidence on: - ADME information. - Structural similarity. - The available evidence suggesting comparable toxicity in mammalian studies. - The assessment in human toxicology. Such approach was proposed both for birds and mammals, for which limited reproductive data with MCPB were submitted. Overall, although some uncertainties were identified, most of the experts agreed that based on the available (eco)toxicological information, MCPA can be considered as surrogate for MCPB for the reproductive risk assessment of birds and wild mammals. Furthermore, the available studies with MCPA and MCPB were reviewed in light of the experts' consultation in the human toxicology area for agreement on the ecotoxicologically relevant endpoint for the reproductive risk assessment for wild mammals. For MCPA (relevant for both MCPA acid and MCPA-thioethyl), the ecotoxicologically relevant endpoint for the long-term mammalian risk assessment was set at 60 mg/kg bw/d (based on the based on reduced foetal weight at highest dose (>10%) in study CA 6.6.2/05 with rat). All experts agreed. For MCPB, the same endpoint should be converted based on molar ratio 0.88. It should be noted that the abovementioned agreement should be considered provisional, pending further discussion in the area of human toxicology. Open points RMS to further assess the ecotoxicological relevance of the observed effects in the 3-generation study with MCPA-thioethyl. The RMS to reflect the meeting discussions in the updated RAR.



Subject	Conclusions Pesticide Peer Review Meeting
data on i) exposure and metabolism (plant and animal) of MCPB and MCPA ii) the effects of MCPB, MCPA and other phenoxy-carboxylates when ingested via gavage vs. dietary route	
Experts' consultation 5.3 Experts to agree on the long-term avian endpoint for MCPB and MCPA. Experts should discuss the use of data on MCPA as surrogate for the hazard assessment of MCPB. Additionally, they should agree on the endpoint for the long-term avian risk assessment for both substances. Particular consideration should be given to: - Any relevant decision/discussion on the use of MCPA data as surrogate for MCPB in the area of mammalian toxicology - The assessment of MCPA (which is under review as active substance) in the area of ecotoxicology, including potentially relevant expert consultations - any additional information by the applicant which may include additional data on i) exposure and metabolism (plant and animal of MCPB and MCPA ii)	The available data were presented and discussed at the meeting: - Two reproduction studies with MCPA were available (B.9.1.1.3.2/01 and B.9.1.1.3.2/02 with <i>Colinus virginianus</i> and <i>Coturnix coturnix japonica</i>, respectively). The lowest NOAEL among these studies was 100.5 mg ae/kg bw/d. - No MCPB was available. Instead, the MCPA endpoint (B.9.1.1.3.2/01) was converted to MCPB in consideration formation fraction of 1, molar mass of 228.7 and 200.6 g/mol for MCPB and MCPA, respectively and resulting molar ratio of 0.88. The NOAEL resulting from the conversion is 114.2 mg ae/kg bw/d. This approach/extrapolation was considered in line with the decision taken under consultation point 5.2. - The LD₅₀/10 were 25.72 and 60 mg a.e./kg bw for MCPB and MCPA, based on experimental acute studies with the respective substances (in agreement with consultation point 5.1). These values, being lower than the measured endpoints, were used at the screening step, while a refinement was proposed based on the measured values, which were considered more realistic for risk assessment purpose. The use of the LD₅₀/10 in the reproductive avian risk assessment was further discussed, considering the recommendation by the EFSA B&M Guidance Document (EFSA, 2009) to apply the LD₅₀/10 from the acute endpoint (when lower than the reproductive endpoint), to account for potential sub-lethal effects. All experts agreed to use the LD₅₀/10 from the acute endpoint from the acute study with MCPB (25.72 mg/kg bw/d) for the setting of the long-term endpoint (for all steps of the risk assessment), according to the recommendation of the EFSA B&M Guidance (EFSA, 2009). For completeness, additional information potentially relevant to the avian risk assessment were also discussed: - A study on the diet of wood pigeon (B.9.1.1.4/02). - a statement on the relevance of the food avoidance/repellence observed in a short term avian dietary study with MCPB (B.9.1.1.4/01).



Subject	Conclusions Pesticide Peer Review Meeting
the effects of MCPB, MCPA and other phenoxy-carboxylates when ingested via gavage vs. dietary route	Concerning the PD study (collection/review of information from several studies), several uncertainties were identified on i) the relevance of the species for risk assessment (i.e., absence of a focal species study); ii) the relevance of the studies referenced in the paper to the representative uses; iii) the quantitative PD proposal given the variability of the reported information across studies and iv) the absence of a transparent relevance/reliability assessment of the underlying information (i.e., the studies referenced in B.9.1.1.4/02). Concerning the food avoidance observed in a single day dietary exposure study with northern bobwhite, it was noted that this is a laboratory experiment not designed to quantify food avoidance or to assess it qualitatively (dietary exposure study). As such the study was not considered to represent the realism of the exposure in the agricultural environment. Its relevance was consequently questioned. The information that could be extrapolated from such study are limited in the remits of the refinement of the risk assessment and should not be considered for a qualitative or quantitative refinement. Open point RMS to carry out the reproductive avian risk assessment using the LD₅₀/10 from the acute endpoints at all tiers.
Experts' consultation 5.4 Experts to discuss the available and new toxicity information on MCPB for non-target terrestrial plants and their use in risk assessment.	A seedling emergence and vegetative vigour study with MCPB sodium was available in the first version of the RAR and invalidated by the RMS. Consequently, two new studies with MCPB Na 400 (KCP 10.6.2/01 and 02, seedling emergence and vegetative vigour respectively) were submitted after the stop of the clock. Therefore, the evaluation of the new studies by the RMS and updated risk assessment required discussion by the RMS. Furthermore, a risk assessment for NTPPs considering the metabolite MCPA was submitted by the RMS. The use of this information required agreement by the experts, in line with the agreement in experts' consultation 5.9 of the TC 146 on MCPA, MCPA-EHE and MCPA-thioethyl. MCPB: The experts agreed with considering study B.9.6.2.1.1/01 invalid, considering the design deviations (i.e., number of plants, lack of key assessment endpoints, shorter observation timing, absence of a phytotoxicity assessment), some of which were considered major. Furthermore, the experts agreed with the assessment by the RMS of the new studies (KCP 10.6.2/01 and 02) and on their use in a deterministic risk assessment, albeit identifying some uncertainties related to the species selection. However, the available information did not allow concluding that the



Subject	Conclusions Pesticide Peer Review Meeting
	probabilistic risk assessment using the endpoints from KCP 10.6.2/01 and 02 was sufficiently robust. MCPA (as metabolite of MCPB): It was noted that the assessment for MCPA as metabolite may not be needed according to SANCO and also data requirements 283-248/2013. Some of the experts noted that although no clear reference is given in the available GDs and data requirements, based on the activity of MCPA as herbicide, a risk assessment for the metabolite MCPA as active substance would be informative. It was also considered that the risk assessment should be carried out with the seedling emergence endpoints to cover for the root-uptake for off-field exposure (also following previous discussions on MPCA, see experts' consultation 5.9 of the TC 146 on MCPA and MCPA-thioethyl, and 5.6. on MCPA-EHE). The risk assessment for the metabolite MCPA was considered useful for illustrative purpose. Open point The RMS to correct the risk assessment for metabolite MCPA referring to it as an illustrative RA, and to reflect the outcome of the discussion from the experts' meeting.
Experts' consultation 5.5 Experts to discuss the proposed approach to address risks to NTOs from metabolites other than MCPA. This discussion is particularly -but not necessarily exclusively- relevant for aquatic organisms.	The strategy for addressing the risk for metabolites to NTOs required discussion, considering: - The proposal by the applicant considering a toxophore assessment and QSAR predictions. - The quantitative risk assessment by the RMS, which assumed metabolites to be either equally or 10 times more toxic than the parent based on the available evidence. - The recommendations by the EFSA aquatic guidance on the approach for assessing risks for metabolites in absence of experimental data, considering non-testing methods (i.e., as described in sections 2.3 and 2.4). - Any changed triggered by the discussions in other areas of the risk assessment (e.g., fate and toxicology) The experts acknowledged that the agreed residue definition by the experts meeting in the fate area for surface water and sediment compartments is the following: • Surface water: MCPB, MCPA acid, benzoic acid (aq. photolysis), o-Cresol (aq. photolysis), 2,4-DHPF (aq. photolysis), 2-HPF (aq. photolysis), MHPB (aq. photolysis), OHMPA (aq. photolysis from MCPA acid). • Sediment: MCPB, MCPA acid, benzoic acid (aq. photolysis), o-Cresol (aq. photolysis), 2,4-DHPF (aq. photolysis), 2-HPF (aq. photolysis), MHPB (aq. photolysis), OHMPA (aq. photolysis from MCPA acid). Furthermore, it was noted that an open point was set by the fate meeting for new PECsoil, PECgw and PECsw/PECsed for MCPB,



Subject	Conclusions Pesticide Peer Review Meeting
	MCPA acid, o-Cresol, benzoic acid, 2,4-DHPF, 2-HPF, MHPB and OHMPA. Accordingly, an open point was set by the ecotoxicology meeting for an updated risk assessment of MCPB and its relevant metabolites. For the soil compartment, MCPA acid was considered the only relevant metabolite (no discussion required). Similarly, no further discussion was deemed necessary for MCPA as aquatic metabolite, given the availability of toxicity data. A structural analysis was presented by the applicant with the aim of demonstrating the loss of the toxophore in the photo-metabolites of MCPB (Vol. 3CA, B.9.10/01). All experts considered the toxophore analysis by itself insufficient to conclude that the metabolites may be substantially less toxic to NTOs than the parent compound. Substantial uncertainty around the QSAR prediction (CA 6.8.3/02) by the applicant was highlighted at the meeting. This included the applicability domain in the QSAR analysis by the applicant. Specifically, the descriptor ranges (i.e., log kow) were considered potentially too broad to properly define an applicability domain. Furthermore, it was noted that validation was carried out with only one compound which seems rather weak and have the purpose of a case-study. Finally, according to the EFSA guidance document on aquatics (EFSA 2013), reliable estimations should ideally be available from more than one (Q) SAR model, which was not the case of the metabolites of MCPB. All experts agreed to consider the QSAR predictions as supportive only, since based on the identified shortcomings, their reliability was questioned. To account for all uncertainties highlighted above and for a conservative approach, in line with EFSA 2013, the following approach was agreed: in absence of reliable data, all experts agreed to use the surrogate endpoint 10 times lower toxicity than the parent for the risk assessment of all relevant metabolites (in case experimental data are not available). Open point • The RMS to revise the risk assessment for metabolites in aquatic organisms reflecting the outcome of the discussion. • The risk assessment for aquatic organism should be updated considering the residue definition agreed at the meeting (i.e., this might trigger consideration of whether a risk assessment for sediment dwellers is required) and the updated PEC values.



Subject	Conclusions Pesticide Peer Review Meeting
	• The RMS to please reflect the data gap for secondary poisoning and BCF determination if triggered by the availability of respective information on log Pow of 2,4-DHPF, 2-HPF and MHPB. • The RMS to consider whether changes triggered by discussions in the area of toxicology (e.g., ADME) and residues section (i.e., plant metabolites) may require revising the metabolite RA for birds and mammals. • The RMS to also address plant metabolites in the context of risk assessment for bees. Additionally, The RMS to revise the RA for soil organisms following the updated exposure assessment.
Experts' consultation 5.6 Expert to discuss the relevance of the use of MCPA data on birds and mammals for the ED assessment of MCPB.	For <u>mammalian species</u>, the ED conclusion for humans also apply to wild mammals: -Although the dataset is limited for MCPB, human toxicology experts agreed to consider as part of the WoE for ED assessment the studies conducted with MCPA, and that based on the available data, at the date of the Review Meeting (TC 141, June 2024), the ED criteria for T-modality are not met for human health for MCPB. - the EAS-modalities for MCPB are considered insufficiently investigated for human health, in particular for A-modality based on the lack of a level 3 study (i.e., Hershberger Assay, OECD TG 441). See also Experts' consultation (EC) 2.10 of the Peer Review Meeting Report TC 141 and TC 142 MCPB – Mamtox-ecotox joint ED&mamtox. Therefore, a conclusion cannot be reached for wild mammals for the A-modality based on the available data (data requirement). For <u>non-mammalian species</u>, the ecotoxicology experts did not support the bridging between MCPA and MCPB for the ED assessment (see EC 5.9 regarding the testing strategy needed for MCPB). Open point The RMS to reflect the outcome of the discussion in a revised RAR and to include the relevant updates for wild mammals when available.
Experts' consultation 5.7 Expert to discuss the conclusion regarding the E-modality in wild mammals, based on RMS concern and pending the outcome of the toxicology discussion.	In human toxicology, the experts agreed that the MCPB is not an ED for E-modality, based on the ToxCast ER pathway prediction model. Therefore, the same can be concluded for wild mammals. See also Experts' consultation 2.10 of the Peer Review Meeting Report TC 141 and TC 142 MCPB – Mamtox-ecotox joint ED&mamtox.



Subject	Conclusions Pesticide Peer Review Meeting
	Open point The RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.8 Expert to discuss the conclusion regarding the T-modality in wild mammals, based on RMS concern and pending the outcome of the toxicology discussion.	In human toxicology Peer Review Meeting TC 141 (June 2024), based on the data available on MCPB and the WoE it was concluded that MCPB does not meet the ED criteria for T-modality for humans. Therefore, the same can be concluded for wild mammals. See also Experts' consultation 2.10 of the Peer Review Meeting Report TC 141 and TC 142 MCPB – Mamtox-ecotox joint ED&mamtox. Open point The RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.9 Expert to discuss -The reliability of the paper 2009. -The proposed testing strategy to investigate EAS-modality (FSTRA vs FSDT) with MCPB. - The proposed testing strategy to investigate the T-modality (choice AMA vs XETA) with MCPB, also based on the outcome of the mammalian discussion. EFSA would like to highlight that the studies should be carried on with the active substance MCPB.	Based on the different physico-chemical and ecotoxicological profile of MCPA and MCPB, experts agreed that MCPA data cannot be used for the ED assessment of MCPB. Thus, studies for assessing the potential ED properties of the substance on non-target organisms shall be submitted with MCPB. -Literature study (2009): The study was conducted with MCPA, whereas the ED assessment should be conducted on MCPB. Therefore, all experts agreed to consider the study as not relevant for the ED assessment of MCPB. See also EC 5.3 in the Peer Review meeting report TC 141 and 146 MCPA Mamtox-ecotox joint ED_ecotox. -Testing strategy – EAS-modalities: all experts agreed that a FSTRA study (OECD TG 229) with MCPB should be submitted. -Testing strategy - T-modality: all experts agreed that an AMA study (OECD TG 231) with MCPB should be submitted. Based on the lack of core data with MCPB on the T-modality in the human dataset, it was not advised to perform a XETA. Open point The RMS to please reflect the outcome on the discussion in the revised RAR and to adapt the ED assessment to the current practices in line with the EFSA Administrative Guidance.
New experts' consultation point	The acute toxicity of the formulation for representative uses was not addressed for birds, fish and aquatics invertebrates. The chronic toxicity of the formulation for representative uses not



Subject	Conclusions Pesticide Peer Review Meeting
proposed by EFSA for completeness: Experts' consultation 5.10 MS experts to discuss whether the available information is sufficient to characterize the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	addressed for birds, mammals, bee larvae and earthworms. Therefore, an assessment of the individual components of the formulation for representative uses was required to conclude on its safety. The available information do not suggest the formulation for representative uses is more toxic compared to the a.s. All experts agreed. It was noted that the applicant proposed a new formulation (CA3115) for representative uses in the context of the renewal, which slightly differs in its composition from the current formulation (CA2635). Most ecotoxicological tests were carried out with CA2635. Based on the assessment of the composition of the two formulations, all experts agreed that both formulations (new and old) of the formulation could be considered as comparable. A data retrieval exercise was carried out for the [REDACTED] co-formulants: [REDACTED] (content [REDACTED]) and [REDACTED] (content [REDACTED]). No concern was raised by the experts on the environmental safety of these [REDACTED] co-formulants.

Pesticides Peer Review TC 141 and TC 146
Lysate of Willaertia magna C2c Maky

REPORT OF PESTICIDES PEER REVIEW TC 141 and 146

LYSATE OF WILLAERTIA MAGNA C2C MAKY – NAS 1107

Rapporteur Member State: AT

5. Ecotoxicology

Date: 12 July 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS Czechia	The National Institute of Public Health - CZ
National Experts nominated by MS France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS Germany	German Federal Institute for Risk Assessment (BfR): German Environment Agency (UBA) ; Julius Kühn-Institut- DE
National Expert nominated by MS Hungary	National Food Chain Safety Office - HU
National Expert nominated by MS Ireland	Department of Agriculture food and the Marine Ireland - IE
National Experts nominated by MS Netherlands	Ctgb - NL
National Expert nominated by MS Poland	E-V-A Sp. z o.o. - PL
National Expert nominated by MS Sweden	Swedish Chemicals Agency - SE
Observer	BAFU - CH
Observers	PRCD, Department of Agriculture, Food and the Marine - IE

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

²

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

Please note that information part of this report may have been masked by EFSA in accordance with Article 63 of Regulation (EC) No 1107/2009 as well as EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009, or EFSA's Practical Arrangements concerning transparency and confidentiality as a consequence of confidentiality requests submitted by the applicant on application dossiers for pesticides active substances or Maximum Residue Levels, respectively. Please note that information disclosed in this report is without prejudice to pre-existing intellectual property rights and data exclusivity clauses set out in Union law, and particularly in Article 62 of Regulation (EC) No 1107/2009.

Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to agree on the acceptability of the studies and information provided by the applicant for non-target arthropods (NTAs) and <i>C. riparius</i> (if available). Experts to agree on the approach and outcome for the risk assessment for NTAs and for <i>C. riparius</i> .	The experts at the meeting considered the two new studies for non-target arthropods acceptable. The experts also agreed with the MAF values used to estimate the predicted environmental concentrations. Considering the quantitative risk assessment outcome, no additional line of evidence is needed to conclude on the risk for non-target arthropods. The experts agreed to accept the waiver for an additional study with <i>C. riparius</i> . Open point RMS to reflect the outcome of the discussion in an updated DAR.
Experts' consultation 5.2 Experts to agree on the waiver for the risk assessment for sediment-dwelling organisms.	The experts at the meeting agreed that data and risk assessment for sediment-dwelling organisms are not needed and can be waived. Open point RMS to reflect the outcome of the discussion in an updated DAR.
Experts' consultation 5.3 Experts to agree on the approach and outcome for the chronic oral risk assessment for honey bees.	The experts agreed that the succeeding crop scenario is not relevant. The experts agreed that, for the treated crop and flowering weeds scenarios, the available weight of evidence does not allow to exclude a high risk. Further data are needed to demonstrate low chronic oral risk. Open point RMS to reflect the outcome of the discussion in an updated DAR.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 Experts to agree on the approach and on the outcome of the risk assessment for <i>Folsomia candida</i> and <i>Hypoaspis aculeifer</i>.	The experts agreed to accept the waiver for data and risk assessment for soil organisms other than earthworms, based on the available information for non-target arthropods other than bees, and the earthworms risk assessment. Open point RMS to reflect the outcome of the discussion in an updated DAR.
Experts' consultation 5.5 Experts to discuss the waiver of the ED assessment, also considering the experts' consultation in the mammalian toxicology section.	For wild mammals, all experts agreed that the same conclusions as humans apply, and a waiver for ED assessment was confirmed. For non-target organisms (NTOs) other than mammals, based on the following: • nature of the active substance (lysis of a concentrate of amoeba); • none of the Lysate compounds have known or potential endocrine disrupting activity; • the natural occurrence of and constant exposure to all the components of Lysate of <i>Willaertia magna</i> C2c Maky; all experts agreed that a waiver for the ED assessment for NTOs is justified. Open point The RMS to reflect the outcome of the discussion in a revised DAR.
Experts' consultation 5.6 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation for representative use(s) 'AXP10' with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Considering the available information, the experts at the meeting concluded that it is possible to fully characterise the safety of the formulation for the representative use. Open point RMS to reflect the outcome of the discussion in an updated DAR.

REPORT OF PESTICIDES PEER REVIEW TC 141 and TC 146

MCPA, MCPA-EHE, MCPA-THIOETHYL – AIR III

Rapporteur Member State: PL

5. Ecotoxicology

Date: 12 July 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS Poland	EVA - PL
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS Czechia	The National Institute of Public Health - CZ
National Experts nominated by MS France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS Germany	German Federal Institute for Risk Assessment (BfR); German Environment Agency (UBA) - DE
National Expert nominated by MS Hungary	National Food Chain Safety Office - HU
National Expert nominated by MS Ireland	Department of Agriculture food and the Marine Ireland - IE
National Experts nominated by MS Netherlands	Ctgb - NL
National Expert nominated by MS Sweden	Swedish Chemicals Agency - SE
Observer	BAFU - CH
Observers	PRCD, Department of Agriculture, Food and the Marine - IE

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Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the acute endpoint for birds considering the available studies with the Bobwhite quail and the Japanese quail.	The selection of the acute endpoint for birds (i.e., geomean) was discussed. Geomean: The experts agreed on the geomean of 600 mg ae/kg bw to be used in the acute risk assessment for birds, calculated from acute studies on <i>C. virginianus</i> and <i>C. coturnix japonica</i> (i.e., B.9.1.1.1/0, B.9.1.1.1/04, B.9.1.1.1/05). The selection of the long-term endpoint for mammals was discussed in the Peer-Review Meeting Report for MCPB, discussion point 5.2. For MCPA (relevant for both MCPA acid and MCPA-thioethyl), the ecotoxicologically relevant endpoint for the long-term mammalian risk assessment was set at 60 mg/kg bw/day, based on reduced foetal weight at highest dose (effect >10%) in study CA 6.6.2/05 with rat. It should be noted that the abovementioned agreement is provisional, pending on further discussions in the area of human toxicology. Open points: RMS to reflect the outcome of the discussion in a revised RAR. RMS to reflect the outcome of the discussion on the reproductive endpoint for MCPA for mammals (captured in the peer-review meeting report of MCPB, point 5.2) in a revised RAR.
Experts' consultation 5.2 Experts to discuss the proposed approach to address risks to non-target organisms (NTOs) from relevant metabolites of MCPA. This discussion is particularly -but not necessarily exclusively-	Overall approach with relevant metabolites: the general approach followed by the RMS to assume 10 times higher toxicity than the parent, where no studies were available with the relevant metabolites, was agreed by all experts. MCPA acid (metabolite of MCPA-thioethyl): not discussed in detail as it has its own data package (MCPA variant). PCOC: all experts agreed to waive the risk assessment in collembolan and mites based on the evidence of its formation only under anaerobic conditions and the high margin of safety in the risk assessment for earthworms.



Subject	Conclusions Pesticide Peer Review Meeting
relevant for aquatic organisms.	MCPA-formate: following the outcome of experts' discussion in the environmental fate area, this relevant metabolite was identified for MCPA-thioethyl (surface water exposure). It was agreed that a risk assessment should be made available considering MCPA-thioethyl as parent. Open points RMS to reflect the outcome of the discussion for PCOC on the risk assessment for collembolans and mites in a revised RAR. RMS to include a risk assessment considering MCPA-formate as a metabolite of MCPA-thioethyl in a revised RAR.
Experts' consultation 5.3 Experts to discuss the relevance and reliability of the literature study by Orton et al. (2009) for the ED assessment of non-target organisms.	Although some drawbacks were identified and the description of the study design was not fully reported, the literature study B.9.11.2.3/01 was considered as reliable with restrictions, and relevant for inclusion in the weight of evidence of the ED assessment for non-target organisms. All experts agreed. Open point RMS to update the RAR with the outcome of the discussion.
Experts' consultation 5.4 Experts to discuss the testing strategy to investigate EAS-modalities for non-target organisms, considering all the variants of MCPA and also the outcome from the expert consultation on the literature study by Orton et al. 2009.	Wild mammals: the ED assessment for wild mammals is pending on the submission and assessment of further information in the human toxicology section. Other non-target organisms (NTOs): The testing strategy for the investigation of the EAS-modalities for NTOs was discussed. Based on the evidence that i) variants MCPA-thioethyl and MCPA-EHE are more toxic compared to the MCPA acid, ii) the three substances have different physical-chemical properties potentially leading to different nature and magnitude of effects, iii) the ED assessment is hazard-based and therefore the substances under assessment should be considered independently, the majority of the experts agreed that a Fish Short Term Reproductive Assay (FSTRA, OECD 229) on the same species and with the inclusion of gonad histopathology assessment should be conducted on all three variants (i.e., MCPA-thioethyl, MCPA acid and MCPA-EHE). For MCPA-EHE, an alternative was proposed in expert consultation point 5.6, i.e., a Fish Sexual Developmental Test (FSDT, OECD 234) with 5 testing concentrations, which could be used in both the ED assessment and to fill the data gap for chronic risk assessment for aquatic organisms. In case of positive findings from the lower-tier studies (either FSTRA or the FSDT for MCPA-EHE, at discretion of the applicant), a mode of action (MoA) should be postulated and further tests may be needed to further investigate the adversity (i.e., Medaka Extended One-Generation Test, MEOGRT – OECD 240, or a fish full-life cycle test with all parameters foreseen to be investigated in the MEOGRT) in line with ECHA/EFSA ED Guidance 2018.



Subject	Conclusions Pesticide Peer Review Meeting
	Open point RMS to reflect the outcome of the discussion in a revised RAR. Data requirement Applicant to submit a Fish Short Term Reproductive Assay (OECD 229, FSTRA) on the same species and with the inclusion of gonad histopathology assessment on all three variants i.e., MCPA-thioethyl, MCPA acid and MCPA-EHE. The applicant may wish to consider conducting a Fish Sexual Development Assay (OECD 234) with 5 testing concentrations to cover the toxicity (see expert consultation point 5.6-8) and the ED characterisation of MCPA-EHE. In case of positive findings, a MoA should be postulated and further tests may be needed to further investigate the adversity (i.e., Medaka Extended One-Generation Test, MEOGRT – OECD 240, or a fish full-life cycle test with all parameters foreseen to be investigated in the MEOGRT) in line with the ECHA/EFSA ED Guidance 2018.
Experts' consultation 5.5 An expert consultation to discuss the testing strategy to investigate the T-modality for NTOs other than mammals may be required, considering all variants of MCPA, depending on the outcome of the mammalian toxicology expert's consultation. It has to be noted that an AMA test is currently ongoing, according to the information provided by the applicant.	Wild mammals: all experts agreed that the same conclusions as for humans apply. Other NTOs: The testing strategy for the investigation of the T-modality for NTOs was discussed. As for the EAS-modalities, based on the evidence that i) variants MCPA-thioethyl and MCPA-EHE are more toxic compared to the MCPA acid, ii) the three substances have different physical-chemical properties potentially leading to different nature and magnitude of effects, and iii) the ED assessment is a hazard-based assessment and therefore the substances under assessment shall be considered independently, the majority of the experts agreed that a <i>Xenopus</i> Eleutheroembryonic Thyroid Assay (OECD 248, XETA) or an Amphibian Metamorphosis Assay (OECD 231, AMA) should be conducted on all three variants i.e., MCPA-thioethyl, MCPA acid and MCPA-EHE. In case of positive findings, a MoA should be postulated and further tests may be needed to further investigate the adversity (i.e., Larval Amphibian Growth and Development Assay, OECD 241) in line with the ECHA/EFSA ED Guidance 2018. Open point RMS to reflect the outcome of the discussion in a revised RAR. Data requirement Applicant to submit a <i>Xenopus</i> Eleutheroembryonic Thyroid Assay (OECD 248, XETA) or an Amphibian Metamorphosis Assay (OECD 231, AMA) on all three variants MCPA-thioethyl, MCPA acid and MCPA-EHE. In case of positive findings, a MoA should be postulated and further tests may be needed to further investigate the adversity (i.e.,



Subject	Conclusions Pesticide Peer Review Meeting
	Larval Amphibian Growth and Development Assay, OECD 241) in line with the ECHA/EFSA ED Guidance 2018.
New experts' consultation point proposed by EFSA for completeness: 'HF Calibra' (from Sipcam Inagra, S.A.) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Based on the different composition, the experts agreed that formulation Fengib was considered as not comparable to the formulation for representative uses 'HF Calibra', and further studies may need to be generated for non-target arthropods (NTAs). All experts agreed that there was no sufficient information to conclude on the environmental safety of the formulation for representative uses 'HF Calibra'. Open point RMS to reflect the outcome of the data retrieval exercise in the revised RAR (Vol. 4).
New experts' consultation point proposed by EFSA for completeness: 'MCPA DMA 500 SL' (from EU MCPA Renewal Task Force – CIECH and from Nufarm) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts agreed that an assessment of the environmental safety of the formulation for representative uses "MCPA DMA 500 SL" was not needed due to its similarities with the a.s. MCPA DMA salt. Open point RMS to reflect the outcome of the data retrieval exercise in a revised RAR (Vol. 4).



Subject	Conclusions Pesticide Peer Review Meeting
“Mixture formulation EVERGREEN COMPLETE’ (‘UKS 151D’) (from Nufarm UK Limited) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Pending on further information required in the area of toxicology, all experts agreed that, based on the available information on co-formulants, concerns were identified on the environmental safety of the formulation. Open point RMS to reflect the outcome of the discussion in a revised RAR (Vol. 4).
New Experts’ consultation 5.6 arisen following the clock stop: Experts to discuss the risk assessment for non-target organisms (NTOs) for the representative formulation "Evergreen Complete, UKS 151D". If available, a combined risk assessment of the three a.s. concurrently present in the product will also be discussed.	The available studies and risk assessment for the formulation for representative uses “Evergreen Complete – UKS 151D”, containing a mixture of three a.s. was discussed. Outcome of the discussions are summarized below for each group of NTOs. Birds In general agreement with the RMS assessment. Overall, based on the identification of several data gaps, the risk assessment (dietary, drinking water and secondary poisoning) could not be finalised (including plant metabolites, pending considerations from residue section). A combined (i.e., additive) risk assessment for the three a.s. should be explicitly considered. Mammals In general agreement with the RMS assessment (pending on the outcome of further discussions in the toxicology area). Overall, based on the identification of several data gaps, the risk assessment (dietary, drinking water and secondary poisoning) could not be finalised (including plant metabolites, pending considerations from residue section). A combined (i.e., additive) risk assessment for the three a.s. should be explicitly considered. Aquatic organisms ‘UKS 151A’ was considered comparable to ‘UKS 151D’. Due to drawbacks in the study design (i.e., exposure) the acute studies with fish (CP 10.2.2.1/01) and aquatic invertebrates (CP 10.2.2.2/01) were dismissed from the risk assessment. Based on the physical-chemical properties and degradation profile of MCPA-EHE, chronic toxicity tests on aquatic organisms (i.e., fish and aquatic invertebrates) with the active substance should be performed. At discretion of the applicant, a Fish Sexual Development Test (i.e., FSDT, OECD 234) with 5 concentrations could be performed to cover the toxicity and ED assessment (see expert consultation point 5.4-8) of MCPA-EHE.



Subject	Conclusions Pesticide Peer Review Meeting
	Overall, based on the identification of several data gaps (hazard and exposure), the risk assessment for aquatic organisms (including water metabolites, pending considerations from environmental fate section) was considered as not finalised. The combined (e.g., additive) risk to the three active ingredients should be explicitly taken into account. Bees All experts agreed that the risk assessment for the representative uses of 'UKS 151D' could not be finalised. Specifically, a data gap was identified for a full data package (i.e., acute oral and contact, chronic and larval tests) characterising the hazard and exposure of MCPA-EHE and 'UKS 151D' for honey bees. Non-target arthropods (NTAs) All experts agreed with the evaluation of studies KCP 10.3.2/01-02, respectively performed on rove and ground beetle, and the risk assessment performed by the RMS (i.e., low risk for NTAs concluded). Earthworms All experts agreed to not consider study CP 10.4.1.1 for use in risk assessment (i.e., no irrigation, no worst-case exposure realism). Therefore, based on the identification of several data gaps (i.e., hazard and exposure), the risk assessment could not be finalised (including soil metabolites, pending considerations from environmental fate section). Soil macro-organisms other than earthworms Study with the predatory mite CP 10.4.2.1/02 could not be considered for evaluation since the study report was not submitted. Therefore, the risk assessment could not be finalised (including soil metabolites, pending considerations from environmental fate section). Soil nitrogen transformation Study CP 10.5.1/01 was considered not suitable for use in risk assessment (i.e., low comparability of used formulation, short-term respiration no longer a data requirement). Therefore, based on the identification of data gaps for hazard and exposure assessment for MCPA-EHE, 'UKS 151D' and relevant metabolites (pending on future environmental fate evaluation), the risk assessment could not be finalised. Non-target terrestrial plants (NTTPs) No formulation data or risk assessment for NTTPs was available. In line with Regulation 284/2013, seedling emergence and vegetative vigour studies with 'UKS 151D' are required and should be used in risk assessment (data gap). Furthermore, a risk assessment for emerging non target plant seedlings off field exposed via root uptake to MCPA acid (as metabolite of MCPA-EHE) should be provided. Overall, the risk assessment could not be finalised. Biological methods for sewage treatment A data gap was identified to address the hazard of MCPA-EHE to organisms involved in the biological methods for sewage



Subject	Conclusions Pesticide Peer Review Meeting
	treatment processes. Overall, the risk assessment could not be finalised. Open point RMS to reflect the outcome of the discussion in an updated RAR.
New Experts' consultation 5.7 arisen following the clock stop: Experts to discuss the risk assessment for honey bees. In particular, the reliability and results of the newly submitted chronic studies with the technical a.s. will be discussed: • B.9.3.1.3/02, MCPA: A chronic larval toxicity study with the honey bee (<i>Apis mellifera</i>). • B.9.5.1.2/01, Chronic toxicity of MCPA DMA 500 g/L to the honeybee <i>Apis mellifera</i> L. under laboratory conditions.	B.9.5.1.2/01 – chronic toxicity study to honeybees: all experts agreed on the validity of the study and on the assessment conducted by the RMS. The NOED_{hpg} of <u>21.9 µg ae/bee/day</u> was agreed for use in risk assessment for sublethal effects. B.9.3.1.3/02 - chronic larval toxicity study with honeybees: some drawbacks were identified which did not compromise the reliability of the study. All the experts agreed to select a NOED of 6.25 µg/ae larvae based on the biological relevance of the observed effects on adult mortality for adult emergence (14.6 % absolute value and >10.4% relative to the control at the LOED). Open points • RMS to update the evaluation of the toxicity studies above by reflecting the meeting discussion. • RMS to include a footnote in the LoEP clarifying that evaporation was not measured in the chronic toxicity study B.9.5.1.2/01. • RMS to update the risk assessment for MCPA (as active substance or metabolite of MCPA-thioethyl) by selecting the larval endpoint from B.9.3.1.3/02, agreed at the meeting (NOED of 6.25 µg ae/larvae). The RAR and LoEP should be updated accordingly. • RMS to also ensure that the MCPB assessment report is updated accordingly. RMS to consider reporting the outcome of the risk assessment according to the SANCO guidance in the updated LoEP.
New Experts' consultation 5.8 arisen following the clock stop: Experts to discuss the suitability of the current approach adopted for chronic risk assessment of variants MCPA acid and MCPA-thioethyl for aquatics i.e., available chronic studies performed with the MCPA acid (or DMA salt) covering also for the variant MCPA-thioethyl.	MCPA-thioethyl and MCPA acid All experts agreed that, based on the physical-chemical properties and the degradation profile of MCPA-thioethyl, studies with the acid variant could be used as surrogate for the variant MCPA-thioethyl concerning the chronic risk assessment for aquatic organisms. MCPA-EHE Please refer to dedicated discussions in experts' consultation 5.4-6.



Subject	Conclusions Pesticide Peer Review Meeting
New Experts' consultation 5.9 arisen following the clock stop: Experts to discuss the endpoint selection and the risk assessment to non-target terrestrial plants for the variants MCPA acid and MCPA-thioethyl.	All available studies with the a.s. (MCPA DMA salt) and the formulations were discussed. MCPA acid Study CA B.9.6.2.1/01 with MCPA DMA salt – vegetative vigour, was considered as not acceptable, based on the identified major deviations (i.e., low sample size, low observation/exposure duration, growth medium compared to available guidelines). The other studies CA B.9.6.2.1/02 – vegetative vigour, CA B.9.6.2.2/01 – seedling emergence and CA B.9.6.2.2/02 – seedling emergence were discussed and unanimously considered less reliable for endpoint selection and quantitative use in risk assessment for several reasons (i.e., including the erratic dose response, comparison of experimental design vs. test guidelines). The endpoint selection for the variant MCPA acid was agreed as the lowest ER₅₀ from CP B.9.11.2/02 – vegetative vigour study (23.9 g ae / ha). MCPA-thioethyl The available studies conducted with 'HF Calibra' were discussed i.e., CP B.9.11.2/01 – seedling emergence and CP B.9.11.2/02 – vegetative vigour. The RMS evaluation of the studies was agreed by the experts, however it was noted that while no remarkable effects could be observed in all tested crops, lettuce (shown to be consistently sensitive in other valid studies with MCPA) was not present in the two studies conducted with 'HF Calibra'. While some uncertainties remain considering that MCPA and MCPA-thioethyl may have different MoA (herbicide vs. growth regulator), a data gap for a study with MCPA-thioethyl covering lettuce was identified. MCPA-EHE Please refer to dedicated discussion in expert consultation 5.6. Open points • RMS to align the endpoint selection in the MCPA and MCPB dossiers: ER₅₀ 23.9 g ae/ha from CP B.9.11.2/02 – vegetative vigour study. • RMS to reflect the outcome of the discussion in both MCPA and MCPB RARs.

Pesticides Peer Review TC 136 and TC 139

Clomazone

REPORT OF PESTICIDES PEER REVIEW TC 136 and TC 139

CLOMAZONE – AIR III after ED clock-stop

Rapporteur Member State: DK

5. Ecotoxicology

Date: 6 June 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS Denmark	Danish Environmental Protection Agency - DK
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS Croatia	Croatian Agency for Agriculture and Food; Institute for Medical Research and Occupational Health - HR
National Expert nominated by MS Czech Republic	National Institute of Public Health - CZ
National Experts nominated by MS France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS Germany	Federal Environmental Agency (UBA); German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS Hungary	National Food Chain Safety Office - HU
National Experts nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS Netherlands	Ctgb - NL
National Experts nominated by MS Poland	National Institute of Public Health - PL
External Expert	Vanessa Mazerolles - FR
Observer	Swiss Federal Office for the Environment - CH
Observers	Croatian Agency for Agriculture and Food - HR
Observer	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT



In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 (T-modality) Experts to discuss the overall ED assessment for the T-modality. Particular attention should be given to the available AMA with regards to: - The validity and reliability of the AMA study and its usability for the ED assessment considering also: • Concentration setting • Concentration analysis/verification • The control performance and the use of the HCD; - Interpretation of the results and overall conclusion of the assay. Experts may pay attention to any information that can be provided based on the mammalian dataset.	1. Expert discussed the biological results and interpretation of the available AMA, in relation to the poor performance of the control. When comparing the control replicates A, B vs. C, D, it was noted that replicates C, D had a significantly lower performance for the majority of the growth parameters and developmental stage. This low performance of replicates C, D was considered to impact the overall reliability of the study, and the exclusion of replicates C, D from the statistical analysis is considered to impact on the statistical power of the test. 2. Therefore, the majority of experts agreed that when considering the poor performance of the control in 50% of the replicates, it is not possible to use the AMA to reach a conclusion for the ED assessment on the T-modality. Open point The RMS to please reflect the outcome of the discussion in the revised RAR.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.5 (EAS modalities) Experts to discuss the overall ED assessment for the EAS modalities. Particular attention should be given to the available FSTRA with regards to: - The design of the study (setting of the concentrations, based on a decrease in fecundity in the two range-finding tests in the absence of signs of over toxicity); - The biological results of the FSTRA. Experts may pay attention to any potential for anti-androgenicity, if indicated for human health, and any other information that can be provided based on the mammalian dataset.	1. Expert discussed the appropriateness of the tested concentrations and the biological result of the available FSTRA. Two range finding tests were conducted. In both, strong to severe negative effects on fecundity were observed and used for the settings of the testing concentration in the definitive test. Expert disagreed with this approach, since an effect on fecundity could be triggered by an ED-MoA, and concluded that higher concentrations could have been tested. 2. Overall, based on the available information (i.e., in-vitro evidence suggesting a potential for an anti-androgenic (AA) MoA, effect observed on fecundity in the range-finding test, low concentration tested in the definitive test) and since the FSTRA may not be suitable to detect substances with potential AA MoA, all experts agreed that the available information is not sufficient to exclude potential ED effects of clomazone on NTOs. Further testing is needed (e.g., RADAR or another test in line with OECD GD 148) to clear off any potential concerns on the AA MoA. Open point The RMS to reflect the outcome of the discussion in the revised
Experts' consultation 5.6 Experts to discuss the impact of the newly submitted level 5 study according to OECD TG 416 on the selection of the ecotoxicologically relevant endpoint for wild mammals and as a consequence on the risk assessment.	1. The impact of the newly submitted 2-generation study with rats in the selection of the ecotoxicologically relevant endpoint was discussed. All available multigeneration and developmental studies were further considered. 2. Overall, the experts agreed that the previously selected endpoint of 84 mg/kg bw/d was not ecotoxicologically relevant since based on maternal toxicity likely caused by reduced food consumption. A NOAEL=100 mg/kg bw/d was selected based on decreased fetal weight and increase in skeletal malformations from one of the available developmental studies. Open point RMS to update the RAR and the LOEP with the newly agreed NOAEL of 100 mg/kg bw/day and revised risk assessment.
New experts' consultation point 5.7 proposed by EFSA for completeness of discussion	The meeting could not conclude on the overall safety of the two formulations used for the representative uses owing to 1. lack of long-term toxicity data towards some group of NTOs for the two formulations



Subject	Conclusions Pesticide Peer Review Meeting
MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	2. lack of any ecotoxicological and toxicological information on co-formulants present in non-negligible amount in the two formulations. Open point RMS to reflect on the outcome in the revised RAR.

REPORT OF PESTICIDES PEER REVIEW

TC 136 and TC 139

DIMETHACHLOR – AIR IV

Rapporteur Member State: HR

5. Ecotoxicology

Date: 6 June 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS HR	Croatian Agency for Agriculture and Food - HR
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety - AT
National Experts nominated by MS DE	Federal Environment Agency (UBA) - DE
National Expert nominated by MS DK	DEPA - DK
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS NL	Ctgb - NL
External Expert	Vanessa Mazerolles - FR
Observer	Agroscope - CH
Observers	Croatian Agency for Agriculture and Food - HR

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Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.1 Experts to discuss and agree on: - The selection of the representative focal species and its relevance for SEU and CEU. - The representativeness of the wood pigeon diet, indicated in the Northern GD, for SEU and CEU. - The acceptability of the new information provided by the applicant to refine the acute risk assessment for birds, and the related risk assessment conclusion. - The acceptability and use in the risk assessment of the new foliar residue decline study provide by the	It is agreed that a low acute risk for birds can be concluded for the intended uses for all EU regulatory zones. Overall, based on the discussion at the meeting on the focal species and the acceptable PD refinement, a low long-term risk can be concluded for birds for the Northern and Central EU regulatory zones. For the Southern EU regulatory zone, it is agreed to consider the available data in a weight-of-evidence. Based on the rapid degradation of the substance and extrapolation from the Northern and Central EU regulatory zones risk assessments, a low long-term risk can be concluded. Considering the information available on the degradation of the active substance, the experts reviewed the refinement proposed for the long-term risk for mammals. It is agreed that the same argumentation on the fast degradation observed should be considered and a low long-term risk can be concluded for mammals for the active substance. For the plant metabolite SYN550004, a low risk can be concluded for the lower application rate, while a high risk cannot be excluded for the higher application rate. Open point: RMS to: - reflect the outcome of the discussion in the revised RAR and LoEP. - clarify in the RAR that Cahier Agriculture Oiseaux is used mainly in France but for other countries but its use in other countries needs to be contextualized.



Subject	Conclusions Pesticides Peer Review Meeting
applicant, and the reliability of the DT50. • The PT refinement and its use for the risk assessment. • The conclusion for the long-term risk assessment.	- amend the risk assessment for mammals based on the agreed weight-of-evidence and present the risk assessment for the metabolite SYN550004
Experts' consultation 5.2 Expert to discuss the available studies on green algae, their reliability, and the endpoint to be used in the risk assessment.	The available toxicity studies on green algae and their reliability were discussed. Experts agreed since the validity criteria are not fulfilled, an endpoint cannot be derived from the study from Grade (1993). However, it can be used as supportive information to assess the sensitivity of algae species. Open point: RMS to remove this study in the list of endpoints, and to add a note in LoEP with regards to the algae species sensitivity to dimethachlor, i.e. <i>Anabaena flos aqua</i> is not the most sensitive algae species. EFSA to include in the conclusions section that <i>Anabaena flos aqua</i> is not the most sensitive species.
Experts' consultation 5.3 Expert to discuss, in relation to the risk assessment of dimethachlor for macrophyte: -The reliability of the endpoints in all the available studies -The endpoint to be used in the risk assessment -The need for additional Tier 1 data on a rooted macrophyte.	The available studies on Macrophytes and their endpoints were discussed. With regards to the study [REDACTED], from which the endpoint is currently used in the risk assessment, it was agreed that the study should be considered valid as the validity criteria are fulfilled. However, given the wide confidence interval, the endpoint calculated is not reliable. Therefore, all the experts agreed to set the endpoint based on visual effect, i.e. ErC50 > 16 µg/L. Experts agreed that this endpoint can be used in the risk assessment. Regarding the need for an additional Tier 1 data on a rooted macrophyte, experts acknowledge that such a study could be justified for calibration purposes between data from Tier 1 and Tier 3. However, as the risk is driven by the algae, the majority of the expert agreed that a new study on rooted macrophytes is not needed. Open point:



Subject	Conclusions Pesticides Peer Review Meeting
	- RMS to check the statistical model fitness for both active substance and product studies and update the RAR, if necessary. - RMS to update the RAR reflecting the discussion above
Experts' consultation 5.4 Expert to discuss the Microcosm studies [REDACTED] 2011; K-CP 10.2.3/01; and [REDACTED] 2011-K-CP 10.2.3/03) and in particular: The reliability of the studies, considering: - the timing of sampling - the period at which the test was conducted - the effect observed in the algal species <i>Ankistrodesmus spiralis</i> - the number and abundances of sensitives species - the endpoint derived from these studies - the FOCUS profile comparison submitted for the microcosm studies, if any. In addition, expert should also discuss their potential use in the risk assessment, if relevant.	The two mesocosms studies were discussed by the experts. [REDACTED] 2011 Sine the period during which the study was performed should also take into consideration the growing period of the plants, in order to be able to see a potential effect, the study is still considered relevant; however, since this might overestimate the recovery, this should be taken into consideration when deciding on the assessment factors. With regards to the sampling times, considering the physico-chemical properties of dimethachlor, it was considered unlikely that recovery following an acute effect at an early date would have been missed. <u>Algae</u> Based on the biological results, experts confirmed that no ETO-RAC can be derived for algae; only an ERO-RAC can be derived, and agreed that the endpoint derived from this study would be an overall NOEAEC for algae of 4.5 µg a.s./L. <u>Macrophytes</u> Regarding macrophytes, based on the effect observed on Elodea experts agreed to a NOEC of 4.5 µg a.s./L and a NOEAEC of 26.8 µg a.s./L. <u>Assessment factor</u> Experts agreed on an AF of 4 to take into consideration the potential overestimation of the recovery, to be applied to the NOEAEC of 4.5 µg a.s./L, for deriving a single ERO-RAC. Open point: - RMS to double-check that the RAR always refers to NOEAEC whenever the endpoint is based on recovery. - RMS to update the RAR and align the content of the table on macrophyte effects with the text summarising this table. - RMS to update the RAR reflecting the above discussion on the mesocosm study from [REDACTED] 2011 and to include relevant graphs to support the discussion.



Subject	Conclusions Pesticides Peer Review Meeting
	2011 Experts agreed that the experimental set up, the selection of species and the timing of the study is adequate. Macrophytes: After discussion of the biological results, experts agreed with the proposed NOEC of 10 µg a.s./L, based on the effects observed in <i>Myosotis palustris</i>, and that a NOEAEC could not be set for macrophytes. Phytoplankton: It was agreed that a NOEC could not be set for phytoplankton based on the data available. Based on the data from <i>Ankistrodesmus</i> sp, a NOEAEC of 3 µg a.s./L could be set for this species. Also, the effects observed for <i>Monoraphidium contortum</i> were discussed and experts agree that a 3A effect is observed at 1 µg a.s./L and should be reported in the table. Overall, experts agreed that a NOEAEC for phytoplankton can be set at 3 µg a.s./L. Zooplankton: All experts agreed that a NOEC of 1 µg a.s./l and a NOEAEC at 10 µg a.s./L could be set, based on the data from <i>Lecane gr Luna</i> and <i>Cyclopoida</i> Assessment factor: Experts considered that for this mesocosm study an AF of 4 is justified in view of the timing when the study was performed, and the related uncertainty on recovery. It should be applied to the NOEAEC of 3 µg a.s./L for the phytoplankton. An AF of 2 for deriving an ETO-RAC is proposed for the zooplankton endpoint. Open point: - RMS to correct the title of the table and graph in the RAR that it corresponds to Table 20 of the study report (macrophytes). - RMS to double check the data reported for <i>Cyclopoida</i> to ensure there are no discrepancies between the tables and plots. - RMS to reflect the conclusion on the mesocosm study from 2011, and update the RAR accordingly. Use in the risk assessment: Since the FOCUS profile comparison is missing, these studies and the derived ERO-RAC cannot be used to refine the RA. Open point: RMS to reflect the conclusion and update the RAR accordingly.



Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.5 Experts from MSs to discuss and agree, - whether indeed no further evaluation of the effects on honey bee development and other honey bee life stages is considered necessary and whether the risk can be considered as low without those data, - whether it is agreed that the available risk assessments and the available evidence in relation to the refinement of the risk identified at Tier 1 (chronic assessment for adult bees of the post-emergent uses) and for the metabolites are sufficient for a low risk conclusion.	As regards the chronic study available for adults, some uncertainties were noted during the meeting. While the study and the related endpoint is still accepted, the following open point was set: Open points: - RMS to flag the uncertainty related to the evaporation in a footnote in the LoEP and further explain this in the revised RAR. - RMS to reflect the outcome of the expert's consultation in the revised RAR. As regards the larval study, again some uncertainties were noted and the experts agreed that while the endpoint can be included in the LoEP, no quantitative risk assessments should be kept using these data, since the study was stopped at day 8, thus does not cover the full brood cycle. The following open point was set: Open point: - RMS to reflect the outcome of the discussion in the revised RAR. - RMS to include in a footnote in the LoEP that food remained and not consumed in the 8-d study was observed. To support the risk assessment, a useful study measuring residues in pollen and nectar after the application of the formulation representing the GAP was available. This study was considered to be able to address the identified concerns at tier 1 for the treated crop scenario (and for the succeeding crop scenario for the metabolite), but not for the weed scenario. The following open point was set: Open point: - RMS to further elaborate in the revised RAR in Vol 3 B.9 CP the residue study – information on location, climatic conditions, application methods, sampling time, etc shall be provided in the summary in the ecotox section. - RMS to perform the tier 1 calculations for the metabolites and include them in the revised RAR. - RMS to correct the typos about the BB risk assessment and SUW vs DW as indicated above. - RMS to reflect the outcome of the discussion in the revised RAR.



Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 5.6 Experts to agree on: - the use of the existing toxicity data package for earthworms and other soil organisms based on the available data with the substance/formulation for representative uses; - if available, the acceptability of new data and studies; - the risk assessment for earthworms and other soil organisms.	<u>Existing data package</u> Although having a study with the active substance dimethachlor could have been useful for having the full ecotoxicological profile of the a.s., also taking into the uncertainty identified in the available studies, the majority of experts agreed that data with dimethachlor are not strictly needed for the risk assessment. <u>Earthworm study</u> The majority of the experts agreed to set the NOEC at 10.8 mg/kg considering the lack of dose response, lack of statistical significance and the fact that, at concentrations higher than 10.8 mg/kg, a reduction >10% was observed. Open point RMS to amend the RAR by correcting the study summary with the correct tested concentrations and to amend the risk assessment using the agreed endpoint. <u>Collembola study</u> The experts agreed that a reliable endpoint could not be derived from the Collembola study with the representative formulation considering the lack of dose response, the % reduction compared to control and the % mortality observed in some of the treatment groups at low concentrations. Open point RMS to revise the RAR and LoEP by deleting the risk assessment for Collembola as no reliable endpoint could be derived. <u>Hypoaspis aculeifer study</u> The experts agreed to use a NOEC of 309 mg/kg for the risk assessment since the EC₁₀ was considered not reliable as no confidence limits could be estimated. Open point RMS to update the risk assessment by using a NOEC of 309 mg/kg in the risk assessment.
Experts' consultation 5.7 Experts to agree on the metabolite's toxicity data package for earthworms and other soil organisms. In particular, experts should	All studies with soil organisms and metabolites were considered valid by the experts as no major limitations were identified and all validity criteria were met. The endpoints from all studies were discussed by the experts. Reliable endpoints from the following studies could not be derived due to consistent biological relevant effects observed at most concentrations, including at the lowest one:



Subject	Conclusions Pesticides Peer Review Meeting
agree on the use of the the available data and further new data and information provided by the applicant and agree on the risk assessment for earthworms and other soil organisms.	- Earthworm study with metabolite CGA50266; - <i>Hypoaspis aculeifer</i> study with metabolite CGA369873 - <i>H. aculeifer</i> study with metabolite CGA50266 - <i>H. aculeifer</i> study with metabolite CGA102935. For the rest of the studies, NOEC or EC₁₀ values were agreed by the experts after considering whether a clear dose-response relationship was observed as well and the biological and or statistical significance of the effects reported. Open points RMS to update the risk assessment for the relevant soil metabolites for all representative uses of dimethachlor with the agreed endpoints for the metabolites and considering the latest agreed PECs from the fate section. For the relevant metabolites for which no endpoint could be derived, to carry out the risk assessment with the endpoint from the representative formulation studies, expressed in active substance, divided by 10.
Experts' consultation 5.8 Experts' from MSs to discuss and agree: - whether the deviations from the TGs in the study conditions are considered to have minor influence on the results of the vegetative vigour and seedling emergence tests with the representative formulation - the endpoints to be considered for the risk assessment - and/or whether further data are considered to be required - whether the conclusion regarding the risk for the	The experts considered the deviations from the test guidelines as minor, therefore considered that the available endpoints from the studies are appropriate to be used in the risk assessment. Open point: RMS to update the RAR reflecting the discussion and conclusions of the meeting.



Subject	Conclusions Pesticides Peer Review Meeting
metabolites is agreed.	
Experts' consultation 5.9 Experts to discuss endocrine disruption criteria for non-target organisms following ED ECHA/EFSA Guidance (2018) and considering new studies conducted by the applicant.	The RMS agreed with the applicant to conduct the following <i>In vivo</i> mechanistic studies: • 21-day fish screening assay (OECD 230) in the Fathead minnow (EAS modalities). • Amphibian Metamorphosis Assay (OECD 231) (T modality). The experts agreed with the AMA, although a XETA could also be a suitable option since there is no indication of endocrine activity and/or adversity in the mammalian dataset. Considering the positive evidence for activity through the E-modality, all experts agreed that a FSTRA, that includes the assessment of reproduction, should be performed instead of the 21-d screening assay. Gonad histopathology should also be assessed. Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation point 2.2 (Confidential) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the composition of the formulation for representative use, the data available for the formulation and for the co-formulants. The experts agreed that the formulated product was sufficiently characterised and no concerns were raised. Open point: RMS to include the information gathered on the individual co-formulants in the updated Vol. 4 of the DAR.

Pesticides Peer Review TC 136 / TC 139
Halosulfuron-methyl

REPORT OF PESTICIDES PEER REVIEW TC 136 / TC 139

HALOSULFURON-METHYL – AIR V

Rapporteur Member State: IT

5. Ecotoxicology

Date: 6 June 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMSs Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) -IT
National Experts nominated by MSs Austria	AGES, Austrian Agency for Health and Food Safety GmbH - AT
National Experts nominated by MS Croatia	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS Denmark	Danish Environmental Protection Agency- DK
National Experts nominated by MSs France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MSs Germany	Federal Environment Agency, Julius Kühn Institute, Institute for Bee Protection - DE
National Experts nominated by MSs Netherlands	Ctgb - NL
External Experts	Vanessa Mazzerolles - FR
Observers	Croatian Agency for Agriculture and Food, Center for Plant Protection - HR
Observers	Agroscope - CH

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticides Peer Review Meeting
Expert consultation 5.1 Experts to discuss and agree on the most appropriate endpoint for wild mammals.	The experts discussed the available data and assessment provided by the Applicant. Based on the clarification and explanation of the RMS the experts agreed with their proposed endpoint for the long-term assessment of wild mammals. A NOAEL of 6.3 mg a.s./kg bw day was agreed to be the appropriate endpoint for the long-term assessment of wild mammals. Open point RMS to reflect the discussion of the meeting and to ensure consistency in B.9 and B.6 section of the RAR regarding body weight gain in rat multi generation study.
Expert consultation 5.2 Experts to discuss the issue with solubility in the aquatic toxicity studies.	The experts discussed the issues with the solubility and agreed with the additional explanations of the RMS. None of the aquatic toxicity studies were considered unreliable for the reasons of solubility.
Expert consultation 5.3 Experts to discuss the validity and reliability of the ELS study of Graves, M. A., Mank, M. A., and Swigert, J. P, 1993, CA 8.2.2.1/01. In particular, the deviations on the solvent concentration and	The experts discussed the reliability of the study and whether the deviations noted should be considered as minor. The experts agreed that the study was sufficiently reliable and the deviations should be considered as minor. However, the experts agreed that the endpoint should be expressed without correction for the recovery in the chemical analysis nor the purity. Open points



Subject	Conclusions Pesticides Peer Review Meeting
temperature and the final endpoint should be discussed.	- RMS to reflect the outcome of the discussion regarding the reliability of the study. - RMS to recalculate the NOEC value without the correction for purity and update the RAR and LoEP. - RMS to update the RA (for all aquatic organisms) based on the newly available PEC values once available.
Expert consultation 5.4 Experts to discuss the endpoint from the Development and emergence in <i>Chironomus riparius</i>, Cockcroft, R., 2005, CA 8.2.5.4/01.	The experts agreed that the study (CA 8.2.5.4/01) should be considered as supportive information only. Open points RMS to reflect the outcome of the discussion and in particular the WoE approach used for the consideration of the relative toxicity of aquatic invertebrates and algae/aquatic plants. RMS to include a NOEC of 0.98 mg a.s./L and the NOEC <6.9 mg a.s./L in the LoEP for aquatic invertebrates in the LoEP with a clear footnote to explain that the endpoint of 0.98 mg a.s./L is not fully reliable, but has been maintained to consider the chronic toxicity to aquatic invertebrates relative to algae and aquatic plants. The endpoint for <i>Chironomus</i> should be removed from the LoEP. RMS should also reflect the outcome of the discussion regarding the reliability of the endpoint from the <i>Chironomus</i> study.
Expert consultation 5.5 Experts to discuss and agree whether the applicant has addressed the requirement for toxicity data on a second algae species.	The experts agreed with the RMS's evaluation of the algae studies and that data are needed for a second species.
Expert consultation 5.6 Experts to discuss the newly available information for addressing the toxicity to <i>Myriophyllum</i> species. Experts may also consider the RMS's assessment of the reliability of the study of CP 10.2.1/06, Jenkins (2006).	Overall, the experts agreed with the assessment of the RMS and their conclusion for the need for a rooted <i>Myriophyllum</i> study.
Expert consultation 5.7	The experts discussed the available aquatic toxicity studies and risk assessment. However, owing to the lack of an agreed exposure assessment the risk assessment could not be discussed.



Subject	Conclusions Pesticides Peer Review Meeting
Experts to discuss the available aquatic toxicity data and risk assessment. In particular, the following points should be covered, but additional ones may also be identified pending on the newly available information: i) Reliability of toxicity studies where there is disagreement between the RMS, MS and Applicant. ii) Completeness of the toxicity data package for the parent, metabolites and formulated product. iii) The studies in the presence of sediment. iv) The results of the field study performed in rice fields Gray, 2005 CP 10.2.3/01.	The experts agreed with the assessment of the RMS regarding the reliability of the aquatic toxicity studies and the completeness of the data package. Data gaps are identified. Open points i) RMS to provide an illustrative risk assessment for aquatic plants in the RAR to understand if a high risk would be indicated. Such assessment should not be included in the list of endpoints. ii) RMS to reflect the outcome of the discussion in the RAR and in particular the conclusion that the study (CP 10.2.3/01) has too many uncertainties even to be considered as supportive information for in-field assessment. iii) RMS to update the AQ RA using the newly available PEC values. iv) RMS to update the risk assessment for metabolites using the newly available PEC values once available.
Expert consultation 5.8 Pending the information submitted by the applicant, experts to discuss the available toxicity data and the risk assessment for honey bees.	The experts discussed the assessment of the RMS regarding the reliability of the available bee studies. The experts agreed with the assessment of the RMS. Data gaps are identified. Open points i) RMS to assess that the purity was taken into consideration only once and not twice. This point concerns all endpoints where there was correction. ii) RMS to check the outcome of the residue's experts meeting and update the RAR accordingly for plant metabolites. iii) RMS to reflect the discussion regarding the available bee studies and risk assessment in the RAR.
Expert consultation 5.9 Experts to discuss and agree the endpoint from the earthworm reproduction study by Rodgers, 2008 (CA 8.4.1/01).	The experts agreed with the NOEC of 62.5 mg a.s./kg soil dw as the relevant endpoint for risk assessment.



Subject	Conclusions Pesticides Peer Review Meeting
Expert consultation 5.10 Experts to discuss the newly available assessment for earthworms and other soil macro-organisms and agree on the outcome.	No new toxicity data were provided by the Applicant. For all, but one metabolite, no risk assessment for soil organisms was available owing to the lack of an exposure assessment. Open points i) RMS to calculate initial PECsoil values for halosulfuron-methyl and its major metabolites based on the agreed endpoints. ii) RMS to correct the endpoint by a factor 2 if the Log Kow is above 2. iii) RMS to reflect the argumentation and discussion regarding the need for a chronic earthworm toxicity study with the formulated product in the RAR.
Expert consultation 5.11 Experts to discuss the available information and risk assessment for NTTP.	Overall, the risk assessment for non-target plants was not considered sufficient, due to the remaining concerns related to the low reliability of the available studies with the active substance, the lack of reliable endpoints based on phytotoxicity and, in particular, the lack of seedling emergence and vegetative vigour studies with the formulation. The experts agreed on setting a data gap for seedling emergence and vegetative vigour studies with the formulation Halosulfuron-methyl 75WG. Open point RMS to reflect this in the discussion and update the RAR accordingly.
Expert consultation 5.12 A discussion with experts on wild mammals might be needed, pending on the human toxicological conclusion.	ED criteria are not met for humans for the T-modality and as such the same conclusion can be reached for wild mammals. A conclusion on the EAS-modalities could not be reached for humans since the data package is not complet, therefore no conclusion is possible for the wild mammals either. Open point RMS to reflect the outcome of the discussion in the revised RAR.
Expert consultation 5.13 Expert to discuss the validity of the XETA.	The reliability of the available XETA was discussed. Since several limitation were identified, all experts agreed that the study should not be considered as formally valid. However, after analysing the limitation and all the data available, all experts agreed that no concern were identified over the ED potential of halosulfuron-methyl for NTOs. Open point



Subject	Conclusions Pesticides Peer Review Meeting
	RMS to reflect the outcome of the discussion in the revised RAR.
Expert consultation 1.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the available information on the representative formulation and co-formulants. Noting that several data gaps have been identified in the RAR, the experts agreed that there were no additional concerns related to the safety of the formulation. Open point RMS to reflect the outcome of the discussion in the revised RAR.

13-17 and 22 May 2024

MINUTES

Pesticides Peer Review TC 136
Spinosad

REPORT OF PESTICIDES PEER REVIEW TC136

SPINOSAD – AIR III, re-assessment of ED following mandate SANTE after ED clock-stop

Rapporteur Member State: NL

5. Ecotoxicology

Date: 22 May 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS Netherlands	Ctgb - NL
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS Croatia	Croatian Agency for Agriculture and Food; Institute for Medical Research and Occupational Health - HR
National Expert nominated by MS Czechia	National Institute of Public Health - CZ
National Expert nominated by MS Denmark	Danish Environmental Protection Agency - DK
National Experts nominated by MS France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Expert nominated by MS Germany	Federal Environmental Agency (UBA); German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS Hungary	National Food Chain Safety Office - HU
National Experts nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS Poland	National Institute of Public Health - PL
Observer	Swiss Federal Office for the Environment - CH
Observers	Croatian Agency for Agriculture and Food - HR
Observer	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT



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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.5 Experts to discuss the available information relevant to the ED assessment for the T-modality of Spinosad for NTOs. Results of the AMA study will be further discussed, where effects are observed at the highest treatment (i.e., 0.72 mg/L a.i.,) on endpoints such as delay in developmental stage, growth parameters (i.e., decrease in normalized hind limb length, snout to vent length and wet weight), and change in thyroid histopathology (i.e., decreased follicular cell	1. For the ED assessment for NTOs of Spinosad for the T-modality, an Amphibian Metamorphosis Assay (OECD 231) was available. The available AMA was considered valid. 2. Spinosad is not considered to meet the ED criteria through EATS-modalities for humans and this also applies to wild mammals. For the other NTOs, experts agreed that the pattern of effects observed at the highest treatment does not follow any known Thyroidal MoA (i.e., antagonist vs. agonist). The effects observed are more likely due to systemic toxicity/intrinsic MoA of the substance as showed by reduced food consumption and reduced body weight.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Subject	Conclusions Pesticide Peer Review Meeting
hypertrophy and hyperplasia). Please also note that further discussions on the population relevance for wild mammals might be needed, based on the outcome of the toxicology discussions for the T-modality.	
Experts' consultation 5.6 Experts to discuss the available information relevant to the ED assessment for the EAS-modalities of Spinosad for NTOs (e.g., FFLC, FSTRA). Results observed in the available FSTRA study will be further discussed (i.e., decrease in fertility and effects on POF in female gonad histopathology). Particular attention will be dedicated to the following points: • Appropriateness of the selection of the testing concentrations considering the effects observed on available studies on fish, and the outcome of the preliminary range-finding test. • Impact of the exceedance from $\pm 20\%$ of the mean measured values of the active substance at the lowest treatment on the overall validity of the study. • Impact of the observed mortality (i.e., $> 10\%$) in the solvent control on the overall validity of the study.	1. For the ED assessment for NTOs of Spinosad for the EAS-modalities, a Fish Short Term Reproductive Assay (OECD 229) was available. Although some minor deviations from the validity criteria of OECD TG 229 were identified, together with other concerns on the VTG methodology and the control under-performance for the fecundity, the FSTRA was considered valid and sufficiently reliable. 2. Spinosad is not considered to meet the ED criteria for humas through EAS-modalities. The Steroidogenesis assay was discussed and considered negative. The same conclusion applies to wild mammals. For the other NTOs, experts agreed that, although some uncertainties were identified, when considered the available data and weight of evidence, the experts considered the FSTRA as negative.



Subject	Conclusions Pesticide Peer Review Meeting
• Consideration of results from available <i>in vitro</i> test (i.e., steroidogenesis assay). Please note that such results will be further discussed in the toxicology area. Please also note that further discussions on the population relevance for wild mammals might be needed, based on the outcome of the toxicology discussions for the EAS-modalities.	

REPORT OF PESTICIDES PEER REVIEW TC 131

PHOSPHINE – AIR V

Rapporteur Member State: ES

5. Ecotoxicology

Date: 11 March 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS ES	National Institute for Agricultural and Food Research and Technology (INIA-CSIC) - ES
National Experts nominated by RMS ES	Ministerio de Sanidad - ES
National Experts nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	German Federal Institute for Risk Assessment (Bfr) - DE
National Expert nominated by MS DE	Federal Environmental Agency (UBA) - DE
National Experts nominated by MS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS NL	Ctgb - NL
National Expert nominated by MS PL	Ministry of Agriculture and Rural Development - PL
National Experts nominated by MS SE	Swedish Chemicals Agency (KEMI) - SE
Observer	Federal Food Safety and Veterinary Office - CH
Observer	Swiss Federal Office for the Environment - CH
Observer	Swedish Chemicals Agency (KEMI) - SE



In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticides Peer Review Meeting
Expert consultation 5.1 Experts to discuss endocrine disruption properties of phosphine on NTOs.	The information presented to support the potential waiver of the ED assessment of phosphine for NTOs, proposed in line with the ECHA/EFSA Guidance 2018 (i.e., an ED assessment may be not scientifically justified, e.g., based on the phys-chem properties or testing is not technically feasible) was discussed among the experts. Considering i) the physchem-properties and the high toxicity of phosphine against vertebrates, ii) the available toxicity data on fish, iii) the technical challenges of testing either gaseous phosphine (no sealing options in available TGs), or metal phosphides (concentrations would be very low or above the MTC considering 1/3 or 1/10 of the available acute fish LC₅₀ as the MTC) in water, and iv) the conclusions reached for the ED assessment for mammals, experts agreed to waive the ED assessment of phosphine for NTOs. Conclusion All the experts supported the waiver for a full ED assessment of phosphine for EATS-modalities. Open point RMS to report the outcome of the discussion in the revised RAR. RMS to align the outcome of this meeting to the Peer Review experts' meeting TC 134 as needed.

REPORT OF PESTICIDES PEER REVIEW TC 131/TC 134

PIRIMICARB - AIRIII

Rapporteur Member State: SE

5. Ecotoxicology

Date: 14 March 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Expert nominated by RMS Sweden	Swedish Chemicals Agency – SE
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS Croatia	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	Federal Environment Agency and German Federal Institute for Risk Assessment - DE
National Expert nominated by MS Greece	Benaki Phytopathological Institute - GR
National Experts nominated by MS Netherlands	Ctgb - NL
National Expert nominated by MS Poland	E-V-A Sp. z o.o. and Ministry of Agriculture and Rural Development - PL
National Expert nominated by MS Slovenia	National Institute of Public Health - SI
National Experts nominated by MS Spain	Ministry of Health, National Institute for Agricultural and Food Research and Technology (INIA-CSIC) – ES
Observer	Agroscope – CH
Observer	BAFU - CH
Observer	Benaki Phytopathological Institute - GR
Observer	Federal Food Safety and Veterinary Office - CH
Observer	Swedish Chemicals Agency - SE
Observer	Swiss Federal Office for the Environment - CH



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Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.9 Experts to discuss the impact of the newly submitted 2 generation study according to OECD TG 416 in the selection of the long-term endpoint for mammals.	1. Experts discussed the impact of the new 2 generation study in rats following the OECD TG 416, on the selection of the long-term endpoint for mammals risk assessment. 2. The experts agreed that the endpoints from the newly available 2 generation study in rats did not affect the previously agreed endpoint for the assessment of wild mammals. Open point RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.10 Experts to discuss the available 21-d study with	1. The experts discussed the available evidence for concluding on the endocrine disrupting properties of pirimicarb through EAS-modalities. The conclusion for humans, the available <i>in vitro</i> evidence for EAS-modalities and the results of the available 21

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Subject	Conclusions Pesticide Peer Review Meeting
fish, the findings and the conclusion that can be drawn from that study and in general of the ED properties of pirimicarb through EAS-modalities. This should also include consideration on the <i>in vitro</i> findings and weight of evidence.	screening assay with fish were considered as part of the weight of evidence. 2. Conclusion Overall, when considering that i) there are some positive <i>in vitro</i> evidence in HTRA (OECD 458) and H295R (OECD 456) (see also TC 131 toxicology) and ii) the available 21-d screening assay (OECD 230) was deemed as not sufficient to exclude/confirm the concerns identified in the level 2 studies due to decrease in VTG in females and several limitations identified by the experts, (animals much older than the suggested age of the OECD TG 230; poor performance of the control in terms of spawning, higher incidence of change in control ovary histopathology than treatments), all the experts agreed that the level of uncertainty is too high to firmly conclude on the EAS-modalities for non-mammalian species. Open point The RMS to reflect the conclusion for the ED assessment of pirimicarb for non-mammalian species for EAS-modalities and to report the conclusion for the EAST-modalities for wild mammals in a revised RAR. The RMS to reflect the outcome of the meeting in the revised RAR and the uncertainty analysis.
Experts' consultation 5.11 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Overall conclusion: experts considered that data retrieval exercise has not been conducted comprehensively. Furthermore, considering the toxicity profile, the experts agreed that there is a concern related to the lack of data for birds, which should be acknowledged in the EFSA conclusion. For aquatic organisms, no additional concerns were raised related to the co-formulants, especially considering the relatively high toxicity of the active substance itself. For other groups of NTOs, sufficient formulation data were available. Open point – RMS to update Vol 4 with information from REACH dossier to make reference and update information on a co-formulant, to confirm that it will not impact on the aquatic toxicity endpoints.

Pesticides Peer Review TC 131/134

Proquinazid

REPORT OF PESTICIDES PEER REVIEW TC 131/134

PROQUINAZID – AIR IV

Rapporteur Member State: SE

5. Ecotoxicology

Date: 14 March 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS Sweden	Swedish Chemicals Agency - SE
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS Croatia	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS Estonia	Agriculture and Food Board - EE
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Federal Institute for Risk Assessment and Federal Environmental Agency (UBA)- DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute - GR
National Experts nominated by MS Slovenia	National Institute of Public Health - SI
National Experts nominated by MS Spain	Ministerio de Sanidad - ES
National Experts nominated by MS Netherlands	Ctgb - NL
National Experts nominated by MS Poland	E-V-A Sp. z o.o. and Ministry of Agriculture and Rural Development - PL
Hearing Expert	Gretchen Ritacco - USA
Observers	Agroscope, BAFU and Federal Food Safety and Veterinary Office - CH
Observers	Estonian Agriculture and Food Board – EE
Observer	Benaki Phytopathological Institute - GR
Observer	Ctgb -NL
Observers	Ministry of Agriculture and Rural Development in Warsaw, Poland - PL
Observer	Swedish Chemicals Agency - SE



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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation (ecotoxicity section) 0.2 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed whether the available information on co-formulants is sufficient for characterising adequately the ecotoxicological risk of the formulation/s for all representative use/s, regarding acute and chronic toxicity. The experts concluded that the assessment by the applicant is insufficient and that a more comprehensive search of information on the ecotoxicity of the co-formulants is missing. However, for birds and mammals, based on the information available, no concern is raised for the assessment of this PPP. For aquatic organisms a concern was identified for the chronic assessment of the representative formulation. For all groups of non-target organisms other than aquatic and terrestrial vertebrates, sufficient toxicity data with the formulation was available and the available risk assessment was considered to cover the toxicity of the formulation. Open point RMS to reflect the outcome of the discussion in the RAR.
Experts' consultation 5.1	The majority of the experts agreed to set the long-term endpoint for mammals at 2.5 mg/kg bw/day considering that

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss the reproductive endpoint for mammals.	there was a 9% statistically significant effect on fetal pup weight at 5 mg/kg bw/day. The experts acknowledged that this endpoint was conservative considering that the effects were <10%. However, since a BMD calculation was not available and the applicant proposed to set the NOAEL at 2.5 mg/kg bw/ day, the experts considered this endpoint to be appropriate. Open point RMS to reflect the outcome of the discussion in the updated RAR.
Experts' consultation 5.2 Experts to discuss the refine risk assessment for mammals. The following refinement RMS: options should be discussed: (i) The relevance and reliability of the residue decline studies with proquinazid and cereals, the resulting DT₅₀ and their use to refine the risk assessment for mammals; (ii) Multiple application refinement; (iii) Refinement of exposure resulting from crop interception (iv) Refinement of exposure based on agronomic practices in vineyards, in case the applicant provide any evidence as required in 5(41).	<u>Refinement of DT₅₀ from residue decline trials and multiple application refinement</u> Due to the fact that there was an insufficient number of reliable sampling points in the residue decline trials and that the samplings that did not cover the critical time period, it was concluded that a reliable DT₅₀ could not be derived from the residue decline trials. Overall, the experts considered that the default DT₅₀ of 10 days should be used for the risk assessment, but the experts acknowledged that the data provided by the applicant suggested that this value was conservative. Therefore, no refined fTWA or refined MAF value could be applied to the risk assessment. <u>Refinement of exposure resulting from crop interception</u> For cereals, the majority experts agreed on using a deposition factor of 0.1. For vineyards, the experts agreed on using the FOCUSgw deposition value of 0.5 for BBCH 10-19 and a deposition factor of 0.4 for BBCH 20-39. <u>Refinement of exposure based on agronomic practices in vineyards</u> The experts did not agree with the applicant about their qualitative arguments that the common vole will not be present in cereals. whether a mixed diet would be reasonable for the common vole. Overall, the experts agreed that a mixed diet is reasonable, but it would depend on the availability of monocots and dicots. For vineyards it was suggested a diet of 80:20 monocot:dicot plants. For cereals, the experts considered that a ratio of 75:25 monocots:dicots would be reasonable based on previous discussions for other active substances. Open points RMS to update the risk assessment for small herbivorous mammals by (i) using the PD values for the common vole, (ii) removing the refinement of fTWA, and (iii) applying the refined interception values. RMS to ensure that a single application rate is presented in the risk assessment.
Experts' consultation 5.3 Experts to discuss the reproductive endpoint for birds	EFSA re-evaluated the data from the <i>Colinus virginianus</i> ([REDACTED] 1998) using the EFSA BMD tool to derive a BMD₁₀ value for 14-day old survivors/female.



Subject	Conclusions Pesticide Peer Review Meeting
from the study by [REDACTED] (1998b).	Considering the fact that the BMDL is 6.5 mg a.s./kg bw/day, and that the data shows a high degree of variability, the experts considered that the BMD analysis with the EFSA BMD tool could be used to support original NOEL of 7.7 mg a.s./kg bw/day for this endpoint. Open point RMS to include the EFSA BMD calculation in the RAR and reflect the outcome of the discussion related to the selection of the endpoint for this study ([REDACTED] 1998).
Experts' consultation 5.4 Experts to discuss the updated risk assessment for aquatic organisms for the active substance and the relevant metabolites. The experts should consider: (i) The updated risk assessment presented by the applicant based on submitted by the applicant; and (iii) The updated risk assessment presented by the applicant based on new PEC_{sw} and PEC_{sed} updated risk assessment for metabolites.	The newly submitted algal studies with metabolites IN-MM986 (Study ID: 221337) and IN-MM991 (Study ID 221338) as well as the studies with <i>Daphnia magna</i> (Study ID: 211087) and <i>Lumbriculus variegatus</i> using spiked sediment (Study ID: 211160) were considered valid. The aquatic risk assessment will need to be updated once definitive PEC_{sw} and PEC sediment values are available. The aquatic risk assessment for metabolites will follow the recommendations of the EFSA (2013) aquatic guidance document. Open points - RMS to update the risk assessment for the sediment-dwelling organisms for the metabolite IN-MM671, and for all metabolites that are triggered (IN-MM986 and IN-MM991, IN-MT884) and the same RAC value could be used as for the metabolite IN-MM671. RMS to update the aquatic risk assessment using the exposure estimates to be calculated following the environmental fate experts meeting.
Experts' consultation 5.5 Experts to discuss the need for a fish full life cycle study to address the data requirements. The experts should consider the bioaccumulation potential of proquinazid, the available studies with fish and the new irradiated water-sediment study [refer to data requirement in 4(79)].	The experts considered that the information in the EFSA (2013) aquatic guidance document regarding the criteria to submit a fish full life cycle (FFLC) test may be difficult to interpret as written. During the meeting, the experts concluded that both criteria need to be met, i.e., bioaccumulation and persistence, in order to trigger the need for a FFLC study. Since the trigger value related to the bioconcentration factor (>1000) is not fulfilled for proquinazid, a FFLC cycle study should not be required for this substance. Open point RMS to update the RAR with the outcome of this discussion. No data gap is needed for a FFLC.
Experts' consultation 5.6 Experts to discuss the risk assessment for non-target terrestrial plants. In particular the experts should discuss:	<u>Screening study (DuPont-12084)</u> The experts at the meeting agreed that, while the study presented several limitations, the study could still be used for the risk assessment of non-target terrestrial plants considering that it was a screening study. New seedling emergence and vegetative vigour studies (220472 and 220473)



Subject	Conclusions Pesticide Peer Review Meeting
(i) The validity of the screening study by (DuPont-12084) to address the data requirements considering the potential limitations identified in the RMS evaluation; (ii) Any studies to be submitted by the applicant related to the data requirement in 5(136); (iii) The risk assessment for non-target terrestrial plants considering all available data.	It was noted that both new studies were conducted with a formulation (GF-3881) different than the representative one and that the full composition for this formulation was not available. <u>Without any information on the composition of the tested formulation</u>, the experts concluded that it was not possible to make a direct extrapolation to the representative product. While it was not demonstrated that both formulations were comparable, the results from the two new studies did not raise any concern. The experts considered that the studies could still be used within a weight of evidence approach. <u>The risk assessment for non-target terrestrial plants considering all available data</u> The experts considered that a quantitative risk assessment using the endpoints derived from the studies with formulation GF-3881 was not needed. Open points - RMS to reflect on the outcome of this discussion, specifically related to the reliability of Tier1 screening assessment and additional information coming from the studies performed with the studies done with GF-3881. RMS to remove the quantitative tier 2 risk assessment using the data with GF-3881 from the RAR and LoEP.
Experts' consultation 5.7 Experts to discuss: - the concentration setting in the AMA. - the AMA results, considering the updated statistical analysis.	Population relevance for wild mammals In the two 2-generation studies available, effect on thyroid histopathology were observed at and above 150 ppm and effect on food consumptions and body weight were reported at and above 300 ppm. Effects on number of implantation sites/female in F1 generation, pup viability (0-4) and born alive in the F2 generation, as well as a reduction in pup body weight in F1 and F2 were also observed at 600 ppm in one of the studies only. In the developmental studies in rat and rabbit, effect on fetal body weight were reported, however at doses at which maternal toxicity was also observed. Overall, considering that: -the effects observed on pups' body weight in several studies are most likely related to the consequence of maternal toxicity, -the effects on pups body weight reported in rabbit are observed at a dose lower than the dose at which effects on thyroid are observed in the two-generation studies on rats; and no dose-concordance with the effects on thyroid can be established, -thyroid effects in rat are reproducible across generational studies, however the effects on reproduction and development are not, indicating that those effects are not linked to the thyroidal MoA.



Subject	Conclusions Pesticide Peer Review Meeting
	All the experts concluded that the effects observed are likely due to maternal toxicity rather than to a thyroidal MoA, and no population relevance of the effects observed in mammals could be established for wild mammals. Open point The RMS to reflect the discussion in the revised RAR and include a conclusion for wild mammals. AMA Both mortality and morbidity was assessed in the range-finding test of the AMA. The experts agreed that since morbidity is not a well-defined parameter, it should not be used in the range-finding test for the setting of the testing concentration. Higher concentrations could have been used in the test to further clarify the results; therefore some concerns over the appropriateness of the testing concentration remain. However, it was agreed that a conclusion may still be drawn based on the available AMA, with the uncertainties mentioned above. In relation to the findings of the AMA, the following was noted: - no significant effect was observed on the developmental stage (DS) in the updated statistical analysis. However, all parameters were analysed by splitting the animals at or above NF60, which should not be done for the DS and the Hind-Limb-Length parameters. - In the three highest treatment levels, the number of tadpoles above NF60 is higher compared to the control (5, 7, 12 and 15 respectively), as well as the more advanced NF stage reached in each treated group (... respectively). This pattern may be suggestive of an accelerated development (e.g. hyperthyroidism); however such effect is not supported by any findings in the other parameters (i.e. no changes in the thyroid histopathology, no statistically significant changes in the DS, no pattern observed in the non-normalized Hind-Limb-Length and Snout-Vent-Length), nor by the thyroidal MoA due to liver enzyme induction (e.g., hypothyroidism), observed in mammals. Overall, considering the available information from the AMA and the conclusions from the mammalian dataset, all experts agreed that a clear pattern of adversity for the T-modality cannot be concluded. Open point The RMS to reflect the outcome of the discussion in the RAR.
Experts' consultation 5.8 Experts to discuss the FSTRA result (decreased fecundity, histopathology), also considering the data	In the FSTRA, no mortality, no effects on wet weight or length was observed; however a statistically significant decrease in reproduction (>32 % effect on fecundity and >9% fertility) was observed at the highest tested concentration and considered to be treatment-related. A statistically significant increase in VTG was also observed at this concentration in female (when including the outliers) with a dose



Subject	Conclusions Pesticide Peer Review Meeting
requirement 5(158) i.e. additional information on the VTG and results with and without outlier.	dependant increasing trend at the concentration below. It was agreed that there was no justification to exclude the outlier. In the histopathology, a slight increase in oocyte atresia occurrence and severity (minimal to moderate) at the two highest concentrations, without dose response, was observed. It was pointed out that the observed statistically significant increase in female VTG may be driven by data from individual specimens and that the pattern of effect observed in the female gonad histopathology (i.e., increase prevalence and severity of oocyte atresia with no dose-response) does not show any logical connection with the increase in female VTG and with the pattern of decrease in fecundity. Overall, based on the available FSTRA, all experts agreed that a clear pattern of EAS-mediated activity could not be identified. Open point The RMS to include the outcome of the discussion in the revised RAR.

Pesticides Peer Review TC 131 / TC 134
Melaleuca alternifolia, essential oil (tea tree oil)

REPORT OF PESTICIDES PEER REVIEW TC 131 / TC 134

MELALEUCA ALTERNIFOLIA, ESSENTIAL OIL (TEA TREE OIL) - AIR IV

Rapporteur Member State: PL

5. Ecotoxicology

Date: 14 March 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by RMS Poland	Ministry of Agriculture and Rural Development and E-V-A Sp. z o.o. - PL
National Experts nominated by MS Austria	Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS Croatia	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS Estonia	Agriculture and Food Board - EE
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Federal Institute for Risk Assessment and Federal Environmental Agency (UBA) - DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute - GR
National Experts nominated by MS Netherlands	Ctgb - NL
National Experts nominated by MS Slovenia	National Institute of Public Health - SI
National Experts nominated by MS Spain	Ministerio de Sanidad - ES
National Experts nominated by MS Sweden	Swedish Chemicals Agency - SE
Observers	Agroscope and BAFU - CH
Observers	Estonian Agriculture and Food Board - EE
Observers	Federal Food Safety and Veterinary Office - CH
Observers	Benaki Phytopathological Institute - GR
Observers	Ctgb - NL



Observers	Ministry of Agriculture and Rural Development in Warsaw, Poland - PL
Observers	Swedish Chemicals Agency - SE

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Expert to confirm the acceptability of the weight-of-evidence approach proposed to refine the risk for small herbivorous mammals.	It was confirmed that Tea tree oil use in permanent greenhouses will result in minimal outdoor exposure. Therefore, for the scenarios with indoor uses, low risk(s) can be confirmed. Several refinements for the long-term high risk for small herbivorous mammals were discussed. Based on the available information, experts agreed that a DT50 of 1 day is adequate, and a low long-term risk can be concluded for small herbivorous mammals. Open point: • RMS to adjust the RAR based on this discussion and remove the refinement proposal for the acute risk assessment to mammals. LoEP should be amended accordingly. • RMS to reflect the outcome of the discussion in the revised RAR and in the LoEP.

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Subject	Conclusions Pesticide Peer Review Meeting
	The RMS to consider the above discussion for the type of structure and remove the long-term risk assessment to mammals for the use in tomatoes in the greenhouse. The RMS to adjust the diet proposed for Vineyard uses as stated above and to reflect the experts agreement on the argument about Tractor disturbance on the WoE table as presented in the RAR.
Experts' consultation 5.2 Experts to discuss the need for evaluation of the risk of secondary poisoning for the relevant compounds in light of the information presented by the RMS, and if available, the additional data provided by the applicant.	Based on the information available for Tea tree oil and its components, it was agreed that a quantitative assessment of the secondary poisoning is not needed. Open point: RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.3 Experts to agree on the risk assessment for birds provided by the applicant, and if needed, confirm the acceptability of the WoE approach.	Based on the data available, it was agreed that it is justified to select the highest endpoint for the acute risk assessment since no effects were observed in the available studies (i.e. the endpoints are greater-than value). In addition, the experts noted the difference in the endpoints is only mathematical and due to a higher concentration of Tea tree oil in the one of the formulated products. A low acute risk can be confirmed. Open point: RMS to reflect the outcome of the discussion in the RAR and to align the LoEP.
Experts' consultation 5.4 Experts to discuss: - the approach in aquatic risk assessment in relation with the most relevant route of exposure to TTO of surface water bodies (see also fate section at 4(43)) - the risk assessment proposal based on the modified exposure assessment.	In line with the agreements reached at the environmental fate meeting TC 132, the RAC values derived for aquatic invertebrates to be used for risk assessment purpose were discussed. It was agreed that, pending new PEC calculations, the risk assessment will be revised. As indicated in the environmental fate meeting TC 132, further consideration of the metabolite UK-14.5 (M2) may be needed. Open point: - RMS to reflect the outcome of the discussion in the updated RAR and to revise the aquatic risk assessment in line with the outcome of the new PEC calculations. - RMS to align the information presented for the newly identified metabolite with the outcome of the environmental fate assessment.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.5 Experts to confirm the acceptability of the risk assessment for aquatic invertebrates provided by the applicant.	Based on the available information indicating that <i>D. magna</i> is more sensitive than insect larvae, it was agreed that a test on a second invertebrate species is not needed. Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.6 ESCORT 2 guidance document indicates that for products with a special mode of action testing should focus on the stages likely to demonstrate effects. In the available literature studies, the most pronounced toxic effects of TTO and/or its constituents were observed after exposure of eggs and larvae, which are not included in the toxicity studies with standard indicator species. Therefore, there is a risk that the effects of TTO on non-target arthropods were underestimated since less sensitive stages were included in testing. Experts to discuss the need for additional studies with the most sensitive life-stages for NTAS and their potential use for the risk assessment.	Based on the available data and information from literature studies, it was agreed that in the available regulatory studies the expected most sensitive life stages are not covered. In line with the data requirement and the above information, all the experts agreed further data are needed to conclude on the risk assessment for NTAs. Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.7 Experts to confirm the acceptability of the risk assessment for NTAs provided by the applicant.	Overall, in line with the current practice and guidance in use, the use of a VDF of 10 in the risk assessment is confirmed. Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.8 Experts to agree on the testing strategy to investigate on the T-modality for non-target organisms, also considering the outcome of the expert consultation in the toxicology area .	The testing strategy for the ED assessment of tea tree oil for NTOs was discussed among the experts. The following testing strategy was agreed among all experts: • For the T-modality: an Amphibian Metamorphosis Assay (OECD 231). • For the EAS-modalities: a Fish Short Term Reproductive Assay (OECD 229) with gonad histopathology.



Subject	Conclusions Pesticide Peer Review Meeting
	In line with ECHA/EFSA Guidance, if any of the level 3 test is positive, a MoA should be postulated and the need for further test should be considered, i.e., a LAGDA (OECD TG 241) if the AMA is positive and/or a MEOGRT (OECD TG 240) or as an alternative a FFLCT with all the parameters foreseen to be investigated in the MEOGRT, if the FSTRA is positive. Open point: RMS to align the discussion as above in the revised RAR.
Experts' consultation 5.9 Experts to agree on the testing strategy to investigate on the EAS-modalities for non-target organisms, also considering the outcome of the expert consultation in the toxicology area .	The testing strategy for the ED assessment of tea tree oil for NTOs was discussed among the experts. The following testing strategy was agreed among all experts: • For the T-modality: an Amphibian Metamorphosis Assay (OECD 231). • For the EAS-modalities: a Fish Short Term Reproductive Assay (OECD 229) with gonad histopathology. In line with ECHA/EFSA Guidance, if any of the level 3 test is positive, a MoA should be postulated and the need for further test should be considered, i.e., a LAGDA (OECD TG 241) if the AMA is positive and/or a MEOGRT (OECD TG 240) or as an alternative a FFLCT with all the parameters foreseen to be investigated in the MEOGRT, if the FSTRA is positive. Open point: RMS to align the discussion as above in the revised RAR.
Experts' consultation 5.10 Experts to discuss the ecotoxicological profile of the co-formulants taking into account the requested additional ecotoxicological data and the corresponding RMS evaluation of these.	On the basis of the information available to the experts at the time of the meeting, for a co-formulant it was not possible to conclude on whether the representative formulation is safe to aquatic organisms in the long-term scenarios. Open point: RMS to reflect the outcome of the discussion in the RAR and to update the information presented in the Vol 4 considering the data available.
Experts' consultation 5.11 Experts to discuss the ecotoxicological relevant endpoint for the risk assessment of wild mammals.	Based on the available dataset, it was agreed to confirm the relevant ecotoxicological NOAEL for reproduction at 25 mg/kg bw/d. Open point: RMS to update RAR to reflect the outcome of the discussion.

REPORT OF PESTICIDES PEER REVIEW TC 130

Formetanate – AIR III

Rapporteur Member State: ES

5. Ecotoxicology

Date: 23 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by RMS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC) - ES
National Expert nominated by RMS Netherlands	Ctgb - NL
National Experts nominated by MS France	ANSES - FR
National Expert nominated by RMS Belgium	Federal Public Service Health, Food Chain Safety and Environment - BE
National Expert nominated by MS Germany	Federal Environment Agency -DE
Observers	Swiss Federal Office for the Environment

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Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 proposed by EFSA MS experts to discuss the refinement of the risk assessment for birds and mammals	The experts discussed the available acute and long-term risk assessment for birds and mammals. Specifically, the proposed refinements were discussed for each Tier 1 generic focal species where a low risk was not indicated in the Tier 1 assessment. The refined RUD value for tomato fruit was accepted as was the refined deposition value. Furthermore, a number of focal species proposed by the applicant were accepted, however, as there were no accompanying ecological refinements, the experts agreed that there was no need to define focal species. A number of the proposed refinements were rejected owing to insufficient data to support the refined parameters (DT50 in fruit, DT50 in foliage, PD values). It was further noted that in line with the previous experts meeting the refined acute dietary endpoint for birds could not be used for the refined assessment. Open points 1. RMS to update the risk assessment in the revised RAR and the LoEP by using the geomean value in the acute risk assessment for birds at all tiers. 2. RMS to reflect the outcome of the discussion related to the acute risk to birds in the revised RAR. 3. RMS to revise the long-term risk assessment for frugivorous birds by using the default ftWA. 4. RMS to reflect the outcome of the discussion relating to the refined long-term risk assessment for birds in the revised RAR. 5. RMS to reflect the outcome of the discussion for the small omnivorous mammals and to consider presenting a refined TER using a DV of 0.2.



Subject	Conclusions Pesticide Peer Review Meeting
	6. RMS to reflect the outcome of the discussion on the acute risk to mammals in RAR and to update the list of endpoints accordingly. 7. RMS to reflect the outcome of the discussion on the long-term risk to mammals in RAR and to update the list of endpoints accordingly. 8. The LoEP should be updated with the outcome of the discussion.
Experts' consultation 5.2 proposed by EFSA MS experts to discuss the refinement of the risk assessment for aquatic organisms	Exposure profiles Experts discussed the results from the position paper submitted by the applicant considering the FOCUS exposure profile for each scenario relative to the exposure profile of formetanate during the microcosm study used as refinement for the risk to aquatic organisms. Overall, although several limitations were observed in the way the results were presented in the position paper, experts agreed they would allow in most cases to achieve a conclusion. Experts agreed (for both early and late application in tomatoes): • For spray drift scenarios (i.e., D6-Ditch, R2-Stream), the mesocosm exposure is considered worst-case compared to the FOCUS exposure profile. • For run-off scenarios (i.e., R3-Stream, R4-Stream), the mesocosm exposure profile is not considered worst-case compared to the FOCUS exposure profile. pH-dependent degradation Experts discussed the concern on pH dependent degradation in the indoor microcosm experiment. Conclusion The experts agreed that based on the available residue decline data, in each replicate the test item degradation can be considered similar and exposure conditions are comparable across the replicates in the mesocosm study. Open point: RMS to revise the RAR, the LoEP and the risk assessment for aquatic organisms based on the agreement of the meeting.

Pesticides Peer Review TC 130
Bacillus subtilis strain RTI477

REPORT OF PESTICIDES PEER REVIEW TC 130

Bacillus subtilis strain RTI477– NAS 1107

Rapporteur Member State: NL

9. Ecotoxicology - Microorganism

Date: 23 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by RMS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC) - ES
National Expert nominated by RMS Netherlands	Ctgb - NL
National Experts nominated by MS France	ANSES - FR
National Expert nominated by RMS Belgium	Federal Public Service Health, Food Chain Safety and Environment - BE
National Expert nominated by MS Germany	Federal Environment Agency -DE
Observers	Swiss Federal Office for the Environment

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Discussion points / Outcome

9. Ecotoxicology - Microorganism

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 9.1 proposed by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the composition of the formulation for representative use and the data available for the formulation and for the co-formulants. The experts agreed that the formulated product was sufficiently characterised and no concerns were raised. Open point: RMS to include the information gathered on the individual co-formulants in Vol. 4 (updated RAR).

Pesticides Peer Review TC 130
Bacillus velezensis strain RTI301

REPORT OF PESTICIDES PEER REVIEW TC 130

Bacillus velezensis strain RTI301 NAS 1107 - NL

Rapporteur Member State: NL

9. Ecotoxicology - Microorganisms

Date: 23 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by RMS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC) - ES
National Expert nominated by RMS Netherlands	Ctgb - NL
National Experts nominated by MS France	ANSES - FR
National Expert nominated by RMS Belgium	Federal Public Service Health, Food Chain Safety and Environment - BE
National Expert nominated by MS Germany	Federal Environment Agency -DE
Observers	Swiss Federal Office for the Environment

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Discussion points / Outcome

9. Ecotoxicology - Microorganisms

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 9.1 proposed by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the composition of the formulation for representative use and the data available for the formulation and for the co-formulants. The experts agreed that the formulated product was sufficiently characterised and no concerns were raised. Open point: RMS to include the information gathered on the individual co-formulants in Vol. 4 (updated RAR).

Pesticides Peer Review TC 130
Pythium oligandrum strain B301

REPORT OF PESTICIDES PEER REVIEW TC 130

Pythium oligandrum strain B301 - NAS

Rapporteur Member State: BE

5. Ecotoxicology - Microorganism

Date: 23 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by RMS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC) - ES
National Expert nominated by RMS Netherlands	Ctgb - NL
National Experts nominated by MS France	ANSES - FR
National Expert nominated by RMS Belgium	Federal Public Service Health, Food Chain Safety and Environment - BE
National Expert nominated by MS Germany	Federal Environment Agency -DE
Observers	Swiss Federal Office for the Environment

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Discussion points / Outcome

5. Ecotoxicology - Microorganism

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Subject	Conclusions Pesticide Peer Review Meeting
New expert consultation point 9.1 proposed by EFSA for completeness of discussion: MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the preparation with respect to the effects on non-target organisms permitting an evaluation of the short- and long-term effects. For the endpoints not addressed by the preparation data, MS experts to discuss the ecotoxicological profile of each individual component other than the main active substance considering also their short- and long-term toxicity.	The experts discussed the composition of the formulation for representative uses and the available data and risk assessment for the co-formulant(s). The experts agreed that the formulated product was sufficiently characterised and no concerns were raised. Open point: RMS to include the information gathered on the individual co-formulant(s) in Vol. 4 (updated DAR).

19-23 February 2024

MINUTES

Pesticides Peer Review TC 130
Phthorimaea operculella granulovirus

REPORT OF PESTICIDES PEER REVIEW TC 130

Phthorimaea operculella granulovirus – NAS 1107

Rapporteur Member State: NL

5. Ecotoxicology - Microorganisms

Date: 23 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by RMS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC) - ES
National Expert nominated by RMS Netherlands	Ctgb - NL
National Experts nominated by MS France	ANSES - FR
National Expert nominated by RMS Belgium	Federal Public Service Health, Food Chain Safety and Environment - BE
National Expert nominated by MS Germany	Federal Environment Agency -DE
Observers	Swiss Federal Office for the Environment

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Discussion points/Outcome

5 Ecotoxicology - Microorganisms

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 0.1 (added by EFSA after column 4) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts discussed the composition of the formulation for representative use, Tutavir, and the data available for the formulation and for the co-formulants. The experts agreed that the formulated product was sufficiently characterised and no concerns were raised. Open point: RMS to include the information gathered on the individual co-formulants in the updated Vol. 4 of the DAR.

REPORT OF PESTICIDES PEER REVIEW TC 129

Daminozide - AIR III after ED clock stop

Rapporteur Member State: CZ

5. Ecotoxicology

Date: 2 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by RMS Czechia	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by MS Finland	Finnish Safety and Chemicals Agency (Tukes)- FI
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Environment Agency (UBA)- DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute- EL
National Experts nominated by MS Italy	ASST FBF SACCO - IT
National Experts nominated by MS Poland	Institute of Environmental Protection- PL
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Slovenia	Independent environmental consultant - SI
Observers	Federal Office for the Environment -CH

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discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points/ Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
New experts' consultation point 5.6 proposed by EFSA for completeness of discussion: MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Considering the available data, the ecotoxicological profile of the representative formulations were comparable to the active substance. Based on the data and information available for the individual co-formulants, a low impact on the safety of the formulations was predicted, therefore the co-formulants did not trigger further concerns. The experts at the meeting agreed that the co-formulants do not increase the toxicity of the formulations. Open point: RMS to reflect the outcome of the discussion in Volume 4.

Pesticides Peer Review TC 124-129
Prothioconazole

REPORT OF PESTICIDES PEER REVIEW TC 124/129

Prothioconazole - AIR III after ED clock stop

Rapporteur Member State: PL

5. Ecotoxicology

Date: 2 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Czechia	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by MS Finland	Finnish Safety and Chemicals Agency (Tukes)- FI
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Environment Agency (UBA)– DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute- EL
National Experts nominated by MS Italy	ASST FBF SACCO - IT
National Experts nominated by RMS Poland	Institute of Environmental Protection- PL
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Slovenia	Independent environmental consultant - SI
External Expert	Vanessa Mazerolles - FR
Observers	Federal Office for the Environment -CH

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Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.8 Experts to discuss: - the reliability of the available data, both regulatory studies and literature data, for the ED assessment through EAS-modalities; - The weight of evidence for EAS modalities; - The conclusion based on the available data. Please note that additional data cannot be requested and submitted at this stage following the 30-month clock stop.	The experts discussed the available studies, i.e., a Fish Short-Term Reproduction Assay (FSTRA) and a literature study on lizards (Xie et al., 2019), their reliability and the related findings. The FSTRA was considered fully valid, although the vitellogenin (VTG) was not considered reliable due to the lack of information such as calibration curve, LOQ, LOD, etc. The study by Xie et al., (2019) was considered not relevant due to the short exposure duration and not reliable due to a number of deficiencies such as lack of replications, no information on the origin of the animals, wide range of temperature, short acclimatation period, an assessment of the reproductive stage of the lizard should have been conducted prior the initiation of the test, etc. Overall, it was noted that, while effects on fecundity were observed in a dose-response manner starting from the mid concentration, no change in oocyte atresia was noted at the mid concentration, therefore no logic sequence of events was observed. In addition, it should be considered that i) there is no <i>in vitro</i> evidence of EAS-mediated ED activity (although the full set of assay is not available), ii) based on the mammalian dataset, the substance was considered not meeting the ED criteria, iii) no evidence of anti-androgenicity was available, which should be considered since FSTRA is not the most suitable test to detect effect caused by substances with anti-androgenic potential. Overall, based on the available results and the above-mentioned identified uncertainties, all experts agreed that a clear pattern of effect leading to potential EAS-mediated activity could not be observed in the FSTRA. The experts agreed that the study by Xie



Subject	Conclusions Pesticide Peer Review Meeting
	et al. (2019) owing to the issues related to its relevance and reliability, provided limited contribution to the overall WoE in the ED assessment of prothioconazole.
New experts' consultation point 5.9 proposed by EFSA for completeness of discussion MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	For both of the formulated products for the representative uses, the experts discussed the available toxicity data. Furthermore, the experts discussed the available information for the individual co-formulant(s) focussing on where data were lacking for the formulated product. Conclusion - Aviator EC 225 1. Sufficient ecotoxicity data were available for the formulation Aviator EC 225 for most groups of NTOs, with the exception of birds (reproductive), mammals (reproductive), fish (chronic), aquatic invertebrates (chronic) and bees (chronic). 2. The experts considered the available information and no concerns were raised regarding the safety of the formulation. 3. For some component(s), a reconsideration for the implications to NTOs should be made pending the toxicological assessment. Conclusion - Redigo FS 100 1. Sufficient ecotoxicity data were available for the formulation Redigo FS 100 for most groups of NTOs, with the exception of birds, mammals, fish (chronic), aquatic invertebrates (chronic) and bees (chronic). 2. The experts considered the available information and no concerns were raised regarding the safety of the formulation. 3. For some component(s), a reconsideration for the implications to NTOs should be made pending the toxicological assessment.

Pesticides Peer Review TC 124-129
Bensulfuron-methyl

REPORT OF PESTICIDES PEER REVIEW TC 124/129

Bensulfuron-methyl- AIR IV

Rapporteur Member State: IT

5. Ecotoxicology

Date: 2 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Czechia	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by MS Finland	Finnish Safety and Chemicals Agency (Tukes)- FI
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Environment Agency (UBA)– DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute- EL
National Experts nominated by RMS Italy	ASST FBF SACCO - IT
National Experts nominated by MS Poland	Institute of Environmental Protection- PL
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Slovenia	Independent environmental consultant - SI
Observers	Federal Office for the Environment -CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject Meeting	Conclusions Pesticide Peer Review
Experts' consultation 5.1 Experts to agree on the endpoints from the reprotoxicity studies with birds.	Two studies were submitted for the derivation of the reproductive endpoint for use in the avian risk assessment: KCA 8.1.1.3/01 reproduction toxicity test with the mallard duck KCA 8.1.1.3/02 reproduction toxicity test with the northern bobwhite Concerns were raised during the written peer review on aspects of the study design and the endpoint derivation, which required further discussion and agreement by the experts. KCA 8.1.1.3/01 Overall, experts agreed that the deviations in temperature and humidity are minor. The deviation in the age of birds was considered substantial. However, it did not seem to affect the reproductive performance. Therefore, the study was considered valid. Considering the evaluation by the RMS and the supporting results of the BMD analysis presented at the meeting, the experts agreed with the NOEC of 35 ppm. The proposed use of historical control data was not considered justified by the experts. KCA 8.1.1.3/02 At the highest tested dose, a reduction (effect size above 10%) of i) viable eggs of the eggs set; iii) successful hatching of eggs set and iii) 14-day old survivors of eggs set was observed. The experts could not exclude that such differences were biologically relevant. Therefore, the NOAEL from this study was set at 1975 ppm. Open points: - RMS to reflect the outcome of the meeting discussion on the assessment of the avian reproductive studies in a revised version of the RAR. - RMS to report an updated RA using the lower endpoint of 35 ppm from the Mallard duck study.



Subject Meeting	Conclusions Pesticide Peer Review
	- Updated exposure assessment should be taken into account if relevant for the risk assessment for birds and mammals.
Experts' consultation 5.2 Experts to decide the ecotoxicological relevant endpoint for conducting the long-term risk assessment for wild mammals.	The experts discussed the available relevant studies for setting the ecotoxicologically relevant endpoint, considering: i) the comments submitted during the peer review; ii) the revised assessment by the RMS and iii) the outcome of the peer review meeting on human toxicology. Overall, - considering the low effect size, the ecotoxicological relevance of the bodyweight effects observed in the 2-generation rat study was questioned - experts agreed to set the ecotoxicologically relevant reproductive endpoint (NOAEL) to 300 mg/kg bw/day considering the effects observed in the developmental study with rabbit (i.e., the developmental NOAEL was set at 300 mg/kg bw per day, based on increased total resorptions and reduced foetal weights (>10%) observed at 1500 mg/kg bw per day). Open point: - RMS to reflect the meeting discussion on the selection of the ecotoxicologically relevant reproductive endpoint for wild mammals in a revised RAR. - RMS to update the risk assessment using the endpoint of the developmental rabbit study (NOAEL 300 mg/kg bw/day).
Experts' consultation 5.3 Expert to discuss the suitability of the study design of the two ELS studies (fathead minnow, 1988, and rainbow trout, 2003), noting that the number of animals was reduced in the available test, and that new data might be submitted.	Rationale and conclusion In consideration of the lack of trends seen in the ELS test with rainbow trout (KCA 8.2.2.1/01), despite the deviations from the OECD guidelines, it was agreed to set the NOAEC at the highest tested concentration (12 mg a.s./L). Open point RMS to update the RAR and the LoEP by indicating that the endpoint derived from the ELS test with rainbow trout (KCA 8.2.2.1/01) is a NOAEC rather than a NOEC. The value (12 mg a.s./L) remains unchanged. In consideration of the trend of effects on weight recorded in the ELS test with fathead minnow (KCA 8.2.2.1/02), despite the lack of statistical significance (likely due to the low level of replication), the experts agreed to set the NOEC at 34 mg a.s./L. No further action identified for the RMS.



Subject Meeting	Conclusions Pesticide Peer Review
Experts' consultation 5.4 Expert to discuss the chronic <i>Daphnia</i> NOEC of the BSM metabolite IN-J0290 (████████, 2022c), considering also that IN-J0290 is a common metabolites of other sulfonylurea active substances.	Rationale and conclusion In consideration of the fact that effects on reproduction occurred at concentrations above 3 mg/L, and in consideration of the fact that the dose-response is relatively flat between 6.3 and 24.9 mg/L, and in consideration of the fact that the lower limit of the derived EC₁₀ (characterised by relatively wide credible intervals) is around 7-9 mg a.s./L, the experts agreed to set the NOEC = 12.4 mg/L for chronic toxicity of metabolite IN-J0290 to daphnids. Open point RMS to reflect in a revised RAR the discussion on the chronic daphnid endpoint selection for metabolite IN-J0290 and to amend the risk assessment and LoEP accordingly. Open point RMS to check if information on common metabolites is available from previous assessments (i.e., EFSA conclusions) of other sulphonylureas substances. If information is available, RMS to consolidate them into the LoEP of bensulfuron (relevant across NTOs and exposure matrixes: i.e., soil, plants and water). Open point (EFSA) EFSA to highlight in the conclusion that the change in the endpoint from this study is also relevant for mesosulfuron. In the agreed LoEP for this substance, the reported NOEC from the present study is reported to be 24.9 mg/L.
Experts' consultation 5.5 Expert to discuss: - The application of the TG 239 validity criteria (CV in the water and solvent control vs pooled control) for the studies KCA 8.2.7/06-07, 2020b and 2020c - Prolongation of the macrophytes studies and which endpoints should be used in the risk assessment, for all the relevant studies (BSM and metabolites). -The reliability of the study with <i>Hygrophila polysperma</i> (████████, 2020c) -The updated SSD for the macrophyte (endpoint	Rationale and conclusion The experts considered in detail each single study. Despite the deviations from standard guideline, and by considering that some of these deviations were justified by the use of non-standard species, the experts agreed that endpoints from all the available studies on macrophytes could be retained in the LoEP and used in the SSD derivation for the risk assessment. Only in the case of the study with <i>Mentha aquatica</i> (KCA 8.2.7/09), the experts agreed to flag that the study has reliability restrictions. Some additional notes, reflected in the open points below, needs to be reported in some study summaries and/or LoEP. The experts agreed with the endpoints initially proposed by the RMS in all cases (including test with metabolites) except one, i.e. the test with <i>Lysimachia nummularia</i> (KCA 8.2.7/08). For this study a re-analysis using the EFSA BMD tool was performed and all experts agreed to retain the newly derived endpoint. The experts further agreed to use all available endpoints with Bensulfuron-methyl and the representative formulation in a tier-2B approach (i.e. SSD). Since endpoints on <i>Lemna gibba</i> are available with both the active substance and with the representative formulation and they are very similar to each other, a geometric mean of these two values should be calculated before fitting the SSD.



Subject Meeting	Conclusions Pesticide Peer Review
included/excluded) and its use in the RA	Open point RMS to flag, in the summary of the study with <i>Spirodela polyrhiza</i> (KCA 8.2.7/02), the inconsistency in the statistical analysis in the report, which should have been conducted by pooling the two controls. RMS to flag that the current analysis is accepted as it represents a worst-case. Open point RMS to update the acceptance status of the study with <i>Lysimachia nummularia</i> (KCA 8.2.7/08) in the RAR. RMS should also include the BMD analysis (resulting $E_rC_{50} = 9.7 \mu\text{g/l}$ with a CI 5.14-20.1 $\mu\text{g/l}$) and update the endpoint selection accordingly (also in the LoEP). This is also relevant for the final SSD. Open point RMS to flag in the RAR and in the LoEP the uncertainties related to the endpoint from the study with <i>Mentha aquatica</i> (KCA 8.2.7/09). Open point RMS to check that endpoints reported in the LoEP for tests carried out with formulations are expressed in terms of a.s and product concentrations, as required. Open point RMS to re-fit the SSD and to re-calculate the related HC5 by considering: (I) the endpoint for <i>Lysimachia nummularia</i> from the BMD analysis; (II) only one data point from <i>Lemna gibba</i>, using the geomean of both study results. The change should be reflected in the risk assessment and in the LoEP.
Experts' consultation 5.6 Expert to discuss the reliability of the available seedling emergence study, and the derived endpoints. Expert should also discuss the choice of the species and the concentrations tested.	The reliability of the seedling emergence study was discussed in relation to potential concerns, including the following: i) Higher seed density than recommended by the OECD TG. ii) Potentially sub-optimal dose selection. iii) Validity criteria (not met for one of the species). iv) Endpoint derivation. v) Species selection. The following conclusions were reached for each of the bullet points reported above: i) Uncertainty around the high seed density was acknowledged. However, high within-replicate variability was not observed in control plants (interpreted as no sign of high competition). ii) No clear justification was submitted by the applicant on this aspect. iii) Validity criteria were met for all species except <i>Beta vulgaris</i>, which emerged at a rate of 60%. The results for this species (but not the others) were considered unreliable.



Subject Meeting	Conclusions Pesticide Peer Review
	iv) A revised dose response analysis carried out using the BMD produced a better fit and representation of uncertainty than what presented by the applicant. v) Potential uncertainty around the species selection was acknowledged. However, trials seem to suggest that BSM is more effective when applied to small (2-3 unfolded leaves) actively growing plants, rather than to earlier stages (i.e. pre-emergence). This may potentially explain the low sensitivity of species in the seedling emergence test. Overall, the study was considered reliable with restriction. The ER50 = 3.1 g a.s./ha [2.2-4.3 g a.s./ha] should be used in risk assessment. Open point RMS to reflect the outcome of the discussion in the study summary for seedling emergence and to highlight all the uncertainty related to the endpoint. Furthermore, the BMD analysis will have to be integrated in the summary and the derived endpoint will be retained. RMS should also update the risk assessment and LoEP by using the endpoint from the BMD analysis and by clarifying that such endpoint is to be considered reliable with restrictions. Open point (EFSA) EFSA to reflect in the conclusion about the uncertainty surrounding the endpoint derivation from the seedling emergence study.
Experts' consultation 5.7 If based on the outcome of the experts' consultation as set in 2(66), it is concluded that the ED criteria are met for humans, a discussion on the population relevance of the adversity identified might be needed for wild mammals as non-target organisms.	The same conclusion as the one reached for humans apply to non-target mammalian species. I.e., bensulfuron-methyl does not meet the ED criteria for EATS-modalities for wild mammals. For other non-target organisms, the available and valid Fish Short-Term Reproduction Assay (FSTRA, OECD TG 229) and an Amphibian Metamorphosis Assay (AMA, OECD TG 231) suggested no perturbation of the ED system through EATS-modalities for non-mammalian vertebrates. Open points: - RMS to amend the RAR in line with the discussion. - RMS to please reflect in the revised RAR the discussions and conclusions on the ED assessment of bensulfuron-methyl for wild mammals. - RMS to amend the AMA study summary with the data corrected for the exclusion of tadpoles at NF>60. - RMS to report in the revised RAR the information about the mortality in the test. - RMS to include additional information on the standard deviation for every parameter in the study summary to better showcase the variability of the available data.



Subject Meeting	Conclusions Pesticide Peer Review
	- RMS to please report in the revised RAR the methodology used for the measurement of vitellogenin (VTG) concentrations.
Experts' consultation 5.8 (set by EFSA after column 4 step) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	None of the co-formulants present in the formulation for representative uses was listed in Article 27 Commission Regulation (EU) 2021/383 of 3 March 2021. No specific concern was highlighted on the ecotoxicological profile of the formulation for representative uses, considering its individual components. Open point RMS to reflect the meeting discussion and the RMS assessment in Vol. 4 of the RAR in relation to characterisation of the ecotoxicological profile of the formulation for representative uses (including consideration of its co-formulants).

REPORT OF PESTICIDES PEER REVIEW TC 124/129

Bixlozone – NAS 1107

Rapporteur Member State: NL

5. Ecotoxicology

Date: 2 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Czechia	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by MS Finland	Finnish Safety and Chemicals Agency (Tukes)- FI
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
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National Experts nominated by MS Greece	Benaki Phytopathological Institute- EL
National Experts nominated by MS Italy	ASST FBF SACCO - IT
National Experts nominated by MS Poland	Institute of Environmental Protection- PL
National Experts nominated by RMS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Slovenia	Independent environmental consultant - SI
Observers	Federal Office for the Environment -CH

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discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the risk assessment for aquatic macrophytes, including: - The endpoints derived from the studies considering the effects on phytotoxicity. - The validity of the <i>Myriophyllum</i> study with F9600-3-OH-propanamide. - Additional studies submitted by the applicant.	Validity of the new macrophyte studies All experts agreed with the RMS that the new study with <i>S. polyrhiza</i> was reliable while the studies with <i>C. demersum</i>, <i>V. beccabunga</i> and <i>E. densa</i> were reliable with restrictions considering the minor limitations identified. Endpoints derived from the studies considering the effects on phytotoxicity Most of the experts agreed with the applicant and RMS proposal of using reliable ErC20 values to cover for the qualitative phytotoxicity effects reported in all macrophyte studies. Refined risk assessment All experts agreed to refine the risk to macrophytes by calculating the geometric mean with the ErC20 values from the studies with <i>Spirodela polyrhiza</i>, <i>Ceratophyllum demersum</i> and <i>Myriophyllum spicatum</i>. For <i>Veronica beccabunga</i>, the lowest concentration of 0.0038 mg a.s./L was agreed as the relevant toxicity value given that phytotoxicity was observed at concentrations above 0.0038 mg a.s./L and that the ErC20 endpoint was considered not reliable. The endpoints from the studies with <i>Egeria densa</i> and <i>Lemna gibba</i> were excluded from this approach as they were one order of magnitude higher than the next highest endpoint. Need for an overspray test design for emerging macrophytes Considering the conservative approach followed based on ErC20 values, that the floating macrophyte <i>S. polyrhiza</i> showed sensitivity to bixlozone when incorporated into the water column



Subject	Conclusions Pesticide Peer Review Meeting
	and that at the moment there are no standardised test guidelines to address hazard from overspray (drift exposure), most experts considered that there is not enough evidence in the dossier indicating that an overspray test on floating macrophytes is needed. Validity of the <i>Myriophyllum</i> study with F9600-3-OH-propanamide Considering that that the critical endpoint, i.e., total shoot length, increased more than twice during the study, and that the validity criterion for the mean coefficient of variation for yield based on shoot wet weight in the control was slightly exceeded, all experts agreed that the study with <i>M. spicatum</i> and the metabolite F9600-3-OH-propanamide is sufficient to demonstrate the lower toxicity of the metabolite and it can be used for the risk assessment as proposed by the RMS. Open point(s): RMS to reflect the discussions in the RAR.
Experts' consultation 5.2 Experts to discuss the risk assessment for aquatic invertebrates, including: - Validity of the available studies; - Approach for the refined risk assessment (acute geomean or SSD) based on the available data.	Validity of studies The study with the rotifer <i>Brachionus calyciflorus</i> was considered to be supportive due to its limitations (unknown age of test organisms, the absence of a reference item test, recommended by the applicable test guideline). Most experts agreed in using the endpoints from the other eight invertebrate species for a refined risk assessment (based on species sensitivity distribution) as the duration of the studies was sufficient and that no major limitations were identified in any of the species. Refined risk assessment Considering that eight valid acute studies with aquatic invertebrates and bixlozone were available, a refined risk assessment based on species sensitivity distribution (SSD) (Tier 2B approach) can be used. The experts agreed that the lowest median 5% hazard concentration between the ETX and the Mosaic models should be used to refine the risk. All experts agreed with the assessment factor of 4 proposed by the RMS after considering it related to the duration of studies with the macro-invertebrates, the lack of a reference substance, and the exact age of the test organisms in some of these studies, and the fact that the lower limit HC₅ derived from the curve is less than one-third of the median HC₅.



Subject	Conclusions Pesticide Peer Review Meeting
	Open point(s): - RMS to update the status of the <i>B. calyciflorus</i> study (it should be considered as supporting information and, therefore, not used in a quantitative risk assessment and it should be removed from the List of Endpoints). - RMS to update the acute risk assessment for aquatic invertebrates using the lowest median HC5 from the eight studies between ETX and Mosaic models.
Experts' consultation 5.3 Experts to discuss (i) the validity of the seedling emergence and vegetative vigour studies, (ii) the endpoints derived from such studies considering the effect on phytotoxicity, and (iii) the risk assessment for non-target terrestrial plants.	Validity of the seedling emergence and vegetative vigour studies Most experts agreed that there were several deviations/limitations from the OECD test guidelines (environmental conditions, number of plants or seeds per pot, venting period), but considered that these were minor and that the studies should be accepted for the risk assessment. Therefore, it was agreed using the seedling emergence and the vegetative vigour studies with the representative formulation for the risk assessment for non-target terrestrial plants while highlighting the different limitations that were identified. Endpoints derived from such studies considering the effect on phytotoxicity The experts agreed that the risk assessment will be conducted with the ER50 values from the standard measurements (ER50= 19 g a.s./ha for tomato from the seedling emergence study). However, all experts agreed on the importance of covering the phytotoxic effects given the mode of action of bixlozone and that reliable ER50 values on phytotoxicity should be included in the RAR and in the List of Endpoints. Open point(s): RMS to estimate ER50 values for phytotoxicity effects from the seedling emergence and vegetative vigour studies and to update the RAR and the List of Endpoints accordingly.
Experts' consultation 5.4 To discuss the findings from the FSTRA and AMA studies for the ED assessment for NTOs.	The experts discussed the available Fish Short-Term Reproduction Assay (FSTRA) and the Amphibian Metamorphosis Assay (AMA). The FSTRA was considered valid, although the VTG was considered not reliable by all the experts due to the lack of information such as calibration curve, LOQ, LOD, etc. The selection of testing concentrations was also questioned by all the experts, since it was based on fecundity, and a higher testing concentration could have been included in the definitive test. Overall, experts agreed that the effects observed in the FSTRA do not follow the expected pattern.



Subject	Conclusions Pesticide Peer Review Meeting
	For the AMA, the experts agreed that the study is valid. Overall, based on the observed effects, all experts agreed that a clear pattern of effect leading to potential T-mediated activity could not be observed. Open point: RMS to reflect the outcome of the discussion in the updated RAR, including the outcome for wild mammals.
Experts' consultation 0.3 (added by EFSA after column 4) MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Overall, experts agreed that based on the information presented by the RMS, the co-formulants present in the representative formulation F9600-4 SC are not expected to increase the toxicity and do not have an impact on the safety of the formulated product. Open point(s): RMS to reflect the outcome of the discussion in the updated RAR and to include the available toxicity data on the individual co-formulants in Volume 4.

REPORT OF PESTICIDES PEER REVIEW TC 124/129

Mepiquat chloride – AIR IV after ED clock stop

Rapporteur Member State: FI

5. Ecotoxicology

Date: 2 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Czechia	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by RMS Finland	Finnish Safety and Chemicals Agency (Tukes)- FI
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
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National Experts nominated by MS Greece	Benaki Phytopathological Institute- EL
National Experts nominated by MS Italy	ASST FBF SACCO - IT
National Experts nominated by MS Poland	Institute of Environmental Protection- PL
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Slovenia	Independent environmental consultant - SI
Observers	Federal Office for the Environment -CH

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discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Expert consultation 5.7 identified after the ED clock stop: Experts to discuss the uncertainties in the available Fish Short Term Reproduction Assay (FSTRA) in order to conclude on the estrogen, androgen and steroidogenesis (EAS)-modalities for non-mammalian spp. For mammalian species, a conclusion shall also be drawn pending on the consultation in the mammalian toxicology section.	The same conclusion as the one reached for humans apply to non-target mammalian species. I.e., mepiquat chloride does not meet the ED criteria for EATS-modalities for wild mammals as non-target organisms. For non-mammalian species, for the EAS-modalities, the discussion was mainly focused on the results of the Fish Short-Term Reproduction Assay (FSTRA, OECD TG 229). Although the uncertainties in the study were noted and discussed, all experts agreed that the study can still be used to draw a conclusion on the ED properties of the substance. For non-mammalian species, no pattern of EAS-mediated endocrine activity is observed. Open points: • RMS to update the RAR by reflecting in the pertinent volume(s) the discussion and agreements at the meeting. • RMS to revise table 8.2.3/5 in Volume B9.
Experts' consultation 5.8 identified after the ED clock stop: Experts to discuss the available ED assessment for the thyroid (T)-modality for mammalian	For the T-modality, the discussion was mainly focused on the results of the Amphibian Metamorphosis Assay (AMA, OECD TG 231). Although it was noted that the selection of the highest tested concentration was not properly done, no evidence of T-mediated disruption is observed in the available amphibian assay. Open point:



Subject	Conclusions Pesticide Peer Review Meeting
(pending on the outcome of the discussion in the mammalian toxicology section) and non-mammalian species considering the available Amphibian Metamorphosis Assay (AMA) where the selection of the tested concentrations is questioned. Other comments received could also need further consideration in an overall weight of evidence/uncertainty analysis.	RMS to update the RAR by reflecting in the pertinent volume(s) the discussion and agreements at the meeting.
Experts' consultation 5.9 identified after the ED clock stop: Experts to revise the current ecotoxicologically relevant endpoint for the reproductive risk assessment to mammals in light of the newly submitted test according to OECD TG 421. See also the new expert consultation points 2.13, 2.14 & 2.15 set in the mammalian toxicology section.	The experts considered the available toxicology data and selected an ecotoxicologically relevant endpoint for the assessment of wild mammals. The endpoint was from the rat multi-generation study and was 155 mg a.s./kg bw per day. Open point: RMS to report in the RAR the absolute body weight (bw) effects from the rat multi-generation study. RMS to update the RAR and the LoEP with the reconsideration of the ecotoxicologically relevant endpoint and the ecotoxicology risk assessment.
New experts' consultation point 5.10 proposed by EFSA for completeness of discussion:	The experts considered the safety of the formulation for representative uses. The experts agreed that, since the formulation contains two active substances, an additive risk assessment was needed. However, no additional concerns related to the safety of the formulation were identified.



Subject	Conclusions Pesticide Peer Review Meeting
MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Open point: RMS to ensure that the RAR reflects the availability and outcome for the additive risk assessment for the two active substances. RMS to clearly conclude on the additive risk assessment for all non-target organisms in the RAR (except when the risk assessment was based on formulation data). RMS to include in the LoEP a footnote reporting for which aquatic studies the 2nd active substance was not measured.

Pesticides Peer Review TC 124-129
Gibberellic acid

REPORT OF PESTICIDES PEER REVIEW TC 124/129

Gibberellic acid – AIR IV after ED clock stop

Rapporteur Member State: SI

5. Ecotoxicology

Date: 2 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Czechia	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by MS Finland	Finnish Safety and Chemicals Agency (Tukes)- FI
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Environment Agency (UBA)– DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute- EL
National Experts nominated by MS Italy	ASST FBF SACCO - IT
National Experts nominated by MS Poland	Institute of Environmental Protection- PL
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by RMS Slovenia	Independent environmental consultant - SI
Observers	Federal Office for the Environment -CH

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discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.5 Experts to discuss the reliability of the available Amphibian Metamorphosis Assay (AMA), the findings and the conclusion regarding the ED potential of gibberellins GA4-GA7 and gibberellic acid GA3.	The experts discussed the available Amphibian Metamorphosis Assay (AMA). The study showed some limitations, e.g., iodide content not reported, high percentage of scoliosis in all animals and especially in control. Nevertheless, the experts considered the study reliable with minor restrictions. The experts noted that a higher percentage of animals in the high treatment level showed acceleration of the development compared to control. Following the experts' meeting TC 124, the experts rediscussed the findings in the available AMA via written procedure. Overall, following the written procedure, some experts were of the opinion that the available AMA showed acceleration of development. Other experts agreed with the RMS that the findings in the AMA, when also considering other aspects of the weight of evidence, i.e., nature of the substance, criteria not met for humans, did not show a convincing pattern of endocrine activity and adversity. Open point: RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.6 Experts to discuss the findings and the conclusion of the overall weight of	The experts discussed the available Fish Short-term Reproduction Assay. The experts noted that the control did not perform well in terms of fecundity and this could have hampered the detection of an effect. Moreover, the vitellogenin (VTG) was considered unreliable owing to methodological limitations leading to low values compared to the normal range.



Subject	Conclusions Pesticide Peer Review Meeting
evidence for the EAS-modalities.	Overall, the majority of the experts except the RMS agreed that, considering the limitations in the study listed above, the study is not reliable, and therefore it cannot be used to draw a conclusion on the ED properties of the substances GA3 and GA4/GA7 on the EAS-modalities. Open point: RMS to reflect the outcome of the discussion in a revised RAR.
New experts' consultation point 5.7 proposed by EFSA for completeness of discussion MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	In light of the available data with the formulation for representative uses 'ProGibb 40 SG', and considering the ecotoxicological profile of its co-formulants, all experts agreed that the co-formulants present in the formulation for representative uses are not expected to have an impact on the safety of the product. Open points: • RMS to reflect the outcome of the discussion in Volume 4. • RMS to extract endpoints from the REACH dossier when available for the different co-formulants and to include them in an updated RAR (Vol.4). • RMS to present the available endpoints with the active substance and the formulation for representative uses for the different groups of non-target organisms in Volume 4.

REPORT OF PESTICIDES PEER REVIEW TC 124/129

Gibberellins – AIR IV after ED clock stop

Rapporteur Member State: SI

5. Ecotoxicology

Date: 2 February 2024

List of participants:

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EFSA statutory staff member	EFSA
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National Experts nominated by MS Czechia	Central Institute for Supervising and Testing in Agriculture- CZ
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National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
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Observers	Federal Office for the Environment -CH

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 Experts to discuss the findings and the conclusion of the overall weight of evidence for the oestrogen, androgen and steroidogenesis (EAS)-modalities.	The experts discussed the available Fish Short-term Reproduction Assay. The experts noted that the control did not perform well in terms of fecundity and this could have hampered the detection of an effect. Moreover, the vitellogenin (VTG) was considered unreliable owing to methodological limitations leading to low values compared to the normal range. Overall, the majority of the experts except the RMS agreed that, considering the limitations in the study listed above, the study is not reliable, and therefore it cannot be used to draw a conclusion on the ED properties of the substances GA3 and GA4/GA7 on the EAS-modalities. Open point: RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.5 Experts to discuss the reliability of the available Amphibian Metamorphosis Assay (AMA), the findings and the conclusion regarding the ED potential of gibberellins GA4-GA7 and gibberellic acid GA3.	The experts discussed the available Amphibian Metamorphosis Assay (AMA). The study showed some limitations, e.g., iodide content not reported, high percentage of scoliosis in all animals and especially in control. Nevertheless, the experts considered the study reliable with minor restrictions. The experts noted that a higher percentage of animals in the high treatment level showed acceleration of the development compared to control. Following the experts' meeting TC 124, the experts rediscussed the findings in the available AMA via written procedure. Overall, following the written procedure and in line with the agreement



Subject	Conclusions Pesticide Peer Review Meeting
	at the TC 124, some experts were of the opinion that the available AMA showed acceleration of development. Other experts agreed with the RMS that the findings in the AMA, when also considering other aspects of the weight of evidence, i.e., nature of the substance, criteria not met for humans, did not show a convincing pattern of endocrine activity and adversity. Open point: RMS to reflect the outcome of the discussion in a revised RAR.
New experts' consultation point 5.6 Experts to consider the implication for the ecotoxicology assessment of the mammalian toxicology expert meeting on re-discussion of the Toxicological reference values (TRVs) in view of the RMS recalculations of the doses of the 2-generation reproductive toxicity study for GA 4/7.	Following reconsideration of the doses tested in the available 2 generation studies, the experts reconsidered the available dataset and the selection of the ecotoxicologically relevant endpoint. The RMS proposed a NOAEL of 300 mg a.s./kg bw per day as relevant endpoint from the developmental studies. All experts agreed with the RMS proposal considering that the malformation observed at 100 and 300 mg/kg bw per day had a very low prevalence and therefore not considered relevant at the level of population. Open point: RMS to update the risk assessment in the RAR and the List of Endpoints using the agreed endpoint.
New experts' consultation point 5.7 proposed by EFSA for completeness of discussion MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of	In light of the available data with the formulation for representative uses 'Novagib', and considering the ecotoxicological profile of its co-formulant(s), all experts agreed that, the co-formulant(s) present in the formulation for representative uses are not expected to have an impact on the safety of the product. Open points: • RMS to reflect the outcome of the discussion in Volume 4. • RMS to extract endpoints from the REACH dossier when available for the different co-formulants and to include them in an updated RAR (Vol.4). • RMS to present the available endpoints with the active substance and the formulation for representative uses for the different groups of non-target organisms in Volume 4.



Subject	Conclusions Pesticide Peer Review Meeting
each individual component other than the active substance.	

Pesticides Peer Review TC 124-129
Indolylbutyric acid

REPORT OF PESTICIDES PEER REVIEW TC 124/129

Indolylbutyric acid – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 2 February 2024

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
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National Experts nominated by MS Finland	Finnish Safety and Chemicals Agency (Tukes)- FI
National Experts nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Environment Agency (UBA)– DE
National Experts nominated by RMS Greece	Benaki Phytopathological Institute- EL
National Experts nominated by MS Italy	ASST FBF SACCO - IT
National Experts nominated by MS Poland	Institute of Environmental Protection- PL
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Slovenia	Independent environmental consultant - SI
Observers	Federal Office for the Environment -CH

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discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to decide whether the information available is enough to waive the need of further assessment for water-related scenarios for birds and mammals and the dietary risk to birds and mammals if seedlings are consumed (see 2(4) and 3(24)).	The formulation for the representative uses is a powder for seedlings to be dipped into. Overall, the experts agreed that the leaf scenario for sprays is not triggered. The soil exposure assessment concluded that there will be no exposure to the soil for the representative GAP, thus the experts agreed a low risk to birds and mammals from exposure via puddles. In the case of exposure from the consumption of seedlings transplanted four weeks after treatment, the experts agreed that an indicative soil DT₅₀ suggests very quick degradation and a limited and minimal exposure of birds and mammals. Overall, the experts agreed a low risk from the consumption of transplanted seedlings for birds and mammals can be concluded. Open point: RMS to reflect the outcome of the discussion regarding the risk to birds and mammals via consumption of contaminated water in the revised RAR. Open point: RMS to reflect the outcome of the discussion in the revised RAR. It should be reflected that the argumentation regarding exposure being less than the background levels could not be relied upon since the underlying studies had not been provided to the RMS and evaluated.
Experts' consultation 5.2 Experts to decide on the risk to aquatic organisms based	The effect of pH on the toxicity of the active substance was discussed. The RMS proposed to conclude pH would have inconsequential effects on the toxicity of the active substance. The majority of the experts agreed with the RMS proposal.



Subject	Conclusions Pesticide Peer Review Meeting
on the available and new information to be submitted by the applicant, the information from e-fate on the estimated exposure levels (PECs sw if calculated or any other information which supports that the use of IBA as PPP would not increase the natural background levels) and the natural background levels and the pH dependency of the toxicity of IBA and/or its metabolites if pertinent is sufficient to conclude on the risk to aquatic organisms. All information available shall be considered in a weight of evidence approach. See also 4(12), 5(10),5(13-14), 5(18). Please note that in the e-fate section it is recommended to avoid the term “negligible” exposure. Therefore, an open point is set as well for the RMS as follows.	Tentative PECsw were provided by the applicant. The RMS reported the PECsw can be considered unrealistically high. These have not yet been validated in the fate section. A provisional acute risk assessment showed a low acute risk for all aquatic organisms by a high margin of safety. It was noted that active substance toxicity data with <i>Myriophyllum</i> were missing and would be needed to comply with the data requirement, as set in EU Reg. 283/2013 and 284/2013. A data gap is suggested for toxicity data with the active substance on <i>Myriophyllum</i>. Pending the results from the study with the most sensitive aquatic plant species, it was agreed that a formulation study with the most sensitive aquatic species may be needed. Considering the toxicity profile of the substance and its mode of action, the experts agreed with the RMS's proposal that a study for sediment dwelling organisms was unnecessary, and the risk can be considered low. It was noted that, although a very high margin of safety is identified following the acute risk assessment and the substance is readily biodegradable, the substance appears to be hydrolytically stable and, in the aquatic toxicity studies, the concentration is maintained for longer than 24 hours (DT90>24 h). The experts noted that if the exposure assessment confirms no, or very low exposure, no chronic aquatic risk assessment would be needed (including the <i>Myriophyllum</i> data discussed above). Nevertheless, the experts agreed that at the time of the meeting: • the underlying data to support the background levels in surface water have not been validated and accepted in the fate section, thus they cannot be relied upon; • the available PECsw are considered tentative and have not been validated in fate section; • an exposure assessment for discharge and recirculation water is missing and it is unclear whether exposure can be excluded for surface water for discharge and recirculation water; • data demonstrating degradation should be provided before toxicity studies are performed. Based on the abovementioned arguments, overall, the experts agreed that there is insufficient information to conclude, and the chronic risk assessment remains open, pending fate assessment. Open point: RMS to remove the supportive EC50 value for lemna from the LoEP. The acute risk assessment should also be included in the LoEP. The LoEP should be updated considering the agreements in the fate section regarding the reliability of the



Subject	Conclusions Pesticide Peer Review Meeting
	assessment of background levels (i.e., remove reference to background levels if they are not considered reliable). Open point: RMS to reflect the outcome of the discussion for the aquatic risk assessment in the RAR
Experts' consultation 5.3 Experts to evaluate the information provided by the applicant for the ED assessment of IBA for non-target organisms. In the case of an ED waiver, experts to agree on whether the information provided by the applicant is enough to waive the need of the ED assessment. See data requirement in 5(68) and experts' consultation in 2(62).	Experts at the meeting considered all the available information for conducting the ED assessment for wild mammals and for non-mammalian species in a weight of evidence approach. While for wild mammals, the same conclusion as for humans could be agreed, for non-mammalian species, an evaluation of the arguments for the waiver of the ED assessment was carried out in detail. The majority of experts agreed that some of the arguments presented related to the possible exposure of indolylbutyric acid are not considered sufficiently supported by data and therefore, those arguments could not be used for waiving of the ED assessment. In particular, the applicant shall substantiate the information related to the contribution of indolylbutyric acid when used as plant protection product to the overall exposure to non-target organisms and natural background levels of the substance in the different environmental compartments including plants. As result of this consultation, all experts agreed to confirm the already set data requirement and the applicant shall decide either i) to provide further information to substantiate the waiver by providing quantitative assessment of the natural background level and the degradation profile the application as PPP of IBA (i.e., exposure of the use below natural background levels) OR ii) to follow the testing strategy in line with the ECHA/EFSA ED Guidance (ECHA/EFSA, 2018) and provide specific ED data to reach a conclusion on the ED criteria in line with the provisions in the Commission Regulation EU No 605/2018. Open points RMS to reflect the outcome of the discussion in a revised RAR. RMS to align all sections of the RAR regarding the references and assessment related to the quantification of IBA in different plant matrices as well as environmental compartments if that information is available and summarize it with a sufficient level of details that allows an independent evaluation.
Experts' consultation point 2.2 (ecotoxicity section)	The experts discussed the composition of the formulation for representative uses.



Subject	Conclusions Pesticide Peer Review Meeting
MS experts to discuss whether the available information is sufficient to conclude on the risk from the formulation(s) for representative use(s). The discussion should cover both the acute and long-term assessments. If data for the PPP are lacking, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts agreed that the formulated product was sufficiently characterised with the exception of the aquatic toxicity for which a study may be necessary (see also discussion point 5.2). Open point: RMS to update Volume 4 to reflect that among the components present in the formulation for representative uses, a basic substance is present and approved for use as a pesticide active substance. The argumentation used for that assessment may also be reflected as supportive information to suggest that the co-formulant is unlikely to be a concern for NTO.

Pesticides Peer Review TC 118/123
Cyprodinil

REPORT OF PESTICIDES PEER REVIEW TC 118/123

CYPRODINIL – AIR III after ED clock stop

Rapporteur Member State: FR

5. Ecotoxicology

Date: 24 November 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by MS AT	Austrian Agency for Food and Health Safety - AT
National Experts nominated by MS BG	Risk assessment center on food chain-BG
National Experts nominated by MS DE	German Federal Environment Agency (UBA)- DE
National Experts nominated by MS EL	Benaki Phytopathological Institute (BPI)-EL
National Experts nominated by RMS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food- HR
National Expert nominated by MS NL	CTGB- NL
Observer (CH)	BAFU - CH
Observer (EL)	Benaki Phytopathological Institute (BPI)-EL

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.3 Expert to discuss: - The effects observed in the AMA and their interpretation, including the MOA analysis and the WoE, for NTOs other than mammals and considering in particular: - potential DIO and NIS inhibition (in vitro data), vs the cytotoxicity observed in the test system. -expected and observed patterns of effect. -the effects on liver at the mid and high doses. - Pending the outcome of the discussion on the T-modality for human health, the relevance for wild mammals at the population level of the effect observed, if needed.	The experts agreed that the AMA is positive for both adversity (delay in developmental stage and decrease in nHLL) and endocrine activity (change in thyroid histopathology). Experts agreed that there were no signs of systemic toxicity considering that the wet body weight was not affected at day 21 and no mortality was seen. The effects on hind limb length and normalized hind limb length (nHLL) were not considered to indicate systemic toxicity. The effects on the T-mediated parameters were not considered secondary to liver toxicity as effects on thyroid gland were also seen in several animals which do not show effects in liver at both the highest and mid concentration. In addition, effects on thyroid are already observed at the concentration below, in the absence of effect in liver. Regarding the MOA (i.e. Liver enzyme induction leading to thyroid effects secondary to liver toxicity), experts agreed that the postulated MOA was not supported by the available data for cyprodinil (AMA results and <i>in-vitro</i> data). It was noted that, with the exception of the MOA analysis, the applicant did not submit additional data, in line with the request and the ECHA/EFSA Guidance, when level 3 tests are positive. Overall, the experts agreed that there was a clear pattern of T-mediated adversity and activity in absence of systemic toxicity. The experts noted that there were no data to dismiss the adversity observed in the AMA. Open point RMS to revise the RAR and LoEP in line with the discussion.



Experts' consultation 5.4 Pending the outcome of the human health discussion on EAS modality, expert should discuss the ED assessment for the EAS modality: -for wild mammals -for NTOs other than mammals	<u>Mamalian dataset and relevance of the effects observed at the population level.</u> The effects observed in mammals in the OECD TG 416 (delayed sexual maturation in F1 males, decreased AGDI in both generation, decrease mean number of implantations (scars) in F0 and F1 leading to decreased mean number of pups born and a reduction in live pups up to the day of culling and decrease number of ovarian follicles in F1) were considered relevant at the level of population by the RMS. The effects could be suggestive of an AA MOA, although other MOAs such as E and S cannot be excluded. All the experts agreed that the effects observed in mammals are adverse for wild mammals since they are relevant at the level of population. <u>Non-target organisms other than mammals</u> The following observations were made on the available FSTRA: - Beside the observed mortality, there were no other effects in other parameters potentially indicative of systemic toxicity (e.g., body weight, behaviour), - No effect on liver histopathology were observed, - The mortality was only observed early in the test and in a limited time window (i.e, between day 4 and day 6), and after the initial days no signs of suffering were noted. - In the same time window one male died in one replicate at the lowest concentration. Based on this, the experts agreed with the ED WG and concluded that the mortality was not treatment related (i.e. no signs of systemic toxicity were seen in the test). The experts also discussed the induction in VTG in males at the highest concentration, and conclude that it was not driven by only one animal. Overall, all the experts agreed that the FSTRA is positive for adversity (decrease in fecundity accompanied by change in female gonad histopathology, GSI increase in males and females) and endocrine activity (increase in VTG in males). The experts discussed one of the plausible MOAs for the effects observed in fish (impaired testosterone/estradiol level leading to reduced fecundity) and agreed that it could be one of the plausible MOA, acknowledging that it was not fully supported by the available data. Overall, taking into consideration both the mammalian and non-mammalian dataset, the experts agreed that:



	- In mammals a pattern of EAS-mediated adversity is observed suggesting a AA MOA although other could be also plausible like E and S MOA. - The effects and changes observed in the available FSTRA would fit with the pattern identified and the possible MOA(s) suggested for mammals. Open point RMS to revise the RAR and LoEP in line with the discussion.
Experts' consultation 5.5 Experts to discuss the impact of the newly submitted study according to OECD TG 416 on the selection of the ecotoxicologically relevant endpoint for wild mammals and as a consequence on the risk assessment.	A new two generation study was available. Therefore, the ecotoxicological relevant endpoint for wild mammals was reconsidered. Based on the new available evidence, the experts agreed to set the ecotoxicological relevant endpoint for wild mammals at 23 mg/kg bw/day based on delay in sexual maturation (i.e. increase age at balanopreputial separation) and decrease in Ano-genital distance observed at 77 mg/kg bw/day as indicated above. Open points: - RMS to update the RAR in line with the discussion including LoEP, Vol 1 and Vol 3. - RMS to revise the chronic risk assessment to mammals and consequently update the pertinent sections in the RAR and LoEP. - RMS to include the finding on the AGDI at the mid dose.



Experts' consultation 5.6 identified by EFSA following ED clock stop MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	A86337C The experts agreed that additional information would be necessary to fully characterize the safety of the formulation for birds, fish and aquatic invertebrates. For earthworms, in line with the core EU data requirements, chronic data with earthworms is necessary (data gap already identified in the context of risk assessment). A14325E Based on the available data the RMS concluded that the data are insufficient to conclude on the ecotoxicological profile of the representative formulation for birds (acute and chronic) and fish (chronic). For mammals, the same conclusion drawn during TC 119 (see report mammalian toxicology for TC 119) applies for both formulations. Open point (applicable to all co-formulants): RMS to complete the assessment of the ecotoxicological profile of the co-formulants and report it in the revised RAR (vol. 4) to enable an independent hazard identification and characterisation. The conclusion of the RMS should be presented clearly and referred to the safety of the co-formulant <i>per se</i> as well as in relation to the concentrations in the PPP. If sufficient information is not available, a data gap will be included in the EFSA conclusion

Pesticides Peer Review TC 118/123
Fenoxaprop-P

REPORT OF PESTICIDES PEER REVIEW TC 118/123

FENOXAPROP-P – AIR III after ED clock stop

Rapporteur Member State: AT

5. Ecotoxicology

Date: 24 November 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by MS AT	Austrian Agency for Food and Health Safety - AT
National Experts nominated by MS BG	Risk assessment center on food chain- BG
National Experts nominated by MS DE	German Federal Environment Agency (UBA)- DE
National Experts nominated by MS EL	Benaki Phytopathological Institute (BPI)- EL
National Experts nominated by RMS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food- HR
National Expert nominated by MS NL	CTGB- NL
Observer (CH)	BAFU - CH
Observer (EL)	Benaki Phytopathological Institute (BPI)- EL

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.6 Expert to discuss the FSTRA and more particularly, considering the whole dataset (in vitro, and in vivo in mammals): - if the FSTRA is considered relevant based on the potential anti-androgenic MOA in mammals, - if the test is considered sufficient to conclude on the EAS modalities for NTOs other than mammals, considering the missing information (gonad histopathology, fertility). The conclusion of the Tox expert group consultation should also be taken into consideration.	The experts concluded that the Fish Short term reproduction assay (FSTRA) study should be considered reliable with restrictions based on the following drawbacks: - A high standard deviation is noted at the highest tested concentration in the vitellogenin (VTG) in males, which cannot be attributed to normal variability, since such variability was not observed in the other treatments and control. - Regarding fecundity, the performance of the control was quite low compared to the treatments, which could hamper the detection of an effect; - In absence of gonad histopathology to complement the assessment of fecundity, the results are uncertain. All the experts agreed that a conclusion cannot be drawn for non-mammalian species for EAS-modalities for the following reasons: - Fenoxaprop-P-ethyl is positive for AA in mammals and the FSTRA may not be the most suitable test to detect AAs - The induction in VTG in males should not be dismissed - The results for fecundity are uncertain due to the low performance of the controls - Gonad histopathology was not assessed which, although not mandatory, is a very relevant parameter that should be routinely assessed, especially in the case of AAs. Open point RMS to amend the RAR and LoEP in line with the discussion



Experts' consultation 5.7 Expert to discuss the relevance for wild mammals of the finding in rat studies, including the Hershberger assay. The discussion should take into consideration the conclusion from the tox expert (see comment 3 and 10 above), the fact that non-intact organisms are used in the Hershberger assay, and the potential indication of adverse effect relevant at the population level for wild mammals.	As per common practice, effects at organ level are not considered relevant for the population. In addition, when considering both the type of effects and the magnitude for the sensitive parameters (e.g gestation length, Number of live births), experts were of the opinion that it is unlikely that those are relevant at the level of population (effects < 10%). Therefore, it was concluded that based on the incomplete dataset and the available evidence, a concern for wild mammals cannot be excluded, and a definitive conclusion on the EAS-modalities for wild mammals cannot be drawn. Open point RMS to amend the RAR and LoEP in line with the discussion
Experts' consultation 5.8 identified by EFSA following ED clock stop MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	Overall, experts agreed that [REDACTED] could represent a critical co-formulant when drawing a conclusion for the safety of the formulation and a concern could not be excluded. In addition, experts agreed that the applicant shall address the chronic toxicity of the formulation. If chronic data are available for the components, an additive assessment could be conducted. Open points: RMS to update the Vol 4 in line with the outcome of the discussion.

REPORT OF PESTICIDES PEER REVIEW TC 118/123

CHLOROTOLURON – AIR III

Rapporteur Member State: BG

5. Ecotoxicology

Date: 24 November 2023

List of participants:

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EFSA statutory staff members	EFSA
National Experts nominated by MS AT	Austrian Agency for Food and Health Safety - AT
National Experts nominated by MS BG	Risk assessment center on food chain- BG
National Experts nominated by MS DE	German Federal Environment Agency (UBA)- DE
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Observer (CH)	BAFU - CH
Observer (EL)	Benaki Phytopathological Institute (BPI)- EL
Translator for BG Ms	Freelance translator/interpreter

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the acute risk to birds including: - RUD values - Focal species and PD values - The body-burden modelling.	The experts agreed to use the default values from EFSA GD 2009 for ground-dwelling arthropods as a surrogate for earthworms RUD values. It was agreed that setting RUD values to 0 mg/kg, based on the fact the fruits are not expected in a cereal field, is not appropriate. The experts' discussed an agreed the focal species that could be used for the refined avian assessment. The experts agreed that model as provided is not sufficient to be used in the RA, highlighting that extrapolation between mammals and birds is not well supported. Overall, the experts agreed the acute RA shows high risk. Open points: i) RMS to update the RAR indicating that the ground-dwelling arthropod RUD values as a surrogate for the RUD for earthworms (i.e. acute RUD = 13.8 mg/kg and for reproductive RUD = 7.5 mg/kg). The RMS should also reflect that the RUD for fruit and carrion cannot be assumed to be 0 mg/kg but the need for such RUDs will be discussed under the focal species and ecological parameters. ii) RMS to update the RAR considering the discussion and agreements during the expert meeting for the focal species selection. The risk assessment should be updated also. iii) RMS to reflect the outcome of the expert meeting regarding the appropriateness of the Body Burden Modelling (BBM) for birds in an update RAR. RMS to remove the BBM from the LoEP. RMS to acknowledge in the RAR that the WG advice was discussed at the meeting. iv) RMS to update the acute RA for birds in the RAR. No new TER values are needed since no quantitative refinements were accepted.



Experts' consultation 5.2 Experts to discuss the use of the TWA RUD for both the refined bird and mammal risk assessment.	Overall, the experts agreed that the proposed AUC derived time-weighted average concentration in ground dwelling arthropods is not appropriate and therefore the assessment should use the default RUD values as indicated in the EFSA 2009 together with the appropriate fTWA value discussed during the meeting. Open point: RMS to update the RA in the RAR removing the refinement of the AUC derived time-weighted concentration values (fTWA x RUD) for arthropods. The RA instead should use the default RUD values from EFSA GD 2009 together with the appropriate fTWA value discussed during the meeting.
Experts' consultation 5.3 Experts to discuss the available residue decline studies and the proposed refined DT50 values.	The experts discussed and agreed that the available residue decline studies were reliable. The experts also discussed the reliability of the available DT50 values and their applicability to the risk assessment. Open points: RMS to update the RAR to indicate no refined DT50 values in Northern zone are available for any matrix. RMS to update the RAR with the agreed DT50 values for central and Southern zone and noting that they are either for the autumn or spring period. The RMS should also update the refined risk assessment using the recalculated fTWA values calculated using the agreed DT50 values (where available). The LoEP should also be updated. RMS to reflect the high variability between values for arthropods, in particular for the central zone (1.7 to 16.9 d) which should be reflected in the overall analysis. RMS to update the study summaries for the 3 residue decline studies to reflect the outcome of the meeting discussion. In particular for the reliability considering the use of other pesticide and the rainfall that occurred during critical time period. RMS to indicate in the RAR the results of the rainfall in the study summary for study B.9.1.1.2/01.



Experts' consultation 5.4 Experts to discuss and agree the avian on reproduction endpoint to be used for the reproductive risk assessment the following particular points should be covered in the discussions: observed - mortality and the variable doses - How the mortality should be accounted for considering reproductive parameters - The endpoint which should be considered for the risk assessment.	The experts discussed the available avian reproduction study B.9.1.1.3/01. The experts considered that the observed mortality should not be excluded from setting the endpoint and furthermore agreed with the new endpoint proposed by the RMS for reproductive effects. The experts agreed that the lowest test concentration should be used for converting the endpoint to NOAEL value. All experts agreed that the appropriate endpoint from the study was the lowest test concentration and the lowest of the two concentrations tested within that group (15 mg a.s./kg diet). When converted to a dose this gives a NOAEL of 1.6 g a.s./kg bw per day. Open points: i) RMS to update the avian reproduction study evaluation to reflect the discussions during the meeting (both for the selection of endpoint and conversion of the endpoint to a dose). The agreed endpoint is 15 mg a.s./kg diet). When converted to a dose this gives a NOAEL of 1.6 g a.s./kg bw per day. ii) RMS to update the reproductive risk assessment for birds with an endpoint of 1.6 mg a.s./kg bw per day. iii) The RMS should also update the LoEP accordingly.
Experts' consultation 5.5 present in risk assessment (of the crop) uses of herbicide mammals. It is important that the experts agree on which scenario should be used for reaching the final conclusion for this use.	Experts at the meeting agreed not to add an additional focal species to include herbivores/omnivore with weeds in their diet in the early BBCH stages 0 to 9 and in the RA for B&M, based on the specific use conditions of the current proposed intended uses in cereals. Open point: RMS to reflect in the RAR that no additional generic focal species are needed for the bare soil scenario for BBCH 0 - 9 considering the specific conditions related to the GAP for chlorotoluron. The RMS should also reflect that some Member States may need to include an additional focal species (including weeds in the diet) at product level assessments pending on the conditions in their MS.



Experts' consultation 5.6 The experts should discuss the refined risk assessment for birds covering all aspects. This includes the following if the applicant choses to support these refinements in the above DR: i) Focal species ii) PT data iii) PD data iv) Use of TWA-RUDs v) Exposure during the breeding season and possibilities of delayed effects vi) Residue values used for each matrix Overall outcome and weight-of-evidence assessment.	The experts discussed and agreed the available refined reproductive risk assessment for birds including the representativeness of the refined values relative to the GAP. Overall, the experts agree that high risk remains for all generic focal species. The RMS will need to update the RA using the DT₅₀ values (i.e. recalculated fTWA values), however it is clear based on the magnitude of failure at tier 1 a high risk will still be identified. The experts also agreed that the plant metabolite desmethylchlorotoluronbenzyl alcohol-glucoside should be considered in the risk assessment for birds and mammals. Open points: i) RMS to reflect on the outcome of the meeting discussion on the PT in a revised RAR and remove the PT refinements for skylark and yellowhammer in the Vol.3 B9 and LoEP. ii) RMS to reflect the outcome of the discussion for the applicants argumentation on the exposure of birds during their breeding season at the expert meeting in the RAR. iii) RMS to reflect in the RAR that the experts did not agree with paragraphs regarding the attractiveness of fields to birds, availability of grain to birds and deshusking seeds by birds. iv) RMS to update the repro RA in the RAR. New TER values should be calculated including the refined DT₅₀ (i.e. and recalculated fTWA values), where appropriate. v) RMS to reflect that desmethylchlorotoluronbenzyl alcohol-glucoside should be addressed for B&M. However, for mammals the metabolite is considered to be covered by the parent but further information is needed to address the uncertainty related to the RA for birds.



Experts' consultation 5.7 Experts to discuss and agree on the reproductive endpoint to be used for the risk assessment of wild mammals.	One two-generation study, one developmental toxicity study with rat and 2 developmental toxicity studies with rabbits were considered. It was proposed to set the ecotoxicological relevant endpoint at 12 mg/kg bw/d based on developmental effects, i.e. number of viable foetuses, in one of the developmental toxicity studies with rabbits. It was noted that there was a difference in the number of viable female foetuses at all concentrations. However, the dose response likely started at the mid dose when considering (i) the huge decrease in viable foetuses in both sexes at the high concentration, (ii) the decrease at low and mid dose was of the same percentage and this is not expected considering the dose spacing of 10, (iii) the combined decrease for males and females is less than 10% at both low dose and mid dose. Open point: RMS to reflect the outcome of the discussion in the revised RAR; Open point: RMS to update the risk assessment in the RAR and LoEP using the endpoint of 12 mg a.s./kg bw per day for mammals.
Experts' consultation 5.8 Experts to discuss the refined reproductive risk assessment for mammals. The exact topics to be discussed will depend on the applicant.	The experts agreed that the proposed focal species and PD value for the large herbivorous mammal was not supported. The only available refinements for the reproductive risk assessment for mammals was the refined fTWA values using the refined DT₅₀ values where applicable. Open points: i) RMS to update the risk assessment based on the discussion for the generic focal species for large herbivorous mammal. ii) RMS to update the RA with the available DT₅₀ for mammals (using cereal seedlings, weeds and ground arthropods). It should be clearly reflected that the refined assessment covers only the area (and time of year) covered by the available DT₅₀ values and does not cover all locations/time of year in the GAP.



Experts' consultation 5.9 Experts to discuss the available refinements for algae and plants and in particular the studies of algal and macrophyte species which include a recovery phase or exposure under cold conditions and agree whether those studies should be considered in the overall weight of evidence.	The Guidance Document for aquatic organisms (EFSA PPR Panel, 2013) clearly mentions that recovery can only be addressed at tier-3 or higher, thus the recovery phase of laboratory test will not be further considered. Nonetheless, endpoints derived during the exposure phase should be listed in the LoEP and considered for the risk assessment, provided that suitable growing was seen in the control. Since during the exposure phase the control growth was limited in tests under cold conditions, the results of these test could not be considered for the risk assessment. Open point: RMS to update the LoEP by including only the exposure phase of the recovery studies (provided that suitable control growth was observed). Remove endpoints from cold condition studies from the LoEP.
Experts' consultation 5.10 Experts to discuss the Tier 2 A (geomean/WoE) and the Tier 2B for algae and macrophytes, including data considered for those refinement, AF, sequence in the tiered approach.	Chlorotoluron inhibits photosynthesis, thus its mode of action should not affect algae and aquatic plants in a substantially different way. This is confirmed by the fact that the sensitivity distribution of the two groups largely overlaps. In light of this, the experts agreed to base the Tier-2 for both groups on a common SSD built with 15 species (Tier-2C RAC of 11.8 µg/L). <i>Glyceria maxima</i> was found to be considerably more tolerant than any other species, but it was not believed that this is an indication that substantially more sensitive species than the one tested would exist. For <i>Lemna minor</i>, the existing endpoint based on frond number would likely not reflect the most sensitive for the species (related to weight). Thus, the experts agreed to exclude <i>Glyceria maxima</i> and <i>Lemna minor</i> from the aforementioned SSD. Open point: RMS to amend the tier-2 risk assessment for primary producers in the RAR and in the LoEP using the HC₅ obtained from merging the dataset from both algae and macrophytes with the only exclusion of <i>Glyceria maxima</i> and <i>Lemna minor</i>. The standard Assessment Factor of 3 should be used.



Experts' consultation 5.11 Experts to discuss the available TKTD for algae and plants.	In considering the advice of the WG, the experts noted many aspects of the models application were positively evaluated. Nonetheless, critical aspects were also highlighted. For SAM-X (algae model), the main criticisms related to the species selection and to the experimental flow-through setup which is necessary for validating the model (and which therefore drives also the endpoint selection). The setup is promising, but there are several aspects that still needs to be further investigated before considering it suitable for regulatory risk assessment. For the <i>Lemna</i> model, the main criticism was related to the unverified assumption that the ratio between frond number (used for calibration and validation of the model) and dry weight (actual output of the model) would remain constant irrespectively of exposure to chlorotoluron. Other minor criticisms were raised, although not considered <i>per se</i> sufficient to dismiss the model use in risk assessment. In light of the above, the experts agreed not consider the modelling simulations as suitable for a Tier-2C₁ risk assessment. Open point: RMS to include a summary of the WG advice in the revised RAR. Highlighting the reasons underpinning the rejection of the use of the two models in risk assessment. It should be in any case clarified that, pending on the changes of the fate assessment, the refinements (as presented by the applicant) would in any case be considered obsolete.
Experts' consultation 5.12 Experts to discuss the newly submitted refined exposure FFLC with medaka. As explained by the applicant in comment 5(167), the study is not a tier 1 study but it's a chronic study with pulsed exposure.	No reliability concerns were raised for either phase 1 (with fathead minnow under constant exposure) or phase 2 (with Japanese medaka under pulsed exposure). Thus, both studies were considered valid. The endpoint from phase 1 will be included in the LoEP, but will not be used in the risk assessment as it was not obtain with the species currently delivering the lowest Tier-1 chronic endpoint for fish. The outcome of phase 2, being a pulsed exposure lasting 15 days, should be used in a Tier-2C risk assessment, thus comparing the exposure in the study with the FOCUS exposure profiles. Open point: RMS to use phase 2 of the study as Tier-2C by comparing the exposure in the study with FOCUS exposure profiles (scenario by scenario). This comparison should consider the AF of 10 and use as baseline the Tier 1 RAC for fish.



Experts' consultation 5.13 Experts to discuss the three available micro/mesocosm studies and related statistical analysis and their suitability for use in risk assessment including, Environmental trigger curve approach, the comparison with the FOCUS exposure profiles.	After considering all the results from the available mesocosms studies in terms of population dynamics, measurement of other parameters (e.g. weight of plants, etc.) and the related statistical analysis, the expert agreed that: - No NOEC or NOEAEC can be derived for algae from the study presented under data point B.9.2.8/15. This is mainly due to the effects observed on periphyton (cyanobacteria and sub-taxon). - A NOEC = 50 µg/L, coupled with an AF of 3, can be set for aquatic plants from the study presented under data points B.9.2.8/16. This is mainly based on the effect on <i>Lemna</i> (frond number measured in time). No NOEAEC could be derived in view of the uncertainty related to the most sensitive endpoint for <i>Lemna</i> (dry weight) at the end of the study, together with the low abundance of species with a suitable MDD category (n=6). - A NOEC = 5 µg/L for both algae and plants could be derived from the study presented under data point B.9.2.8/18. This is based on effects on phytoplanktonic species (e.g. <i>Chroomonas sp.</i>) and on metaphyton. An AF = 2 should be used for the risk assessment. Significant effects observed on metaphyton at later dates at treatment levels higher than 5 µg/L hampered the establishment of a NOEAEC for algae. - Profiles from both studies presented under data points B.9.2.8/16 and B.9.2.8/18, lowered by the appropriate AF, can in principle be used in the comparison with the FOCUS exposure profiles. However, the exposure profile from the study presented under data points B.9.2.8/16 can only be used for plants. Open point Considering the change in the PEC_{sw} and the agreed endpoint, the Tier-3 risk assessment needs to be revised. RMS to revise the RAR and the LoEP accordingly. RMS to conduct the Tier-2 risk assessment for both algae and plants and go to Tier 3 RA only for plants only for those scenarios failing the RA. For algae, the Tier-3 RAC is lower than Tier-2B.



Experts' consultation 5.14 Experts to discuss the available FFLC with medaka and the endpoint re-calculation submitted by the applicant.	The experts acknowledged that the available FFLC with Japanese Medaka presents several uncertainties, mainly related to the control performance. Nonetheless, when weighed against the fact that significant mortality was seen at the highest treatment levels, the experts agreed not to dismiss the study. Thus, even accounting of the uncertainties of the study, it was agreed that, for chronic fish, the NOEC (=119 µg/L) from the FFLC study with medaka should be the basis for the Tier-1 chronic fish RAC. Open point: RMS to amend the Tier-1 RA in the RAR and LoEP by using a NOEC of 119 µg/L as a basis for the chronic RAC for fish.
Experts' consultation 5.15 Experts to discuss the Tier 1 risk assessment for algae and the use of the lowest available endpoint vs the endpoint from standard species.	When the lowest available endpoint is obtained with a non-standard species, the lack of consideration of such endpoint at the Tier-1 would risk reverting the conservativeness gradient across tiers (i.e. a Tier-2 more conservative than the Tier-1). Thus, the experts agreed that at the Tier-1, the lowest absolute endpoint for algae (E_rC_{50} = 51.1 µg/L) should be used together with the standard assessment factor of 10. The experts also agreed, for macrophytes, the use of the endpoint already selected by the RMS (E_rC_{50} = 38 µg/L based on wet weight for <i>Lemna gibba</i>). Open point: RMS to report in the RAR all relevant endpoints for all studies with macrophytes (at least E_rC_x for wet weight and dry weight). Open point: RMS to include the risk assessment for the pertinent surface water metabolites in the LoEP also considering the revised PEC_{sw}. The the recalculated PEC_{sw}.



Experts' consultation 5.16 Experts to discuss the risk assessment for bees according to the EFSA Guidance Document (EFSA, 2013) considering the available dataset and all relevant routes of exposure. Any additional data/evidence submitted by the applicant should also be discussed at the meeting.	The chronic risk assessment to bees submitted by the applicant and based on ECPA (2017) was not accepted by the experts. All experts agreed that a risk assessment following the EFSA (2013) bee guidance document is necessary to assess the risk of chlorotoluron for all relevant exposure routes. Open point: RMS to update the risk assessment by including a risk assessment for bees according to the EFSA guidance (2013) and to update the list of endpoints accordingly.



Experts' consultation 5.17 The experts should discuss the risk assessment for non-target terrestrial plants. In particular, the experts should discuss: - The seedling emergence and vegetative vigour studies (CP 10.6.2/01 and CP 10.6.2/02, respectively), including: - o the adequacy of the plant species tested in the seedling emergence and vegetative vigour tests; see comment 5(264); - o the endpoints based on phytotoxicity effects; see data requirement in 5(262) and comments in 5(266), 5(267) and 5(273); - o the lack of analytical verification of stability in application solutions; see data requirement in 5(272). - The validity of the germination and vegetative vigour study (CP 10.6.2/03) and its use in the risk assessment; see comment in 5(268); - The risk assessment approach: Use of a HC₅ of 43.5 g a.s./ha being higher than the lowest endpoint in a probabilistic approach;	Different limitations were identified in all studies available to assess the risk of chlorotoluron for non-target terrestrial plants (NTPs) and, therefore, no reliable endpoints could be derived from any of the studies. Therefore, the risk assessment to NTPs cannot be finalised with the current data package and a data gap will be set. A metabolite risk assessment for NTPs is not required. Open point: RMS to reflect the outcome of the discussion in the updated RAR; the endpoint should be removed from the list of endpoint.



see comments in 5(265),
5(270);
- The risk assessment for
the metabolite
chlorotoluron benzoic
acid; see data
requirements in 5(276)
and 5(277).



Experts' consultation 5.18 Experts to decide whether the available data are sufficient to conclude on the ED properties of chlorotoluron for non-target organisms (all EATS modalities). New information should be taken into account, particularly, the new AMA (see data requirement 5(289)), the information on gonad histopathology and the statistical re-evaluation in of the FFLC study as stated in 5(142). In addition, the issue about the MTC as described in 5(321) should be clarified and considered for the assessment. See also 5(142), 5(178), 5(289), 5(290), 5(311), 5(321), 5(322),5(325). A conclusion for wild mammals as non-target organisms should be also included. This will need to be done based on the outcome of the discussion set in experts' consultation 2(113).	Based on the conclusion for humans (i.e., further data are necessary to conclude whether chlorotoluron meets the ED criteria for the EATS-modalities), experts at the meeting concluded that this would also apply for wild mammals as non-target organisms. For non-mammalian species, the experts' meeting conclusion were as follows: - T-modality: All experts agreed with the RMS conclusion and no evidence of T-mediated endocrine activity could be observed in the available Amphibian Metamorphosis Assay. - EAS-modalities: The available Fish life-cycle toxicity test was not deemed sufficient to conclude on the ED properties of chlorotoluron due to major drawbacks (e.g., lack of plasma vitellogenin measurements and questionable reproductive performance of the control fish) and further data would be necessary. At the meeting, the experts agreed that further data are needed to conclude on the ED properties of chlorotoluron for EAS-modalities. In particular the following studies should be submitted: • 21-day fish assay (i.e., Short-Term Screening for Oestrogenic and Androgenic Activity, and Aromatase Inhibition Assay in line with OECD TG 230) with Japanese medaka (<i>Oryzias latipes</i>), including gonad histopathological assessment. • If this level-3 study is positive, further data would be needed to further investigate the adversity (i.e., a Medaka Extended One Generation Reproduction Test (MEOGRT) fully in line with OECD TG 240 or a new Fish life-cycle Toxicity test with Japanese medaka where all the parameters foreseen to be investigated in a test in line with OECD TG 240 need to be provided). Open point: RMS to reflect the outcome of the discussion in the revised RAR.



Experts' consultation 5.19 proposed by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The available toxicity data with the representative formulation and the available data for individual co-formulants were discussed. On the basis of the information available to the meeting, it was provisionally agreed that no additional concerns are identified for the PPP for non-target organisms. Open points: i) RMS to check if there are toxicity values available for those co-formulants to support the argument of no-concern. ii) RMS to reflect the outcome of the discussion in the revised RAR. iii) RMS to include the assessment of the co-formulants in volume 4.

REPORT OF PESTICIDES PEER REVIEW TC 118/123

FLUDIOXONIL – AIR III after ED clock stop

Rapporteur Member State: FR

5. Ecotoxicology

Date: 24 November 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff members	EFSA
National Experts nominated by MS AT	Austrian Agency for Food and Health Safety - AT
National Experts nominated by MS BG	Risk assessment center on food chain-BG
National Experts nominated by MS DE	German Federal Environment Agency (UBA)- DE
National Experts nominated by MS EL	Benaki Phytopathological Institute (BPI)-EL
National Experts nominated by RMS FR	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS HR	Croatian Agency for Agriculture and Food- HR
National Expert nominated by MS NL	CTGB- NL
Observer (CH)	BAFU - CH
Observer (EL)	Benaki Phytopathological Institute (BPI)-EL

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.8 Experts to discuss the available Amphibian Metamorphosis Assay (AMA) and its findings. The experts should discuss whether the available study provide positive evidence for endocrine activity and if, pending on the possible mode of action (MoA), further data may be needed to conclude, although they cannot be requested any longer.	The experts discussed the available valid Amphibian Metamorphosis Assay (AMA) and its findings. Overall, when considering the available evidence: • decrease in growth parameters (i.e., snout-vent length (SVL), hindlimb length (HLL) and whole body weight (WBW)) at day 7, • decrease in developmental stage, SVL and WBW at day 21, • gross malformation in HLL and forelimb (which prevented the staging of some tadpoles and therefore were excluded from the analysis of developmental stage), • no evidence of T-mediated endocrine activity in the available in vitro tests; all experts agreed that the available data do not suggest a convincing pattern of T-mediated endocrine activity and adversity. The experts rather considered such effects as suggestive of systemic toxicity rather than a pattern linked to T-mediated endocrine mode of action (MoA). Open point RMS to update the RAR (Vol 1, Vol 3 and LoEP) according to the meeting discussions. RMS to include a conclusion on wild mammals for the T-modality in the updated RAR (Vol 1, Vol 3 and LoEP), if not already present.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.9 Experts to discuss: • The choice of the tested concentrations in relation to the maximum tolerated dose (MTC) for the Fish Short-Term Reproduction Assay (FSTRA) and Fish Sexual Development Test (FSDT); • the findings in the available fish toxicity study, i.e., FSTRA; FSDT and fish-full-life-cycle test (FFLCT) • the overall weight of evidence for oestrogen-androgen-steroidogenesis (EAS)-modalities for non-target organisms. Pending on the conclusion drawn for humans, the experts should also discuss: • the relevance at the level of population of the identified adversity for EAS-modalities.	The experts discussed the available evidence from fish studies and the conclusion on wild mammals, following the conclusion reached for humans. The experts discussed the relevance at the level of population of the EAS-adversity identified in mammals. Based on the type, magnitude of effects, the experts concluded that the pattern of EAS-mediated adversity is relevant at the level of population and therefore adverse for wild mammals. Based on the effects observed, the experts also agreed that the available FSTRA, FSDT and FFLCT confirm that an ED mode of action (MoA) cannot be excluded for non-mammalian species, similarly as to mammals. Overall, a pattern of EAS-mediated activity/adversity suggesting an anti-androgenic (AA) MoA was indicated based on the available data in mammals and non-mammalian spp. In conclusion, based on the available evidence from fish and mammals, all experts agreed that for the active substance fludioxonil the ED criteria for the EAS-modalities were met for non-target organisms. Open point RMS to update the RAR (Vol 1, Vol 3 and LoEP) in line with the discussions.
New experts' consultation point as a follow up from the ED discussions: Experts to discuss the impact of the new available study (new OECD TG 416) on the selection of the endpoint for risk assessment of wild mammals and as a consequence on the risk assessment.	Since a new two-generation study according to OECD TG 416 was available, the experts discussed its impact on the selection of the ecotoxicologically relevant endpoint for mammals. Although the 2 available two-generation studies were not fully comparable because 2 strains were used, it was noted that the LOAEL was in both studies 3000 ppm. Therefore, all experts agreed that the NOAEL of 58 mg/kg bw per day is sufficiently protective considering the dose at which effects were seen in both studies. Open points: - RMS to reflect the outcome of the discussion in the revised RAR and LoEP. - RMS to revise the long-term risk assessment for wild mammals.



Subject	Conclusions Pesticide Peer Review Meeting
New experts' consultation 5.10 MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts considered the available ecotoxicity data for the formulations for representative uses. Where data were lacking, the results of the data retrieval exercise for the individual components were considered. Overall, it was suggested that the RMS will need to conduct the "retrieval of toxicity information" for the co-formulants. If no information is available, this will be reported as a data gap in the EFSA conclusion. Open point (applicable to all co-formulants): RMS to complete the assessment of the ecotoxicological profile of the co-formulants and report it in the revised RAR (Vol. 4) to enable an independent hazard identification and characterisation.

REPORT OF PESTICIDES PEER REVIEW

WRITTEN PROCEDURE (follow up to the Pesticide Peer Review TC 99 from March 2023)

FLUFENACET – AIR III

Rapporteur Member State: PL

5. Ecotoxicology

Date: Written procedure from 13/10 to 24/10

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
Federal Institute for Risk Assessment (BfR)	DE
Estonian Agricultural Board	EE
Tragsatec on behalf of Ministerio de Sanidad (MISAN)	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
E-V-A Sp. z o.o.	PL
Observer (1)	AT

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.5 (Follow up to the discussions held at the Pesticides Peer Review TC 99 on 29 March 2023) Experts to discuss the available Extended AMA. In particular, the experts should discuss: a. If the validity and performance criteria of the AMA (OECD TG 231) apply; b. If the changes observed in HLL should be considered as due to systemic toxicity or sign of ED-adversity; c. How to consider the change in normalised HLL vs the change in time to reach NF 62. d. The increase in follicular cell hypertrophy at the	An Extended Amphibian Metamorphosis Assay (EAMA) conducted in line with Ortego et al., (2021) was available for the assessment of the endocrine disrupting properties of flufenacet through the T-modality. As supportive information, some parameters investigated in the available Early life stage (ELS) and Fish Full Life Cycle (FFLC) test were also considered in the assessment for the T-modality, i.e. embryo time to hatch and % swim up. a. If the validity and performance criteria of the AMA (OECD TG 231) apply; The experts discussed that both the validity criteria for the AMA and some of the LAGDA may be applicable, i.e. weight of control(s) at stage NF 62 should reach 1.0 ± 0.2. This latter criterion was not met in the available EAMA. Although all experts agreed that this is not sufficient to invalidate the study, this was considered as a source of uncertainty. b. If the changes observed in HLL should be considered as due to systemic toxicity or sign of ED-adversity; c. How to consider the change in normalised HLL vs the change in time to reach NF 62 All experts agreed that when animals reach a stage $NF \geq 60$, the HLL should likely not be considered a diagnostic parameter. This was corroborated by the available data showing the nHLL and the time to reach NF 62 in the opposite direction. d. The increase in follicular cell hypertrophy at the highest tested concentration. The change in the thyroid histopathology at the highest tested concentration were considered a compensatory mechanism considered a compensatory response that the organism is expending energy to



Subject	Conclusions Pesticide Peer Review Meeting
highest tested concentration Please note that according to the ECHA/EFSA GD parameters considered sensitive to but not diagnostic are those parameters which may be due to ED or any other MoA and should not be mixed up with parameters clearly indicating systemic toxicity, such as mortality.	counteract the chemical insult via thyroid-specific processes. However, the decrease in body weight were considered to suggest systemic toxicity at the same concentration. Overall, all the experts considered likely that flufenacet interferes with the HPT axis, however it could not be excluded that the T-mediated effects were secondary to systemic toxicity (i.e., decrease in wet weight both at day 7 and study termination). The experts also discussed whether the adverse effects identified in rodents, i.e., change in thyroid histopathology and change in thyroid hormones in different species and studies and at different dose level accompanied by effects in the DNT study, were adverse at the level of the population. The experts agreed that the population relevance of the observed effects cannot be excluded when considering: (i) the effects observed in the available DNT study, i.e., changes in the linear measurement of the caudate putamen in females at PND 72. The effect is linked to learning, emotion, attachment behaviour and motor functions. Although certain of these parameters were measured in the available DNT, the test is not exhaustive. (ii) the DNT IVB for flufenacet is negative and therefore DNT changes consequent to altered THs homeostasis cannot be excluded; while it is unlikely that flufenacet would act as a direct developmental neurotoxicant. This was further confirmed following the written procedure for the ED assessment for humans done in October 2023. Open point: RMS to report the outcome of the discussion in the revised RAR.

REPORT OF PESTICIDES PEER REVIEW TC 114-117

ELEMENTAL IRON – NAS

Rapporteur Member State: AT

5. Ecotoxicology

Date: 20 September 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by RMS Austria (4)	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Belgium (1)	Federal Public Service Health, Food Chain Safety and Environment- BE
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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the available toxicity data for birds and their use in risk assessment.	No avian acute study with the representative formulation was submitted. However, a study (KCP 10.1.1.1/01) was available, testing the effects of a non-representative formulation to the Japanese quail. Concerning the acute endpoint selection, experts agreed that the bridging between formulations is not fully justified (i.e., study KCP 10.1.1.1/01 could not be considered informative of the assessment of the representative formulation). Nonetheless, study KCP 10.1.1.1/01 could be considered supportive for the current assessment of elemental iron. It was agreed that the endpoint from study KCP 10.1.1.1/01 should be reported in the List of endpoints (LoEP) with a footnote acknowledging that the formulation "Slug & snail killer" was not considered fully comparable to 'Final bite'. A standard reproductive study with birds was not available. Instead, a surrogate chronic toxicity endpoint chronic (NOEL of 34 mg/kg/bw/d) was derived from a non-GLP open-literature publication listing nutritional requirements of birds (KCA 8.1.1.3/06). However, experts finally agreed that the endpoint from KCA 8.1.1.3/06 is not suitable for a quantitative risk assessment, but considered it suitable as supplementary information for use in a qualitative assessment. Open points: - The RMS was requested to reflect the outcome of the discussion on the acute and reproductive avian endpoint in the revised DAR - The RMS was requested to include the endpoint from KCP 10.1.1.1/01 in the LoEP with a footnote acknowledging that



Subject	Conclusions Pesticide Peer Review Meeting
	the formulation “Slug & snail killer” was not considered fully comparable to ‘Final bite’ - The RMS was requested to remove the surrogate reproductive endpoints from the LoEP and to delete the quantitative (illustrative) long-term risk assessment from the DAR and LoEP.
Experts’ consultation 5.2 Experts to discuss the available toxicity data for wild mammals and their use in risk assessment.	The available acute study (KCA 5.2.1/01) with the active substance from the open literature was assessed as acceptable with restrictions in the human toxicology section. A second valid acute study (CP 10.1.2.1/01) with the representative formulation was submitted by the applicant, showing no significant mortality in the animals exposed to the test item (LD50 > 2000 mg product/kg bw, corresponding to 20 mg a.s./kg bw). It was agreed that the study with the active substance (KCA 5.2.1/01) should not be used in a quantitative risk assessment due to major deviations in its design relative to standard Test Guidelines (TGs). The study with the formulation (CP 10.1.2.1/01) was deemed suitable for risk assessment. No valid reproductive study was available. However, a non-standard, open literature study (KCA 5.3.2/02) which was not conducted under GLP was available. This study was not considered suitable for a quantitative risk assessment. However, the information could be used in a (qualitative) weight of evidence. Open points: The RMS was requested to: - reflect the outcome of the discussion on the acute and reproductive mammalian endpoint selection in a revised DAR; - revise the acute risk assessment to mammals by using the endpoint derived from the study with the representative formulation; - remove the endpoint from the study KCA 5.3.2/02 from the LoEP; - remove the semi-quantitative reproductive risk assessment from the the DAR/LoEP.
Experts’ consultation 5.3 Experts to discuss the risk assessment for birds, including the weight of evidence.	A semi-quantitative (illustrative) risk assessment was performed by the RMS according to the EFSA Guidance Document on risk assessment for birds and mammals³. The resulting TER calculations did not indicate low risk for all exposure scenarios. Therefore, a weight of evidence (WoE) approach was proposed by the RMS. Additionally, a WoE was deemed to require discussion in other areas of the risk assessment.

³ European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. *EFSA Journal* 2009; 7(12):1438. doi:[10.2903/j.efsa.2009.1438](https://doi.org/10.2903/j.efsa.2009.1438).



Subject	Conclusions Pesticide Peer Review Meeting
	Experts agreed that exposure of birds, such as in the case of grit consuming species, cannot be excluded. Yet, the experts concluded that sufficient information is available to conclude low acute and reproductive risk based on the following lines of evidence: • Elemental iron is an essential trace element, which serves as essential nutrient in animal and plant physiology; • Elemental iron has very low solubility in water, it is naturally occurring in the environment; • The relative contribution of the representative uses to the background levels of iron in soil, surface water and sediment is low; • Iron is authorised in EU as human food additive and food supplement (e.g., in the case of iron deficiency); • Iron compounds have been assessed as safe as animal feed additive in the EU (e.g., see 10.2903/j.efsa.2015.4109); • There is no indication or evidence of endocrine disrupting properties/toxicity of elemental iron found in the available studies and in the literature; • Low risk for birds and mammals was concluded by EFSA in previous assessments of ferric compounds (notably ferric pyrophosphate which has a similar granular bait uses as elemental iron); • In addition, iron uptake is tightly regulated in vertebrates, and iron input from pesticide use is not considered to significantly contribute to natural background levels of elemental Fe, Fe³⁺ or Fe²⁺ in soil/sediment or groundwater/surface water. Overall, low acute and reproductive risk was concluded to birds and mammals. Open point: RMS to report the weight of evidence low risk conclusion for birds and mammals in the revised DAR, reflecting the meeting discussion. The WoE risk assessment should be aligned with what reported in other areas of the risk assessment.
Experts' consultation 5.4 Experts to discuss the risk assessment for wild mammals, including the weight of evidence.	A semi-quantitative (illustrative) risk assessment was performed by the RMS according to the EFSA Guidance Document on risk assessment for birds and mammals³. The resulting TER calculations did not indicate low risk for all exposure scenarios. Therefore, a weight of evidence (WoE) approach was proposed by the RMS. Additionally, a WoE was deemed to require discussed in other areas of the risk assessment. Therefore, a meeting discussion was deemed necessary to agree on the risk assessment for mammals. The experts concluded low acute and reproductive risk based on the same WoE approach reported in 5.3.



Subject	Conclusions Pesticide Peer Review Meeting
	Open point: The RMS was requested to remove the current semi-quantitative reproductive risk assessment and to report the WoE risk assessment for wild mammals the revised DAR.
Experts' consultation 5.5 Experts to discuss the effect and risk assessment for earthworms, including consideration of i) the lower tier hazard and risk assessment; ii) the background exposure; iii) the higher tier field study.	According to the environmental fate assessment, the contribution of the representative uses to the soil concentration of elemental iron relative to the background level was considered low. On the other hand, high Tier-1 risk was identified from the representative uses of Final bite in the ecotoxicology section (i.e., using the endpoints derived with the formulation for representative uses). Additionally, an earthworm field effect study was available. An experts' consultation was set to discuss the available data on exposure and effects of earthworm and to conclude on the risk assessment. Considering the environmental fate assessment, the risk from exposure to the active substance was considered addressed. However, experts concluded that a formulation risk assessment was still required. Therefore, the high risk indicated at the lower tier was considered to require further refinement. The available higher-tier effect study was discussed by the experts, who concluded that the risk from the representative uses of 'final bite' to earthworms is low based on the outcome of the higher tier assessment. Open point: - RMS to reflect the outcome of the discussion in the revised DAR. It should be made clear that the Tier1 risk assessment of the product was considered needed irrespectively of the background levels of the elemental iron - RMS to include more details on the 'history' of pesticide use in the test fields in the study summary.
Experts' consultation 5.6 Experts to discuss the waiving proposed for the ED assessment.	The need of specific <i>in vivo</i> data for conducting the ED assessment was not considered necessary. Instead, experts agreed the waiver of a proper ED assessment due to several reasons such as the solubility of the substance and the lack of evidence of potential ED properties in the current <i>in vivo</i> and <i>in vitro</i> data, to mention a few. Experts at the meeting agreed that further testing does not appear scientifically necessary. The waiver of the ED assessment is accepted. As result of the discussion, the following open point was agreed: Open point: RMS to include appropriate references to support the waiver, to use the proper wording related to the solubility of elemental iron



Subject	Conclusions Pesticide Peer Review Meeting
	and to align the waiver for the ED assessment for both human health and environment and properly reflect it in Volume 1.
Experts' consultation 5.7 proposed by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts' considered the available ecotoxicity data for the formulation for representative use. Where data were lacking, the results of the data retrieval exercise for the individual components were considered. Sufficient ecotoxicity data were available for the representative product for NTAs, soil organisms, bees and non-target terrestrial plants (NTTPs). The experts' considered the available information and no concerns were raised for NTAs, soil organisms, bees and NTTPs and the other NTO groups. Open points: - RMS to complete the assessment of the toxicological profile of the co-formulants and report it in the revised DAR Volume 4 to enable an independent hazard identification and characterisation for NTOs, reflecting the outcome of the meeting discussion. The conclusion of the RMS should be presented clearly, separately from the applicant's conclusion (if relevant), and referred to the safety of the co-formulant per se as well as in relation to the concentrations in the PPP. - RMS to complement their assessment of the formulation by adding references to the relevant legislations/EU assessments, in alignment with what indicated in the consultation point 2.7 of the Pesticide Peer Review TC 114 (04 – 08 September 2023) for human toxicology. - RMS to update in a revised DAR the statement on the comparability of Final Bite and "slug & snail killer", accounting for the meeting discussion.

REPORT OF PESTICIDES PEER REVIEW TC 114/117

FORMETANATE – AIR III

Rapporteur Member State: ES

5. Ecotoxicology

Date: 20 September 2023

List of participants:

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EFSA statutory staff member	EFSA
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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.10 Experts to discuss the reliability and the findings of the available AMA.	The experts discussed the available Amphibian Metamorphosis Assay (AMA) with particular regard to the exclusion from the analysis of the replicates 3 and 4 at the highest treatment level because considered compromised (high mortality) and the findings in the remaining replicates of the highest treatment level. The experts concluded that the findings in the available AMA suggested a pattern of systemic toxicity which is in line with the MoA of formetanate, i.e., AChE inhibitor and also in line with the conclusion of the ED assessment for humans.
Experts' consultation 5.11 Experts to discuss the appropriateness of the selection of the test, and the findings concentrations in the available FSTRA study.	The experts discussed the available Fish Short Term Reproduction Assay (FSTRA) with particular regard to the concentrations tested since no effects were observed in any of the measured parameters. The experts agreed that the concentration chosen in the FSTRA were in line with existing fish studies. Moreover, testing higher concentrations could trigger systemic toxicity considering the steep dose response observed in available mortality data in fish and amphibians. Therefore, the experts agreed that the FSTRA is suitable to conclude on the ED properties of formetanate through EAS-modalities.
Experts' consultation 5.12 proposed by EFSA MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with	The experts considered the available ecotoxicity data for the formulation for representative use. Where data were lacking, the results of the data retrieval exercise for the individual components were considered. i) The experts agreed that studies performed with Dicarazole 500 SP can be used to support the assessment of Dicarazole 10 SP. ii) Sufficient ecotoxicity data were available for the representative product, or Dicarazole 10 SP, for most



Subject	Conclusions Pesticide Peer Review Meeting
respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	groups of NTOs with the exception of birds (reproductive), mammals (reproductive), fish (chronic), and soil macro-organisms other than earthworms. iii) A data gap was identified for formulation data for soil macro-organisms other than earthworms. iv) The experts considered the available information and concluded no concerns were raised for the reproductive toxicity to birds and chronic toxicity to fish. Open point: RMS to reflect the outcome of the discussion and include the co-formulants assessment in the RAR. The RMS should indicate the need for soil macro-organism toxicity data with the formulated product.

REPORT OF PESTICIDES PEER REVIEW TC 114/117

LENACIL – AIR III

Rapporteur Member State: BE

5. Ecotoxicology

Date: 20 September 2023

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Discussion points / Outcome

5. Ecotoxicology

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Experts' consultation 5.5 Experts to discuss the Xenopus Eleuthero Thyroid Assay (XETA) result and in particular: - the high fluorescence observed in run 3 in the test medium control and its possible influence on the outcome of the test (i.e. % of induction). The result with and without trimming should be considered. - the lack of GLP certification. Note that the trimming as reported in OECD TG 248 should not be systematic.	Regarding the XETA, it was agreed that the trimming of the data did not change the outcome of the test. Regarding the lack of GLP certification, GLP studies are a legal obligation laid down in the Regulation (EU) No 283/2013 which only mentions few derogations to that obligation. These derogations are not applicable in the case of the XETA. In any case, since for this substance an Amphibian Metamorphosis Assay (AMA) is also available, the XETA can be used as additional information in the weight of evidence. Although the study is valid and there are no reasons to dismiss the 3rd run, the results show some uncertainties, as 2 runs suggest an induction of fluorescence >12% and the 3rd run shows an induction below 12% because of the high fluorescence of the control. Overall, all experts were of the opinion that the XETA does not seem to suggest endocrine activity, however there is high uncertainty because of the considerations mentioned for the 3rd run, i.e., lack of repeatability. Open point: RMS to reflect the outcome of the discussion on the XETA in an updated RAR.
Experts' consultation 5.6 Experts to discuss the results from the Amphibian Metamorphosis Assay	The RMS considered that the change observed on normalized hind-limb-length (nHLL) was not treatment related as it was only observed at the intermediate concentration. The median developmental stage at the high concentration was lower (57) compared to the control (58), but when looking at the distribution of developmental stage across concentrations and animals, the distribution of the data was not dissimilar and therefore it was not considered a clear delay.



Subject	Conclusions Pesticide Peer Review Meeting
(AMA) and more particularly: - The results for normalised hind limb length, and the use of the historical control data (HCD); - The developmental stage; - The tail curvature and its potential effect on the measurement of the endpoints; - The thyroid histopathology. In addition, based on the outcome of the AMA and XETA discussion, the experts should also discuss the outcome of the ED assessment for the T-modality.	Effects on tail curvature are frequently observed in the Amphibian Metamorphosis Assay (AMA). They might be due to the diet or genetic. The RMS considered this as a recurring effect and not something induced by the treatment. Only the wet weight was statistically significantly increased compared to the control at day 21. In the thyroid histopathology, there was a slight increase in prevalence of thyroid hyperplasia and a decrease in prevalence of hypertrophy, however, it was considered minimal and not T-mediated. However, the increase in thyroid hyperplasia occurs both at the intermediate and high concentrations. Some experts considered the effects on nHLL likely not T-mediated as data on nHLL suggest an acceleration while the developmental stage suggests a delay. Therefore, the 2 parameters do not seem to show a pattern of T-mediated activity. Overall, the majority of the experts considered the AMA negative as there wasn't a clear pattern of T-mediated endocrine activity, with some uncertainties which could be listed in an uncertainty analysis. This uncertainty analysis should also include the XETA. Open point: - RMS to reflect the outcome of the discussion on the AMA in an updated RAR. - RMS to include an uncertainty analysis for the T-modality, covering the uncertainty from both the XETA and the AMA.
Experts' consultation 5.7 Expert to discuss the Fish Short Term Reproduction Assay (FSTRA) results and more particularly: - The results for the vitellogenin (VTG) level in females and the non-statistically significant dose-response decreasing trend observed; - The VTG level in males and its high variability/ range; - Histopathological results;	Considering the individual vitellogenin (VTG) measurements in females, the high variability within each treatment and replicate was confirmed. Considering the data per replicate, no clear dose-response trend could be observed. In addition, all the values are in the same range (between 10^7-10^8), which is a normal order of magnitude for females. Regarding the VTG measurement in males, the increase in VTG is also considered to be due to few animals having high VTG values and the data showing high variability. In addition, the high values do not show any pattern. The gonad histopathology in females showed minimal change, which did not trigger any change in fecundity. Therefore, the experts agreed with the RMS that overall, there is no clear pattern of EAS-mediated activity in the available FSTRA. Overall, all the experts agreed that the available FSTRA was negative and agreed with the RMS assessment for the EAS-modalities. Open point:



Subject	Conclusions Pesticide Peer Review Meeting
- In addition, the experts should discuss the outcome of the ED assessment for the EAS modalities.	RMS to reflect the outcome of the discussion in a revised RAR.
Experts' consultation 5.8 (proposed by EFSA for completeness of discussion): MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	The experts considered the available ecotoxicity data for the formulation for representative use. Where data were lacking, the results of the data retrieval exercise for the individual components were considered. The experts agreed that: a) Sufficient ecotoxicity data were available for the formulation for representative uses for most groups of non-target organisms (NTOs) with the exception of birds (reproductive), and mammals. b) The experts considered the available information and concluded that pending on the open point identified, no concerns were raised for the reproductive toxicity to birds. c) For one component, a reconsideration for the implications to NTOs should be made once the data gaps identified for the toxicology assessment have been fulfilled. Open point: RMS to search for chronic toxicity data for birds for 2 components in the formulation and to confirm there is no toxicity data available for birds. This should be reported in the Volume 4.

18 – 20 September 2023

MINUTES

Pesticides Peer Review TC 117

Clove oil

REPORT OF PESTICIDES PEER REVIEW TC 117

CLOVE OIL – AMEND OF APPROVAL CONDITIONS

Rapporteur Member State: MT

5. Ecotoxicology

Date: 20 September 2023

List of participants:

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
New experts' consultation point 5.1 proposed by EFSA Experts to discuss the chronic aquatic risk assessment, considering the particular exposure conditions and environmental fate of the clove oil.	The fate experts discussed the soil aerobic and adsorption studies available in the dossier conducted on eugenol as lead component of clove oil, also considering the outcomes of the studies assessed for the approval of eugenol in light of the confirmatory data (see EFSA Technical Report, 2017) and assessed in the Eugenol dRAR of 2023. Comparing the different soil aerobic studies, a similar pattern was noted, with a high formation of non-extractable residues already at day 0 and a fast disappearance of the low percentage of eugenol after the first collected data point. Although some deviations from the OECD 307 Guideline were reported, experts noted that obtaining an appropriated study compliant with the guideline is challenging, also considering the volatility of eugenol. However, experts acknowledged on the fast degradation of eugenol. The default DT50 value derived from the ECHA guidance for readily biodegradable substances (i.e., 14.1 days at 20°C) was considered too conservative and, in a weight of evidence approach, experts suggested that a DT50 of 1 day is a good estimation for the degradation of clove oil in soil. Updated calculations with a DT50 of 1 day led to PEC surface water values up to max 10^{-6} µg/L, despite of the choice and use of the adsorption endpoints, i.e., K_{foc} and 1/n, derived from the new adsorption study proposed by the Applicant or from default values. Experts from the ecotoxicology section agreed that the new calculated PEC surface water estimations reflect very low concentrations in water, thus exposure can be considered very low, and therefore the chronic risk assessment for the aquatic organisms is not triggered. This is also applicable to the acute risk assessment. All the experts agreed to use the PEC calculated



Subject	Conclusions Pesticide Peer Review Meeting
	in surface water to support the conclusion that exposure to surface water would be very low and to waive for chronic ecotoxicity data. As the adsorption endpoints might be relevant in determining the PEC for the groundwater compartment, and since the new proposed study is currently under evaluation in the renewal of eugenol for which the peer-review is still on-going, experts proposed and agreed to include two sets of PEC groundwater calculations in the current DAT, i.e. considering the default worst-case values ($K_{foc} = 10 \text{ mL/g}$, $1/n \text{ } 0.9$) and the values derived from the new submitted adsorption study ($K_{foc} = 98.1 \text{ mL/g}$; $1/n \text{ } 0.971$). The consequences of the joint e-fate/ecotox experts' discussion led to the following open points for the RMS. Open points for e-fate RMS: • RMS to add the study summary and evaluation of the soil aerobic degradation study in the eugenol 2023 RAR in the updated version of the addendum to the DAR. • RMS to include the soil aerobic degradation study in the eugenol 2023 RAR in the list of studies relied on, provided to the Commission when the peer review has been finalised. • RMS to reflect the outcomes of the discussion related to the proposed DT50 of 1 day in soil and the considerations on the adsorption study proposed by the Applicant in updated versions of Vol. 1, Vol. 3 B.8 (CA), Vol.3 B.8 (CP) of the addendum to the DAR and in the LoEP. • RMS to report in the LoEP the rate of degradation values derived from the available soil aerobic degradation studies and specify in the box of the geometric mean that a DT50 of 1 day was agreed in a weight of evidence approach during the experts' meeting. • RMS to consider that the potential for drainage to occur for clove oil in drip irrigation applications in greenhouse based on the current GAP can be considered very low. Therefore, a new water/sediment study is not anymore considered necessary, and exposure of surface water can be excluded. • In any case, RMS is asked to recalculate all the PECs for the relevant compartments (surface water and groundwater) based on the agreed DT50 in soil of 1 day and on 8 applications of 50 kg/ha. For the two compartments, RMS is asked to provide calculations considering both the default worst-case values ($K_{foc} = 10 \text{ mL/g}$, $1/n \text{ } 0.9$) and the values derived from the adsorption study submitted by the Applicant ($K_{foc} = 98.1 \text{ mL/g}$; $1/n \text{ } 0.971$). If no risk is identified, RMS to only



Subject	Conclusions Pesticide Peer Review Meeting
	include in the LoEP the PEC calculations based on default values. • RMS is asked also to include an extra set of PEC calculations in groundwater considering a single application of 50 kg/ha, if any issue is identified for the 8 applications. This set of calculation should be included only in the revised DAR and not in the list of endpoints. Open points for ecotox RMS: • RMS is asked to summarise the outcome of the discussion in updated versions of Vol. 1, Vol. 3 B.9 (CA), Vol.3 B.9 (CP) of the addendum to the DAR and in the list of endpoints, including the contextualisation of the waiver for the risk assessment for aquatic organisms considering the discussion above and the results of the PECsw. • RMS is asked to delete the acute risk assessment from the LoEP and from the revised version of the addendum to the DAR.

18 - 20 September 2023

MINUTES

Pesticides Peer Review TC 117
Dichlorprop-P

REPORT OF PESTICIDES PEER REVIEW TC 117

DICHLORPROP-P – follow up on TC 92

Rapporteur Member State: IE

5. Ecotoxicology

Date: 20 September 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria (4)	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Belgium (1)	Federal Public Service Health, Food Chain Safety and Environment- BE
National Experts nominated by MS Czechia (1)	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by MS Denmark (1)	Danish EPA- DK
National Experts nominated by MS France (3)	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany (3)	Julius Kühn-Institut (JKI), Federal Research Centre for Cultivated Plants- DE German Environment Agency (UBA)– DE
National Experts nominated by RMS Ireland (1)	Department of Agriculture, Food and the Marine of Ireland - IE
National Experts nominated by MS Malta (2)	Malta Competition and Consumer Affairs Authority (MCCAA)- MT
National Experts nominated by MS Netherlands (1)	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Spain (1)	INIA-CSIC- ES
Observers (2)	Agroscope- CH Malta Competition and Consumer Affairs Authority (MCCAA)- MT



In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation point proposed by EFSA as follow up from TC92 Considering the new extended 1-generation study submitted during the ED clock-stop, experts to re-discuss the point of departure to be used in the risk assessment.	1. In the context of the assessment for endocrine disruption, a new extended one generation study with rats according to OECD TG 443 was submitted. This new study triggered a reconsideration of the previously agreed ecotoxicologically relevant endpoint to be used in the risk assessment of wild mammals. 2. The experts at the meeting agreed to set the new NOAEL at 35.9 mg/kg bw per day from the newly submitted Extended One Generation Study (EOGRT). This decision was taken considering: • The existing 2-generation study and the EOGRT are consistent in terms of reproductive and offspring effects observed; • No reproductive effects were observed in the one generation study at approximately the same doses of the LOAEL of the above multigeneration studies; • The existing preliminary one generation study was considered as only supportive study owing to a number of limitations. Open point RMS to revise the RAR reflecting the outcome of the discussion and update the risk assessment and the LoEP with the new agreed endpoint.

Pesticides Peer Review TC 114/117
Pyrimethanil

REPORT OF PESTICIDES PEER REVIEW TC 114/117

PYRIMETHANIL – AIR III

Rapporteur Member State: CZ

5. Ecotoxicology

Date: 20 September 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria (4)	Austrian Agency for Health and Food Safety (AGES)- AT
National Experts nominated by MS Belgium (1)	Federal Public Service Health, Food Chain Safety and Environment- BE
National Experts nominated by RMS Czechia (1)	Central Institute for Supervising and Testing in Agriculture- CZ
National Experts nominated by MS Denmark (1)	Danish EPA- DK
National Experts nominated by MS France (3)	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany (3)	Julius Kühn-Institut (JKI), Federal Research Centre for Cultivated Plants- DE German Environment Agency (UBA)– DE
National Experts nominated by MS Ireland (1)	Department of Agriculture, Food and the Marine of Ireland - IE
National Experts nominated by MS Malta (2)	Malta Competition and Consumer Affairs Authority (MCCAA)- MT
National Experts nominated by MS Netherlands (1)	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by MS Spain (1)	INIA-CSIC- ES
Observers (2)	Agroscope- CH Malta Competition and Consumer Affairs Authority (MCCAA)- MT



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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.6 identified following ED clock stop: Experts to discuss the testing strategy, the findings in the available study and the overall conclusion of the ED assessment for non-mammalian species through EAS-modalities.	1. The experts considered the testing strategy, all the available information and weight of evidence to conclude on the ED properties of pyrimethanil through EAS-modalities for non-target organisms other than mammals. In particular, in determining whether pyrimethanil interacts with the oestrogen mediated pathway, the number and type of effects induced, and the magnitude and pattern of responses observed across the available information were considered. 2. All the experts agreed that the testing strategy was not ideal, as not fully in line with the recommendations of the ECHA/EFSA Guidance, i.e., 2 level 3 studies available: a 21-d fish screening assay (FSA) followed by an EASZY according to OECD TG 251. Nevertheless, the experts agreed that based on the available data it can be concluded that the available dataset and weight of evidence do not suggest a pattern of EAS-mediated endocrine activity. Some concerns were raised on a possible perturbation of the E pathway based on increase in male VTG in the available FSA. However, the experts agreed that the individual data showed variability and were not consistent across animals and replicates and therefore, the increase in male VTG was not considered treatment related. This was confirmed by the available EASZY, although some uncertainties were agreed upon that test, i.e., suitability in case of rapidly metabolised substances as pyrimethanil. The experts also agreed that the analysis presented in the available position paper, although considered thoroughly in the assessment, was of limited value (e.g., pyrimethanil concentrations in the literature papers were much lower than the one tested in the FSA, the molecular docking analysis only considered ERα).



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.7 identified following ED clock stop: Experts to discuss the impact of the newly submitted EOGRT on the selection of the ecotoxicologically relevant endpoint for wild mammals and as a consequence on the risk assessment.	1. The appropriate endpoint for the risk assessment for wild mammals was reconsidered in light of the newly available extended one generation reproductive study. As a result, the lowest endpoint, considered to provide a relevant endpoint for the assessment of wild mammals, was from the developmental toxicity study with rabbits. 2. Conclusion The experts' agreed with the proposal of the RMS and that the most appropriate endpoint for the assessment of wild mammals was 45 mg a.s./kg bw per day. 3. Open point The RMS should reflect the outcome of the discussion of the selection of the most appropriate reproductive endpoint for wild mammals in the revised RAR.
Experts' consultation 5.8 identified following ED clock stop: Experts to discuss the available evidence for the ED assessment of non-target organisms through the T-modality . In particular, it is noted that some papers on amphibians have been considered not relevant because only adversity was investigated, i.e., Effects of long-term exposure to two fungicides, pyrimethanil and tebuconazole, on survival and life history traits of Italian tree frog (<i>Hyla intermedia</i>); Chronic exposures to fungicide pyrimethanil: multi-organ effects on Italian tree frog (<i>Hyla intermedia</i>).	1. An Amphibian Metamorphosis Assay (AMA) and a literature paper were available for the assessment of the endocrine disrupting properties through the T-modality. 2. The experts agreed that the AMA was valid and reliable and that there was no positive evidence for endocrine activity through the T-modality. The available relevant literature paper was not considered reliable. Overall, the experts agreed that there was no positive evidence for T-related activity of pyrimethanil. Open point: RMS to update the revised RAR in line with the outcome of the discussion.
New experts' consultation point 5.9 proposed by EFSA for completeness of discussion MS experts to discuss whether the available	1. The experts' considered the available ecotoxicity data for the formulation for representative use. Where data were lacking, the results of the data retrieval exercise for the individual components were considered. 2. Conclusion i) The experts agreed that toxicity data was with the previous formulation BAS 605 01 F can be considered



Subject	Conclusions Pesticide Peer Review Meeting
information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	comparable to the current representative formulation BAS 605 04 F (for ecotoxicity). ii) Sufficient ecotoxicity data were available for the representative product, or BAS 605 01 F, for most groups of NTOs with the exception of birds (acute and reproductive), mammals (reproductive), fish (chronic). iii) The experts' considered the available information and concluded no concerns were raised for the acute and reproductive toxicity to birds and chronic toxicity to fish. iv) For one component, a reconsideration for the implications to NTO's should be made once the data gaps identified for the toxicology assessment have been fulfilled. Open point: RMS to reflect the outcome of the discussion and refine the search for the co-formulants by checking in all the databases agreed upon. RMS to update the search for chronic data for aquatic invertebrates, birds and fish.

REPORT OF PESTICIDES PEER REVIEW TC 114

RIMSULFURON – AIR III mandated for ED assessment

Rapporteur Member State: SI

5. Ecotoxicology

Date: 08 September 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Experts nominated by MS Austria (3)	Austrian Agency for Health and Food Safety (AGES) - AT
National Experts nominated by MS Belgium	Federal Public Service Health, Food Chain Safety and Environment - BE
National Experts nominated by MS Czech Republic (2)	The National Institute of Public Health - CZ
National Experts nominated by MS Germany (2)	German Federal Institute for Risk Assessment (BfR) – DE German Environment Agency (UBA) - DE
National Experts nominated by MS Spain	National Institute for Agricultural and food research and technology (INIA) - ES
National Experts nominated by MS France (2)	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Ireland	Department of Agriculture, Food and the Marine of Ireland – IE
National Experts nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS Lithuania	The State Plant Service under the Ministry of Agriculture - LT
National Experts nominated by MS Netherlands (2)	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) - NL
National Experts nominated by RMS Slovenia	National Institute of Public Health - SI



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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the appropriate testing strategy to investigate the EAS-modalities of rimsulfuron, also taking into account the outcome of the mammalian toxicology experts' consultation.	The data package to conduct the assessment for endocrine disruption (ED) through EATS-modalities in non-target organisms other than mammals was not complete. A testing strategy in line with the recommendation of the ECHA/EFSA guidance (2018) was proposed and discussed. For wild mammals, the same conclusion reached for humans applies. T-modality Rimsulfuron is not an endocrine disruptor in wild mammals, in line with the conclusion for humans, based on lack of a clear pattern of T-mediated adversity in a complete dataset. For non-mammalian species, when considering the lack of adversity in mammals based on a complete dataset and the lack of positive evidence for endocrine activity, the experts agreed with the following testing strategy: • XETA (Xenopus eleutheroembryonic thyroid assay) (according to OECD 248). However, the applicant earlier committed to perform an Amphibian Metamorphosis Assay (AMA). • In case of positive result/s, scenario 2a(i) applies and further data will be needed to support the mode of action (MoA) analysis, following the testing strategy as reported in the ECHA/EFSA ED Guidance 2018 (i.e., LAGDA (Larval Amphibian Growth and Development Assay), OECD 241). EAS-modalities For wild mammals, in line with the conclusion reached for humans, further data are needed (level 2&3 studies and in case of positive evidence from those tests, level 5 study).



Subject	Conclusions Pesticide Peer Review Meeting
	For non-mammalian species, based on the positive evidence from ToxCast and the potential consequence on spermiogenesis in mammals, the following strategy was agreed: • A FSTRA (Fish Short-Term Reproduction Assay) (in line with OECD TG 229) with the inclusion of the gonad histopathology assessment for both sexes. The histopathology assessment should include both the staging and the qualitative assessment of the gonads. • If concerns related to anti-androgenicity are identified, additional tests might be needed, such as the Rapid Androgen Disruption Activity Reporter (RADAR) assay (OECD 251) or Androgenized female stickleback screen (AFSS) (OECD GD 148). • In case of positive result/s based on the previous studies for at least one modality, scenario 2a(i) applies and further data will be needed to support the MoA analysis, following the testing strategy as reported in the ECHA/EFSA ED guidance 2018 (i.e., MEOGRT (Medaka Extended One Generation Reproduction Test), OECD 240).

Pesticide Peer Review TC 110/113
Quinolin-8-ol (8-hydroxyquinoline)

REPORT OF PESTICIDE PEER REVIEW TC 110/113

QUINOLIN-8-OL (8-HYDROXYQUINOLINE) AIR IV

Rapporteur Member State: ES

5. Ecotoxicology

Date: 30 June 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by MS Germany	German Federal Institute for Risk Assessment (BfR) - DE
National Expert nominated by MS Germany	German Environmental Agency- DE
National Expert nominated by MS Greece	Benaki Phytopathological Institute- EL
National Expert nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention ICPS- IT
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)- NL
National Expert nominated by MS Slovakia	National Reference Laboratory for Pesticides, University of Veterinary Medicine and Pharmacy in Košice- SK
National Expert nominated by RMS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC)- ES
National Expert nominated by MS Sweden	Swedish Chemicals Agency - SE
Observers	Federal Office for the Environment FOEN - CH



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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Risk assessment for aquatic organisms - Expert to discuss the chronic endpoint for vertebrate's aquatic toxicity (sublethal endpoint in the AMA vs lowest endpoint in fish: <i>O. mykiss</i> 28 d NOEC = 7.9 µg/L 8-HQ)	The Amphibian Metamorphosis Assay (AMA) and Fish Short-Term Reproduction Assay (FSTRA) are screening test that were developed for ED assessments and they were not designed to derive robust endpoints to be used in the risk assessment. In addition, the lowest concentration from the AMA at which sublethal effect are observed (exposure to 12.8 µg/L Beltanol, equivalent to 3.99 µg/L 8-HQ) was approximately two times lower than the endpoint for fish (<i>O. mykiss</i> 28 d NOEC = 7.9 µg/L 8-HQ) which could be considered to be within what is expected for experimental variability. Conversely, the PPR Opinion for amphibian and reptiles suggests that rainbow trout might be a good surrogate for amphibian toxicity. Some experts considered that the observed effects in the AMA study should not be ignored since it suggests that the early life stages of amphibians could be more sensitive than fish early life stages. Overall, the experts agreed that a robust endpoint could not be derived from the AMA study, but the higher sensitivity of amphibians should be acknowledged as an uncertainty. It was noted that there seemed to be an error in some of the updated risk assessment tables for aquatic organisms in the updated RAR. An additional open point was identified for the RMS to check the value used for PEC soil in the risk assessment for soil organisms following the discussions in the fate and behaviour meeting.



Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to update the aquatic risk assessment tables in the RAR (including 9.4-1 and 9.4.2) and to reflect the outcome of the experts' discussion on the AMA study noting the uncertainty with potential higher sensitivity of amphibians. Open point: RMS to check the value used for PEC soil in the risk assessment for soil organisms following the discussions in the fate and behaviour meeting.
Experts' consultation 5.2 Experts to discuss the ED assessment of 8-hydroxyquinoline and more particularly: - use of the Beltanol (PPP) instead of the active substance and the potential effect of ■ co-formulan - concentration tested in the AMA vs FSTRA - Histological result in the AMA - AMA interpretation - FSTRA interpretation - Additional test needed if any	T-modality The AMA study was considered valid, although some drawbacks were noted. Given the mortality observed at the highest tested concentration (8% when excluding one compromised replicate), experts agreed that the highest tested concentration was at the Maximum Tolerated Concentration (MTC). The main findings in the thyroid histopathology were thyroid atrophy; this change is considered as a sensitive to but not diagnostic parameters. In addition, if the delay in development was due to a T-MOA, thyroid hypertrophy would be expected. Treatment-related effects were observed on liver, small intestine and gills and gills cavity (apoptosis/single necrotic cells) in all treated group. No effect was observed on kidney. Experts agreed that the effects observed do not seem to suggest a pattern of T-mediated MoA but they are more likely due to systemic toxicity. Experts also discussed the positive evidence available from ToxCast, i.e. THTR antagonist and TPO inhibition. Overall, those findings were agreed not to show selective inhibition. EAS-modalities A Fish Short-Term Reproduction Assay (FSTRA) was available, performed with the formulated product Beltanol. Since 8% mortality was observed at the highest tested concentrations, experts agreed that this concentration was at the MTC. Therefore, that concentration should not be considered further to draw a conclusion on the ED properties of the substance. The experts discussed the decrease in dorsal pad observed at all treatments. Since that observation was only a visual observation and this parameter was not assessed during the validation of the FSTRA, it was agreed that the reduced dorsal



Subject	Conclusions Pesticide Peer Review Meeting
	pad does not give an indication of endocrine activity through EAS-modalities. Given the lack of effect at the lowest and intermediate concentrations (in particular no effects were observed in vitellogenine and tubercles counted), experts agreed that no pattern of EAS endocrine activity was observed. Regarding the use of the formulation in the AMA and the FSTRA, the presence of [REDACTED] in the formulation was not seen as a concern as it will not be available in the test medium due to its [REDACTED]. This is confirmed by the [REDACTED] throughout the study. Since [REDACTED]'s [REDACTED] co-formulant, testing with the formulated product is considered equivalent to testing with the active substance. Overall, all experts agreed the following: -The conclusion for human (criteria not met for the EATS-modalities) applies to wild mammals. -The use of the formulation in the AMA and the FSTRA is not a concern, and the studies may be used to conclude on the ED properties of 8-hydroxyquinoline. -The AMA study should be considered reliable with restrictions due to the drawbacks observed. -The AMA study does not suggest a pattern of T-endocrine activity. - Based on the available evidence (AMA and Toxcast data) a pattern of T-mediated endocrine activity was not observed. - The FSTRA study does not suggest a pattern of EAS-endocrine activity and no further testing is needed. Open point -RMS to reflect the outcome of the discussion in the revised RAR -RMS to better discuss the selection of the tested concentrations and explain the rational for using Beltanol in the available studies in the FSTRA and the AMA. -RMS to check (based on raw data) and update the mean nHLL in the revised RAR -RMS to report the conclusion for humans and wild mammals in the revised RAR -RMS to report the complete ED assessment in Vol. 1



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.3, added by EFSA after column 4 step. MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	All toxicity studies (except for birds) were done with the formulation for representative uses, and such formulation only presents [REDACTED] co-formulant (without classification for aquatic organisms). Only use in a permanent greenhouse is considered. Based on the above, the experts agreed that no additional concerns were identified related to the safety of the formulation for the representative use. Open point: RMS to reflect the outcome of the discussion regarding the safety of the formulation in the CP document of the RAR.

19-26/27 – 30 June 2023

MINUTES

Pesticide Peer Review TC 110/113
Deltamethrin

REPORT OF PESTICIDE PEER REVIEW TC 110/113

DELTAMETHRIN – AIR III

Rapporteur Member State: AT

5. Ecotoxicology

Date: 30 June 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by RMS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS Germany	German Environmental Agency- DE
National Expert nominated by MS Greece	Benaki Phytopathological Institute- EL
National Expert nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention ICPS- IT
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)- NL
National Expert nominated by MS Slovakia	National Reference Laboratory for Pesticides, University of Veterinary Medicine and Pharmacy in Košice- SK
National Expert nominated by MS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC)- ES
Observers	Federal Office for the Environment FOEN - CH



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²

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the acute toxicity endpoint for birds for deltamethrin. For a similar substance, there was evidence that canaries were notably more sensitive. Furthermore, on the basis of the data available for this substance, there was evidence that dosing via a gelatin capsule to canaries resulted in a much lower estimate of toxicity compared with when the substance was dissolved in a carrier before dosing (refer to Pesticides Peer Review Meeting report 174 and background documents for beta-cyfluthrin). The experts should consider whether a concern is also raised for deltamethrin and, if so, what impact does it have	<u>Acute endpoint for birds</u> The experts considered to take the lowest of the available acute toxicity endpoints for the risk assessment for birds. Since the endpoint was for <i>Serinus canariai</i>, the extrapolation factor according to EFSA (2009) was not applied. The experts considered that this was a sufficiently conservative endpoint for the risk assessment. <u>Long-term endpoint for mammals</u> The experts agreed DNT endpoints were of ecotoxicological relevance. Therefore, the experts agreed on the use of the NOEL of 0.25 mg/kg in the long-term risk assessment for wild mammals. <u>Long-term endpoint for birds</u> The experts agreed that the reproduction study with the bobwhite quail was not reliable since the control birds did not perform sufficiently. The experts also agreed that an additional safety factor should be applied to cover for the DNT effects observed in the toxicology studies but are not properly assessed by the avian toxicology data. Such assessment factor should be applied to the NOEL for sublethal effects in the acute toxicity study with <i>Serinus canariai</i>. The resulting endpoint for the long-term risk assessment for birds is 12.5 mg a.s./kg bw per day. Open points



Subject	Conclusions Pesticide Peer Review Meeting
on the hazard characterization. See reporting table 5(6) Additional discussion points: Experts to discuss: The reliability of the avian reproduction study (██████ 1991a) with the bobwhite quail. The endpoint to be used for the long-term risk assessment for wild mammals. The endpoint to be used for the long-term risk assessment for birds.	RMS to reflect the outcome of the meeting discussion on the selection of the appropriate acute avian endpoint for risk assessment in a revised RAR. Owing to an error noted in the updated GAP table, the RMS should add clarification on the footnotes a) and b) of the GAP, which refer to the single and multiple application. RMS to include a reflection of the DNT studies for the selection of the long-term endpoint for mammals in a revised RAR. Additionally, to revise the risk assessment using the endpoint of 0.25 mg a.s./kg bw per day and update the LoEP accordingly. RMS to delete the endpoint from the unreliable reproduction study with the bobwhite quail from the LoEP RMS to reflect the discussion on DNT-Type effects on birds in an updated RAR RMS to update the reproductive RA for birds in the RAR and LoEP using the NOEL of 12.5 mg a.s./kg bw.
Experts' consultations 5.2 Experts to discuss on the opportunity to accept the data from the study on <i>A. bahia</i> by ████████ (2012) for the use of the endpoint in the risk assessment for aquatic organisms.	The original issue triggering the expert consultation was related to the validity of the chronic study on <i>Americamysis bahia</i>. In light of the information collected during the years on studies performed with the same guideline (OPPTS 850.1350), and in light of the validity criteria set in the newer ASTM International E1191- 03a guideline, it was concluded that the study is valid. Concerning the drawbacks of the analytical methods, in consideration of the fact that this study provides the lowest chronic endpoint and in consideration of the very low RAC determined by this, it was agreed that it would be more cautious to retain the present endpoint for the risk assessment. Nonetheless, it was agreed that the uncertainty around the quantification of the endpoint should be acknowledged in the RAR and in the LoEP. As open point, the RMS should highlight the uncertainty in the LoEP around the chronic endpoint derived from the test with deltamethrin on for <i>A. Bahia</i>.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.3 Experts to discuss the available bioaccumulation studies and to agree on whether a reliable BCF value could be established based on those. The discussion should also consider whether a BAF study is needed.	The studies included in the dossier for addressing the bioconcentration of deltamethrin were considered to have too many and too significant deviations compared to the current standard to be considered as reliable. Lack of achievement of validity criteria, lack of achievement of steady-state, lack of lipid and growth measurement and correction, temperature outside the recommended range for the tested species were only some of such deviation from the only study following a standardised protocol. In view of all the above, it was agreed that no reliable BCF could be estimated for deltamethrin. Furthermore, it was agreed that a dietary approach would have been preferable, in view of the phys-chem characteristics of deltamethrin. Therefore, a data gap for further data on fish bioconcentration was identified (i.e., a dietary exposure BAF study). An open point was set for the RMS to reflect the agreement in a revised RAR.
Experts' consultation 5.4 Experts to discuss and agree on the appropriate endpoint(s) (related to ETO and ERO options, if appropriate) and AF to be used for the risk assessment of aquatic invertebrates as derived from the mesocosms studies. In performing such discussion, the experts should consider all the uncertainty raised by the RMS plus others raised in this RT (e.g., possible different toxicity of the formulation used in the studies compared to the a.s.).	In consideration of the effects observed even at the lowest tested concentrations in both mesocosms, it was agreed that no ETO-RAC could be established from either experiment. Furthermore, recovery of the most sensitive species (i.e., <i>Chaoborus</i> and <i>asellus</i>) within 8 weeks from the first treatment was not considered to be sufficiently demonstrated in the experiment. Thus, no ERO-RAC either could be established from the mesocosms. An open point for the RMS was set to reflect the outcome of the discussion on the mesocosm studies in a revised RAR. In consideration of this agreement and of the one for point 5.9 (on TKTD modelling), it was noted that the aquatic risk assessment is reverted to tier 1. Nonetheless, acute data on multiple species are available in the dossier, which may be considered for a tier-2 RAC. In addition, PEC for metabolites concerning the use in permanent greenhouse are currently based on Focus step 2 (and thus assuming a field application). Thus, further open points were set for the RMS: • To investigate the possibility to provide refined PEC sediment (a.s. and metabolites) and surface water (metabolites)



Subject	Conclusions Pesticide Peer Review Meeting
The experts should also discuss whether the exposure characterisation to deltamethrin over time is suitable for the risk assessment.	calculations for the use on tomato in permanent greenhouse. Additionally, to revise the RAR accordingly • To investigate the possibility to include a Tier-2 acute risk assessment (following the recommendations of the EFSA aquatic guidance document) based on a geomean approach for invertebrate species and to revise the RAR accordingly.
Experts' consultation 5.5 Experts from member states to discuss the available field studies and the related risk assessments for NTA.	All the higher tier field studies were discussed in the context of the risk assessment for the representative uses. Due to several methodological issues, none of the studies for in-field habitats were considered to be suitable to demonstrate that a recovery of the in-field species might happen within a year. Although some uncertainties were noted also regarding the off-field studies; the majority of the experts agreed that the NOER of 0.23 g a.s./ha could be used for the off-field risk assessments. This endpoint however is lower than the predicted exposure rate for most of the representative field uses. Therefore, an open point was set for the RMS to update the off-field risk assessments and consider appropriate RMMs. Open point: RMS to update the off-field risk assessment for the representative field uses considering the outcome of the experts' consultation discussion points 5.5, 5.6 and 5.10. RMS to reconsider the proposal of risk mitigation measures for the off-field risk assessment for the representative field uses.
Experts' consultation 5.6 Experts from member states to discuss the available data on residue decline and the related risk assessments for NTA.	The available information for residue decline has several limitations and the number of trials was not considered to be sufficient. Therefore, the experts agreed that no refinement can be used considering these data and the currently proposed refinement has to be removed from the RAR. Therefore, an open point for the RMS was agreed to remove the currently applied refinement. Open point: RMS to update the NTA risk assessment by removing the existing refinement for wheat and cauliflower.
Experts' consultation 5.7 Experts from MSs to discuss the available	As an additional point, some reliability issues of some laboratory studies were discussed, and it was agreed that the highlighted uncertainties should be flagged in the LoEP. Therefore, an open point was set for the RMS to add a footnote in the LoEP for the concerned studies and the corresponding risk assessments.



Subject	Conclusions Pesticide Peer Review Meeting
higher tier effect studies for honeybees and their use in the risk assessment. Experts should pay attention in particular to the following issues: - extrapolation of the studies (application regime/ formulation used) to the GAP uses - attractiveness of some crops - if risk mitigation can be proposed Expert to discuss also whether a conclusion on the risk can be reached for bumble bees.	As regards the available semi-field and field studies, several drawbacks were identified. Therefore, some studies were invalidated, some others classified as supporting information. Open points were set for the RMS to amend the RAR accordingly. The experts at the meeting agreed that a low risk to honeybees and bumble bees could not be demonstrated with the available data and this outcome of the meeting should be reflected in the RAR. Open point: RMS to add a footnote in the LoEP for the concerned studies and the corresponding risk assessment Open point: RMS to revise the categorisation of the tunnel studies in the revised RAR: The studies by [REDACTED] (2001a) and [REDACTED] (1999) should be invalidated. All other studies should be categorised as supporting information Open point: RMS to reflect the outcome of the discussion in the updated RAR (re-categorisation of the field studies) Open point: RMS to reflect the outcome of the discussion in the updated RAR.
Experts' consultation 5.8 Experts to discuss the available data and assessment on the ED potential of deltamethrin.	For non-mammalian species, neither the endocrine activity nor the endocrine adversity was sufficiently investigated for EATS modalities. The experts agreed that the available dataset is not complete to draw a conclusion on the ED properties of deltamethrin in non-target organisms. The postulated non-ED MoA and its supporting evidence were not considered sufficient to exclude any ED potential of deltamethrin. Moreover, the methodology followed for measuring and reporting the sex ratio of fish was poorly detailed and therefore considered insufficient to consider that parameter as reliably assessed.



Subject	Conclusions Pesticide Peer Review Meeting
	In line with ECHA/EFSA Guidance, the following testing strategy should be followed: • A test in line with OECD 248 (i.e., XETA) to sufficiently investigate the endocrine activity through the T-modality • A test in line with OECD TG 229 (with the inclusion of gonad histopathology) to sufficiently investigate the endocrine activity through the EAS-modalities. If one of those tests is positive, a MoA should be performed and additional data may be needed to further investigate adversity, i.e., LAGDA and/or Medaka extended one generation. It is also recommended that if evidence of anti-androgenicity becomes available, a FSTRA may not be the most suitable test. In that case the following alternatives may be selected: • A test in line with OECD TG 234 (i.e., Fish Sexual Development Test) • A test in line with OECD TG 251 (Rapid Androgen Disruption Activity Reporter (RADAR) assay) followed by a FSTRA (if no positive evidence for anti-androgenicity is observed) • A test in line with OECD Guidance 148 (i.e., Androgenised Female Stickleback Screen) Additionally, in order to complement the dataset, the literature search should be updated in line with Appendix F of the ECHA/EFSA Guidance. Open point: -RMS to clarify how the Sex Ratio was measured and how the raw data was re-assessed. -RMS to re-evaluate the literature studies in a consistent way, specifically regarding the issue of the analytical measurements. -RMS to reflect the outcome of the discussion in the updated RAR.
New experts' consultation point 5.9 proposed by EFSA for completeness of discussion	• In chronic studies, there is evidence of sub-lethal effects (e.g. on growth and reproduction) occurring at lower concentrations than the ones triggering lethal effects. This makes the use of GUTS unsuitable to address the risk assessment of aquatic invertebrates for deltamethrin.



Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss the reliability of the TKTD modelling studies submitted by the Applicant in response to data requirement 5(140). This discussion should take into account the input of the WG on effect modelling and should rely on the guidance provided by the TKTD opinion (EFSA PPR Panel, 2018). Furthermore, the relevance of the study for the overall risk assessment for aquatic organisms should be discussed and agreed upon.	• While the modelled species are certainly sensitive to deltamethrin, other species demonstrated to be equally or even more sensitive in either Tier-1 lab studies or Tier-3 mesocosm studies. Thus, the species selection was considered insufficient to address the risk to aquatic invertebrates as a whole. • The underlying experimental data were not always compliant with the minimum requirements set in the EFSA TKTD SO (EFSA PPR Panel, 2018). This was particularly true for validation datasets. It was questioned why many experiments carried out under constant/semi-constant exposure were used for validation instead of calibration. Datasets used for calibration were generally more appropriate. • The modelling per se was generally found to be of acceptable quality, with some exception, the most notable one being the GUTS-RED-IT for <i>Cloen dipterum</i>, where even the calibration was not considered acceptable. In consideration of the above, it was concluded that the application of GUTS in the case of deltamethrin was not considered justified in light of the data presented and should not be used for the risk assessment. The following open points for the RMS were agreed: • to reflect the meeting discussion on the Tier 2c proposal for the risk assessment of aquatic invertebrates in a revised RAR; • to include the endpoint from the Tier-1 lab data with <i>Asellus</i> in the LoEP, of to clarify in a revised RAR the reason for invalidating the study; For those experiments on <i>Gammarus</i> used in the TKTD modelling for which raw data could not yet be found, to highlight in a revised RAR if this information is missing and/or to highlight the mismatch between the data used for modelling and the available graphical representation, as discussed in the advice of the WG.
New experts' consultation point 5.10 proposed by EFSA for completeness of discussion MS experts to discuss whether the available	Aquatic organisms In consideration of the available data on formulations, the acute and chronic ecotoxicological safety of the formulations Decis EW 15 and Deltamethrin 2.5 EC (MEGHMANI) was considered addressed. In consideration of the limited available data on formulations and of the retrieved information on co-formulants, the acute and



Subject	Conclusions Pesticide Peer Review Meeting
information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the ecotoxicological profile of each individual component other than the active substance.	chronic ecotoxicological safety of the formulation Deltamethrin 25 EC (AIDDAD) was considered addressed. As open point, the RMS is required to: • correct the typo in the name of the Bayer formulation in the RMS document on co-formulants; • report in the confidential part of the RAR the data on co-formulants which were used as a basis for the comparison. <u>Bees</u> The available laboratory data with the active substance and the formulations (representative and other formulations) were compared and the comparisons indicated that the toxicity of the representative formulations is not higher than the a.s. Therefore, for the case of Deltamethrin 25 EC (AIDDAD); Deltamethrin 2.5 EC (MEGHMANI) and Decis EW 15 (Bayer) the acute and chronic ecotoxicological assessment is covered by the assessment of the a.s. <u>Soil organisms</u> Deltamethrin 25 EC (AIDDAD) data were not available for soil organisms. Therefore, it was acknowledged that data requirements in the Reg. 284/2013 were not addressed for this formulation. For Deltamethrin 2.5 EC (MEGHMANI) and Decis EW 15 data were available it was agreed to update the risk assessment for soil organism to ensure that the formulations were sufficiently covered. As open point, the RMS is requested to check that the appropriate endpoint was used in risk assessment considering the cases where the endpoint for the formulations were lower than the a.s. <u>Birds and mammals</u> The toxicology meeting already discussed the available information for mammals. For birds, considering the overall toxicity profile of the active substance, the experts did not consider there was a need for additional information for birds and that the assessment for the active substance would be sufficient to conclude on the safety of the representative formulations.

MEETING MINUTES – 19-26/27-30 June 2023
Pesticide Peer Review TC 110/113
Deltamethrin



Subject	Conclusions Pesticide Peer Review Meeting
	Open point, for the RMS to ensure that outcome of the discussions on PPP and coformulants are reflected in the three CP Volumes for the formulations for representative uses.

REPORT OF PESTICIDE PEER REVIEW TC 110/113

BUPROFEZIN – AIR IV

Rapporteur Member State: IT

5. Ecotoxicology

Date: 30 June 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Austria	Austrian Agency for Health and Food Safety (AGES)- AT
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Expert nominated by MS Germany	German Environmental Agency- DE
National Expert nominated by MS Greece	Benaki Phytopathological Institute- EL
National Expert nominated by RMS Italy	International Centre for Pesticides and Health Risk Prevention ICPS- IT
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)- NL
National Expert nominated by MS Slovakia	National Reference Laboratory for Pesticides, University of Veterinary Medicine and Pharmacy in Košice- SK
National Expert nominated by MS Spain	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC)- ES
Observers	Federal Office for the Environment FOEN - CH



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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 (follow-up discussion to the TC 109) Experts to agree on the long-term endpoint selection for mammals	At the Pesticide Peer Review TC 109 (22-26 May 2023) the ecotoxicologically relevant endpoint for the reproductive risk assessment for wild mammals was agreed to be the NOAEL of 100 ppm (equivalent to 6 mg a.s./kg bw per day) derived from B.6.6.1/01 (based on statistically significant decrease of pup body weight at 1000 ppm) However, such agreement was considered provisional, pending the discussion by the human toxicology experts (see TC 110), which was not yet finalised at the time of the discussion on the reproductive endpoint for wild mammals. Therefore, a follow-up discussion was deemed necessary to reach a final agreement on the endpoint selection At the Pesticide Peer Review TC 113 (27-30 June 2023) the meeting considered that no other agreement reached by the human toxicology meeting (TC 110) challenged the previously agreed endpoint. All experts agreed that the ecotoxicologically relevant endpoint for the reproductive risk assessment for wild mammals was the NOAEL of 100 ppm (equivalent to 6 mg a.s./kg bw per day) derived from B.6.6.1/01 (based on statistically significant decrease of pup body weight at 1000 ppm) The following open points identified in TC 109 (see discussion point 5.2) were therefore confirmed: - the RMS was requested to reflect in a revised RAR the detailed justification for the endpoint selection



Subject	Conclusions Pesticide Peer Review Meeting
	considering the data presented and discussed at the peer review meeting. - The RMS was requested to include in a revised RAR clear reference to the additional information (i.e., data and justification) provided by the applicant following the stop-of-the-clock, and to clearly indicate the reasoning for excluding any insufficient piece of information or refinement option for risk assessment (this should be ensured for mammals and other NTOs, whenever relevant) - to clarify in the GAP if uses should also cover non-permanent structures.
Experts' consultation 5.8 To discuss the appropriate testing strategy to investigate T-modality, based on the outcome of the tox expert consultation.	1. The rationale leading to the conclusion a. Based on the outcome of the assessment for humans (i.e., criteria met for the T-modality), the experts discussed the relevance for wild mammal populations of the adversity observed in mammals and relevant for humans (i.e., change in thyroid weight and thyroid histopathology). b. The experts also discussed the available dataset for non-mammalian species. Based on this dataset, neither the T-mediated adversity nor the endocrine activity was sufficiently investigated 2. Conclusion a. Although concerns were raised that the effects observed in mammals may trigger neurodevelopmental effects in pups, the majority of the experts agreed that based on the available dataset, the adversity is considered unlikely to be relevant at the population level (no DNT study available and no other effects observed that could be linked to the T-MoA identified). b. For non-mammalian species, all the experts agreed that both an AMA or a XETA might be performed to complete



Subject	Conclusions Pesticide Peer Review Meeting
	the dataset to sufficiently investigate the endocrine activity. Open point: RMS to reflect the outcome of the discussion in the updated RAR and to amend the line of evidence in line with the agreed endpoint.
Experts' consultation 5.9 experts to discuss the testing strategy to investigate the EAS-modalities. Due to concerns over potential anti-androgenic activity indicated in in-vitro studies, EFSA proposes performing a level 4 Fish Sexual Development Test FSDT (OECD 234 TG), since the level 3 FSTRA may have low sensitivity to detect anti-androgenic activity (ECHA EFSA ED Guidance, 2018).	1. The rationale leading to the conclusion For non-mammalian species, the available studies were the following: two reproductive studies on birds, one fish early life stage (FELS, on rainbow trout), two fish full life-cycle (FFLC, on fathead minnow and sheepshead Minnow) and a fish 28 days assay (on fathead minnow) investigating fecundity were available. 2. Conclusion The experts discussed and agreed that, considering the lack of a suitable chronic endpoint for fish and to complement the dataset to draw a conclusion on the ED properties of buprofezin through EAS-modalities, a FFLCT with an appropriate choice of the concentrations and all the parameters foreseen to be investigated in a Medaka Extended one generation, would be needed. Open point: RMS to reflect the outcome of the discussion in the updated RAR and to amend the line of evidence in line with the agreed endpoint.
Experts' consultation 5.10 Experts to discuss the potential concerns over activity of Buprofezin as androgenic antagonist and for binding for the androgenic receptor, to define the testing strategy for investigation of the EAS-modalities. See also 5(101).	See outcome of the point 5.9 above

22 - 26 May 2023

MINUTES

Pesticide Peer Review TC 109 Pyrethrins

REPORT OF PESTICIDE PEER REVIEW TC 109

PYRETHRINS – AIR IV

Rapporteur Member State: IT

5. Ecotoxicology

Date: 26 May 2023

List of participants:

Status	Name of institution/attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Austria (2)	Austrian Agency for Health and Food Safety (AGES)
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Experts nominated by MS Germany (2)	German Federal Institute for Risk Assessment
National Expert nominated by MS Germany	Julius Kuehn Institute, Institute for Bee Protection
National Expert nominated by MS Netherlands (2)	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by RMS Italy (2)	International center for pesticides and health risk prevention (ICPS)
Observers (2)	Swiss Federal Office for the Environment (BAFU)

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MEETING MINUTES – DD Month 20YY
Pesticide Peer Review TC 109
Pyrethrins



discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to decide what to do with the studies for which no sufficient information was available to fully validate the analytical method.	Experts at the meeting evaluated in detail the missing information for each of the analytical methods that were not fully validated in order to see if they could be considered as fit for purpose (in line with the agreement in EFSA, 2019). In addition, experts also considered the risk assessment for each of the taxa where this consideration was needed to see the margin of safety and the reliability of the derived endpoints. Some of the missing information such as the lack of chromatograms and the unsuitability of the matrix where the validation was concluded as major drawbacks. Overall, all experts considered the analytical method for the aquatic studies as fit for purpose and therefore, the endpoints can be considered suitable for risk assessment acknowledging the uncertainties regarding the analytical methods with the exception of the short-term studies with birds and the studies with NTTPs, where the analytical method was considered not fit for purpose nor fully validated. Open points as result of the discussion: -RMS to revise the conclusion of each of the studies in line with the discussion and update the LoEP accordingly. -RMS to revise the aquatic risk assessment using the lowest available endpoint with aquatic invertebrates. -RMS to revise the risk assessment to non-target terrestrial plants (NTTPs) in line with the discussion.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 Expert to set the ecotoxicological relevant endpoints for conducting the long-term risk assessment to mammals.	Based on the available data set for mammalian toxicology, a NOAEL of 10 mg/kg bw per day was selected as ecotoxicological relevant endpoint for long-term risk assessment based a effects in pups body weight in a 2-gen reproductive toxicity study with rats. The endpoints set in other relevant studies were based on non-effects; therefore, all experts agreed that the one selected and proposed by the RMS is the best one in the available dataset. However, considering the data gap set in the neurotoxicity assessment and the request of further data for the ED assessment (which includes a new reproduction toxicity test with rodents), this endpoint was considered provisional. In light of the new data, when submitted, this endpoint will need to be reconsidered and as consequence, the risk assessment will be revised. Open points as result of the discussion: -RMS to update the RAR by presenting the recalculated endpoint in terms of mg/kg bw/day. -RMS to update the RAR in line with the discussion indicating that the endpoint is provisional and therefore the endpoint and the risk assessment would need to be revised in light of the new data to be submitted (see experts' consultation point 5.12 below).
Experts' consultation 5.3 Experts to decide whether the available information is sufficient to address the risk to birds in higher tiers. New data might need to be considered if submitted by the applicants.	This experts' consultation point was set based on the request of considering all possible risk assessment scenarios in line with the current guidance in-use; however, as consequence, the risk to birds was not changed and no further refinements were considered necessary. Therefore, the experts' consultation point became obsolete. No action needed. The refinements proposed bythe applicant for terrestrial vertebrates were discussed under experts' consultation point 5.4.
Experts' consultation 5.4 Experts to agree on the risk assessment to wild mammals (common vole) as conducted. New information might need to be	The refinement based on the updated deposition factors provided by the FOCUS groundwater guidance 2014 was considered suitable by the experts. Based on that, the risk to small herbivorous mammals could be concluded as low for those cases where high risk was previously identified. However, since the ecotoxicologically relevant endpoint is provisional, this risk assessment conclusion needs to be considered tentative as well in light of the new data.



Subject	Conclusions Pesticide Peer Review Meeting
considered if submitted by the applicants.	The other refinements proposed were not supported by the data or were not scientifically supported for its use in the risk assessment. The study for refining the PD of small herbivorous mammals assumed common voles as appropriate focal species without any further consideration and the portion of the diet was proposed to be refined based on a study not available. The kinetic assessment of the residue trials was not considered valid by the e-fate experts and this assessment was not evaluated for all the residue trials; thus, a new MAF as refinement option could not be obtained. In addition, based on the information in the residue section, several plant metabolites could occur in items suitable for birds' and mammals' dietary exposure. Experts agreed that the risk assessment due to plant metabolites would need to be updated based on the discussion in the residue section. Open points as result of the discussion: -RMS to revise the risk assessment for mammals based on agreement at the experts' meeting, including that this risk assessment is tentative because of the provisional endpoint. -RMS to liaise with residue experts after their meeting and to include the risk assessment for relevant plant metabolites where needed.
Experts' consultation 5.5 Experts to discuss several aspects of the aquatic risk assessment with regards to: - The acute data on fish where fish were longer than what it is recommended in the OECD TG; - The use of an SSD acute based on NOECs and an AF for such refinement;	During the commenting phase of the initial RAR for the renewal of the approval process, several issues were noted that could impact the aquatic risk assessment. These issues and the conclusions reached at the experts meeting are summarized below: 1. In the acute toxicity studies fish longer than the indication in the test guideline for several species. This raised an issue on the sensitivity and whether the endpoints derived could underestimate the toxicity of the substance. The majority of experts agreed that this is a major deviation in the studies with <i>Lepomis macrochirus</i> and with <i>Gasterosteus aculeatus</i> and those endpoints could not be used in the SSD. Open point as result of the discussion:



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- The applicability of the existing BCF value considering the drawbacks of the study and if the QSAR estimation could help to confirm the existing BCF; - The risk assessment with chironomids; - The overall risk after considering the experts' consultation for the mesocosm study as indicated in experts' consultation 5(74).	- RMS to update the evaluation of the studies in the RAR in line with the conclusion at the experts' meeting. 2. SSD approach: considering the outcome of the discussion, the SSD approach was not considered longer valid by the experts and the geomean calculation using the following three studies with <i>Oncorhynchus mykiss</i>, <i>Cyprinodon variegatus</i> and <i>Danio rerio</i> was proposed and agreed. A calculated geomean of 11.8 µg/L with AF of 100 shall be used for risk assessment. Open points as result of the discussion: - RMS to remove the risk assessment based on the SSD. - RMS to present Tier 1 risk assessment with fish with lowest endpoint and to present the Tier 2 risk assessment for fish based on the agreed geomean. 3. Validity of the BCF study and QSAR estimation. The experts at the meeting agreed to use the BCF derived from the study because although the validity criteria was not strictly fulfilled, the deviations noted were not considered a major drawback. The reliability of the endpoint was noted to be not affected by those deviations and it is supported by the QSAR estimation. Open points as result of the discussion: - RMS to reflect the outcome of the discussion in the RAR. - RMS to add the footnote at the list of endpoints highlighting the decision of the experts' consultation. 4. Risk assessment for sediment dwelling organisms. RMS did not derive endpoints from the available studies since analytical measurements were not considered appropriate. A proposal was agreed by the experts at the meeting and a recalculation of the NOECs from the studies will be done by RMS. In addition, a consideration of the risk assessment for metabolites occurring in sediments needs to be updated in the revised RAR in line with the outcome of the e-fate information and the indications agreed at the meeting. Open points as result of the discussion:



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	- RMS to recalculate the NOEC from both sediment dwellers studies considering the TWA information from the studies and update the risk assessment by using the lowest endpoint. - RMS to conduct the risk assessment for sediment metabolites in line with the specifications above. The same approach should be applied to all relevant surface water metabolites. - RMS to reflect the outcome of the discussion and update the RMS evaluation for both studies. In addition, to remove the reference to Tier 2C in the RMS evaluation box. 5. The mesocosms study was discussed under experts' consultation point 5.7.
Experts' consultation 5.6 Experts to decide how to consider the studies for which the batches were not characterized in the risk assessment.	For several ecotoxicity studies, the batches were not well-characterized and no additional information was provided by the applicant. Experts at the meeting agreed that this will result in a data gap in the EFSA conclusions. Open points as result of the discussion: - EFSA to reflect the data gap in the conclusion. RMS to check the vol 3 and to align to the general conclusion in vol 4 (e.g., the conclusion reported on 230/089).
Experts' consultation 5.7 Experts to discuss the results of available mesocosm study and agree on which AF shall be used.	The suitability of the mesocosm, the endpoint to be derived and the AF were discussed by the experts at the meeting. All the experts agreed with the proposed endpoint of 0.28 µg/L by the RMS. In addition, an AF of 3 was agreed, deriving an ETO-RAC of 0.09 µg/L based on steep dose response observed for some organisms (e.g., <i>Asellus aquaticus</i>). Overall, all experts agreed that the mesocosm study was reliable and could be used in the risk assessment provided that further information becomes available on predicted peak concentration, interval between the peaks and duration of each peak for all uses failing the Tier 1 risk assessment. This should then be compared with the exposure profile in the mesocosm for confirming its suitability. Open points as result of the discussion: -RMS to conduct the comparison as described above.



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	-RMS to reflect the discussion and amend the RAR and LoEP as relevant. -RMS to conduct the risk assessment for aquatic organisms for all the uses included in the GAP (it was noted that uses in the permanent glasshouse and ornamentals were not available in the RAR).
Experts' consultation 5.8 Experts to discuss the available risk assessment to honey bees noting that new information will be submitted (acute oral and contact data, 10-d chronic tox study and 22-d larvae study). In addition, any other new and existing data (existing tunnel study) shall be discussed in order to conclude on the overall risk to bees.	Experts at the meeting agreed with the endpoints derived from the newly submitted ecotoxicity studies with honey bees. The risk assessment was conducted, and high risk was identified for the several scenarios. Refinement options were not considered appropriate (i.e., residue studies in lettuce discussed in several discussion points during this experts' consultation). Mitigation measures were proposed but not supported by data, therefore the risks identified to honey bees remain unresolved for the in-field uses. Open point as result of the discussion: RMS to update the RAR in line with the discussion.
Experts' consultation 5.9 Experts to discuss the NTAs risk assessment based on the new and existing data.	New ecotoxicity data with <i>A. rhopalosiphi</i> and <i>T.pyri</i> were submitted. In addition, one aged residue study was available and the use of supervised residue trials in lettuce were proposed by the applicant to change the used MAF. The available ecotoxicity studies were considered valid; however, they were not sufficient to exclude the risk. The available aged residue study was conducted with only 1 spp. and extrapolation between species is not foreseen according to the current methodology. The refinement based on the degradation of the substance could not be used since a quantitative assessment could not be underwent and deficiencies in the studies were noted. High in-field risk remains unresolved for all in-field uses of pyrethrins for non-target organisms. As result of the experts' consultation, the following open points were highlighted: -RMS to amend the risk assessment in line with the discussion.



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	-RMS to clarify in the revised RAR that the aged residue study is suitable only to refine the risk for the tested species and cannot be extrapolated to other species.
Experts' consultation 5.10 Experts to decide on whether the risk assessment for earthworms is valid in line with the current practises and consistency with other dossiers.	Since the substance was not incorporated in the soil as indicated in the EU data requirements and there is not enough evidence of the proof of exposure to earthworms in the study, experts agreed to set data gap for a new study in line with OECD TG 222 where the test item is mixing into the soil. Open points as result of the discussion: -RMS to reflect the outcome of the discussion and remove the risk assessment in the RAR and LoEP. -RMS to add the footnote in the LoEP where the study is listed, clarifying that study was not used in the risk assessment.
Experts' consultation 5.11 Experts to decide on whether the available information for the formulation is enough to waive the need of the data representative and formulation. Experts to consider information new earthworms' study) if submitted.	RMS pointed out a misunderstanding and noted that the <i>Folsomia</i> and <i>Hypoaspis</i> tests submitted were not performed with three different formulated products but with three different batches of technical material which are all well-characterized. After this clarification no further discussion was needed; however, a few open points were set to clarify better the situation in the revised RAR. Open points as result of the discussion: -RMS to clarify in the LoEP and the study summaries that the studies were conducted with technical material. -RMS to add the table at beginning of the Vol 3 B9 CA summarizing the test substances and the different code names. -RMS to update the risk assessment in the LoEP where the TER seems to be missing for flowering brassica.
Experts' consultation 5.12 Experts to decide if the available information is sufficient to conclude on whether the ED criteria for new met organisms.	In line with the ECHA/EFSA ED guidance and the evidence of potential neurotoxicity, it was agreed to request further data for drawing a conclusion on the potential ED properties of pyrethrins for humans for the EATS-modalities. This request of further data applies also to wild mammals as non-target organisms. A consideration of the population relevance of the identified adversity will need to be revised considering the evidence requested (i.e., a study in line with OECD TG 443 with the inclusion of a cohort 1a and 1b and the mating of the 1b to produce a 2nd generation including the DNT arm needs to be submitted). For further information, consult the



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	Pesticides Peer-Review meeting TC 106 for mammalian toxicology. For non-mammalian species as non-target organisms, no specific ED-mediated parameters were available and the proposal of the testing strategy in line with the ECHA/ EFSA ED guidance was agreed by the experts as follows: (data requirement) - EAS-modalities: a FSTRA in line with OECD TG 229 needs to be submitted. - T-modality: An AMA in line with OECD TG 231 needs to be submitted. Applicant informed RMS that both studies are currently on-going. In case of positive evidence from the above-mentioned studies, further data (level 4/5 studies) shall be submitted. Open points as result of the discussion: -RMS to update the ED assessment in Vol 1 in line with the outcome of the discussion, also reflecting the need of further contextualize the findings in ██████████/2017 when new data become available. -RMS to update the RAR in line with the discussion reflected above and including if needed, a complete testing strategy in line with the ECHA/EFSA ED guidance (ECHA/EFSA, 2018).
New experts' consultation point 5.13 proposed by EFSA for completeness of discussion MS experts to discuss whether the available information is sufficient to characterise the full ecotoxicological profile of the formulation(s) for representative use(s) with respect to the acute and chronic toxicity. If certain endpoints are not covered, MS experts to discuss the	Acute data for birds, mammals, fish, aquatic invertebrates and bees were available for the active substance and the representative product PyGanic 1.4. It was noted that when formulated, the representative product does not seem to pose higher acute toxicity than the technical active substance. Moreover, it was noted that none of the co-formulants in the product PyGanic 1.4 is listed in the Reg 283/2021. Based on the above, experts concluded that it is plausible that the risk assessment for the active substance covers the risk assessment of the representative formulation. However, to have all available information in the RAR, the following open points were identified: -RMS to double check that there is no concern for co-formulants based on the information on the ECHA website to be reported in vol 4.

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ecotoxicological profile of each individual component other than the active substance.	-RMS to confirm the toxicity of the a.s. versus the toxicity of formulation to different organisms and draw a conclusion in the revised RAR.

22 - 26 May 2023

MINUTES

Pesticide Peer Review TC 109 Buprofezin

REPORT OF PESTICIDE PEER REVIEW TC 109

BUPROFEZIN – AIR IV

Rapporteur Member State: IT

5. Ecotoxicology

Date: 26 May 2023

List of participants:

Status	Name of institution/attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Austria (2)	Austrian Agency for Health and Food Safety (AGES)
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Experts nominated by MS Germany (2)	German Federal Institute for Risk Assessment
National Expert nominated by MS Germany	Julius Kuehn Institute, Institute for Bee Protection
National Expert nominated by MS Netherlands (2)	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by RMS Italy (2)	International center for pesticides and health risk prevention (ICPS)
Observers (2)	Swiss Federal Office for the Environment (BAFU)

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points / Outcome

5. Ecotoxicology

Please note that information part of this report may have been masked by EFSA in accordance with Article 63 of [Regulation \(EC\) No 1107/2009](#) as well as [EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation \(EC\) No 1107/2009](#), or [EFSA's Practical Arrangements concerning transparency and confidentiality](#) as a consequence of confidentiality requests submitted by the applicant on application dossiers for pesticides active substances or Maximum Residue Levels, respectively. Please note that information disclosed in this report is without prejudice to pre-existing intellectual property rights and data exclusivity clauses set out in Union law, and particularly in Article 62 of Regulation (EC) No 1107/2009.

Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss and agree on the long-term endpoint selection to be used in the risk assessment for birds, with particular reference to the following studies (and considering any new information submitted by the applicant): - CA 8.1.1.3/01 - CA 8.1.1.3/02	Two reproductive studies were available: - bobwhite quail CA 8.1.1.3/01 - mallard duck CA 8.1.1.3/02 Following concerns that reproductive toxicity was observed at concentrations below the proposed NOEC raised during the written procedure of the peer review, the applicant was given the opportunity to provide new information. Therefore, it was considered that the endpoint selection required further discussion, considering the submission of any new data. - bobwhite quail CA 8.1.1.3/01 The meeting discussed the statistical and biological relevance of the observed effects and their dose response relationship (including any additional information by the applicant). Particular consideration was given to the mean bodyweight of 14-day old survivors. Experts did not consider that the additional information provided by the applicant were sufficient to exclude the biological and statistical relevance of the effects observed on the body weight of 14 days old survivals in the highest tested concentration. Therefore, all the experts agreed that the NOEC should be set at 500 ppm. - mallard duck CA 8.1.1.3/02 The meeting discussed the statistical and biological relevance of the observed effects and their dose response relationship (including any additional information by the applicant). The key responses discussed at the meeting were the % of hatchlings of



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	live three-week embryos; the % of hatchlings of the eggs set and the % of 14-day old survivors of the eggs set. Overall, considering i) the dose dependency of effect across these three key parameters; i) the magnitude of the observed differences in the performances of the highest treatment level relative to the control for several key parameters, the experts concluded that the NOEC from the reproductive toxicity study with the mallard duck was 500 ppm. Open points: -The RMS is requested to update the evaluation of the reproductive toxicity study with the bobwhite quail and mallard duck (i.e., CA 8.1.1.3/01 and 02 respectively) by reflecting the reasoning for the endpoint selection discussed at the peer review meeting. The risk assessment (when required) and LoEP should be updated accordingly. -the RMS was requested to ensure that any new information on the derivation of the EC₁₀ and EC₂₀ (for birds and the other relevant non-target organisms) provided by the applicant (including relevant updates) is adequately summarised in the updated RAR. Ideally, the summary at the end of each relevant study should be amended with such information and its assessment and any data gap should be clearly highlighted.
Experts' consultation 5.2 Experts to agree on the long-term endpoint selection for mammals.	Following concerns raised during the written peer review on the endpoint selection and on the reliability status of mammalian long-term toxicity data, it was deemed necessary to reach an agreement on the selection of a single ecotoxicologically relevant reproductive endpoint for use in the risk assessment for wild mammals. Such agreement will need to take into consideration the outcome of the discussion by the human toxicology section, which will only be finalised after TC 109. The studies B.6.6.1/01 (2-generation reproductive toxicity) and B.6.6.1/02 (one-generation reproductive toxicity) were discussed in detail, with particular reference to the bodyweight effects. Despite studies B.6.6.1/01 and B.6.6.1/02 lacking key assessments for the ED assessment, these studies were deemed suitable for the derivation of the mammalian reproductive



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	endpoint, acknowledging the additional (minor) deviations highlighted by the RMS. All experts at the meeting provisionally agreed with the assessment by the RMS and considered the deviations (i.e., absence of investigations of thyroid/epididymis/cervix/oestrus cycle in B.6.6.1/01 and of thyroid/epi/seminal vesicles/histopathological changes in B.6.6.1/2) not to impact the reliability of the ecotoxicologically relevant response variables. The effects on pup body weight were considered biologically relevant and the NOAEL of 100 ppm (equivalent to 6 mg a.s./kg bw/d) derived from B.6.6.1/01 was provisionally agreed for use in risk assessment. Such agreement will need to take into consideration the outcome of the discussion by the human toxicology section, which will only be finalised after TC 109. Open points -The RMS was requested to reflect in a revised RAR the detailed justification for the endpoint selection considering the data presented and discussed at the peer review meeting. -Pending on the outcome of the human toxicology assessment and the follow-up discussion for ecotoxicology, the RMS might be required to update the endpoint selection and risk assessment accordingly. -The RMS was also requested to include in a revised RAR clear reference to the additional information (i.e., data and justification) provided by the applicant following the stop-of-the-clock, and to clearly indicate the reasoning for excluding any insufficient piece of information or refinement option for risk assessment (this should be ensured for mammals and other NTOs, whenever relevant)
Experts' consultation 5.3 Experts to discuss the available long term fish studies (i.e., CA 8.2.2.1/01, CA 8.2.2.2/01, CA 8.2.2.2/02, CA 8.2.2.2/03). Therefore, to agree on their validity and reliability and endpoint derivation, considering any additional	The long-term fish endpoint was challenged during the written peer review. Therefore, it was deemed necessary to discuss the available long term fish studies (i.e., CA 8.2.2.1/01, CA 8.2.2.2/01, CA 8.2.2.2/02, CA 8.2.2.2/03) and to agree on their validity, reliability, and endpoint derivation, considering any additional information provided by the applicant. Finally, it was deemed necessary to agree on the long term-endpoint selection for risk assessment. <u>- Study CA 8.2.2.1/01</u> In this study mean length, dry weight, and wet weight were considered key responses. Additionally, it was noted that in terms of effect sizes (see table below with indicative values)



Subject	Conclusions Pesticide Peer Review Meeting
information provided by the applicant. Finally, to agree on the long term-endpoint selection for risk assessment.	length may not have been the most sensitive endpoint. Overall, the majority of experts agreed on the NOEC of 0.052 mg/L based on the observed effects on weight. <u>- Study 8.2.2.2/01</u> all experts agreed on the NOEC of 0.011 mg/L, considering that the lower tested concentration only showed effects on the length of males, and that the selection of the lower point would be based on a very slight difference (i.e., a 3% effect, which was considered of questionable biological relevance). The experts considered that the NOEC of 0.011 mg/L would be supported by a larger number of parameters being affected with statistical significance. <u>- Study CA 8.2.2.2/02</u> It was highlighted that statistically significant effects on spawning frequency and number of eggs produced were observed at all test concentration, suggesting that no NOEC could be set which covers for these reproductive parameters. All expert acknowledged that a clear dose response could not be observed and that this may be explained by the high variability across replicates. However, it was agreed that there were strong effects on reproduction at all tested doses (spawning frequency and number of eggs produced). Therefore, all experts agreed that the reproduction was likely the key parameter in driving risk assessment. Overall, the meeting agreed that no NOEC could be derived from the study CA 8.2.2.2/02. <u>- Study CA 8.2.2.2/03</u> A new study was provided by the applicant to cover the reproduction endpoint. Such study was conducted according to the US EPA (2002) guidance “A Short-term Method for Assessing the Reproductive Toxicity of Endocrine Disrupting Chemicals using the Fathead Minnow”. The meeting acknowledged that that the exposure period of this study was not comparable to the fish full life cycle (i.e., 21-day exposure). Additionally, it was acknowledged that although statistically significant effect was not observed, potentially meaningful differences in egg laying and spawning frequency were observed across treatment levels. Indeed, it was clarified that because of its design 8.2.2.2/03



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	should be considered a screening study. As such it was not designed to derive an endpoint for risk assessment purposes. Indeed, FSTRA study design was published as a screening tool for ED assessment. Because of its design, statistical power, number of doses and dose spacing the design was not considered suitable for NOEC derivation. Open points -the RMS was requested to amend the study (CA 8.2.2.1/01) evaluation, by reflecting the meeting discussion and the rationale for the endpoint selection. Such evaluation should also include details of the EC_{10, 20} assessments (general point, relevant across studies). The NOEC agreed by the meeting is 0.052 mg/L based on effects on weight. The RAR and LoEP should be amended accordingly. -RMS to reflect the outcome of the discussion in the RAR for the study 8.2.2.2/01. All experts agreed on the NOEC of 0.011 mg/L, considering that the lower tested concentration only showed effects on the length of males, and that the selection of the lower point would be based on a very slight difference (i.e., a 3 % effect, which was considered of questionable biological relevance). The experts considered that the NOEC of 0.011 mg/L would be supported by a larger number of parameters being affected with statistical significance -The RMS was requested to reflect the discussion of study CA 8.2.2.2/02 in a revised RAR. Additionally, the RMS was asked to provide details of the statistical appendix provided by the applicant. When revising the risk assessment, the RMS will need to ensure that no long-term endpoint from this study is used. -RMS to reflect in a revised RAR the outcome of the assessment of CA 8.2.2.2/03 (i.e., supplementary info). -RMS to reflect in a revised RAR the outcome of the discussion on the endpoint derivation for use in the long-term fish risk assessment. RMS was requested to provide an illustrative risk assessment with LOEC derived in the study CA 8.2.2.2/02 to assess whether it would result in a high risk identified.
Experts' consultation 5.4	The experts were requested to discuss the uncertainties related to the use of the BCF value derived from the study CA 8.2.2.3/01.



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Experts to discuss any further information submitted by the applicant in relation to the uncertainties related to the use of the BCF value derived from the study CA. 8.2.2.3/01, with particular reference to the implications for the assessment of secondary poisoning for birds and mammals.	The RMS acknowledged a key deviation of the study, related to the lack of a measurement of the lipid content. However, they also suggested that repeating a vertebrate study on this premise might be unreasonable. Therefore, the RMS suggested to use the BCF in the risk assessment acknowledging the uncertainties related to the lack of a measurement of fat content. To support this approach the RMS provided an illustrative assessment showing a margin of safety. Overall, all experts agreed with the assessment performed by the RMS. Open point: RMS to add the illustrative assessment (i.e., secondary poisoning for birds and mammals) showing the margin of safety of the risk assessment in the RAR and to reflect the outcome of the meeting discussion. RMS to add a footnote to the LoEP to transparently reflect the uncertainties around the use of the BCF value.
Experts' consultation 5.5 Experts to discuss the acute endpoint for aquatic invertebrates, particularly in relation to the reliability of the LC₅₀ derived in CA 8.2.4.2/02 for <i>A. bahia</i>;	The reliability of the acute toxicity study 8.2.4.2/02 with <i>A. bahia</i> was questioned during the written peer review. In this study high mortality (85%) in the intermediate dose of 0.017 mg/L was observed in absence of significant effects in any other treatment. This pattern was not considered treatment-related taking into account the results of the long-term mysid study (where no similar mortality was observed at 0.019 mg/L over a much longer exposure period). Therefore, experts agreed that the study was suitable for risk assessment (LC₅₀ > 0.058 mg/L). The RMS proposed a geomean EC₅₀ for the acute risk assessment for aquatic invertebrates using the endpoints from <i>Daphnia</i> (CA 8.2.4.1/02), Grass shrimp (CA 8.2.4.2/01) and Mysid shrimp (CA 8.2.4.2/02). Such approach was considered appropriate by the experts. Open point RMS to reflect to outcome of the discussion on the assessment of the acute mysid study (CA 8.2.4.2/02) and the geomean approach.
Experts' consultation 5.6 Experts to discuss the validity of the long-term mysid studies, considering	The validity of the two long-term mysid studies (CA 8.2.5.2/01 and CA 8.2.5.2/02) was questioned during the written peer review due to the reproductive performances in the control being outside the recommended ranges by the TG OPPTS 850.1350.



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the additional information on the reliability of the studies by [REDACTED] 2015b and [REDACTED], 2007 provided by the applicant. It should be noted that i) the endpoint from [REDACTED] 2015b yielded the lowest (long-term invertebrate) endpoint and was, therefore, used in risk assessment; ii) the acute hazard assessment may suggest higher sensitivity of <i>A. bahia</i> relative to <i>Daphnia</i>. In case a reliable long-term endpoint for <i>A. bahia</i> cannot be derived, it should be discussed whether the remaining studies are sufficiently protective to address the long-term risk to all aquatic invertebrate species.	However, a data collection was conducted summarizing the reproductive performances of long-term mysid studies (>15) submitted in the framework of the EU peer review was done, suggesting that the reproductive performances were never up to the standards required by the TG OPPTS 850.1350. The average number of offspring per female per reproductive day across studies was indeed much lower than the recommendation of 3 (see dashed line). Therefore, the meeting agreed to look pragmatically at the reproductive performances while assessing the validity of the long-term mysid studies against OPPTS 850.1350. Overall, for CA 8.2.5.2/01, the NOEC of 19 µg/L in risk assessment. This endpoint was preferred for risk assessment purposes over CA 8.2.5.2/01 considering the much lower reproductive performances of the females (i.e., daily average offspring production) in the latter study. Open points CA 8.2.5.2/01 - RMS to include a footnote in the LoEP acknowledging the meeting decision on the validity of the study - RMS to reflect the meeting discussion on the endpoint derivation (NOEC of 19 µg/L) CA 8.2.5.2/02 - RMS to include details of the calculation of the reproductive output as per the validity criteria of OPPTS 850.350 TG in a revised RAR - The endpoint from this study should be deleted from the LoEP, as it was considered a supportive.
Experts' consultation 5.7 Experts to discuss on the suitability of the available NTA dataset to address the risks assessment, considering the mode of action of the substance (i.e., growth inhibition) and possible ovicidal effects.	The suitability of the available dataset to address possible ovicidal, ovo-larvicidal and moulding effects of buprofezin (considering its mode of action) in NTAs (including bees) required further discussion, considering the concerns highlighted in the written peer-review For NTAs, experts considered that additional tests covering both direct and indirect effects on eggs would be needed to conclude on the risk. Such decision was considered consistent with former EFSA conclusions for other substances with similar mode of action.



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	Therefore, a knowledge gap was identified for information covering the potential direct ovicidal effect for NTOs. For bees, experts considered the available Tier-1 data insufficient to fully address the MoA of buprofezin. Additionally, the available semi-field study with honey bees was not considered supportive for risk assessment due to major drawbacks in the study results and design (i.e., the uncertainties related to the use of a different formulation than the one for representative uses; the absence of a statistical analysis of the results; the dosing and performances of the positive control; the duration which was insufficient to detect effects on egg laying). Overall, experts considered the available dataset for bees was insufficient to fully address the MoA of buprofezin. Open points <u>Non-Target Arthropods (NTAs)</u> - The RMS was requested to update the Risk Assessment in the Vol. 3 B9 CP and LoEP acknowledging the need of further testing addressing potential ovicidal and ovo-larvicidal effects of buprofezin from direct exposure to the substance in addition to the available testing strategy (considering the MoA of the substance). <u>Bees</u> - The RMS was requested to update the Risk Assessment in the Vol. 3 B9 CP and LoEP acknowledging the need of further testing addressing potential ovicidal and ovo-larvicidal effects of buprofezin - The assessment of the study CP 10.3.1.3/01 should be updated by acknowledging the meeting discussion (the study is not considered supportive for risk assessment) The LoEP should be updated accordingly by deleting the study CP 10.3.1.3/01
Experts' consultation 5.8 To discuss the appropriate testing strategy to investigate T-modality,	This point will be discussed in June's meeting. Background information will be added before June's meeting.



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based on the outcome of the tox expert consultation.	
Experts' consultation 5.9 experts to discuss the testing strategy to investigate the EAS-modalities. Due to concerns over potential anti-androgenic activity indicated in in-vitro studies, EFSA proposes performing a level 4 Fish Sexual Development Test FSDT (OECD 234 TG), since the level 3 FSTRA may have low sensitivity to detect anti-androgenic activity (ECHA EFSA ED Guidance, 2018).	This point will be discussed in June's meeting. Background information will be added before June's meeting.
Experts' consultation 5.10 Experts to discuss the potential concerns over activity of Buprofezin as androgenic antagonist and for binding for the androgenic receptor, to define the testing strategy for investigation of the EAS-modalities.	This point will be discussed in June's meeting. Background information will be added before June's meeting.
New Experts' consultation 5.11 proposed by EFSA for completeness of discussion MS experts to discuss whether the available	MS experts were asked to discuss whether the available information for buprofezin was sufficient to characterise the ecotoxicological safety of the formulation for representative uses with respect to the acute and long-term toxicity to non-target organisms (i.e., through a "whole mixture" or "individual component" approach. Open point



Subject	Conclusions Pesticide Peer Review Meeting
information is sufficient to characterise the full toxicological profile of the formulation(s) for representative use(s) with respect to the acute, genotoxicity, short- and long-term toxicity. If certain endpoints are not covered, MS experts to discuss the toxicological profile of each individual component other than the active substance.	The RMS was requested to ensure that the ecotoxicological potential of the formulation for representative uses is addressed. Unless exhaustive information is available on the hazard/risk to NTOs of the formulation for representative uses, based on the discussion during the experts meeting, the RMS should report what information is available to assess the ecotoxicological profile of the co-formulants contained in the (individual) formulation. Such information should gather existing assessments and studies to be included in a revised RAR (volume 4) to enable an independent hazard/risk identification and characterization (acute and long-term) of the chemically identified co-formulants to NTOs, including mixtures.

REPORT OF PESTICIDE PEER REVIEW TC 104

MEPANIPYRIM – AIR III (MANDATED)

Rapporteur Member State: BE

5. Ecotoxicology

Date: 28 April 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by RMS Belgium	Federal Public Service Health, Food Chain Safety and Environment
National Expert nominated by MS Finland (2)	Finnish Safety and Chemicals Agency
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS)
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by MS Poland	National Institute of Public Health NIH - National Research Institute

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.3 Experts to discuss the reliability of the Amphibian Metamorphosis Assay (AMA) CA 8.2.3/01. Among others, the following issues impacting reliability will be discussed: • Test concentrations' selection (Maximum Tolerated Concentration (MTC) potentially not reached, influence of solubility). • Solvent control data. • Histopathological data. The additional information and clarification provided by the applicant at Reporting table points 21, 35, 36 and 39 will be taken into account during the experts' consultation.	• Regarding the test concentrations in the available Amphibian Metamorphosis Assay (AMA), the selection was based on a range-finding test and the solubility of the substance. • The solvent was showing statistically significant changes compared to the negative control in some of the measured parameters (i.e., nHLL), although it was used in accordance with the relevant OECD guidelines. • The two highest treatment levels showed an increase in incidence of follicular cell hyperplasia and hypertrophy compared to the solvent control. This latter was also shown a higher incidence of follicular cell hyperplasia and hypertrophy compared to the negative control. No individual data on the staging of the animals at study termination were available. Overall conclusion The experts agreed that: • the choice of the tested concentrations was appropriate. • the findings in the treatments should be compared to the solvent control when there is a statistically significant difference between the negative and solvent control. This is in line with more recent OECD guidelines and common practice. • since it was not possible to match the histopathological changes with the stage of each animal, the interpretation of the data was hampered, and it could not be ruled out whether the changes observed in the thyroid histology are a clear indication of positive evidence of endocrine activity through the T-modality. Open point RMS to include more details on the choice of the tested concentrations, and to reflect the outcome of the discussion in the revised RAR.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 Experts to discuss the reliability of the Fish Short-Term Reproduction Assay (FSTRA) CA 8.2.3/02. Among others, the following issues impacting reliability will be discussed: • Test concentrations' selection (i.e. highest treatment potentially overcoming MTC – mortality 16.7%). • Validity criteria of fecundity in control replicates.	• Population relevance of the adverse effects observed in mammals. Mepanipyrim was considered meeting the ED criteria for EAS-modalities in humans. Considering the available dataset, a pattern of EAS-mediated adversity was identified based on histopathological changes in the testicular seminiferous epithelium in rats, deregulation in estrus cycle in rats, follicular cysts in the ovaries of the rats, decrease of prostate weight and testes weight in dog and occasional occurrence of uterus endometrial hyperplasia, hydrometra and uterine adenocarcinoma. All those effects and additional adverse effects were reconsidered to assess the relevance at the level of population for wild mammals. Overall conclusion Effects on ovary and testes histopathology, fertility, number of embryonic or foetal deaths and viable foetuses and post-implantation loss are relevant at the level of population and therefore the conclusion drawn for humans applies to wild mammals as non-target organisms. Open point RMS to include an assessment and a conclusion on the ED assessment for wild mammals in line with the discussions. • Fish Short-Term Reproduction Assay (FSTRA) The reliability of the study was questioned since at the highest test concentrations a mortality of 16.7% was observed. Also, the validity criterion related to fecundity in control was not completely fulfilled. Overall, the experts considered the study valid since it is not uncommon that a successful breeding group exhibits a lower fecundity during the exposure phase and that in the OECD 229 (more recent than OPPTS TG) a definite number regarding the number/eggs/female is not given. Overall, although the study has some reliability issues (i.e., only two concentrations can be used lowering the statistical power of the test; low spawning performance in one of the negative control replicate, high level and high variability of the VTG measurement in males), the study results do not seem to show a pattern of endocrine activity. Open point: RMS to reflect the outcome of the discussion in the revised RAR.

REPORT OF PESTICIDE PEER REVIEW TC 104

Amidosulfuron – AIR III

Rapporteur Member State: FI

5. Ecotoxicology

Date: 28 April 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Belgium	Federal Public Service Health, Food Chain Safety and Environment
National Expert nominated by RMS Finland (2)	Finnish Safety and Chemicals Agency
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS)
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by MS Poland	National Institute of Public Health NIH - National Research Institute

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.7 Experts to discuss the available information in the FSTRA and whether it is possible to conclude if the ED criteria are met for EAS-modalities.	A valid FSTRA in line with OECD TG 229 was available. Overall, the study does not show a clear pattern of EAS endocrine activity. Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.8 Experts to agree on the validity of the XETA and whether if based on the available information it can be confirmed that amidosulfuron is not an ED for the T-modality for non-mammalian spp.	The results of the study suggested that overall, the study can be considered negative; however, the lack of GLP compliance of the study for the biological part questions its suitability in the regulatory context. Open point: RMS to reflect the outcome of the discussion in the revised RAR.

REPORT OF PESTICIDE PEER REVIEW TC 104

Picloram – AIR III

Rapporteur Member State: PL

5. Ecotoxicology

Date: 28 April 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Belgium	Federal Public Service Health, Food Chain Safety and Environment
National Expert nominated by MS Finland (2)	Finnish Safety and Chemicals Agency
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS)
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by RMS Poland	National Institute of Public Health NIH - National Research Institute

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 Experts to discuss the available dataset from NTOs including the new data that will be submitted as proposed by the applicant. I.e., AMA and FSTRA will be submitted. Experts should decide if based on the available information, it is possible to conclude if the ED criteria for non-target organisms are or are not meet. Please consider further data that can be submitted as indicated in this point 5(40) and in 5(38). In addition, the outcome of the ED assessment for humans should be considered for wild mammals as non-target organism.	The current ED assessment for picloram can be summarized as follows: - For wild mammals as non-target organisms the same conclusion as the one reached for humans applies (i.e., further data needed for A- and S- modalities and no ED for E- and T- modalities). For further information on the data required see the report of the Pesticides Peer-Review meeting TC 100 (Mammalian toxicology section). - For non-target organisms other than wild mammals, the available dataset was considered sufficient for the investigation of potential endocrine activity. No evidence of EATS-mediated endocrine activity was observed. Open point: RMS to update the RAR by including the outcome of the Experts' consultation.

REPORT OF PESTICIDE PEER REVIEW TC 104

PENOXSULAM – AIR IV

Rapporteur Member State: IT

5. Ecotoxicology

Date: 28 April 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by RMS Belgium	Federal Public Service Health, Food Chain Safety and Environment
National Expert nominated by MS Finland (2)	Finnish Safety and Chemicals Agency
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS)
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the available ED data with non-mammalian species and the conclusion drawn by the RMS for non-target organisms.	An amphibian metamorphosis Assay (AMA) and a Fish Short-Term Reproduction Assay (FSTRA) were available to sufficiently investigate the endocrine activity through T and EAS modalities respectively. Conclusion All experts agreed that the AMA and FSTRA were valid and reliable; both studies did not show any evidence of EATS-mediated endocrine activity. Open point RMS to reflect the outcome of the discussion of the experts' consultation in a revised RAR.

REPORT OF PESTICIDE PEER REVIEW TC 104

Phenmedipham – AIR III

Rapporteur Member State: FI

5. Ecotoxicology

Date: 28 April 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Belgium	Federal Public Service Health, Food Chain Safety and Environment
National Expert nominated by RMS Finland (2)	Finnish Safety and Chemicals Agency
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by MS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS)
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by MS Poland	National Institute of Public Health NIH - National Research Institute

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 Experts to decide on the relevance of the T-mediated adversity for wild mammals if, based on experts' consultation in 2(15), it is considered that the substance can be ED for humans. See experts' consultation in 2(15) and 5(53), 5(58), 5(65), 5(74), 5(90). In addition, for non-target organisms other than mammals: Experts to decide on whether the available information and biological results from the EAMA are sufficient to draw a conclusion for the T-modality for NTOs other than mammals. Experts to decide how to consider the validity criteria of the EAMA and the outcome of the study in view of the fact that it is not a standard OECD TG, not recognized by the available ED guidance.	Phenmedipham was considered not to meet the ED criteria for T-modality in humans as no T-mediated adversity and activity have been observed in the available studies; therefore, there was no need of discussing the population relevance of the adversity that would be relevant for wild mammals. The same conclusion as the one for humans applies to wild mammals as non-target organisms for the T-modality. For non-mammalian species, <i>in-vivo</i> data with amphibians obtained from an Extended Amphibian Metamorphosis Assay (EAMA) showed an increase of histopathological changes in the thyroid in absence of systemic toxicity. In addition, from US EPA ToxCast program, positive evidence of TPO inhibition ((CCTE_Simmons_AUR_TPO_dn) was observed at a concentration below to a non-specific mono-oxygenase protein inhibition (Quantilum_inhib_2_dn assay). The biological findings in the EAMA do not allow to draw a conclusion on the T-mediated adversity. Overall, the experts concluded that the available data showed positive evidence for thyroid endocrine activity both <i>in vitro</i> and <i>in vivo</i> as indicated above. No firm conclusion could be drawn regarding T-mediated adversity. Open point The RMS to update the RAR and the LoEP in line with the discussion at the meeting.



Experts' consultation 5.5 (I) Experts to decide on the relevance of the EAS-mediated adversity for wild mammals if, based on experts' consultation in 2(17), it is considered that the substance can be ED for humans. See also 5(38). Experts' consultation 2.19: MSs experts to discuss the outcome of the extended one-generation reproductive toxicity (EOGRT) study in rats and <u>its implications on the toxicological endpoints and human health and ecotoxicological risk assessment</u> in an experts' meeting. Experts' consultation 5.5 (II) In addition, particularly related to non-target organisms, experts to decide on whether the results of the available FSTRA can be used to conclude on the ED properties of the substance throughout the EAS-modalities for NTOs other than mammals. ToxCast data might also to be considered.	As result of the long-term stop of the clock, new information was submitted for the purpose of the ED assessment. However, one of the tests (extended one-generation reproductive toxicity (EOGRT) study in rats in line with OECD TG 443) also triggered the revision of the ecotoxicological relevant endpoint which is used for drawing a conclusion on the long-term risks to wild mammals associated to the exposure of phenmedipam. Since the effects observed in the newly submitted EOGRT study were not considered relevant at population level (i.e., hemosiderin pigmentation in kidney in F1 males and spleen females F1 seen in conjunction with haematological findings), the ecotoxicological endpoint for wild mammals, agreed in the Pesticides Peer-Review meeting PPR 169, does not change and it is confirmed as valid. The risk assessment based on that endpoint shall be presented in the revised RAR and LOEP. Phenmedipham was considered not to meet the ED criteria for EAS modalities in humans based on the lack of EAS-mediated adversity; therefore, there was no need of discussing the population relevance of the adversity. The same conclusion as the one for humans applies to the wild mammals as non-target organisms for the EAS-modality. For non-mammalian species, a valid Fish Short-Term Reproduction Assay (FSTRA) in line with OECD TG 229 was available. In lack of reliable vitellogenin (VTG) measurements (experts at the meeting considered VTG measurements unreliable) and in light of the identified adverse effects (i.e., histopathological changes in the female gonads seen in absence of systemic toxicity and in conjunction with a decrease in fecundity), all experts agreed that a clear conclusion could not be drawn based on this study. Open points i) RMS to update the RAR and LOEP by considering the new information from the EOGRT and to confirm the risk assessment for wild mammals in the ecotox section by using the previously agreed endpoint. ii) RMS to update the RAR by including the conclusions for wild mammals in the ED assessment for non-target organisms in line with the outcome of the discussion. iii) RMS to update the RAR in line with the discussion at the meeting related to the EAS-modalities for non-mammalian species.

24 - 28 April 2023

MINUTES

Pesticide Peer Review TC 102
Picloram

REPORT OF PESTICIDE PEER REVIEW TC 102

PICLORAM – AIR III

Rapporteur Member State: PL

5. Ecotoxicology

Date: 28 April 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Germany	Federal Environmental Agency (UBA) (DE)
National Expert nominated by MS Greece	Benaki Phytopathological Institute (BPI) (EL)
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by RMS Poland	Institute of Environmental Protection – National Research Institute (PL)

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the endpoint from the Avian Reproduction Study of 2002 with Picloram Acid in Northern Bobwhite (<i>Colinus virginianus</i>).	During the consultation phase, the selection of a NOEL from an avian reproduction study based on 14-day old bobwhite quail survivors as a percentage of eggs laid was commented. The selection of the most relevant endpoint for avian reproduction was discussed at the meeting. The results on body weight of 14-day old survivors were presented. The mean body weight was lower, but not statistically significant, than in the control. The effects did not follow a dose-response, as the effect size in the highest treatment group (1500 mg/kg of treatment) was about the same as the 750 mg/kg treatment. It was noted that the differences between the two highest doses and the control are slightly below 10%. Considering the lack of a clear dose-response and the small effect size observed in the two highest treatment groups, all experts agreed that body weight changes of 14-day old survivors should not be considered in the endpoint selection. Therefore, the NOEL of 750 mg/a.e./kg (65 mg a.e./kg bw day) based on 14-day old bobwhite quail survivors as a percentage of eggs laid previously proposed is confirmed at the meeting.
Experts' consultation 5.2 Experts to discuss the available dataset from NTOs including the new data that will be submitted as proposed by the applicant. I.e., AMA and FSTRA will be submitted.	This point will be discussed in TC 104 ecotoxicology session on ED properties.



Subject	Conclusions Pesticide Peer Review Meeting
Experts should decide if based on the available information, it is possible to conclude if the ED criteria for non-target organisms are or are not met. Please consider further data that can be submitted. In addition, the outcome of the ED assessment for humans should be considered for wild mammals as non-target organism.	
Experts' consultation 5.3 Experts to discuss the suitability of the available toxicity data to address the risks for aquatic organisms from the representative uses (i.e., a.s., representative product and relevant metabolites). Particularly, to discuss the following points: - The study Vol.3 B9 AS - B.9.2.2.1/01 on the toxicity of technical picloram acid to the embryo, larval, and juvenile stages of the Rainbow trout, in relation to the compliance with the OECD 210 validity criteria and exposure duration. - The studies on aquatic macrophytes:	Early Life Stage (ELS) study with the rainbow trout One ELS study with the rainbow trout conducted with the a.s. was available. Some drawbacks were highlighted during the commenting phase, especially concerning the fact that on the last experimental day the oxygen saturation levels were below 60% in the second lowest treatment group. At the meeting this deviation was not considered sufficient to invalidate the study, considering that further vertebrate testing should be avoided in this specific case. The lack of a GLP status for this study was also discussed. It was considered that such deviation should not impact the validity of the study, considering that the experiment was conducted before the entry into force of the regulation on data requirements for active substances. New EC₁₀ calculations were provided by the applicant and accepted by the RMS. Open point: RMS to update the aquatic risk assessment for all groups of organisms based on the update exposure assessment. In the case FOCUS step 3 is not sufficient to reach a conclusion of low risk, exposure modelling for FOCUS step 4 should be used. Furthermore, the EC₁₀ value should be used for the long-term risk assessment for fish and a footnote should be included in the LoEP acknowledging the uncertainty around the endpoint derivation (i.e., deviation from the OECD 210 and the lack of a GLP status). The studies on aquatic macrophytes (<i>Lemna gibba</i>) Studies with <i>Lemna gibba</i> were available with the a.s. (including a new study submitted after the stop-of-the-clock) and formulation. The RMS assessment of the available toxicity studies with <i>Lemna gibba</i> reported several deviations of the



Subject	Conclusions Pesticide Peer Review Meeting
1. <i>L. gibba</i>: Vol.3 B9 (AS) B.9.2.7/2 (j72) and Vol.3 B9 (CP) B.9.3.1/04 in relation to the limitations highlighted during the peer review, including the need to further address responses other than frond number. 2. <i>M. spicatum</i>: CA B.9.2.7/1 and CP B.9.3.1/05, with particular reference to the need to carry out separate measurement on plant without roots. The need to analytically confirm the concentration of picloram in the test medium in CP B.9.3.1/05. - The suitability of the new data provided by the applicant to address the data gaps in the risk assessment identified by the RMS and during the peer review - The need to further address risks to aquatic plants for the a.s. (<i>Lemna gibba</i> and <i>Myriophyllum spicatum</i>) - The need to further address the risks to aquatic organisms for 4-amino-2,3,5-trichloropyridine - The need to further address the risks to algae (i.e., green algae and freshwater diatom) and aquatic plants (<i>Lemna gibba</i> and <i>Myriophyllum</i>	study results from the OECD TGs. These deviations concerned the studies submitted before the stop-of-the-clock. The meeting discussed the available studies with <i>Lemna gibba</i>, where it was concluded that the studies are suitable for risk assessment. Open points: - Formulation data: RMS to update the study summary to reflect the outcome of the discussion. The endpoint should be added to the LoEP with a footnote reflecting the deviations (i.e., the low number of replicates and the lack of assessment endpoints other than frond number). - A.s. data: RMS to update the study summary (Vol.3 B9 (CA) B.9.2.7/2 (j72)) to reflect the outcome of the discussion. The endpoint from this study should be added to the LoEP with a footnote reflecting the deviations acknowledged in the study assessment and in the meeting discussion (i.e., the low number of replicates and the lack of assessment endpoints other than frond number). <u>The studies on aquatic macrophytes (<i>Myriophyllum spicatum</i>)</u> Studies with the a.s. and formulation were available at submission which were only considered supplementary by the RMS due to drawbacks in the way length measurements were carried out (i.e., lack of a separate assessment of plant without roots) and other deviations from the OECD protocol. New studies were submitted which were considered reliable by the RMS. The meeting agreed with the assessment by the RMS. Open point: for the RMS to correct the unit in new formulation study with <i>Myriophyllum spicatum</i> (i.e., mg/L) in the commenting box by the RMS in the Vol. 3 B9 (CP). Open point: RMS to revise the RAR by reflecting the meeting discussion for aquatic organisms <u>The studies on algae</u> The RMS proposed that the endpoint from the study on <i>Navicula pelliculosa</i> with the a.s. was not reliable owing to concerns with the statistical analysis and the lack of a full dose response. This resulted in the endpoint for yield not being considered as reliable. The RMS was concerned that the study was not sufficiently reliable to show that green algae were the most sensitive algae species (which would lead to a data gap).



Subject	Conclusions Pesticide Peer Review Meeting
spicatum) for GF-224. - The need to further address the long-term risks for the PPP.	At the meeting, growth rate was considered the preferred endpoint for risk assessment. Additionally, the study was considered sufficiently reliable for demonstrating the sensitivity of this species relative to green algae. Overall the study with the a.s. was considered sufficiently reliable. Additionally, in line with the data requirements for PPP, a second study on a second algal species was not deemed required. Open points: - RMS to reflect the outcome of the discussion in the RAR and to update the LoEP to include the endpoint for <i>Navicula pelliculosa</i> (a.s.) in the LoEP. - RMS to update the RAR to reflect a study with a second algae species is not required for the representative PPP (i.e., not to identify a data gap). The LoEP should also be updated accordingly. <u>Availability of long-term endpoints for the PPP</u> - Please refer to discussion point 5.4 below. <u>Risk assessment for the metabolites</u> The risk assessment for 4-amino-2,3,5-trichloropyridine was conducted with the endpoint for <i>M. spicatum</i>. The meeting agreed that in line with the EFSA aquatic GD (2013) a screening assessment for other aquatic organisms. Additionally, it was considered that the risk assessment should cover all ecotoxicologically relevant metabolites (i.e., taking into account the revised exposure assessment). This applies to all non-target organisms (i.e., including the dietary assessment of NTOs, such as birds, mammals and bees). Open points: - RMS to updated the aquatic risk assessment in the RAR and LoEP for metabolite 4-amino-2,3,5-trichloropyridine to include a screening assessment for all taxa other than myriophyllum where an endpoint is available. - RMS to update the risk assessment for all non-target organisms (including birds and mammals and bees) with a screening assessment for additional metabolites listed in the LoEP (e.g., oxamic acid and 4-amino-5,6-dichloropicolinic acid). The risk assessment for metabolites such as 4-amino-2,3,5-trichloropyridine should be updated considering the revised exposure assessment.
Experts' consultation 5.4	Based on the initial assessment by the RMS the risk assessment for the formulation for the representative uses was not addressed for all non-target organisms. Following the stop-of-



Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss, in light of the new information provided by the applicant, the risk assessment for NTOs (with particular consideration to aquatic organisms) from exposure to the representative formulation. In doing so, experts may want to take into consideration the conclusions drawn at the pesticides peer review meeting on recurring issues on ecotoxicology (see EFSA Supporting publication 2019:EN-1673).	the-clock the applicant submitted new data. An expert discussion was considered necessary to agree on whether the hazard/risk assessment for non-target organisms would cover the formulation for representative uses (i.e., PPP and co-formulants), in light of the new data submitted by the applicant. The following open points were identified: <u>Aquatics:</u> - RMS to reconsider the applicant's additive risk assessment and to update it considering the revised exposure assessment for picloram. The assessment should also include fish and aquatic invertebrates. The assessment should be included in the revised RAR and LoEP. - RMS to reflect the outcome of the discussion on the representative PPP for aquatic organisms in the RAR and in particular to reflect that the low MDR values suggest that additional co-formulants are not of particular concern for aquatic organisms - RMS to remove the currently proposed risk assessment for the PPP considering the toxicity is driven only by picloram from the LoEP and reflect in the RAR that it only considers the exposure of picloram - RMS to remove the formulation assessment in terms of mg formulation per L since the exposure estimate only considered spray-drift - RMS to reflect the outcome of the need for a chronic risk assessment for aquatic organisms in the RAR, once the exposure and risk assessment will be revised. <u>Soil organisms:</u> - RMS should check the argumentations for the soil macro-organism assessment once the updated soil exposure assessment is available. The margin of safety should be checked, and the argumentation updated. - RMS to ensure that the PECsoil for the formulation are included in the fate section of the LoEP. <u>General:</u> - RMS to update the LoEP to ensure that the endpoints for the PPP are expressed both in terms of the PPP and in terms of the active substance (picloram only). - RMS to reflect the discussion on the PPP and co-formulants in the RAR. - RMS to ensure that the ecotoxicological potential of the formulation for representative uses is addressed. Unless exhaustive information is available on the hazard/risk to NTOs of the (individual) formulation, based on the discussion during the experts meeting, the RMS should report the available information to assess the ecotoxicological profile of the (individual) co-formulants



Subject	Conclusions Pesticide Peer Review Meeting
	contained in the formulation. Such information should gather information on existing assessments and studies to be included in a revised RAR (volume 4) to enable an independent hazard/risk identification and characterisation (acute and long-term) of the chemically identified co-formulants to NTOs, including mixtures.

24 - 28 April 2023

MINUTES

Pesticide Peer Review TC 102
Penoxsulam

REPORT OF PESTICIDE PEER REVIEW TC 102

PENOXSULAM – AIR IV

Rapporteur Member State: IT

5. Ecotoxicology

Date: 28 April 2023

List of participants:

Status	Name of institution / attendee
EFSA statutory staff member	EFSA
National Expert nominated by MS Germany	Federal Environmental Agency (UBA) (DE)
National Expert nominated by MS Greece	Benaki Phytopathological Institute (BPI) (EL)
National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by RMS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) (IT)
National Expert nominated by MS Poland	Institute of Environmental Protection – National Research Institute (PL)

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the available ED data with non-mammalian species and the conclusion drawn by the RMS for non-target organisms.	This point was discussed at Pesticide Peer review TC 104.
Experts' consultation 5.2 Experts to discuss the refined risk assessment probabilistic approach for terrestrial non-target higher plants. The experts should discuss which is the best approach to build the species sensitivity distribution considering the available dataset.	<u>Refined risk assessment probabilistic approach for terrestrial non-target higher plants</u> It was agreed that different assessment endpoints (shoot weight, phytotoxicity/visual injury) should not be merged for building species sensitivity distribution (SSD) curves. The risk assessment for non-target terrestrial plants will be refined on the basis of SSD built on the ER₅₀ values for shoot fresh weight from the vegetative vigour study with formulation 'GF-1076'. The experts agreed that the probabilistic risk assessment based on visual injury data should be included in the revised RAR. It was acknowledged that the quantitative reliance on this data for risk assessment at the EU/MS level would require additional consideration. The experts agreed to base the risk assessment on the SSD calculated without unbound values, as proposed by the RMS. The experts also agreed that, considering the shape of the SSD, the position of the data relative to the fitted curve, the protectiveness of the HR₅ of the most sensitive endpoint, the



Subject	Conclusions Pesticide Peer Review Meeting
	use of the median HR₅ (over the lower limit of the 95% confidence interval) were justified. The experts agreed that an assessment factor of 1 should be used in the probabilistic risk assessment, in line with the currently noted guidance. Open point: RMS to reflect the outcome of the discussion in the updated RAR. Specifically: - To include the probabilistic risk assessment for fresh weight in addition to visual injury in the revised RAR. However, the risk assessment conclusion should be based on fresh weight with an acknowledgment that a different outcome would not be achieved using visual injury. - To include the additional SSDs presented at the meeting (e.g., fresh weight from the vegetative vigour study) in the revised RAR, clarifying their use in risk assessment. - To include additional details on the fulfilment of the normality assumption and goodness of fit of the SSDs. <u>Safety of the formulation for representative uses</u> The formulation GF-1075 was noted to be of higher acute toxicity to fish than the active substance (a.s.) by a factor > 10. As a consequence, a long-term study with fish should have been provided according to Reg. 284/2013. The RMS clarified that the data requirements of Reg. 284/2013 for the formulation 'GF-1076' were fulfilled by the applicant. However, some of the data used the older version of the formulation for representative uses ('GF-1075') as surrogate, which has not the same composition of GF-1076. Therefore, the RMS was requested to perform an individual components assessment. GF-237 was used as surrogate for the formulation for representative uses in acute bird risk assessment. This formulation was not more acutely toxic than the active substance to birds. This formulation has not the same composition of GF-1076. However, it was noted that the formulation GF-237 did not show clear higher toxicity to birds than the active substance to mammals, considering the differences in the rate tested across tests. The experts at the meeting considered that further tests on birds with the formulation GF-1076 should be carefully considered in view of animal welfare reasons. The need for further testing on birds with GF-1076 would also require additional consideration of



Subject	Conclusions Pesticide Peer Review Meeting
	the safety assessment of the individual components of the representative formulation (relative to the one(s) of GF-237). A direct bridging of the two formulations was not considered immediately supported. Such extrapolation would require weighing the evidence listed above in a reasoned justification. Open points: - RMS to reflect that the formulation GF-1075 was more acutely toxic to fish than the a.s. by a factor >10. Therefore, a long-term study with fish should have been provided according to Reg. 284/2013. - RMS to ensure that the ecotoxicological potential of the formulation(s) for representative uses are addressed (according to Reg. 284/2013). Unless exhaustive information is available on the hazard/risk to non-target organisms of the (individual) formulation(s), based on the discussion during the experts meeting, the RMS should report what information is available to assess the ecotoxicological profile of the co-formulants contained in the (individual) formulation(s). Such report should gather existing information, assessments and studies and include them in a revised RAR (volume 4) to enable an independent hazard/risk identification and characterisation (acute and long-term) of the chemically identified co-formulants to non-target organisms, including mixtures. - RMS to reflect on the acute hazard assessment to birds, in view of the meeting discussion.

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MINUTES

Pesticide Peer Review TC 102
Paraffin oil CAS 8042-47-5

REPORT OF PESTICIDE PEER REVIEW TC 102

PARAFFIN OIL CAS 8042-47-5 – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 28 April 2023

List of participants:

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National Expert nominated by MS France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) (FR)
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by MS Poland	Institute of Environmental Protection – National Research Institute (PL)

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the relevance/use of tier 1 studies with aquatic organisms with the different representative formulations for the risk assessment of paraffin oil considering the physicochemical properties and behaviour of oils in water (whether the exposure in the aquatic tier 1 studies and the tested species can be considered as a representative worst case). The joint discussion with the e-fate experts should also be considered.	<u>Calculation of predicted environmental concentrations</u> The majority of experts agreed that the exposure assessment for permanent greenhouse uses would need to consider 0.1% emissions via drift in line with the EU-level guidance documents (this applies to Neudorff). Open point: RMS to amend the exposure and risk assessment for permanent greenhouse uses considering 0.1% emissions via drift. <u>Tier 1 effect studies</u> Overall, all experts agreed that, considering the specificity of this hazard assessment, which was primarily based on tests carried out with the formulations for the representative uses (all including [REDACTED] and agitation in the system), the tier 1 risk assessment based on the concentration approach is justified. Open point: RMS to reflect in the updated RAR the outcome of the discussion, by: (i) Clearly identifying the tests for which agitation was ensured in the test system. Alternatively, to clarify if there is evidence that the test substance was maintained in the water column; (ii) Reporting the rationale for using a concentration approach in the tier 1 risk assessment. <u>Exposure assessment in higher tier studies</u> Overall, the experts agreed:



Subject	Conclusions Pesticide Peer Review Meeting
	(i) That a concentration-based approach may be a suitable way to resolve the risk assessment, although acknowledging that the 2-D approach is likely more representative of the field exposure; (ii) That a 2-D approach may be considered as a suitable option, should reliable 2D nominal endpoints (i.e., expressed as $\mu\text{g a.s./m}^2$) be available. A 1:1 conversion of the concentration in the water column into a deposition area would not be justified. Similarly, the use of conversion factors were not considered scientifically underpinned. Accordingly, the dimension compensation approach (as presented by the applicant) was not supported by the experts; (iii) Should a 2-D approach be used (see experts' consultation 5.2) an open point for the RMS to provide predicted environmental concentration values expressed in relation to surface area was identified. Open point: RMS to amend the risk assessment accordingly (refer to experts' consultation 5.2).
Experts' consultation 5.2 Experts to discuss the mesocosm study (study code NEU-001/4-50) (KCP 10.2.3/01) with the representative formulation NEU 1130 I EW. In particular, the experts should discuss: (i) the reliability of the study indicating several limitations of the study); (ii) the assessment factor applied to derive the ERO-/ETO-RAC; (iii) the relevance of the approach followed at the joint experts' consultation fate/ecotox on rape seed oil (TC 65, November 2021) should be discussed in an experts' meeting	The reliability of the microcosm study (study code NEU-001/4-50) (KCP 10.2.3/01) with the representative formulation NEU 1130 I EW was discussed. Considering all limitations and uncertainties identified in the microcosm study (e.g., analytical methods used in the study were not fit for purpose, low number of species tested), the majority of experts agreed that it should only be considered as supportive, i.e., to be used qualitatively for the risk assessment but not quantitatively. Open point: RMS to reflect the outcome of the discussion in the RAR. The risk assessment should be updated without the use of the mesocosm endpoint as a higher tier approach.



Subject	Conclusions Pesticide Peer Review Meeting
that could be jointly done with e-fate experts. The discussion on the FOCUS exposure profile could be jointly done with e-fate experts.	
Experts' consultation 5.3 Experts to discuss the mesocosm study (report No: BCP-002/4-52) (KCP B.9. 3.3/01) with the representative formulation BCP 405 D. In particular, the experts should discuss: (i) the reliability of the study; (ii) the assessment factor applied to derive the ERO-/ETO-RAC; (iii) the relevance of the approach followed at the joint experts' consultation fate/ecotox on rape seed oil (TC 65, November 2021) should be discussed in an experts' meeting that could be jointly done with e-fate experts.	Mesocosm study (Report No: BCP-002/4-52) (KCP B.9. 3.3/01) Several methodological concerns of the study were discussed but, overall, it was agreed that the mesocosm study was reliable. For the EU level assessment, the experts agreed on using the ETO RAC with an AF of 3 for single and multiple applications to account for the effects seen on Notonectidae at the NOEC and probably even some recolonisation. It was discussed which representative uses with BCP405D can be covered by the mesocosm study. No accumulation of effects was seen in the study after six at 0.03 mg formulation/L. It was agreed using the ETO-RAC for up to six applications. For the representative uses with more than six applications, the experts agreed that the applicant would need to provide an uncertainty analysis for covering both the exposure and the effect assessment. Indeed, considering the uncertainties identified in the study it would be very beneficial if the applicant would provide a proposal for an uncertainty analysis for all uses in the GAP. Risk assessment for sediment-dwelling organisms Although acute tier 1 studies with sediment dwelling organisms are not available for any of the formulations, the experts agreed that, for the representative uses with BCP405D, the risk assessment is covered by the mesocosm study. Use of the mesocosm study with BCP405D for the uses with NEU 1130 I EW and Paraffin oil 79% EC The experts agreed that the extrapolation from BCP405D to NEU 1130 I EW was not sufficiently justified, also considering the differences in toxicity between both formulations in the tier 1 studies for some taxa (e.g. acute toxicity to <i>Daphnia</i>). The extrapolation from BCP405D to PL Paraffin oil 79% EC was also not well justified, also considering the classification of the co-formulants present in the latter formulation. Open points:



Subject	Conclusions Pesticide Peer Review Meeting
	- RMS to reflect the outcome of the discussion in the updated RAR and to estimate the endpoint in nominal a.s./m². RMS to remove the risk assessment for more than six applications with BCP405D from the RAR and list of endpoints.
Experts' consultation 5.4 Experts' to discuss: (i) the comparability/equivalence of the different representative formulations with paraffin oil also considering any evidence presented by the applicants; (ii) the geometric mean approach for fish based on the three acute studies. Note to the RMS: The discussion on the equivalence between formulations will also be relevant to address several comments received in other parts of the Ecotoxicology section.	<u>Comparability/equivalence of the different representative formulations with paraffin oil</u> Considering that formulation PL Paraffin oil 79% EC had co-formulants with hazard classification to aquatic organisms, extrapolation from this product to the others (NEU 1130 I EW and BCP405D/CCL742), which had no co-formulants with hazard classification, was not agreed by the experts. Additionally, the experts agreed that, given the differences in composition and in formulation types (i.e., (emulsion in water (EW) or oil emulsion (EC)), it was not sufficiently justified the claim that formulations are comparable. Several considerations specific for fish (acute and chronic) were discussed and agreed: - An extrapolation from PL Paraffin oil 79% EC to the other formulations (which include an EW formulation) was considered questionable. However, careful consideration should be given to animal welfare and the margin of safety of the final RMS' assessment, before requesting further data on fish. - The chronic fish study with NEU 1130 I EW will be used in an illustrative risk assessment for all representative uses. - It was suggested that an extrapolation from BCP405D/CCL742 for the acute risk assessment for fish with PL Paraffin oil 79% EC would be justified, taking into account that BCP405D/CCL742 yielded the lowest acute endpoint for fish. Open points: - RMS to ensure that the applicants argumentations on the comparability between the formulations for representative uses, if any, are evaluated. - RMS to ensure that the evaluation of such information is included in the revised RAR (or to acknowledge that no sufficient information was provided, if that is the case). - RMS to update the risk assessment for aquatic organisms. <u>Safety of the representative formulations</u> On open point was set to ensure that the ecotoxicological potential of the formulations for representative uses are addressed (according to Reg. 284/2013). Open point:



Subject	Conclusions Pesticide Peer Review Meeting
	RMS to ensure that the ecotoxicological potential of the formulation(s) for representative uses are addressed. The RMS should report what information is available to assess the ecotoxicological profile of the co-formulants contained in the individual formulations. Such report should gather existing information, assessments and studies and include them in a revised RAR (volume 4) to enable an independent hazard/risk identification and characterisation (acute and long-term) of the chemically identified co-formulants to non-target organisms including mixtures. <u>Geometric mean approach for fish based on the three acute studies</u> Considering the differences between the formulations, the experts did not agree in calculating the geometric mean from endpoints derived from studies performed with different formulation. Therefore, two separate endpoints were proposed, one for each formulation. For the two acute fish studies with NEU 1130 I EW, the experts agreed to use the lowest endpoint (LC₅₀= 40.5 mg a.s./L) for tier 1 risk assessment. Open points: - RMS to clarify that both acute endpoints for fish with the formulation NEW 1130 I EW were expressed as geometric mean measured concentration and to amend the LoEP accordingly. - RMS to amend the acute risk assessment for fish as follows: - o By using the endpoints of the two formulations separately. Additionally, the lower endpoint for the NEU 1130 I formulation (LC₅₀= 40.5 mg a.s./L) should be used for tier 1 risk assessment.
Experts' consultation 5.5 Experts to discuss the reliability of the toxicity study using spiked sediment on <i>Chironomus riparius</i> (Document No.: BCP-001/4-29) (KCA B.9.2.5.3.1/01) and the endpoint to be derived from the study in case it is considered valid for the aquatic risk assessment of paraffin oil.	The experts agreed that, while the validity criteria were met, the two available studies with <i>Chironomus riparius</i> presented issues with the analytical measurements (i.e. intermediate measurements were not taken and the test substance was not detected at test end). The studies should be categorised only as supportive but their endpoints should not be used in the tier 1 risk assessment as they were considered not fully reliable. Open points: - RMS to reflect the outcome of the discussion in the RAR. - RMS to state in the RAR that these two studies are considered as supportive information, their endpoints



Subject	Conclusions Pesticide Peer Review Meeting
	should not be used quantitatively in the risk assessment and, therefore, remove them from the list of endpoints.
Experts' consultation 5.6 Experts to discuss the uncertainties of the current risk assessment for non-target arthropods other than bees based on tier 1 (glass plate) and extended/aged-residue studies where the test substance was applied prior the introduction of the test organisms as well as the need for additional toxicity data considering the physical mode of action of paraffin oil.	The experts agreed that the available studies on non-target arthropods (i.e. extended laboratory and aged-residue studies, glass plate studies were not available) should be considered valid and that they could be used only to assess the in-field recovery. The experts also agreed that extended laboratory or aged-residue studies cannot be used to assess the off-field risk since they are not suitable to assess potential effects of insecticides with a physical mode of action. A data gap will be set for the off-field risk assessment. The hazard assessment of insecticides with a physical mode of action should be discussed in a general experts' meeting. Open point: RMS to reflect the outcome of the discussion in the RAR.
Experts' consultation 5.7 Experts to discuss the acceptability of the extrapolation from the different representative formulations for the risk assessment of bees and non-target arthropods other than bees. Please also refer to the comparability of the different representative formulations of paraffin oil (experts' consultation 5.4).	The experts considered that, with the available evidence, it was not possible to properly assess the comparability between formulations; therefore, the risk assessment for the uses with one formulation should be performed considering the endpoint derived from the study with that formulation (no extrapolation between formulations). To perform the risk assessment for bee larvae for the uses with PL Paraffin oil 79% EC, the lowest endpoint from the two available studies should be used. For the chronic and larvae risk assessment for the representative uses with formulation NEU 1130 I EW, the experts agreed in setting a data gap as no studies were available. The experts agreed that, based on the study design of the tier 1 acute contact studies with bees where 1 or 2 µl of test substance is applied onto the bee thorax and the fact that the available semi-field studies could not rule out potential acute effects on bee foragers due to overspray of paraffin oil, the experts agreed that the acute risk via contact exposure was not properly addressed for paraffin oil by the standard studies. Open points: - RMS to reflect the discussion and the decisions in the updated RAR. - RMS to remove the risk assessment for bees based on acute contact exposure.



Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.8 Experts to discuss the reliability of the larval toxicity test on honeybees (Document No.: S16-03030) (KCA 8.3.1.3/01 and KCA 4.1.2/13) and its use in the risk assessment for paraffin oil.	The experts were of the opinion that the low recovery rates of paraffin oil in the diet of the bee larval study with the representative formulation BCP405D (Document No.: S16-03030) may have been caused due to the properties of paraffin oil which tends to form a layer on top of the diet, resulting in an uneven distribution. However, the experts considered that the recovery rates of paraffin oil in the larval diet (between 17% and 66% of the nominal concentrations) should not have an impact in the overall reliability of the study as the analytical dose verification of the test item stock solution and test item solutions from day 3 until day 6 resulted in recovery rates between 82% and 107 % of the nominal concentrations across all test item groups. All experts agreed to use the endpoint from the study for the risk assessment for bees. Open point: RMS to reflect the outcome of the discussion in the RAR.
Experts' consultation 5.9 Experts to discuss (i) the relevance of the earthworm studies considering the application method of the test substance and the mode of action of paraffin oil, and (ii) the critical endpoints for the earthworm risk assessment.	Relevance of the available earthworm chronic studies Although not part of the EU data requirements, it was agreed to not disregard the overspray tier 1 studies with paraffin oil as they could also provide relevant information for the risk assessment. For the uses with the representative formulation NEU 1130 I EW, the endpoint from the overspray study, which was lower than that from the soil incorporation study, will be used for the risk assessment. Extrapolating data across formulations was questioned because, by looking at the available tier 1 data with soil organisms, there seemed to be differences in toxicity between the formulations. Critical endpoints for the earthworm risk assessment Considering the differences in toxicity between formulations and that overspray studies might result in lower endpoints than soil incorporation studies, the following endpoints were agreed: - For the representative uses with BCP405D, a corrected NOEC of 405 mg a.s./kg soil, derived from the overspray study with that same formulation will be used for the risk assessment. - For the representative uses with NEU 1130 I EW, a corrected NOEC of 117.5 mg a.s./kg soil, derived from the overspray study with that same formulation will be used for the risk assessment. - For the representative uses with PL Paraffin oil 70%, a corrected NOEC of 117.5 mg a.s./kg soil, which was the lowest endpoint obtained from the two studies where the test



Subject	Conclusions Pesticide Peer Review Meeting
	substance was oversprayed (endpoint from NEU 1130 I EW/Promanal Neu), will be used for the risk assessment. Open point: RMS to update the tier 1 risk assessment for earthworms considering the outcome of the discussion.
Experts' consultation 5.10 Experts to discuss the reliability of the earthworm field study (Document No. 76450023) (CP B.9.7.2.2/01) with BCP405D and its use in the risk assessment for paraffin oil.	The experts agreed that the earthworm field study (Document No. 76450023) could in principle be used to refine the risk for the single application uses with BCP405D. However, considering the agreed endpoint for earthworms, low risk would be concluded at tier 1 for all representative uses with that formulation. Due to some trends suggesting potential negative effects in abundance and biomass for some species even one year after application, the majority of experts agreed that the study could not be used for demonstrating lack of effects of BCP405D to earthworms. Open point: RMS to reflect the discussion in the RAR (the field study is relevant and reliable with some restrictions, but it cannot be used to proof lack of effects to earthworms).
Experts' consultation 5.11 Experts to discuss: (i) the endpoint for Collembola for BCP405D considering the available data set; (ii) the reliability of the collembolan field study (Document No. 76458020) (CP B.9.7.3.1/01) with BCP405D and its use in the risk assessment for paraffin oil.	<u>Endpoint for Collembola for BCP405D</u> The experts agreed that the two collembola tier 1 studies should be used for the risk assessment since all validity criteria were met and no major limitations were identified. Overall, all experts agreed that, even after considering the differences between the control groups from the two available studies, the best approach was merging the two data sets and setting the NOEC for reproduction at 415 mg formulation/kg soil d.w. Open point: RMS to use the agreed endpoint for the risk assessment of formulation BCP405D. <u>The reliability of the collembolan field study with BCP405D (Document No. 76458020) and its use in the risk assessment for paraffin oil</u> The experts considered that collembolan field study is reliable. Although effects on Collembola were observed right after the application of the test substance; complete recovery was achieved after one year. Considering the application scheme of



Subject	Conclusions Pesticide Peer Review Meeting
	the study (1 x 87.6 kg a.s./ha and 1 x 43.8 kg) the experts agreed that it could not be used to refine the risk for the uses of BCP405D on potatoes (10 x 12.26 kg a.s./ha). Open point: RMS to reflect the outcome of the discussion in the RAR.
Experts' consultation 5.12 Experts to discuss whether a correction factor of 2 should be applied to the endpoints derived from soil studies using 5% peat content considering the mode of action of paraffin oil. Any additional evidence/justification submitted by the applicant should also be discussed at the meeting.	At the general experts' meeting (EFSA, 2015) the application of a correction factor of 2 was decided to be applied for substance with log P_{ow} of >2 even if a lower organic matter content was used in the OECD test soils (for example 5% instead of 10%), until better guidance would be available. A correction factor was also applied for the studies with rapeseed oil (a similar substance with the same mode of action as paraffin oil). All experts agreed that a correction factor of 2 should be applied to all tier 1 studies with soil organisms using 5% peat. Open point: To reflect the outcome of the discussion in the updated RAR.

REPORT OF PESTICIDE PEER REVIEW TC 99

FLUFENACET – AIR III

Rapporteur Member State: PL

5. Ecotoxicology

Date: 29 March 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
Federal Institute for Risk Assessment (BfR)	DE
Estonian Agricultural Board	EE
Tragsatec on behalf of Ministerio de Sanidad (MISAN)	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
E-V-A Sp. z o.o.	PL
Observer (1)	AT

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.5 Experts to discuss the available Extended AMA. In particular, the experts should discuss: a. If the validity and performance criteria of the AMA (OECD TG 231) apply; b. If the changes observed in HLL should be considered as due to systemic toxicity or sign of ED-adversity; c. How to consider the change in normalised HLL vs the change in time to reach NF 62. d. The increase in follicular cell hypertrophy at the highest tested concentration Please note that according to the ECHA/EFSA GD	An Extended Amphibian Metamorphosis Assay (EAMA) conducted in line with Ortego et al., (2021) was available for the assessment of the endocrine disrupting properties of flufenacet through the T-modality. As supportive information, some parameters investigated in the available Early life stage (ELS) and Fish Full Life Cycle (FFLC) test were also considered in the assessment for the T-modality, i.e. embryo time to hatch and % swim up. a. If the validity and performance criteria of the AMA (OECD TG 231) apply; The experts discussed that both the validity criteria for the AMA and some of the LAGDA may be applicable, i.e. weight of control(s) at stage NF 62 should reach 1.0 ± 0.2. This latter criterion was not met in the available EAMA. Although all experts agreed that this is not sufficient to invalidate the study, this was considered as a source of uncertainty. b. If the changes observed in HLL should be considered as due to systemic toxicity or sign of ED-adversity; c. How to consider the change in normalised HLL vs the change in time to reach NF 62. All experts agreed that when animals reach a stage $NF \geq 60$, the HLL should likely not be considered a diagnostic parameter. This was corroborated by the available data showing the nHLL and the time to reach NF 62 in the opposite direction. d. The increase in follicular cell hypertrophy at the highest tested concentration. The change in the thyroid histopathology at the highest tested concentration were considered a compensatory mechanism considered a compensatory response that the organism is



Subject	Conclusions Pesticide Peer Review Meeting
parameters considered sensitive to but not diagnostic are those parameters which may be due to ED or any other MoA and should not be mixed up with parameters clearly indicating systemic toxicity, such as mortality.	expending energy to counteract the chemical insult via thyroid-specific processes. However, the decrease in body weight were considered to suggest systemic toxicity at the same concentration. Overall, all the experts considered likely that flufenacet interferes with the HPT axis, however it could not be excluded that the T-mediated effects were secondary to systemic toxicity (i.e., decrease in wet weight both at day 7 and study termination). The experts also discussed whether the adverse effects identified in rodents, i.e., change in thyroid histopathology and change in thyroid hormones in different species and studies and at different dose level accompanied by effects in the DNT study, were adverse at the level of the population. The experts agreed that the population relevance of the observed effects cannot be excluded when considering: (i) the effects observed in the available DNT study, i.e., changes in the linear measurement of the caudate putamen in females at PND 72. The effect is linked to learning, emotion, attachment behavior and motor functions. Although certain of these parameters were measured in the available DNT, the test is not exhaustive. (ii) the DNT IVB for flufenacet is negative and therefore DNT changes consequent to altered THs homeostasis cannot be excluded; while it is unlikely that flufenacet would act as a direct developmental neurotoxicant. Open point: RMS to report the outcome of the discussion in the revised RAR.
Experts' consultation 5.6 Experts to discuss: • The findings in the available FSTRA • The suitability of the FSTRA following the evidence that flufenacet may act as anti-androgen in the Hershberger assay.	According to the ECHA/EFSA testing strategy a Fish Short Term Reproduction Assay was also further generated to sufficiently investigate the EAS-mediated endocrine activity. In the available FSTRA decrease in fecundity accompanied by oocyte atresia were observed mainly at the top concentrations. At the highest concentration a slight 6.6% decrease in fertility was observed. No change in the VTG and SSC in females. All the experts agreed that based on the findings in the FSTRA and the conclusion on mammalian data, no strong concern for AA is highlighted and therefore overall flufenacet is unlikely to be an endocrine disruptor through EAS-modalities. Open point: RMS to report the outcome of the discussion in the revised RAR.

REPORT OF PESTICIDE PEER REVIEW TC 99

PYDIFLUMETOFEN – mandate, NAS 1107

Rapporteur Member State: FR

5. Ecotoxicology

Date: 29 March 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
Federal Institute for Risk Assessment (BfR)	DE
Estonian Agricultural Board	EE
Tragsatec on behalf of Ministerio de Sanidad (MISAN)	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
E-V-A Sp. z o.o.	PL
Observer (1)	AT

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Expert to discuss the ED assessment for the T-modality and more particularly: - The setting of the highest tested concentration (1000 vs 300 µg/L) in the AMA vs the MTC - The reduction of HLL at 300 µg/L (non significant reduction of 15%) and the decreasing trend of the nHLL parameter at day 21 - The high level in the control histopathology of mid follicular cell hypertrophy - The liver histopathology finding - And the uncertainties related to these finding	The experts discussed the test design and the findings in the available Amphibian Metamorphosis Assay (AMA). Overall, based on the results of the range finding test and on the available acute fish data, all experts agree that the test concentrations applied in the AMA were considered as acceptable. All experts agreed that the non-significant effect observed on HLL and nHLL at day 21 could be considered as biologically relevant, however they are not likely to be T-mediated effects. Also, expert agreed that the high level of mid follicular cell hypertrophy in the control animals was considered as a normal physiological finding to a certain extent, although in this case the incidence was definitely too high. Moreover, the reporting did not allow to match the developmental stage of each single animal making the interpretation of the change in thyroid histopathology not straightforward. The explanation for the effects observed in liver histopathology (increased incidence and severity of hepatocellular vacuolation, non-specific finding suggesting that the energy intake in those frogs was insufficient relative to physiological requirements for growth and activity) were not found convincing for the ED WG. It was noted that a high incidence of spinal curvature was observed in the control and at all treatment groups. Although this is not considered to have an impact on the evaluation of the T-mediated parameters, it has an impact on the overall reliability of the test because of the very high incidence observed. This may have an impact on the weight of the tadpole and growth parameters in general, since when spinal curvature is severe, tadpoles might not be able to feed correctly. Overall, all the experts agreed that no pattern of T-mediated endocrine activity was observed in the available AMA. However, the uncertainties observed in the study (spinal curvatures,



Subject	Conclusions Pesticide Peer Review Meeting
	thyroid histopathology, liver histopathology) made the interpretation of the results less straight forward and the study less reliable. Open point The RMS to reflect the conclusion of the meeting in the revised RAR.
Experts' consultation 5.2 Expert to discuss the ED assessment for the EAS-modality, and more particularly, for the FSTRA: -The decrease in fecundity: dose response at the 2 highest dose (18 and 39% reduction, respectively; stat. significance only at the highest concentration). -The VTG decreased at all concentration (flat concentration-response), its significance vs the variability of the endpoint and the relation to liver toxicity -Histopathology: the increased prevalence and severity of oocyte atresia observed -The liver histopathology finding (increase in necrosis/apoptosis). And the related uncertainty.	The experts discussed the findings in the available Fish Short Term Reproduction Assay (FSTRA). The experts agreed that the decrease in fecundity was observed in a clear dose response manner. The experts were of the opinion that the findings in the liver were considered physiologically normal for actively spawning females. Therefore, the changes in the VTG level cannot be due to liver toxicity. However, the MS experts in the peer-review meeting were not convinced that the change in the VTG level can be treatment-related considering the lack of dose response and the dose spacing. It was noted that oocyte atresia was observed at the same incidence at the lowest and highest tested concentration, although the severity was increased at the highest concentration. No other changes were observed. Overall, the lack of a clear dose response in several parameters was considered the main source of uncertainty. Based on this, the experts agreed that the findings in females (decrease-depressed/flat VTG without dose response, increased oocyte atresia, and decreased fecundity) are not suggesting a convincing and strong pattern of endocrine activity. It was noted by the experts that additional data could help the interpretation of the findings in the FSTRA. Overall, the ED criteria are not considered met also in light of the outcome of the assessment for humans. Open point RMS to report the outcome of the discussion in the RAR.

23 - 26 January 2023

MINUTES

Pesticide Peer Review TC 95 Fenpropidin

REPORT OF PESTICIDE PEER REVIEW TC 95

FENPROPIDIN – AIR III

Rapporteur Member State: CZ

5. Ecotoxicology

Date: 26 January 2023

List of participants:

Institute	Member States Country code
Central Institute for Supervising and Testing in Agriculture	CZ
Federal Environmental Agency (UBA)	DE
Julius Kühn-Institute	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Chair	PL
Hearing expert	NL
Observer	CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the ecotoxicologically relevant endpoint for wild mammals.	The experts considered all the available studies and agreed to set a NOAEL of 20 mg/kg bw/d, based on the following considerations: • The NOAEL of 11.4 mg/kg bw/d is considered overall conservative based on the high dose spacing in the 2-generation rat study; • Evidence suggest that all generations are equally sensitive with regard to body weight reduction; • In the available rabbit developmental study, no effects on body weight are observed up to the highest concentration of 20 mg/kg bw/d; • In the available DNT study, the effect on body weight was <10% at 27/67 (during lactation) mg/kg bw/d. Open point RMS to amend the RAR and LoEP by revising the risk assessment with the new agreed endpoint. The outcome of the discussion should be reflected in the revised RAR.
Experts' consultation 5.2 Expert to agree on the testing strategy for the ED assessment of fenpropidin.	The dataset for concluding on the ED properties of humans and wild mammals was complete. For non-target organisms, neither endocrine activity nor endocrine adversity was sufficiently investigated, and further data are needed to conclude on whether the criteria according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 are met. Conclusion For wild mammals, in line with the conclusion drawn for humans, the ED criteria were not considered met for the EATS-



Subject	Conclusions Pesticide Peer Review Meeting
	modalities based on a complete dataset and lack of endocrine adversity. For Non-target organisms, the following testing strategy was proposed and agreed: 1) Fish short-term reproduction assay (OECD 229) with Fathead minnow. 2) Amphibian Metamorphosis Assay (OECD 231). If one of the tests above gives positive indication for endocrine activity, a MoA should be postulated and further information may be needed to investigate endocrine mediated adversity, i.e., level 4 or 5 Studies according to OECD TG 241 and/or OECD TG 240, in line with the ECHA/EFSA ED Guidance. The experts, in line with the RMS, agreed that considering that no T-mediated adversity was observed in mammals based on a complete dataset, a <i>Xenopus</i> Eleutheroembryonic Thyroid Assay (XETA) according to OECD TG 248 could also be sufficient, instead of the AMA, in this case. However, it was clarified that an AMA is already ongoing. Open point: RMS to reflect the outcome of the discussion in the revised RAR
Experts' consultation 5.3 Experts to discuss - The mesocosm studies from 1997 and 2007 and their respective relevance in the setting of the NOEAEC - The significance of effects on <i>Chroomonas</i> sp. - The 2 options proposed by the RMS (mesocosm ETO-RAC 0.065 vs Mesocosm ERO-RAC 0.13 µg/L) and the choice of the AF to set the	Setting the endpoints: Mesocosm study (1997) study: Based on the clear decrease of <i>Chroomonas</i> sp population with recovery taking up to 35 days after the first application, the effect on <i>Chroomonas</i> sp. at the lowest concentration tested was classified as Effect class 3A. The majority of experts agreed that the NOEC for chlorophyll a could be set at 0.13 ug a.s./L. As a whole, it was agreed that no overall NOEC value could be derived from the mesocosm study (1997), based on effect class 3A observed on <i>Chroomonas</i> sp. Several concerns were also raised for this study (i.e. contamination of the control, analytical measurements that did not confirm the second peak of exposure, especially at the two lowest concentrations, presence of fish in the mesocosm) that add some uncertainties to the endpoint derivation. Experts agreed to set the NOEAEC at the concentration 0.13 ug a.s/L in order to account for the uncertainty reported above. Mesocosm study (2017) The study is reliable but less ecologically relevant and less representative than the first mesocosm study, since only 8



Subject	Conclusions Pesticide Peer Review Meeting
ETO and ERO-RACs. - The higher tier risk assessment: determination of ETO-RAC, representativeness of exposure regimes in the mesocosms for the proposed GAP and comparison to the FOCUS profile - If the mesocosm studies shows a sufficiently low sensitivity of macroinvertebrate to justify the non-necessity to submit a test on lumbriculus, usually requested for fungicides, beside the test on Chironomus.	algae species have an MDD class 1 (of which only 3 species of green algae identify). Therefore, results from this study will be used to support the endpoint setting in first mesocosm study from 1997. It was agreed to not consider the effects observed on macrophytes (increased growth) as adverse. It was agreed that no NOEC could be derived since effects of fenpropidin classified as Effects class 3A were observed in all tested concentrations. A NOEAEC of 1.0 µg a.s./L was proposed based on effect on filamentous algae; However, it was not possible to confirm that the recovery actually occurred over this time at this concentration. Therefore, it was agreed to set the NOEAC at 0.3 µg a.s. /L since at this concentration a clear recovery could be confirmed within 8 weeks. <u>Derivation of the ETO-RAC and ERO-RAC:</u>no ETO-RAC could be derived in the absence of NOEC values. It was agreed to use the endpoint from the first mesocosm study from 1997 (0.13 µg a.s./L) since this study was more ecologically relevant. It was agreed to use an AF of 3 based on the fact that there are two mesocosms studies available. When these studies are considered together, they provide adequate information and therefore, an AF of 3 is sufficient to address the existing uncertainties ERO-RAC: $1.3\mu\text{g a.s./L} / 3 = 0.43 \mu\text{g/L}$. <u>A new algae study</u> was provided with 2 different endpoints for 72h and 96h. Since validity criteria were met at both time periods, and the 96h-endpoint is lower than the 72h-endpoint, all the experts agreed to consider the lower 96h-endpoint in the derivation of tier 1 RAC for algae (ErC50 of 0.299 µg a.s./L). <u>Higher tier risk assessment</u> Exposure profiles and their comparison could not be discussed as during EFATE meeting $\text{PEC}_{\text{sw/sed}}$ were not accepted and new calculations are required. Some experts would prefer to have a follow up meeting to discuss the new exposure profiles in detail. <u>Lumbriculus:</u> In the second mesocosm study (2007) there was one representative of Annelida and no effect was observed. However, this was only one species so no firm conclusion could be taken based on the mesocosm studies. It was noted that the risk assessment for <i>Chironomus</i> exposed via sediment passed with a large margin of safety. And that terrestrial earthworms do not seem to be highly sensitive to fenpropidin. It was agreed



Subject	Conclusions Pesticide Peer Review Meeting
	that there is no strong evidence to request this study with <i>Lumbriculus</i>, in the case of Fenpropidin. Open point: • RMS to reflect the discussion in the RAR and update the endpoints accordingly (NOEC and NOEAEC) in both mesocosms studies (1997 and 2007). <u>First mesocosm study (1997):</u> No NOEC could be derived; NOEAEC=0.13 µg/L <u>Second mesocosm study (2007):</u> No NOEC could be derived; NOEAEC=0.3 µg/L • RMS to amend the tier 1 risk assessment for algae based on new tier 1 RAC derived using 96h-ErC50 (0.299 µg a.s./L). • RMS to perform the exposure profile comparison once results of the new surface water modelling are available from Efate. • RMS to reflect the discussion in the RAR and use the newly agreed ERO-RAC (1.3 µg a.s./L / AF: 3) to update the higher tier risk assessment. • RMS to add the justification in the RAR on why there is no need for <i>Lumbriculus</i> study.
Experts' consultation 5.4 Experts to discuss: - The extended laboratory studies for NTAs and their reliability; - The aged residues studies reliability; - Any new information submitted; - Relevance and appropriateness (3D, spraying scheme vs exposure period, dilution rates) of the two higher studies used for refinement of the in-field risk; - The updated in-field risk assessment for	<u>New tier 1 (glass plate) studies</u> All experts agreed with the evaluation performed by the RMS and considered the new glass plate studies with the standard species <i>Aphidius rhopalosiphi</i> (CA 9.5.2.1/09) and <i>Typhlodromus pyri</i> (CA 9.5.2.1/10) reliable and acceptable. <u>Extended laboratory studies</u> All experts agreed with the evaluation performed by the RMS on the reliability and acceptability of the extended laboratory studies with the indicator species <i>A. rhopalosiphi</i> (CP 9.5.2.2/01 and CP 9.5.2.2/02) and <i>T. pyri</i> (CP 9.5.2.2/09 and CP 9.5.2.2/03) and with the additional species <i>Bembidion tetracolum</i> (CP 9.5.2.2/06), <i>Chrysoperla carnea</i> (CP 9.5.2.2/10) and <i>Phytoseiulus persimilis</i> CP 9.5.2.2/04 and CP 9.5.2.2/05) The study CP 9.5.2.2/01 with <i>A. rhopalosiphi</i> was considered unacceptable as not all validity criteria were fully met. All other studies were considered by the experts reliable and acceptable since all validity criteria were fulfilled and no major deviations were identified. <u>Aged-residue studies</u> The experts considered that both aged-residue studies with <i>T. pyri</i> (CP 9.5.2.2/07) and <i>P. persimilis</i> (CP 9.5.2.2/08) were



Subject	Conclusions Pesticide Peer Review Meeting
non-target arthropods.	not reliable due to the high mortality levels observed in the control groups in the different bioassays. The experts agreed that none of these studies can be used to refine the in-field risk. <u>Relevance and appropriateness (3D, spraying scheme vs exposure period, dilution rates) of the two higher studies used for refinement of the in-field risk</u> The relevance of the aged-residue studies was not discussed at the meeting since both studies were considered not reliable by the experts. <u>Risk assessment</u> • Tier-1: All experts agreed with the risk assessment performed by the RMS based on the new available glass plate studies. The in-field risk needs further refinement while a low off-field risk could be concluded for all representative uses of fenpropidin. • Tier-2: All experts agreed with the chosen endpoints for additional species for the Tier-2 risk assessment and with the risk assessment performed by the RMS. The in-field risk for the higher rate was acceptable for all species except for of <i>B. tetracolum</i>, <i>Coccinella septempunctata</i> and <i>P. persimilis</i>. The in-field risk for the lower application rate was acceptable for all species with the exception of <i>P. persimilis</i>. A low off-field risk could be concluded for all NTAs. • Refinement of the in-field risk assessment: All experts agreed that the available data were sufficient to conclude low risk for <i>B. tetracolum</i> using a weight-of-evidence approach. For <i>C. septempunctata</i>, however, the available data were consider not sufficient to exclude the in-field risk for this species. The risk for <i>P. persimilis</i> for both intended application rates could not be refined because the aged-residue study was considered not reliable by the experts. <u>Open points:</u> • RMS to correct the report number in the extended laboratory study CA 9.5.2.1/10 with <i>T. pyri</i> in the RAR • RMS to check and correct the information on the test design in the extended laboratory study CP 9.5.2.2/05 with <i>P. persimilis</i> in the list of endpoints • RMS to correct the author and report number of the extended laboratory study (CP 9.5.2.2/10) with <i>C. carnea</i> in the RAR • RMS to check the all extended laboratory studies and provide the details in the study summaries on the application procedure (whether whole plants or detached leaves were treated with the test item). • RMS to correct the information about the plant species used in the aged-residue study (CP 9.5.2.2/07) in the RAR and in the list of endpoints.



Subject	Conclusions Pesticide Peer Review Meeting
	• RMS to reject the aged-residue study (CP 9.5.2.2/07) for the risk assessment and remove it from the list of endpoints. • RMS to amend the information of comparability of formulations used in ecotoxicology studies in the introduction section of Vol 3-B.9 CP. • RMS to amend the NTA risk assessment for both application rates accordingly.
Experts' consultation 5.5 Experts to discuss: - The new (adult and larvae) studies submitted for bees; - The new honeybees semi-field studies; - The updated risk assessment for bees including all new data submitted and including the risk from consumption of guttation fluid, flowering weeds and metabolites.	Reliability-Laboratory studies: • Acute toxicity study to adult bees (1984): It was agreed not to use the oral endpoint for regulatory use since only 2 concentrations were tested, and problems with solubility of the test item were reported. However, since the study is performed at the right season (August), the study may be used to support the sensitivity of the adult bees in the new acute toxicity study (2020), which was performed late in the season (October). • New acute toxicity study to adult bees (2020). Concern was raised by some experts regarding the sensitivity of bees used in this study due to timing of the study (October). Since the sensitivity of bees to fenpropidin was not higher in the available acute toxicity study from 1984, the experts agreed that this new study (2020) can be considered as fully reliable and might be used for risk assessment. • New chronic toxicity to adult bees-feeding study (2018). The study is considered reliable. It was noted potentially biologically relevant effect were observed at the proposed NOEDD. Experts agreed, based on the visual inspection of data, to set the NOEDD at 1.74 µg a.s./bee/day. • New chronic oral toxicity study (2016) (10 days) to adult honeybees. Since the concentration of the test item in the feeding solutions and in the stock solutions was not analytically verified, the expert agreed that the endpoints from the study are not reliable and cannot be used in the risk assessment. However, as the study indicate that the formulation might be considerably more toxic than the active compound, a data gap for a new chronic oral toxicity study (10 days) to adult honeybees with the formulation is settled • New acute oral tox to bee larvae-single exposure 2018. The study is valide, however, due to short study duration (8 instead of 22 days) the study is not relevant for the risk assessment. • New acute oral tox to bee larvae-repeated exposure (2018a). The study is reliable without restrictions. Expert



Subject	Conclusions Pesticide Peer Review Meeting
	agreed with the derived endpoints which may be used in the risk assessment. • New chronic repeated exposure to larvae (2016). The duration was only 8 days instead of 22 days. At the proposed NOEDD value (1.544 µg a.s./larvae) 30.30 % mortality was observed. Based on inspection of the data all the experts agreed on setting the NOEDD at the lower dose (0.62 µg A7516D/ larvae), at which 9 % mortality is observed. The experts agreed that the study is reliable with restrictions but due to too short duration, it cannot be used in the risk assessment. However, it was concluded that the formulation seems to be more toxic to larvae than the active substance and a data gap for a new 22 days chronic repeated exposure to larvae with the formulation is identified. <u>New honeybees semi-field studies</u> • New colony feeding study (2018) Concern was expressed regarding the statistical power of the study. However, the study can be considered as additional information. No clear effect could be seen in brood development; some effect could be seen in colony strength. Bees in the treatment groups exhibited behavioural abnormalities at level clearly exceeding this observed in controls. Expert agreed that behavioural effect in the study were treatment related. Overall, the expert agreed that study was considered relevant as supportive information, and indicate that fenpropidin may potentially have effects on the colony strength, on the number of cells covered with brood, and on the bees' behaviour. In addition, the experts conclude that no NOEDD value could be derived from the study. • New Semi-field (tunnel) test (2018) Concern was also raised by the experts regarding low statistical power. Contamination of untreated flowers and leaves with the test item was observed, and significant effects on bee brood were observed at T1, with no reasonable explanation. A high mortality of control worker bees was observed, which could also not be explained by the virus infestation alone. Therefore, the general poor health of the bee colonies was identified as a concern by the experts. Overall, the majority of the experts agreed that the study was not reliable and could not be used in risk assessment • New semi-field (tunnel) test (2019) Similarly as in the previous semi-field study from 2018, contamination of untreated pollen, flowers and leaves with the test item was observed. A high mortality in control was observed, which might be attributed to test design (bees are



Subject	Conclusions Pesticide Peer Review Meeting
	confined in tunnels). Concern was also raised by the experts regarding the low statistical power of the test design. Overall, the experts agreed to consider the study reliable with restrictions, due to the deficiencies highlighted above. No treatment related effects was seen on mortality, however results from the study indicate potential effects of fenpropidin on bee behaviour. Statistically significant effect were observed on colony strength in all treatment groups at some or majority of observation occasion. Overall, the majority of experts agrees that due to potential behavioural effect and potential effect on colony strength it is not possible to derive NOEDD from this study. <u>Updated risk assessment for bees including all new data submitted, including the risk from consumption of guttation fluid, flowering weeds and metabolites:</u> - A data gap is identified for the chronic toxicity to adult bees with the representative formulation; since the available endpoint was disregarded by the experts during the discussions on the reliability of the available studies. - The proposal to consider the flowering weed scenario of low relevance for cereals was not agreed. The experts agree that the weed scenario could be potentially not relevant for early BBCH cereals, but might be relevant for BBCH stages > 30. It was noted that the 10% trigger for ground coverage by weeds does not exist in EFSA 2013. - During the discussion the experts rejected the semi-field study of 2018, and from the other semi-field study (2019) no reliable NOEDD could be derived. In addition, the colony feeding study (2018) was considered as indicative of potential effect of fenpropidin on bees with no reliable endpoint established. Taking this into account the semi-field studies could not be used to refine the chronic risk to adult bees within the treated crop, therefore a high risk cannot be excluded. - Regarding guttation, two public literature studies were submitted (Zumkier et al., 2019, Joachimsmeier et al., 2012). In the first study the number of datapoints is not sufficient to conclude on any trend (2 datapoint for barley and 1 for wheat). In the second study guttation in cereals at BBCH >30 could not be completely ruled out, even though it was noted that droplets at these stages are small. It was pointed out by the experts that in general multiple conditions must be fulfilled to observe significant guttation, especially at later BBCH stages. Therefore, based on the



Subject	Conclusions Pesticide Peer Review Meeting
	available data the relevance of this scenario cannot be fully confirmed or excluded. - Regarding the tier I risk assessment for the metabolite CGA289268, the expert agreed with the approach taken by the RMS. An acceptable acute risk for adult bees and chronic risk to larvae could be concluded. However, the chronic risk to adult bees was high. The refinement based on the two semi-field studies from 2018 and 2019 was not agreed since the residual level of the metabolite was measured in neither study, and the studies are not useable in risk assessment (see above). Therefore, a data gap to further address the chronic risk to adult bees for the metabolite is identified. Conclusion: Overall, expert agreed that a high chronic risk to adult bees cannot be excluded. The following data gaps were identified: - Data gap for chronic adult bees studies and for larvae (22 days) with the representative formulation, which is more toxic compared to the a.s. - Further data to address the chronic risk to adult bees for fenpropidin and the representative formulation - Data gap to further address the chronic risk for adult bees for the metabolite CGA289268. - In addition, the risk from the guttation scenario could not be finalized. - Furthermore, the experts agreed that the weed scenario is relevant for cereals at BBCH > 30. Open points: Laboratory studies: - RMS to correct the endpoint from the new chronic toxicity to adult bees-feeding study (2018) study (NOEDD = 1.74 µg a.s./bee/day). - RMS to remove the endpoints of the new chronic oral toxicity study to adult honeybees (2016) from the LoEP and all relevant RAR volumes. - RMS to correct information on the test duration and the unit of the endpoint (larvae, not bee) in the new acute oral tox to bee larvae-single exposure (2018) study in the LoEP and in respective volumes of the RAR. - RMS to update the table 8.3.1.3-6 (New acute oral tox to bee larvae-repeated exposure, 2018a) with the corrected mortality data.



Subject	Conclusions Pesticide Peer Review Meeting
	- RMS to restore the new chronic repeated exposure to larvae study from 2016 in the LoEP and to indicate the data gap identified. Higher tier studies: - RMS to reflect in the updated RAR the outcome of the discussion on the new colony feeding study (2018) - RMS to update the RAR with the outcome of the discussion and to reject the first semi-field study from 2018 from the LoEP and the risk assessment. - RMS to remove the NOEDD from the second semi-field study (2019) from the LoEP and to reflect the outcome of the discussion in the RAR. Risk assessment: - RMS to reflect the outcome of the discussion from the meeting in the RAR and to update the risk assessment for bees accordingly.
Experts' consultation 5.6 Experts should discuss the setting of the NOEC in the earthworm reproduction study CGA114900/4662 -Vol. 3, CP, B.9.7.1.2 i), sub-lethal effects of A7516B on earthworms	Considering the effects above 15% observed on reproduction (i.e., number of juveniles produced) at the two highest concentrations (13.3 and 26.7 kg formulated product/kg soil dry weight (dw)) and the concentration-response observed, all experts agreed to set the NOEC of the earthworm reproduction study CGA114900/4662 with the formulation A7516-B at 5.33 mg formulated product/kg soil dw. Open point: RMS to amend the earthworm risk assessment considering the agreed NOEC value of 5.33 mg formulated product/kg soil dw and to amend the list of endpoints accordingly.
Experts' consultation 5.7 New experts' consultation point added by EFSA. Experts to discuss the refined reproductive risk assessment for small herbivorous mammals: - Focal species (NEU, CEU and SEU) - Refined deposition values (BBCH 30 – 40 and BBCH >40) - Refined PD values - Residue decline	<u>Focal species (northern, central and southern Europe)</u> Overall, the experts agreed to keep the common vole as the focal species in cereals to address the risk to herbivores feeding guild within the central zone, despite the lack of the respective monitoring studies. This refinement should not apply to the southern and northern zones, where other species are considered representative for the herbivores feeding guild. <u>Refined deposition values (BBCH 30 – 40 and BBCH >40)</u> Overall, the majority of the experts agreed on using a deposition factor of 0.1 for cereals BBCH >40 for all food items of the vole diet. The discussion for BBCH 30-39 was not necessary because at this stage range the risk assessment for all generic focal species was already addressed at Tier-1. <u>Refined PD</u>



Subject	Conclusions Pesticide Peer Review Meeting
e. The final risk assessment considering the minimum and maximum application rates.	The majority of the experts agreed that cereals cannot be excluded as part of the vole's diet and agreed on using a ratio of 25% dicot plants : 75% monocot plants. <u>Residue decline</u> All experts agreed with the RMS that the results of the residue decline trials with only two sampling points could not derive a reliable DT₅₀ in cereals that could be used quantitatively to refine the long-term risk assessment to herbivorous mammals. <u>The final risk assessment considering the minimum and maximum application rates</u> The experts agreed on the following options to refine the long-term risk assessment to mammals for all representative uses of fenpropidin and the minimum and maximum application rates: (i) To consider the common vole as a focal species for herbivorous mammals in cereals >BBCH40 for the central zone only with a diet consisting of 75% monocots and 25% dicots; (ii) using a deposition factor of 0.1 for all food items of the vole diet. Open point: RMS to reflect in the RAR the outcome of the discussion.

Pesticide Peer Review TC 93
Metconazole

REPORT OF PESTICIDE PEER REVIEW TC 93

METCONZAOLE – AIR III

Rapporteur Member State: BE

5. Ecotoxicology

Date: 20 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health, Food chain safety and Environment	BE
Federal Environmental Agency (UBA)	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
State Plant Service under the Ministry of Agriculture	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Observer	CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.8 Experts to discuss the appropriateness of the tested concentrations in the XETA test.	The lack of indications of any systemic toxicity in the available XETA questioned whether the maximum tolerable concentration (MTC) could be placed. Considering the information provided in the range finding tests and the indications reflected in the pertinent test guideline (TG) for the definition of the MTC, it was agreed that the study design fit for purpose for the ED assessment. The test is considered acceptable, therefore, the endocrine activity for the T-modality is sufficiently investigated and negative. Overall, all experts agreed that by considering the outcome of the mammalian toxicology assessment and the results from the XETA, it can be concluded that the ED criteria are not met for the T-modality for non-mammalian species. Open point The RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.9 Experts to decide whether the available information is sufficient to draw a conclusion on the ED criteria for the EAS-modalities for non-target organisms other than mammals.	Several issues were raised during the commenting phase regarding: - The suitability of the FSTRA study in relation with i) the selection of the tested concentration, ii) the selection of the tested species, iii) the lack for certain ED-related parameters due to the selection of the tested specie, and - The observations in the FFLCT and the contextualization of the effects-doses in the ED assessment.



Subject	Conclusions Pesticide Peer Review Meeting
Experts shall consider: i) The issues raised during the commenting phase in the FSTRA with zebrafish: - Suitability of the dose selection and proof of the reachability of the MTC; - Suitability of the fish species tested and uncertainties related; - Impact of the lack of EAS-mediated parameters (i.e., SSC, gonad histopathology investigations) for the assessment. ii) The issues related to the available FFLC with fathead minnow: - the effects on fertility observed in the 1-generation of the FFLC test that were observed in absence of systemic toxicity; - the suitability of the tested doses and the integration of both tests (FSTRA and FFLC) for the ED assessment. iii) The in vitro information in ToxCast for metconazole.	Considering that some effects were seen in the available FSTRA study in absence of mortality, experts agreed that it can be assumed that the MTC is close to the highest tested concentration. Therefore, the study design was considered appropriate. The selection of the tested species and the lack of EAS-mediated parameters linked to that selection was discussed by the experts and for the purpose of which this study was requested, it was concluded that this was a minor uncertainty. The observations in the FFLCT were considered by the experts and the observation in fertility was considered concomitant to systemic toxicity. Although there is a positive evidence from ToxCast for aromatase inhibition, no EAS-mediated adversity is observed based on a complete dataset. Therefore, it was overall agreed by the experts that metconazole does not meet the ED criteria for EAS-modalities for non-mammalian species. Open points RMS to reflect the outcome of the discussion in the revised RAR. RMS to report the missing information on the time to first spawn which was mentioned in the reporting table. RMS to check the available information in ToxCast and complete the RAR accordingly (if needed, based on what reported in the ED assessment for humans).

REPORT OF PESTICIDE PEER REVIEW TC 93

PYRACLOSTROBIN – AIR III

Rapporteur Member State: DE

5. Ecotoxicology

Date: 20 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health, Food chain safety and Environment	BE
Federal Environmental Agency (UBA)	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
State Plant Service under the Ministry of Agriculture	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Observer	CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.8 Experts to decide on whether the identified effects are biologically relevant or if on the contrary, it can be concluded that the substance is not T active.	A statistically significant change in fluorescence (>12%) was observed at all doses in the pooled runs for the spiked mode, which was not captured in the analysis provided by the applicant and the RMS. Considering the principles of the applied test guideline (TG), this shall be flagged as statistically significant difference, but this was not the case, questioning the suitability of the statistical method used. EFSA has conducted a re-statistical evaluation on the available raw data a divergence on the results and outcome of the test was concluded. The difference on the results obtained in the statistical evaluation conducted by applicant and RMS and EFSA and the relevance of the observations need further discussion. Conclusion By taking into account all the uncertainties introduced by the different statistical methods presented and the interpretation of the current TG, the majority of experts agreed that the test is sufficiently reliable and it can be concluded that it is T-inactive, since: • all the validity criteria from OECD 248 were met, • no dose-response was observed among the tested treatments in pooled or individual runs, • the difference in the means across treatments (pooled runs) could mainly be driven by one replicate in the spiked mode, • the statistical approach conducted by the study director was in line with the indications given in the TG. In conclusion, based on a T-inactive XETA where some uncertainties were noted and the results from the mammalian toxicology dataset (no indication of T-mediated endocrine



Subject	Conclusions Pesticide Peer Review Meeting
	activity and adversity), it can be concluded that pyraclostrobin does not met the ED criteria for T-modality for non-target organisms. The majority of experts agree with the above. Open points RMS to reflect the outcome of the discussion in the revised RAR. RMS to report in the revised RAR the statistical analysis as done by RMS which verify that the assessment of the applicant is correct.

Pesticide Peer Review TC 93
Trinexapac-ethyl

REPORT OF PESTICIDE PEER REVIEW TC 93

TRINEXAPAC-ETHYL – AIR III (mandated)

Rapporteur Member State: LT

5. Ecotoxicology

Date: 20 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health, Food chain safety and Environment	BE
Federal Environmental Agency (UBA)	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
State Plant Service under the Ministry of Agriculture	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Observer	CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Expert consultation 5.3 Expert to discuss: - The concentration setting in the FSTRA in relation to the other available toxicity data, and also considering the concentration tested in the AMA, - and the result seen in male histopathology (increased germ cell degeneration and decreased spermatozoa).	Appropriateness of testing concentrations: Extensive argumentation to support the setting of the maximum tested concentration was provided by the applicant (i.e., Wheeler et al. 2013). However, experts noted that the approach proposed by Wheeler et al. (2013) does not reflect the one recommended in the OECD 229. As such, to use of studies with different life-stages (i.e. ELS) for the selection of the highest tested concentration is not recommended in the TG 229. Overall, when considering all the available information and evidence, experts agreed that the choice of the tested concentrations in the FSTRA was fit for purpose for the ED assessment. Histopathological changes in male fish: Results on males histopatology needed also further consideration by the experts. All experts agreed that by taking into account that the majority of abnormalities were observed in one single animal showing abnormalities, the changes of the histopathology observed in males are of no concern. Overall, based on the results of the study, the experts agreed that the available evidence do not show a pattern of endocrine activity through EAS-modalities. Therefore, it can be concluded that trinexapac-ethyl does not met the ED criteria for EAS-modalities for Non-target organisms other than mammals according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. Open point:

MEETING MINUTES – 20 January 2023
Pesticide Peer Review TC 93
Trinexapac-ethyl



Subject	Conclusions Pesticide Peer Review Meeting
	RMS to reflect the outcome of the discussion in the revised RAR.

Pesticide Peer Review TC 93
Milbemectin

REPORT OF PESTICIDE PEER REVIEW TC 93

MILBEMECTIN – AIR III

Rapporteur Member State: DE

5. Ecotoxicology

Date: 20 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health, Food chain safety and Environment	BE
Federal Environmental Agency (UBA)	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
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Observer	CH

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Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 identified following the ED clock stop Experts to discuss the findings of the Amphibian Metamorphosis Assay (AMA) study (Vol. 3 CA, KCA 8.2.3/03) and the relevance/reliability of the Historical Control Data.	The experts discussed the appropriateness of the tested concentrations in the available Amphibian Metamorphosis Assay (AMA). The experts also discussed the changes observed in the normalised Hind Limb Length both at day 7 and 21 and in the thyroid histology. The experts agreed that based on a preliminary 14-day test with amphibians, the selection of tested concentrations is appropriate. The experts also agreed that the AMA was not showing a consistent pattern of endocrine activity since: • The decrease in normalized Hind Limb Length (nHLL) at day 7 was not dose dependent and was not confirmed at day 21 where an increase was seen; • The increase in nHLL at day 21 did not follow a dose response; • The changes observed in the thyroid histopathology at the lowest and highest concentration were attributed to the different developmental stage of the animals compared to the control animals. The experts also agreed that Historical Control Data (HCD) should not be used to dismiss treatment-related findings in the investigated parameters when compared to the concurrent control. Overall, milbemectin is considered not to meet the ED criteria for the T-modality according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

MEETING MINUTES – 20 January 2023
Pesticide Peer Review TC 93
Milbemectin



Subject	Conclusions Pesticide Peer Review Meeting
	Open point RMS to reflect the outcome of the discussion in a revised RAR.

16 - 18 January 2023

MINUTES

Pesticide Peer Review TC 92
Mecoprop-P

REPORT OF PESTICIDE PEER REVIEW TC 92

MECOPROP-P – AIR III (ED re-assessment)

Rapporteur Member State: IE

5. Ecotoxicology

Date: 18 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Central Institute for Supervising and Testing in Agriculture	CZ
National Institute of Public Health	CZ
Federal Institute for Risk Assessment (BfR)	DE
National Institute for Agricultural and food research and technology (INIA)	ES
Ministerio de Sanidad	ES
Tragsatec	ES
Department Agriculture Food and the Marine Ireland, Pesticides Registration & Control Division	IE
State Plant protection Service	LV
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Observers (2)	CH

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.



Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the outcome of the AMA, more particularly the significance of the effect seen at day 7 on normalised HHL at the two highest concentrations.	Experts indicated that no clear dose response is identified in the available nHLL data at day 7. The findings at day 7 are not confirmed at day 21, nor any effect can be observed on the developmental stage and histopathological assessment. All experts agreed that, based on the available information, including the evidence for mammals, the observed effects do not indicate a pattern of activity through the T-modality. All the experts agreed the above and concluded that for non-target organisms and the T-modality, the ED criteria are not met according to point 3.8.2 of Annex II of Regulation (EC) 1107/2009 as amended by Regulation 2018/605. Open point The RMS to update the ED assessment to reflect the outcome of the discussion, in the revised RAR. RMS to amend the typo observed in the nHLL (Normalised Hind Limb Length) at the highest test concentration at day 21 (0.369 instead of 0.396 mg/L).
Experts' consultation 5.2 Expert to discuss the FSTRA and more particularly:	Several abnormalities in the control fish, e.g., reduced dorsal pad in males, discolouration, vertical stripes in females or missing vertical stripes in males, changes in territoriality were observed. These observations in control were considered to possibly impair the interpretation of the results. The general opinion is that the study has to be identified as reliable with restrictions due to the identified visual and behavioural abnormalities in the control, however it can still be used in the



Subject	Conclusions Pesticide Peer Review Meeting
- the reliability of the study given the effect seen in the control - the outcome of the FSTRA, including the visual abnormalities and behavioural changes. This should also be considered in light of the finding in mammalian studies for the EAS modalities.	ED assessment since all the measured parameters did not seem to be affected in the control. All the experts agreed the above and concluded that for non-target organisms and the EAS-modalities, the ED criteria are not met according to point 3.8.2 of Annex II of Regulation (EC) 1107/2009 as amended by Regulation 2018/605. Open point The RMS to reflect the outcome of the experts' consultation in the revised RAR. Considering the new studies provided in the mammalian toxicology section (Extended One Generation Toxicity study (EOGRT)), the RMS should check the implication of the available EOGRTS (OECD 443, results discussed in Experts' consultation 2.2 of mammalian toxicology TC 92) for the risk assessment of wild mammals. If the new endpoints are lower than the currently available ones and relevant for wild mammals, a revised risk assessment for wild mammals may be needed.

16 – 18 January 2023

MINUTES

Pesticide Peer Review TC 92
Dichlorprop-P

REPORT OF PESTICIDE PEER REVIEW TC 92

DICHLORPROP-P – AIR III (mandated for ED re-assessment)

Rapporteur Member State: IE

5. Ecotoxicology

Date: 18 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Central Institute for Supervising and Testing in Agriculture	CZ
National Institute of Public Health	CZ
Federal Institute for Risk Assessment (BfR)	DE
INIA	ES
Ministerio de Sanidad	ES
Tragsatec	ES
ANSES	FR
Department Agriculture Food and the Marine Ireland	IE
State Plant protection Service	LV
Ctgb	NL
Hearing expert	ES
Observers (2)	CH

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.4 Expert to discuss the FSTRA and more particularly: - the reliability of the study given the effect seen in the control - the outcome of the FSTRA, including the visual abnormalities and behavioural changes.	Several abnormalities in the control fish, e.g., reduced dorsal pad in males, discolouration, vertical stripes in females or missing vertical stripes in males, changes in territoriality were observed. These observations in control were considered to possibly impair the interpretation of the results. The general opinion is that the study has to be identified as reliable with restrictions due to the identified visual and behavioural abnormalities in the control, however it can still be used in the ED assessment since all the measured parameters did not seem to be affected in the control. All the experts agreed the above and concluded that for non-target organisms and the EAS-modalities, the ED criteria are not met according to point 3.8.2 of Annex II of Regulation (EC) 1107/2009 as amended by Regulation 2018/605. Open point The RMS to reflect the outcome of the experts' consultation in the revised RAR. Considering the new studies provided in the mammalian toxicology section (Extended One Generation Toxicity study (EOGRT)), the RMS should check the implication of the available EOGRTS (OECD 443, results discussed in Experts' consultation 2.2 of mammalian toxicology TC92) for the risk assessment of wild mammals. If the new endpoints are lower than the currently available ones and relevant for wild mammals, a revised risk assessment for wild mammals may be needed.

16 – 18 January 2023

MINUTES

Pesticide Peer Review TC 92
Biphenyl-2-ol (2-phenylphenol)

REPORT OF PESTICIDE PEER REVIEW TC 92

BIPHENYL-2-OL (2-PHENYLPHENOL) – AIR IV

Rapporteur Member State: ES

5. Ecotoxicology

Date: 18 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Central Institute for Supervising and Testing in Agriculture	CZ
National Institute of Public Health	CZ
Federal Institute for Risk Assessment (BfR)	DE
INIA	ES
Ministerio de Sanidad	ES
Tragsatec	ES
ANSES	FR
Department Agriculture Food and the Marine Ireland	IE
State Plant protection Service	LV
Ctgb	NL
Hearing expert	ES
Observers (2)	CH

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the endocrine disruption (ED) properties of 2-phenylphenol in non-mammalian species, considering the available data and their possible drawback, the suitability of OPP (=2-phenylphenol, ortho-phenylphenol, biphenyl-2-ol), to eventually cover the sodium salt ortho-phenylphenol.	<u>Suitability of OPP (=2-phenylphenol, ortho-phenylphenol, biphenyl-2-ol) to cover the toxicity of the sodium salt ortho-phenylphenol:</u> Based on the physico-chemical properties, all experts agreed that OPP covers SOPP in the available toxicity tests. <u>ED assessment for T-modality, Amphibian Metamorphosis Assay (AMA):</u> Overall, by considering the whole body of evidence: • slight delay in development observed at the highest treatment level; • no dose-response found; • no significant effects observed in other relevant endpoints; • no significant changes in the thyroid histopathology; • negative ToxCast; • the mammalian results where no effect was observed All experts agreed in concluding that the test substance is not thyroid active and does not meet the ED criteria according to point 3.8.2 of Annex II of Regulation (EC) 1107/2009 as amended by Regulation 2018/605. <u>ED assessment for EAS-modalities, 1 Fish Short-term Reproduction Assay (FSTRA) (2012) and a reproductive study with fathead minnow (2002):</u>



Subject	Conclusions Pesticide Peer Review Meeting
	Overall, although in both studies there were issues on fecundity in the control replicates, and overt mortality (29%) was observed in [REDACTED] (2012) (i.e. one replicate was excluded because all fish died and in another replicate one female died too), all the experts agreed that, although the reproductive parts of both studies should be considered with caution (i.e. not valid according to the validity criteria in OECD TG 229), the results of the other parameters may still be considered as valid and considered for the ED assessment. All experts agreed that the ED criteria for the EAS-modalities were not met for the test substance according to point 3.8.2 of Annex II of Regulation (EC) 1107/2009 as amended by Regulation 2018/605. However, considering all the identified issues, it was agreed to also present an uncertainty analysis. Open point The RMS to reflect the outcome of the discussion in the revised RAR. The RMS to: • perform an uncertainty analysis for the EAS-modality, • report the complete histopathology results for the Fish Short-term Reproduction Assay (2012), • include in the RAR consideration for the poor performance of the control in the other available reproductive study with fathead minnow (2002).

16 – 18 January 2023

MINUTES

Pesticide Peer Review TC 92
Metrafenone

REPORT OF PESTICIDE PEER REVIEW TC 92

METRAFENONE – AIR III

Rapporteur Member State: LV

5. Ecotoxicology

Date: 18 January 2023

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Central Institute for Supervising and Testing in Agriculture	CZ
National Institute of Public Health	CZ
Federal Institute for Risk Assessment (BfR)	DE
INIA	ES
Ministerio de Sanidad	ES
Tragsatec	ES
ANSES	FR
Department Agriculture Food and the Marine Ireland	IE
State Plant protection Service	LV
Ctgb	NL
Hearing expert	ES
Observers (2)	CH

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.3 identified following the ED clock stop Experts to discuss the outcome of the Xenopus eleutheroembryonic thyroid signaling assay (XETA) test, i.e. positive effect seen at the lowest concentration only.	The results of the available Xenopus eleutheroembryonic thyroid signaling assay (XETA) with metrafenone were discussed. A non-statistically significant change in fluorescence greater than 12% was observed at the lowest tested concentration in the spiked mode. In line with the decision logic for the interpretation of the results of the XETA, figure 2 (OECD TG 248), the individual run should be further investigated for reproducibility of the dose response curve and it should be considered whether the test has to be repeated. According to the OECD TG 248, the conclusion from the current XETA should not be that it is negative, but that the individual run should be further investigated for reproducibility of the dose response curve and it should be considered whether the test has to be repeated. Moreover, the experts discussed that: • the application of the trimming should be carefully considered and thoroughly justified when applied; • the exclusion of runs due to not documented issues should be avoided. The experts also discussed the discrepancies between the results obtained when applying different statistical methods. Although it was noted that the use of mixed effects ANOVA (described in Annex 13 of the OECD TG 248 as one possible way to conduct the statistical evaluation) is one of the statistical methods described in the OECD TG 248, other statistical methods shall not be excluded (see also reference in paragraph 48 of the OECD TG 248).



Subject	Conclusions Pesticide Peer Review Meeting
	Based on the above discussion, all experts agreed to consider the results from the available XETA as equivocal and therefore a conclusion on whether the ED criteria according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, are met for the T-modality cannot be drawn, also considering that the XETA is the only available study for non-mammalian species. Open point RMS to reflect the outcome of the above discussion in a revised RAR.



REPORT OF PESTICIDE PEER REVIEW TC 84

GLYPHOSATE – AIR V

Rapporteur Member State: Assessment Group on Glyphosate (AGG) consisting of FR, HU, NL, SE

5. Ecotoxicology (endocrine disruption (ED) properties)

Date: 02 December 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health	BE
Federal Institute for Risk Assessment (BfR)	DE
Federal Environmental Agency (UBA)	DE
Ministry of Environment and Food of Denmark, Environmental Protection Agency	DK
TRAGSATEC	ES
Finnish Safety and Chemicals Agency (Tukes)	FI
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
National Food Chain Safety Office (NEBIH)	HU
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Swedish Chemicals Agency (KemI)	SE
National Institute of Public Health	SI
External experts (2)	EFSA



Pesticide Peer Review TC 84 (01– 02 December 2022)
Glyphosate

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

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Pesticide Peer Review TC 84 (01– 02 December 2022)
Glyphosate

Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.24 Experts to discuss: 1. the relevance and reliability of the available studies (both regulatory and from literature) and assessed parameters for their use in the weight of evidence for ED assessment; 2. the information that can be derived from the available studies based on: tested item, test system (including species, where necessary) study design and parameters assessed; 3. the weight of evidence for ED leading to the overall conclusion on whether the criteria as laid down in point 3.8.2 of Annex II	1. Relevance and reliability of the studies considered for the assessment of the endocrine disrupting (ED) properties of glyphosate were discussed. It was agreed that for the studies considered for the ED assessment there is no reason to deviate from the criteria discussed and agreed during the Pesticide Peer Review Experts' TC 82. It was also agreed that the choice of the tested concentrations and related Maximum Tolerated Concentration (MTC)) should not be considered as a criterion for relevance. Open point RMS to reconsider the relevance and reliability based on the agreement at the Pesticide Peer Review Experts' TC 82, see open point related to experts' consultation point 5.4 (bird studies), 5.10 and 5.12 (aquatic organisms). RMS to revise the relevance of the available studies in line with the criteria agreed, e.g., choice of tested concentrations and related MTC should not be considered a criterion for relevance. Moreover, the assessment of the studies should be reconsidered based on the specific comments given for each individual study as discussed during the meeting. 2. The experts discussed the studies considered in the ED assessment, with a particular focus on those that were captured by the literature search, even outside the timeframe considered for conducting the search.



Pesticide Peer Review TC 84 (01– 02 December 2022)
Glyphosate

Subject	Conclusions Pesticide Peer Review Meeting
to Regulation 1107/2009 are met. Please note that EFSA is of the opinion that the maximum tolerated concentration (MTC) should not be used to consider a paper as not relevant/reliable, and this is in line with the ED assessment done for humans.	Open point RMS to cross-check which studies evaluated in 2017³ (Annex of RAR addendum of 2017) were captured by the systematic literature review conducted for the current evaluation. Studies that have not been re-assessed and are outside the timeframe considered for the current renewal need special attention, to try to better understand why some have been captured and some others not. If a plausible explanation cannot be given after this cross-check, all the studies previously evaluated might need to be considered in the current evaluation. Formally, in line with the legislation, there is no legal obligation to consider newly available data submitted outside of the dedicated public and targeted consultations or after the deadline of the window for providing the additional information within the clock stop period, unless they constitute adverse data (cf Article 56 of Regulation (EC) No 1107/2009 regarding information on potentially harmful or unacceptable effects). For this reason, although a systematic review of the literature has not been carried out by EFSA or the RMS, EFSA identified newly available papers on glyphosate even outside of the legal requirements and collected a list of studies as a result. Open point RMS to include the RMS evaluation of the study by Verderame et al., 2022 in the revised RAR: Verderame M, Chianese T, Rosati, L, Scudiero R, 2022. Molecular and Histological Effects of Glyphosate on Testicular Tissue of the Lizard <i>Podarcis siculus</i>. International Journal of Molecular Sciences, 23(9), 4850. It was noted that inclusion of studies considered for the ED assessment was not always consistent, e.g., in some cases studies with the formulations were mentioned, and in some other cases not.

³ EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate. EFSA Journal 2017;15(9):4979, 23 pp. doi:10.2903/j.efsa.2017.4979



Pesticide Peer Review TC 84 (01– 02 December 2022)
Glyphosate

Subject	Conclusions Pesticide Peer Review Meeting
	Open point RMS to amend the ED assessment in the RAR by clarifying and consistently reporting what studies are used for the ED assessment for the different taxa. RMS to revise the Appendix E as needed in line with the discussion. 3. The RMS presented the ED assessment. EFSA with the support of the EFSA ED Working Group (WG) also conducted an assessment of the available information. Overall, the conclusion of the ED assessment of both the RMS and EFSA was aligned, although the dataset considered was not fully congruent. All MSs agreed that based on the available evidence, glyphosate does not meet the ED criteria according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. Open points 1. RMS to revise the ED assessment and include the missing studies. a. RMS to conduct the reliability and relevance and uncertainty analysis of the endpoints measured in the studies. 2. RMS to make a reference to the EFSA ED WG WoE report. RMS to revise the WoE by clarifying the studies that were considered in the ED assessment and how they were weighted, and by clarifying which studies were not considered (not relevant, reliable). The newly added studies should also be included, e.g., Verderame et al., 2022.
New experts' consultation point proposed by EFSA for completeness of discussion (October 2022): Experts to consider some potentially relevant newly available publications arisen	Formally, in line with the legislation, there is no legal obligation to consider newly available data submitted outside of the dedicated public and targeted consultations or after the deadline of the window for providing the additional information within the clock stop period, unless they constitute adverse data (cf Article 56 of Regulation (EC) No 1107/2009 regarding information on potentially harmful or unacceptable effects). For this reason, although a systematic review of the literature has not been carried out by EFSA or the RMS, EFSA has identified newly



Pesticide Peer Review TC 84 (01– 02 December 2022)
Glyphosate

Subject	Conclusions Pesticide Peer Review Meeting
after the public consultation/ reporting table stage. EFSA identified a number of publications that might be considered potentially relevant and therefore it was agreed to share these selected studies with MSs to allow a peer review and further consideration in the expert meetings. In particular, MS experts are asked to share their views whether these potentially relevant articles might be considered more critical or may alter the weight of evidence in the current assessment and to determine if any eventual follow up would be needed.	available papers on glyphosate even outside of the legal requirements and collected a list of studies as a result. For non-target organisms, the only relevant study identified in the above exercise for the assessment of the endocrine disrupting properties of glyphosate is Verderame <i>et al.</i>, (2022). See open point under expert consultation point 5.24 EFSA noted that for mammalian toxicology all the relevant studies identified were included, assessed for reliability and weighted in the EFSA ED WG WoE Report (see open point on this item under experts' consultation point 2.29).



REPORT OF PESTICIDE PEER REVIEW TC 82

GLYPHOSATE – AIR V

Rapporteur Member State: Assessment Group on Glyphosate (AGG) consisting of FR, HU, NL, SE

5. Ecotoxicology

Date: 2 December 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Umweltbundesamt / German Environment Agency (UBA)	DE
Federal Research Centre for Cultivated Plants Institute for Bee Protection	DE
DEPA	DK
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
National Food Chain Safety Office (NEBIH)	HU
Department of Agriculture, Food and The Marine	IE
Ctgb	NL
Swedish Chemicals Agency	SE
Kmetijski Inštitut Slovenije / Agricultural Institute of Slovenia	SI
External experts (4)	EFSA
Hearing expert in private capacity	N/A
Observers (4)	CH



Pesticide Peer Review TC 82 (21 November – 2 December 2022)
Glyphosate

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Pesticide Peer Review TC 82 (21 November – 2 December 2022)
Glyphosate

Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 The appropriate endpoint for the reproductive risk assessment to wild mammals should be discussed and agreed.	The experts discussed the most appropriate reproductive endpoint for the risk assessment for wild mammals considering all of the data available in the toxicology section B.6 of the RAR. Overall, the experts at the meeting decided that, further to the assessment of the RMS, the ecological relevance of the endpoints should be considered. When the ecological relevance is considered, the most appropriate endpoint is 150 mg a.s./kg bw per day from the rabbit developmental toxicity study and is based on observed developmental and maternal effects occurring at 200 mg a.s./kg bw per day. All experts were in agreement with the endpoint. The meeting agreed that this endpoint should be used for all wild mammal species. The meeting agreed that there was no additional information from the open literature which should be further considered for the selection of the appropriate endpoint. Open point RMS to reflect the outcome of the discussion in the RAR for the selection of the reproductive endpoint to be used for the assessment of wild mammals and to update the risk assessment in the RAR and list of endpoints (LoEP).



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Experts' consultation 5.2 The appropriate reproductive toxicity endpoint for birds should be discussed and agreed. This discussion should be combined with the discussion under expert consultation point 5.4 where information from the literature studies should be considered.	The experts discussed the appropriate reproductive toxicity endpoint for birds considering the 4 reproduction studies available in the RAR and whether there were any suitable data from the literature (the latter was discussed under expert consultation point 5.4). Overall, all experts agreed with the RMS' proposal that the endpoint for risk assessment should be the no observed adverse effect level (NOAEL) of 117 mg a.s./kg bw per day based on the mallard duck study. Open point RMS to reflect in the RAR (and to update the list of endpoints (LoEP) accordingly) that the endpoint from study CA 8.1.1.3/005 (1978) on the mallard duck is not valid, considering the lack of analytical verification. The RMS may also reflect that the peer review expert meeting agreed to use a NOAEL of 117 mg a.s./kg bw per day based on the mallard duck study (1999, CA 8.1.1.3/004).
Experts' consultation 5.3 The appropriate acute toxicity endpoint to be used in the risk assessment for wild mammals should be discussed and agreed.	The experts discussed the appropriate acute toxicity endpoint to be used in the risk assessment for wild mammals considering all of the data available in the toxicology section B.6 of the RAR. Overall, considering the following: - The unusually large body of evidence showing the occurrence of sublethal effects in acute mammal studies - consideration that the overall risk assessment is not driven by acute effects (i.e., the reproductive risk assessment for wild mammals is what drives the outcome of the assessment) - acknowledgement that this is not a standard approach for acute risk assessment considering that the risk assessment methodology is calibrated against lethal effects - the geomean approach was proposed to account specifically for the observed sublethal effects The meeting agreed with the new proposal by the RMS specifically for glyphosate. Therefore, the geomean LD₅₀ (3447 mg/kg bw) should be used for the screening and Tier-1 assessment.



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	Open point RMS to reflect the outcome of the discussion for the selection of the acute toxicity endpoint for wild mammals and update the risk assessment in the RAR and LoEP by using the geomean endpoint (3447 mg/kg bw) in the screening and Tier-1 assessment.
Experts' consultation 5.4 The experts should discuss the study of 'Ruuskanen S. et al. (2020), Female Preference and Adverse Developmental Effects of Glyphosate-Based Herbicides on Ecologically Relevant Traits in Japanese Quails' and any other relevant literature which provide information on the effects of glyphosate to birds. The discussion should focus on two aspects: i) Firstly, the experts should discuss whether the literature studies provide any reliable standard endpoints (i.e., those mentioned in EFSA (2009)³ and in OECD 223, OECD 206 or the EPA OCSPP 850.2300) to be used in the acute and reproductive risk assessment. ii) Secondly, the experts should discuss and reflect whether there are additional endpoints coming from the literature which are not	The experts at the meeting considered the assessment of the RMS of the literature data for birds. The meeting agreed that some of the endpoints assessed in the three studies by Ruuskanen et al, 2020^{1, 2, 3} (see references below) may be of ecological relevance, such as those relating to reproductive output and embryonic development. The experts agreed with the RMS that the relevance criteria for the tested formulation discussed under expert consultation point 5.10, will mean that the relevance classification for these studies will be amended to "less relevant but supplementary". Overall, the experts agreed that the reliability assessment for the three studies by Ruuskanen S. et al. 2020 should be updated considering the reliability criteria agreed under expert consultation point 5.12 and the additional reliability criteria for food consumption and timing of exposure. Open points RMS to reflect the outcome of the discussion on bird literature studies in a revised RAR. Additionally, the RMS is requested to update the reliability assessment (three studies by Ruuskanen S. et al., 2020^{1, 2, 3}) considering the reliability criteria agreed under expert consultation point 5.12 and the additional reliability criteria for food consumption and timing of exposure. The RMS will also need to update the relevance assessment for these studies. RMS to move the exposure criterion of exposure duration from table 3 to table 1 in the RAR CA Appendix literature and to clarify that the criterion also considers the timing of the exposure related to the endpoint being measured.

³ EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. doi:10.2903/j.efsa.2009.1438



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normally assessed in the standard regulatory studies.	References cited from the open literature ¹ Ruuskanen S. <i>et al.</i> 2020. Female Preference and Adverse Developmental Effects of Glyphosate-Based Herbicides on Ecologically Relevant Traits in Japanese Quails Environmental science & technology (2020), Vol. 54, No. 2, pp. 1128-1135 ² Ruuskanen, S., Rainio, M.J., Uusitalo, M. et al. Effects of parental exposure to glyphosate-based herbicides on embryonic development and oxidative status: a long-term experiment in a bird model. Sci Rep 10, 6349 (2020). https://doi.org/10.1038/s41598-020-63365-1 ³ Ruuskanen S, Rainio MJ, Gómez-Gallego C, Selenius O, Salminen S, Collado MC, Saikkonen K, Saloniemi I, Helander M. Glyphosate-based herbicides influence antioxidants, reproductive hormones and gut microbiome but not reproduction: A long-term experiment in an avian model. Environ Pollut. 2020 Nov;266(Pt 1):115108. doi: 10.1016/j.envpol.2020.115108. Epub 2020 Jul 5. PMID: 32768925.
Experts' consultation 5.5 Experts to discuss and agree on the risk assessment for birds and mammals from plant metabolites.	The experts discussed and agreed on the risk assessment for birds and mammals from plant metabolites. The discussion considered the risk from metabolite AMPA and also whether there were additional metabolites which require assessment. Overall, the meeting agreed with the assessment from the RMS that the risk to birds and wild mammals from the plant metabolite AMPA in primary crops is covered by the assessment for the parent. In addition, the risk from AMPA in rotational crops is considered to be addressed considering that the concentration in plant would not exceed that of the parent in primary crops. In addition, assuming it was confirmed that there are no additional metabolites in plants above 10% (other than those discussed above), the experts agreed that the risk to birds and mammals from plant metabolites is addressed. Open points - RMS to include an assessment in the B.9 section of the RAR confirming that there are no additional plant metabolites exceeding 10%, considering the valid data presented in the residues section.



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	- RMS to reflect in a revised RAR the meeting discussion on the risk assessment for birds and mammals from plant metabolites.
Experts' consultation 5.6 Experts to discuss the refined risk assessment for mammals. This discussion may include a risk assessment using a refined DT₅₀ in plants and/or population modelling.	The discussion was separated into three main points: i) reliability of the refined DT₅₀ value, ii) the available population modelling and iii) the final reproductive risk assessment for small herbivorous mammals. <u>i) Reliability of refined DT₅₀ value</u> Overall, the experts agreed that, since only a single reliable DT₅₀ value was available, a quantitative refinement of the DT₅₀ in risk assessment was not appropriate. However, it was concluded that a qualitative use of the residue dissipation studies may be appropriate, i.e., to note that some data were available suggesting that the dissipation is faster than the default value of 10 days. <u>ii) Reliability of the population modelling</u> Overall, the experts agreed with the evaluation as performed by the RMS, noting several additional aspects as outlined in the open points below. Therefore, the experts concluded that the modelling could not be used to refine the risk to small herbivorous mammals for the representative uses under assessment. <u>iii) Overall outcome of the reproductive risk assessment for small herbivorous mammals</u> Overall, the experts agreed that the RMS should update their assessment reflecting on the relevance of the exposure scenarios for small herbivorous mammals by considering their likely presence. In addition, the RMS should reflect that a quantitative reduction of the exposure estimate cannot be done for the spot applications without suitable data. Instead, the RMS should reflect that the spot application should be considered as a qualitative argumentation. Open points - The RMS should update the study evaluations of the 4 GLP trials (IF-93/04572-01, AS/1911/CN, IF-93/13842-01, AS/1912/CN) to provide an evaluation of the geographical independence of the



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	study sites, in accordance with the recommendations of EFSA (2019)⁴. - The RMS should also reflect the outcome of the discussion regarding the reliability of the refined DT₅₀ value in the revised RAR. The endpoint should not be included in the LoEP. - RMS to update the risk assessment taking into account the exposure scenarios where the presence of small herbivorous mammals was considered unlikely. - In addition, the RMS should reflect that a quantitative reduction of the exposure estimate cannot be done for the spot applications without suitable data. Instead, the RMS should reflect that the spot application should be considered as a qualitative argumentation. Open points - RMS to include the applicants' summaries on the population model in the revised RAR. - RMS to include the evaluation of the model and model study in the Appendix of the RAR. - RMS to update the study evaluation of the population modelling in the RAR including that the exposure modification factor (EMF) of 5 shall be considered as a positive control. - RMS to reflect the additional concerns and uncertainties identified in the meeting regarding the suitability of the available modelling for the current risk assessment, in the study evaluation in the Appendix of the RAR: - There is a need for justification that the modelled spp. (common vole) is appropriate for the EU GAPs under assessment - problem formulation: relevance of the modelling GAPs in comparison to the GAPs under assessment - geographical relevance of the model to the EU territory - an updated reliability assessment for the toxicology data package in the context of the evaluation of the model - The modelling should have explored the consequences of structural uncertainty due to the implemented way of density regulation in the model. In particular, the assumption of less

⁴ EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117pp. doi:10.2903/sp.efsa.2019.EN-1673



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	resources for maintaining than for establishing home-range. (A question that could be replied is “Why is population density not decreasing when food resources significantly decrease due to glyphosate application?”) - Considering the specificity to the GAP uses under assessment, a consideration should be given to the realism and conservativeness of the landscape scenario in relation to the assumptions on spray drift, mowing events, timing, rate and frequency of application, dissipation of the active substance in plant matrices, assumption of the complete wilting after 10 days.
Experts’ consultation 5.7 Experts to discuss the assumptions that have been made for the bird and mammals risk assessment for the uses to railway tracks and for invasive species.	The experts discussed the assumptions that have been made for the bird and mammals risk assessment for the uses to railway tracks and for invasive species. Overall, the meeting agreed with the principles of the RMS assessment for the railway track uses but considered that some additional reflections should be made in the RAR (see open points). Overall, the experts agreed with the assessment by the RMS for the use to invasive species with the additional note that the high interception value would not be suitable in the case of the cut-stem (included in the GAP) or treatment of less established plants. Nevertheless, in these cases a qualitative argumentation can be made considering that the application is via spot treatment and applications to cut-stem and young plants are not expected to be made to extensive areas of the field. However, should application be made to more extensive treatment areas, the available assessment would not cover this situation. Open points - The RMS should clarify in the RAR that the underlying assumption for the exposure assessment for the use to railways is that spray direction is downward and that the embankments are not treated with a side-ward sprayer.



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	- The RMS should update the risk assessment by assuming the worst-case drift value of 0.47% from HardSPEC (Hollis et al, 2017⁵). - RMS to reflect the additional argumentations for invasive species including consideration of cut stem and young plants and the additional qualitative arguments concluded at the meeting. RMS to perform updated calculations for the spot treatment using the revised endpoint for mammals.
Experts' consultation 5.8 Experts to discuss the endpoints obtained from studies where pH was (potentially) lowered by high concentrations of glyphosate in its acid form along with their use in the risk assessment.	When glyphosate active substance is tested in its acid form at high concentrations, it may significantly lower pH of the test medium if not buffered. There is evidence that, in some experiments, the observed effects on aquatic organisms are not linked to direct toxicity of glyphosate, but rather to the induced acid conditions. To disentangle true effect of glyphosate from pH alteration, it was agreed that the approach taken by the RMS is appropriate in terms of excluding data points obtained under conditions of pH being outside the range recommended in the relevant OECD guidance. It was also agreed that for literature studies in which pH was not measured and glyphosate acid was tested at concentration > 10 mg/L, the reliability score will be impacted (refer to expert consultation point 5.12 for the dedicated discussion and related open points).
Experts' consultation 5.9 Experts to agree on the classification of literature aquatic studies where analytical verification of the tested concentrations is completely lacking or incomplete.	Analytical verification of the tested concentration is an important quality-related aspect of ecotoxicological tests with aquatic organisms that ensures the accuracy of the endpoints derived from such studies. The database available for glyphosate presents different situations in terms of analytical verification, with different levels of associated uncertainty. Four categories were agreed to identify the reliability of dossier and literature studies and the related usability in the risk assessment:

⁵ Hollis, Ramwell, Holman and Whelan, HardSPEC A First-tier Model for Estimating Surface- and Ground-Water Exposure resulting from Herbicides applied to Hard Surfaces. Updated Technical Guidance on Model Principles and Application for version 1.4.3.2. Version 2.1, April 2017.
https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/hardspec/HardSPEC_Guidance.pdf



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	1. Verification of test item in solution throughout the experiment according to OECD. <u>Reliable. Can be used for endpoint setting (quantitative risk assessment).</u> 2. Verification of test item at the beginning of the test. <u>Reliable with restrictions. Can be used for EP setting (quantitative risk assessment).</u> 3. Verification of test item in stock solutions and presence of dose-response. <u>Reliable with restrictions. Can be used for endpoint setting (quantitative risk assessment).</u> 4. No analytical verification at all. <u>Supportive or Unreliable. Not to be used for quantitative risk assessment, but in principle usable in uncertainty analysis.</u> Open point RMS to update the reliability assessment of the available studies in a revised RAR by following these recommendations, to be incorporated in the outcome of expert discussion point 5.12.
Experts' consultation 5.10 Pending on the comparison between different formulations used in literature studies and the representative formulation 'MON 52276' and the active substance, experts to consider whether the available ecotoxicological data should be considered for potential use of endpoints obtained with these formulations for the risk assessment.	The following conclusions were agreed in order to improve the readability and the consistency of the methodology used for classifying the relevance of literature studies concerning the formulation being tested in the reported experiments. 1. Application of the flow diagram presented by EFSA, based on the following steps: • Is there information on the formulation? • If NO: Potentially relevant but insufficient information. • If YES: Is there evidence of forbidden surfactants? • If YES: Not relevant. • If NO: Is the composition similar to 'MON 52276'? • If YES: Relevant. • If NO: Less relevant but supplementary. 2. Check that any of the trade names of the representative formulation included in Volume 4 (for all applicants) have been used in literature studies. If this is the case, extrapolation should be carried out according to point 3. 3. Extrapolation at all points throughout the flow diagram is possible if formulations have the same trade name, they are used in the same country within 4 years. These criteria should



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	be applied in any case, irrespective of the suspected presence of forbidden surfactants (e.g., polyoxyethylene tallow amine (POEA)). 4. To use the agreed Relevance vs. Reliability table in terms of usage of study data for the risk assessment. 5. In the last point of the workflow proposed at the meeting, the relevance has to be proven against the formulation for representative uses 'MON 52276'. 6. The endpoints categorised under relevant + reliable or reliable with restrictions should be included in the list of endpoints (LoEP). All experts agreed with the conclusions. Open points: 1. Application of the flow diagram should be captured in the RAR (point 1 of the overall conclusions above) and categorisation of the available studies should be harmonised. 2. Captured in point 2 of the overall conclusions above. 3. Captured under point 3 of the overall conclusions above. 4. After the RMS completed the update of points 1-3 in the RAR, it should be confirmed that the available assessments cover the formulation for the representative uses and the active substance (e.g., including co-formulants). 5. Captured under point 6 of the overall conclusions above.
Experts' consultation 5.11 Experts to consider the available data to conclude on whether the toxicity of glyphosate to fish covers toxicity to the aquatic stages of amphibians.	The following conclusions were achieved at the meeting: 1. All studies on the aquatic stages of amphibians need to be reviewed in terms of relevance and reliability criteria as agreed (see expert consultation points 5.10 and 5.12). It is key that these criteria are applied consistently. 2. Since relevant and reliable chronic endpoints for amphibians are not available, it is not possible to compare chronic hazard for fish and amphibians. A full comparability between fish and aquatic stages in amphibians would anyway be hampered by the different endpoints being measured for the two groups.



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	3. The current comparison based on the lowest endpoint for fish and the geomean for amphibians was considered not appropriate in view of uncertainty in the geomean calculation for amphibians pooling data from different life stages of the same species and in view of such comparison not being balanced. Thus, it was agreed that the comparison between fish and amphibians should be based on the lowest endpoint from each group. On such basis, the acute hazard for glyphosate active substance to amphibians is covered by the one for fish. 4. There is a need to remove Moutinho et al. (2020) from the acute studies, since it presents results for a 23-day exposure duration. 5. As information was provided only on a limited number of studies and formulations, the RAR should reflect that the data requirement for providing details on formulation was not completely fulfilled by the applicants. 6. Following the discussion and the agreement achieved under expert consultation point 5.10, the relevance classification of the study from Wagner et al. (2017) might need to change from 'Relevant' to 'Less relevant but supplementary'. This would hamper its use for a quantitative comparison of the representative endpoint for fish and amphibians. 7. Some data with the formulations without POEA seem to indicate a higher toxicity than the active substance to amphibians. However, it is unknown how comparable these formulations are to the representative one. The inability to compare them was because such comparison was not provided by the applicants. Specifically for the literature study by Tartu et al. (2022) identified by EFSA as potentially relevant for the assessment: 8. Some of the key reliability points could not be fully addressed by looking at the information included in the paper, however it was agreed that the authors would not be contacted, since it is outside of the scope of the peer-review to further contact the authors at this point of the process. 9. A summary of Tartu et al. (2022) should be included in the RAR and evaluated for relevance and reliability. 10. It was agreed that the information available for analytical verification is insufficient to conclude that this was actually



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	performed for the experiment reported in the paper. The reliability classification should follow what was agreed under expert consultation points 5.9 and 5.12. 11. The example set by Cheron et al. 2020, not captured in the literature review submitted by the applicants, will be considered in the discussion point related to the coverage of the literature review. Open points: RMS to update the RAR with the following conclusion: • Clarify that the acute hazard of glyphosate to amphibians is covered by the one for fish; • Update every comparison by taking the lowest endpoints amongst the relevant and reliable ones for both fish and amphibians; • Relevance and reliability of the amphibian studies should be revised according to what was agreed under expert consultation points 5.12 and 5.10; • To remove the endpoint from Moutinho et al. (2020) from the list of acute studies in the RAR; • To reflect that the data requirement for providing details on formulation was not completely fulfilled by the applicants; • To clarify that some data with the formulations without POEA seem to indicate a higher toxicity than the active substance to amphibian, and the implication of this. • RMS to include a summary of Tartu et al (2020) in the RAR and assess its relevance/reliability. References cited from the open literature Cheron M and Brischoux F, 2020. Aminomethylphosphonic acid alters amphibian embryonic development at environmental concentrations. <i>Environ Res</i>, 190:109944. doi: 10.1016/j.envres.2020.109944 Moutinho MF, de Almeida EA, Espindola ELG, Daam MA and Schiesari L, 2020. Herbicides employed in sugarcane plantations have lethal and sublethal effects to larval <i>Boana pardalis</i> (Amphibia, Hylidae). <i>Ecotoxicology</i>, 29:1043-1051. doi: 10.1007/s10646-020-02226-z Tartu S, Renoirt M, Cheron M, Gisselmann L-L, Catoire S and Brischoux F, 2022. Did decades of glyphosate use have selected for resistant amphibians in agricultural habitats? <i>Environ Pollut</i>, 310:119823. doi: 10.1016/j.envpol.2022.119823



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	Wagner N, Muller H and Viertel B, 2017. Effects of a commonly used glyphosate-based herbicide formulation on early developmental stages of two anuran species. Environ Sci Pollut Res Int, 24:1495-1508. doi: 10.1007/s11356-016-7927-z
Experts' consultation 5.12 Experts to discuss the reliability criteria and classification system to be used for all studies.	The following conclusions were achieved at the meeting: To ensure the same levels of evaluation for both literature and dossier studies, the following reliability classification should be used (<u>based on the agreed classification under expert consultation point 5.9</u>), and to ensure that the categories are equivalent among dossier and literature studies: • Reliable: used for the quantitative risk assessment • Reliable with restrictions: used for the quantitative risk assessment • Supportive (to be used in assisting for uncertainty analysis in the risk assessment). • Unreliable: not to be used. It was agreed that in order to acknowledge situations which are deemed of concern for downgrading the studies, at the bare minimum, the following key criteria should be considered: 1. <u>Test method:</u> if the study is conducted according to OECD protocols, it has to meet the OECD validity criteria. 2. <u>Analytical measurement:</u> see expert consultation point 5.9. 3. <u>pH measurement:</u> see expert consultation point 5.8, even though it is a specific point for the glyphosate acid. 4. <u>Performance of negative control</u> is suitable. If control / information on the control is not available, or in case of very clear deviation (e.g. high mortality), the study should not be used for quantitative endpoint derivation. 5. <u>Level of detail of results:</u> Raw data are not required. Table or plots that are reporting data for each tested dose, and the associated variability among replicates. 6. <u>Statistical methods:</u> qualitative assessment of robustness of statistical methods (at the bare minimum, replication is present and statistical methods are reported). 7. <u>General characteristics of the organisms:</u> information on age/life stage, sex and/or size of organisms should be available, when appropriate.



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	8. Reporting of test item: in case of formulation/product, the dosing can be expressed with sufficient level of certainty as concentration of glyphosate active substance. For all the criteria which are applicable: • If even one of the key criteria is not met, the study should be downgraded as Unreliable or Supportive. • If one to two of the key criteria is not met: Supportive. • If three or more of the key criteria are not met: Unreliable. Open point RMS to update the reliability evaluation of the studies in the RAR according to the abovementioned criteria.
Experts' consultation 5.13 Experts to assess whether any new literature study provided after the commenting phase has an impact on the aquatic risk assessment.	The following conclusions were achieved at the meeting: • There is a need to update the reliability and relevance classification for all studies in light of the agreement of expert consultation points 5.10 and 5.12. • For acute fish: Wan et. al, 1989 should be downgraded based on a lack of biological information. • For chronic fish: Abdulkareem et al, 2014 should also be downgraded due to multiple issues. Du-Carree et al, 2021: no relevant effect was seen at the only tested concentration. Therefore, no endpoint should be set based on this study. • For acute invertebrates: Bringolf et al, 2007 was considered to be not sufficiently reliable for endpoint derivation due to lack of detailed reporting of the results. In the Akcha (2012), no relevant adverse effect was seen at the highest tested concentration. • For chronic invertebrates: Bringolf et al, 2007 should be revised since it is potentially relevant and reliable and might have an impact on the selected endpoint for chronic invertebrates. It was agreed that the endpoints measured in the Janssens (2017) study are not relevant since emergence rate was not measured; growth rate was only measured at the final instar larvae. Baglan et al, 2018: there was also no impact in the highest tested concentration. • For aquatic plant/Glyphosate: Roshon, 1997: The study is not useable for endpoint derivation based on the lack of analytical verification. Available data show that the ErC₅₀ for shoot length



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	should be higher than the highest tested concentration (2.987 mg/L). - For aquatic plant/AMPA: Tajnaiova et al, 2020, should be considered supportive only at best. This could feed into the uncertainty analysis to indicate that <i>Lemna</i> would be more sensitive than <i>Myriophyllum aquaticum</i>. General conclusion: the data from literature are not impacting on the endpoints selection previously performed by the RMS with the only exception represented by Bringolf et al, 2007, which should be reconsidered for the derivation of the chronic endpoint for invertebrates. Open points - RMS to reconsider the study from Bringolf et al, 2007, that could impact the chronic risk assessment for invertebrates. - RMS to reconsider the reliability and the relevance classification of the literature studies presented at the meeting in line with the outcome of the expert consultation points 5.10 and 5.12. References cited from the open literature Abdulkareem SI, Lawal NO and Moyebi OD, 2014. Effect of lethal and sublethal concentrations of glyphosate on some biochemical parameters and growth responses of African catfish (<i>Clarias gariepinus</i>). Egyptian Academic Journal of Biological Sciences B Zoology, 6:47-54 Akcha F, Spagnol C and Rouxel J, 2012. Genotoxicity of diuron and glyphosate in oyster spermatozoa and embryos. Aquat Toxicol, 106-107:104-113. doi: 10.1016/j.aquatox.2011.10.018 Baglan H, Lazzari CR and Guerrieri FJ, 2018. Glyphosate impairs learning in <i>Aedes aegypti</i> mosquito larvae at field-realistic doses. J Exp Biol, 221. doi: 10.1242/jeb.187518 Bringolf RB, Cope WG, Mosher S, Barnhart MC and Shea D, 2007. Acute and chronic toxicity of glyphosate compounds to glochidia and juveniles of <i>Lampsilis siliquoidea</i> (Unionidae). Environ Toxicol Chem, 26:2094-2100. doi: 10.1897/06-519R1.1 Du-Carree JL, Morin T and Danion M, 2021. Impact of chronic exposure of rainbow trout, <i>Oncorhynchus mykiss</i>, to low doses of glyphosate or glyphosate-based herbicides. Aquat Toxicol, 230:105687. doi: 10.1016/j.aquatox.2020.105687 Janssens L and Stoks R, 2017. Stronger effects of Roundup than its active ingredient glyphosate in damselfly larvae. Aquat Toxicol, 193:210-216. doi: 10.1016/j.aquatox.2017.10.028



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	Roshon RD, 1997. A toxicity test for the effects of chemicals on the non-target submersed aquatic macrophyte, <i>Myriophyllum sibiricum</i> Komarov. University of Guelph. 496 pp. Tajnaiova L, Vurm R, Kholomyeva M, Kobera M and Koci V, 2020. Determination of the Ecotoxicity of Herbicides Roundup((R)) Classic Pro and Garlon New in Aquatic and Terrestrial Environments. <i>Plants (Basel)</i>, 9. doi: 10.3390/plants9091203 Wan MT, Watts RG and Moul DJ, 1989. Effects of different dilution water types on the acute toxicity to juvenile Pacific salmonids and rainbow trout of glyphosate and its formulated products. <i>Bull Environ Contam Toxicol</i>, 43:378-385. doi: 10.1007/BF01701872
Experts' consultation 5.14 Experts to agree on the relevance of the exposure via overspray for aquatic macrophytes in view of the intended uses of glyphosate. In case this is found to be relevant, the experts should discuss and agree on the outcome of the risk assessment in view of the additional information provided by the applicants.	The following conclusions were achieved at the meeting: 1. In light of the robustness of the study by Sesin et al. (2020) and in light of the mode or action of glyphosate, all the experts unanimously agreed on the relevance of the exposure route via overspray of the emerging part of the macrophyte. 2. In light of the test item (containing POEA) and the non-standard species used in the study, it was considered that no relevant endpoint could be derived from Sesin et al. (2020). 3. It was agreed not to carry out an illustrative risk assessment using endpoint from Sesin et al. (2020). The data gap identified by the RMS will remain and further information should be requested to assess this route of exposure. References cited from the open literature Sesin V, Davy CM, Stevens KJ, Hamp R and Freeland JR, 2021. Glyphosate Toxicity to Native Nontarget Macrophytes Following Three Different Routes of Incidental Exposure. <i>Integr Environ Assess Manag</i>, 17:597-613. doi: 10.1002/ieam.4350
Experts' consultation 5.15 Experts to agree on the relevant chronic endpoint for fish.	The following conclusions were achieved at the meeting: 1. Study CA 8.2.2.1/002: It was agreed that the more appropriate endpoint from this study is the NOEC (1 mg/L) in order to cover the lethargy effect. However, the study can only be retained for



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The discussion should consider: - That the endpoint currently set by the RMS (NOEC = 1 mg/L) is based on lethargy/mortality observed in the study (2000, CA 8.2.2.1/002); - That the reliability of any endpoint obtained from study (2000, CA 8.2.2.1/002) has been questioned; - That it is theoretically possible to replace the NOEC with an EC₁₀ for the same parameters, in consideration of the additional information provided by the applicants and of the estimation provided by DE (i.e. mortality EC₁₀ = 4.6 mg/L [2.45 – 6.75]); - The reliability and the outcome of the available early life stage (ELS) study CA 8.2.2.1/001 (2010) on rainbow trout also in light of the additional information provided by the applicants; - The reliability and the outcome of the available fish full life cycle (FFLC) study (CA 8.2.2.2/001), also in light of the additional information provided by the applicants;	endpoint derivation if the analytical methods used are considered fit for purpose (see open point below). 2. Early life stage (ELS) study CA 8.2.2.1/001: All experts agreed with the approach proposed by the RMS and to set the NOEC at 2.804 mg a.e./L. It was decided not to retain any value from the EC₁₀ parameter for hatching because, particularly the lower limit of the EC₁₀, it was considered to be poorly representative of the experimental results (below the NOEC where no effects were recorded). 3. Fish full life cycle (FFLC) study CA 8.2.2.2/001: All experts agreed with the approach proposed by the RMS to consider the study uniquely as supportive, mainly due to the analytical methods not being considered fit for purpose. 4. Other literature studies: After considering the available data from literature, the experts at the meeting did not identify reason to lower the chronic endpoint for fish. Rather, they considered that literature data could support the currently selected endpoint. Open point RMS to check if the analytical methods are available and fit for purpose for the study CA 8.2.2.1/002. If yes, the study could be used for endpoint derivation and in this case, the more appropriate endpoint agreed is the NOEC (1 mg/L) in order to cover the lethargy effect. If not, the study should be downgraded in terms of reliability classification.



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- All other available information, including literature data (e.g. Uren Webster et al., 2014)⁶.	
Experts' consultation 5.16 Experts to discuss the reliability and the potential use of any endpoint from the study by Dai, P. et al., 2018 in the risk assessment for bees.	The test design of the study by Dai et al., 2018 is very similar to OECD 239 guidance. However, several key aspects of the design are missing or not reported. Furthermore, the statistical trend observed on the larval survival is not supported by the other biological observations. The experts agreed that the reliability of the study needs to be reclassified according to the criteria agreed under expert consultation point 5.12. In addition, the experts agreed that the reliability and the relevance of all the studies on bees from the literature should be reclassified according to the criteria agreed under expert consultation points 5.10 and 5.12. Open point RMS to further evaluate Dai et al. (2018) using the reliability criteria agreed under expert consultation point 5.12, except for the reliability criterion addressing pH. RMS to reflect the potential changes in a revised RAR. Open point RMS to evaluate all the other available bee studies from literature included in the RAR using the reliability criteria agreed under expert consultation point 5.12, except for the reliability criterion addressing pH. RMS to evaluate all available bee studies from literature using the relevance criteria agreed under expert consultation point 5.10. RMS to reflect the potential changes in the revised RAR after consulting the table under expert consultation point 5.10. References cited from the open literature Dai, P., Yan, Z., Ma, S., Yang, Y., Wang, Q., Hou, C., Wu, Y., Liu, Y., Diao, Q., 2018. The herbicide glyphosate negatively affects midgut bacterial

⁶ Uren Webster TM, Laing LV, Florance H and Santos EM, 2014. Effects of glyphosate and its formulation, roundup, on reproduction in zebrafish (*Danio rerio*). *Environ Sci Technol*, 48:1271-1279. doi: 10.1021/es404258h



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	communities and survival of honey bee during larvae reared in vitro. J. Agric. Food Chem. 66, 7786–7793. https://doi.org/10.1021/acs.jafc.8b02212
Additional point on (re) classification of the studies from the literature; follow up exercise in view of the open point identified in experts' consultation 5.16, above.	Details of two selected bee studies from the literature (Tome et al., 2020 and Herbert et al., 2014) were discussed in order to check whether the relevance and reliability criteria as agreed under experts' discussion points 5.10 and 5.12 are applicable. The experts considered that those criteria (except the one on the pH) are applicable for these types of studies as well. As regards the classification of the two studies, some key information on the methodology is missing. Therefore, they should be considered as supporting information. Open point RMS to revise the study classification of Tome et al. (2020) and Herbert et al. (2014) to “relevant, supportive”, reflecting the meeting discussions. See also open point above: “RMS to evaluate all the other available bee studies from literature included in the RAR using the reliability criteria agreed under expert consultation point 5.12, except for the reliability criterion addressing pH. RMS to evaluate all available bee studies from literature using the relevance criteria agreed under expert consultation point 5.10. RMS to reflect the potential changes in the revised RAR after consulting the table under expert consultation point 5.10”. References cited from the open literature Herbert, L.T., Vázquez, D.E., Arenas, A., Farina, W.M., 2014. Effects of field-realistic doses of glyphosate on honeybee appetitive behaviour. J. Exp. Biol. 217, 3457–3464. https://doi.org/10.1242/jeb.109520 Tomé, H.V.V., Schmehl, D.R., Wedde, A.E., Godoy, R.S.M., Ravaiano, S.V., Guedes, R.N.C., Martins, G.F., Ellis, J.D., 2020. Frequently encountered pesticides can cause multiple disorders in developing worker honey bees. Environ. Pollut. 256. https://doi.org/10.1016/j.envpol.2019.113420
Experts' consultation 5.17	No valid tier 1 (glass plate) studies are available with any of the two indicator species (<i>Aphidius rhopalosiphi</i> and <i>Typhlodromus pyri</i>). Therefore, the risk assessment for non-target arthropods (NTAs) other than bees is mainly based on higher tier studies: (i) extended



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Experts to discuss whether the overall data set of toxicity studies (i.e. extended studies with the standard species <i>Aphidius rhopalosiphi</i> and <i>Typhlodromus pyri</i>, and studies with additional species, <i>Poecilus cupreus</i>, <i>Pardosa</i> sp. and <i>Aleochara bilineata</i>) is sufficient to perform a risk assessment for non-target arthropods other than bees according to ESCORT 2⁷ and the SANCO Guidance Document on Terrestrial Ecotoxicology (EC, 2002)⁸.	laboratory studies with the indicator species, and (ii) laboratory studies with the ground-dwelling spider <i>Pardosa</i> sp. and the ground beetle <i>Poecilus cupreus</i>. The available data set suggests a rather low toxicity of glyphosate to NTAs. All experts agreed that the data set available is sufficient to perform the risk assessment according to ESCORT 2. Open point RMS to reclassify the relevance of the available two NTA studies from the peer reviewed open literature (Mirande et al., 2010; Siddhapara et al., 2012) according to the classification system agreed under expert consultation point 5.10. References cited from the open literature Mirande et al., 2010. Side-effects of glyphosate on the life parameters of <i>Eriopis connexa</i> (Coleoptera: Coccinellidae) in Argentina. Communications in Agricultural and Applied Biological Sciences, 75: 367-72 Siddhapara et al., 2012. Toxicity of some commonly used insecticides / herbicides on <i>Zygogramma bicolorata</i> Pallister (Coleoptera: Chrysomelidae). Biological Control, 26: 251-254
Experts' consultation 5.18 Experts to discuss the reliability of the extended laboratory study on <i>Aleochara bilineata</i> (CP 10.3.2.2/007). The outcome of the discussion should be taken into account when discussing the overall dataset for non-target arthropods.	An extended laboratory study with the rove beetle <i>Aleochara bilineata</i> was submitted to support the risk assessment for non-target arthropods (NTAs) other than bees. One of the validity criteria indicated in the test guideline (Grimm et al., 2000), is that a minimum reduction of 50% reproductive capacity relative to the control treatment is achieved in the reference item treatment. However, the toxic reference used in the study (chlorpyrifos) led to 100% mortality so that the minimum reproductive capacity relative to the control of the reference toxic could not be estimated.

⁷ SETAC (Society of Environmental Toxicology and Chemistry), Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet MC, Lewis G, Oomen PA, Schmuck R and Vogt H (eds), 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT 2 workshop.

⁸ European Commission, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002.



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	In addition, the compound used as the toxic reference (chlorpyrifos) was different than that recommended in Grimm et al. (2000). Besides, the use of chlorpyrifos was not justified and the concentration used in the study was not validated, as required by the test guideline. All experts at the meeting agreed that the study should be considered as supportive. Reference Grimm C, Reber B, Barth M, Candolfi MP, Drexler A, Maus C, moreth L, Ufer A and Waltersdorfer A, 2000. A test for evaluating the chronic effects of plant protection products on the rove beetle <i>Aleochara bilineata</i> (Coleoptera: <i>Staphylinidae</i>) under laboratory and extended laboratory conditions. In book: Guidelines to evaluate side effects of plant protection products to non-target arthropods. Editors: IOBC / OILB
Experts' consultation 5.19 Experts to discuss the appropriateness of the toxic reference concentrations used in the laboratory studies with non-target arthropods. The outcome of the discussion should be taken into account when discussing the overall dataset for non-target arthropods.	The toxic reference (positive control) used in the extended laboratory studies with non-target arthropods (NTAs) (specifically, studies CP 10.3.2.2/007, CP 10.3.2.2/001, CP 10.3.2.2/002, CP 10.3.2.2/003, CP 10.3.2.2/005, CP 10.3.2.2/008) was not in line with the relevant test guidelines because, either a different compound was used, or it was used at a higher concentration than that recommended in the applicable guideline. Other drawbacks and limitations were also identified in all those studies. The RMS evaluation of such deviations including the overall validity of the studies was presented by the RMS. All experts at the meeting agreed with the RMS evaluation and with the final conclusions for each NTA laboratory study (unanimous agreement). No open point was set for the RMS.
Experts' consultation 5.20 Experts to discuss the endpoints (NOER, LR₅₀ and ER₅₀) derived from the extended laboratory study on <i>Typhlodromus pyri</i> (Report No.: MON-09-3).	A dose-response for mortality (Abbott corrected) was observed at the extended laboratory study with <i>Typhlodromus pyri</i> (Report No.: MON-09-3). At the highest concentration (16 L/ha) there was 40% mortality which was statistically significant compared to the control group. Therefore, a 50% lethal rate (LR₅₀) > 16 L/ha was agreed by all experts. As regards the reproductive endpoint, a no observed effect rate (NOER) = 8 L/ha had been initially proposed based on statistical



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	significance. However, at that concentration, there was a 14% decrease in reproduction compared to the control group, which could be considered as biologically relevant. Therefore, all experts agreed with setting the NOER for reproduction at 3 L/ha. Also, for reproduction, all experts agreed with setting an $ER_{50} > 12\text{L/ha}$ based on a dose-response that was observed at the highest three concentrations and a 56.5% reduction in reproduction at 16 L/ha. Open point RMS to update the RAR and the list of endpoints with the agreed NOER value of 3 L/ha for the extended laboratory study with <i>T. pyri</i>.
Experts' consultation 5.21 Experts to agree on the endpoints to be used for risk assessment for soil organisms.	Endpoints used for the soil risk assessment From the available regulatory studies with soil organisms, EC_{10} values could only be estimated from the earthworm chronic study with the soil metabolite AMPA. The no observed effect concentration (NOEC) derived from that study was used for the risk assessment since it is lower than the EC_{10}. The experts agreed with the endpoints that were already present in the list of endpoints for all groups of soil organisms (unanimous agreement). Peer reviewed publication by Correia and Moreira (2010)⁹ The relevance and reliability of the peer-reviewed publication by Correia and Moreira (2010) were discussed. Several limitations pertaining to the study design and results of the study were identified by the experts. The experts agreed that the reliability assessment of the publication Correia and Moreira (2010) should be revised in light of the concerns raised at the meeting. The reliability key criteria agreed upon under expert consultation point 5.12 should be used (when applicable) (unanimous agreement). Open point RMS to update the study evaluation of the peer reviewed study by Correia and Moreira (2010) and to revise the reliability assessment accordingly, acknowledging the concerns raised at the meeting.

⁹ Correia FV and Moreira JC. 2010. Effects of Glyphosate and 2,4-D on Earthworms (*Eisenia foetida*) in Laboratory Tests. Bulletin of Environmental Contamination and Toxicology, 85: 264–268. <https://doi.org/10.1007/s00128-010-0089-7>



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Experts' consultation 5.22 Experts to discuss the issues raised for the two vegetative vigour studies (CP 10.6.2/002 (2014) and CP 10.6.2/005 (2021)) and the updated risk assessment for non-target terrestrial plants.	The available two vegetative vigour studies were compared and discussed. Due to some issues, mainly due to the considerably lower light intensity, the CP 10.6.2/002 study was agreed to be labelled as reliable with restrictions, while the CP 10.6.2/005 study was considered as reliable. This resulted in that the lowest endpoint from the two studies should be considered in the updated deterministic risk assessment. The available probabilistic risk assessment was not considered protective by the experts at the meeting (therefore not to be considered) since reliable endpoints from the available studies indicate higher sensitivity. Open point RMS to re-evaluate the literature studies available in the revised RAR based on the criteria agreed upon under expert consultation points 5.10 and 5.12 (except the criterion on pH). Open point RMS to reflect the results of the discussion in the risk assessment for non-target terrestrial plants and update the RAR.
Experts' consultation 5.23 Experts to discuss the risks to reptiles and terrestrial phases of amphibians.	The experts discussed the available information to assess risks to reptiles and terrestrial phases of amphibians. This consisted of several literature studies (see references below) and a risk assessment included in the RAR which followed the proposal made in EFSA PPR Panel (2018). <u>Conclusion for the literature studies:</u> Overall, considering all literature information, none of the studies were considered fully relevant considering the tested material. Of those that were "less relevant but supplementary", only some of the assessment endpoints (i.e., growth and length) were considered potentially relevant. Reliability issues were noted, with none of the studies being completely reliable. The only observed effect on a potentially relevant endpoint was from Poletta et al. (2011). However, the biological relevance of these effects may need to be further considered acknowledging the low effect levels, some of which were only observed at one growth stage (i.e., 2-4% change at birth and 3 months, but not at 12 months).



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	Conclusion for the risk assessment: Overall, the experts agreed that the illustrative risk assessment provided by the applicants is not acceptable and cannot be relied upon to address the risks to terrestrial phases of amphibians. Additionally, a number of additional uncertainties and incorrect assumptions were identified. The experts noted that a similar illustrative risk assessment was not presented for reptiles. Open points - RMS to update the study summaries for reptiles and terrestrial phases of amphibians based on the criteria agreed upon under expert consultation points 5.10 and 5.12. The RMS should also reflect the relevance of the endpoints relating to size, such as growth and size (e.g., snout-to-vent length). - RMS to reflect in the RAR the additional uncertainties and incorrect assumptions which were not already captured concerning the illustrative risk assessment for terrestrial phases of amphibians, as discussed in the experts' meeting. - The illustrative oral risk assessment provided by the RMS should be revised by modifying the crop interception, the correct residue per unit dose (RUD) values and by acknowledging the additional uncertainties related the assumptions on drift. References EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Ockleford C, Adriaanse P, Berny P, Brock T, Duquesne S, Grilli S, Hernandez-Jerez AF, Bennekou SH, Klein M, Kuhl T, Laskowski R, Machera K, Pelkonen O, Pieper S, Stemmer M, Sundh I, Teodorovic I, Tiktak A, Topping CJ, Wolterink G, Aldrich A, Berg C, Ortiz-Santaliestra M, Weir S, Streissl F and Smith RH, 2018. Scientific Opinion on the state of the science on pesticide risk assessment for amphibians and reptiles. EFSA Journal 2018;16(2):5125, 301 pp. Poletta GL, Kleinsorge E, Paonessa A, Mudry MD, Larriera A, Siroski PA, Genetic, enzymatic and developmental alterations observed in Caiman latirostris exposed in ovo to pesticide formulations and mixtures in an experiment simulating environmental exposure, Ecotoxicology and Environmental Safety, Volume 74, Issue 4, 2011, Pages 852-859.



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Experts' consultation 5.24 Experts to discuss: - the relevance and reliability of the available studies (both regulatory and from literature) and assessed parameters for their use in the weight of evidence for endocrine disruption (ED) assessment; - the information that can be derived from the available studies based on: tested item, test system (including species, where necessary) study design and parameters assessed; - the weight of evidence for ED leading to the overall conclusion on whether the criteria as laid down in point 3.8.2 of Annex II to Regulation 1107/2009 are met. Please note that EFSA is of the opinion that the maximum tolerated concentration (MTC) should not be used to consider a paper as not relevant/reliable and this is in line with the assessment done for humans.	<i>Please refer to the Pesticide Peer Review TC 84 Mammalian toxicology – Ecotoxicology joint ED session (1-2 December 2022)</i>
Experts' consultation 5.25	<u>Applicant's approach</u>



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The experts should discuss the applicants updated biodiversity assessment. The exact points and structure of discussion will be decided in discussion with the RMS following their assessment of the submitted additional information.	Overall, the experts considered that the applicant's approach followed to assess the risk to biodiversity was inadequate and that the applicants could have: i) Performed an unbiased systematic data collection; ii) Considered higher tier studies to cover the links between the non-target organisms; iii) Attempted to perform an assessment using the proposed (by the applicants) operationalised specific protection goals for biodiversity; iv) Addressed the points of the additional data requested to the applicants after the public consultation. All experts agreed that a data gap will need to be identified in the EFSA conclusions to address the above points and therefore to address the data requested after the public consultation i.e. • The data collection should be done in a systematic manner and the information structured appropriately. This should be done considering the proceeding bullet points; • The direct effects on the target weeds (including the impact on the seed bank), non-target plants, non-target arthropods and bees should be quantified. Such quantification should consider the magnitude and duration of the impact in a spatial and temporal context. The quantification of the direct effects should then inform the extent of potential indirect effects via trophic interactions; • The assessment of biodiversity should be done to address all representative uses. Nevertheless, it may be more practical to focus the biodiversity assessment for a few representative scenarios (defined considering the GAP); • If proposed, specific mitigation should be linked to the representative uses. It is also suggested that the applicants demonstrate how both specific and general mitigation addresses the identified risks. Please note that only mitigation proposed by the applicants or the RMS can be considered as part of the assessment. <u>Relevance of peer-reviewed open literature to inform the biodiversity risk assessment</u> The experts agreed that: i) The relevance of the formulation is not critical for studies considering the indirect effects of weed removal (i.e., those studies where there is evidence that the indirect effect is driven by weed



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	removal which will depend on the test system). In this case all formulations are relevant; ii) For other studies (where weed removal is not the primary direct effect), relevance of the formulation should be aligned to the already agreed flow-chart, meaning that studies done with glyphosate, the formulation for representative uses or equivalent are considered relevant. Those done with polyoxyethylene tallow amine (POEA) are not relevant. Those with unknown formulation details are 'potentially relevant but insufficient information'. Those with known formulation details are 'less relevant but supplementary'; iii) Refer to expert consultation point 5.10 for the general discussion on the relevance of the formulations. Overall, the experts agreed that the relevance of the studies should be assessed relative to the uses under assessment (i.e., the Good Agricultural Practice (GAP)). It was agreed that the use in the study should resemble those in the GAP and those studies which were not performed in accordance, should be down-weighted in terms of relevance. It was suggested that the most appropriate manner would be to perform a structured weight of evidence (WoE) approach covering all the available information, and the data which are of low relevance would be weighted appropriately. Risk mitigation measures (RMM) The experts considered: i) The proposed RMM is likely to be beneficial. Whether it is sufficient on its own, however, will be context and landscape dependent; ii) The adequacy of the size limitation of the field (>15 ha) and threshold for 100% of the treated area has not been demonstrated; iii) The applicants did not specify the quality of the multi-functional field margin (MFFM) and the experts considered that it is likely to have an impact on its effectiveness; iv) The extent to which the MFFM, and its quality, mitigates the effects has not been quantified by the applicants; v) It is suggested that the above points are reflected in the data gap identified.



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	The experts discussed various approaches that could be done in the future to further enhance the assessment of indirect effects to biodiversity. Overall, in general the experts agreed with the proposals made by the EFSA Working Group regarding future activities related to the assessment of biodiversity in the context of prospective environmental risk assessment. Open point RMS to update the study evaluations regarding the revised relevance criteria for formulations and study conditions relative to the GAPs. Terrestrial vertebrates Overall, the expert agreed that the two relevance criteria previously agreed (see points i) and ii) under <i>Relevance of peer-reviewed open literature to inform the biodiversity risk assessment</i> above) would be sufficient for discriminating studies conducted under conditions that are clearly departing from the representative uses of glyphosate included in the GAP. These studies would be considered of low relevance and, while the evidence they present will be transparently reported, it will also be made clear that such evidence would be of low relevance for the present assessment in the context of glyphosate re-approval. As regards how review and meta-analysis papers should be considered for the biodiversity risk assessment, the experts agreed that: i) Reviews should not be included in the WoE tables; ii) However, they may be discussed in the general consideration of what information is available. The RMS can reflect that the underlying studies mentioned in the review were not available to them which emphasises the need for a proper systematic search of the literature as requested in the additional data request made to the applicants. Open points RMS to update the study evaluation for the terrestrial vertebrate studies to reflect the relevance assessment. The RMS is also requested to ensure that it is clear how the glyphosate treatments were made in the studies; i) The RMS may also consider updating their assessment of reliability of the studies to ensure that there is harmonisation in the approach



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	of the evaluation of the terrestrial vertebrates studies and the other groups of non-target organisms; ii) RMS to update their WoE assessment to incorporate the level of relevance for the information included; iii) All reviews should be removed from the WoE tables. The general reviews may be reflected in the general discussion or a second table. The reviews with glyphosate may also be acknowledged in the general discussion. <u>Aquatic organisms</u> Overall, the experts agreed with the RMS WoE assessment, however, the following additional points should be emphasised: i) No conclusion can be reached given the lack of systematic literature search; ii) Reviews should not be included in the WoE assessment; iii) The studies performed with formulations containing POEA should be reassessed for their relevance in line with the agreements made above; iv) In principle a Regulatory Acceptable Concentration based on Ecological Threshold Option (ETO RAC) covers indirect effects as indicated in the EFSA PPR Panel aquatic guidance¹⁰ with exception of some aspects (e.g., disruption of the biofilm, community shifts in microbes, direct effects on macrophytes via spray-drift, indirect effects driven by direct effects occurring outside of the water system) which are not currently covered by the guidance document. <u>Open points</u> RMS to update the RAR with the followings: i) RMS to reflect the discussions with regard to: - The impact on emerging aquatic macrophytes exposed via spray-drift and potential consequential indirect effects; - The direct effects on emerging aquatic macrophytes; - The additional points of consideration given in the additional data request for the applicants (e.g., considerations on impact on decomposition processes in aquatic systems and

¹⁰ EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290



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	fitness impairment, and thus reproduction impairment, due to lack of plant food (e.g. pollen and nectar) for many species of insects which have aquatic life stages as well); ii) No conclusion can be reached given the lack of systematic literature search; iii) Reviews should not be included in the WoE assessment; iv) The studies performed with formulations containing POEA should be reassessed for their relevance in line with the agreements made above; v) In principle an ETO RAC covers indirect effects as indicated in the EFSA PPR Panel aquatic guidance document (EFSA PPR Panel, 2013). For glyphosate, the risk assessment is based on Tier 1 which, by default, provides an ETO RAC. It was, however, questioned whether this is inclusive of all types of effects (e.g., disruption of the biofilm, community shifts in microbes, direct effects on macrophytes via spray-drift, indirect effects driven by direct effects occurring outside of the water system); vi) The RMS is also requested to consider the general open points made for the terrestrial vertebrates (where relevant). Bees Open points RMS to update the RAR: i) By considering the general open points made for the terrestrial vertebrates (where applicable); ii) By reflecting that the conclusions with respect to the field size and threshold for multifunctional field margins (MFFM) under 'risk mitigation measures', above, are also relevant for bee biodiversity; iii) To remove the data gap referred to the Laberge et al. (1995) publication.¹¹ Non-target arthropods (NTAs) The relevance status of the peer reviewed publications included in the biodiversity assessment should be revised based on the relevance criteria agreed upon for terrestrial vertebrates.

¹¹ Laberge L, Couture G, Legris J, Langevin R. 1995. Evaluation des impacts du glyphosate utilisé dans le milieu forestier. Ministère des Ressources naturelles Direction de l'environnement forestier Service du suivi environnemental.



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	Although no relevant publications addressing indirect effects on NTAs were provided by the applicants in the biodiversity assessment, when considering the representative uses of glyphosate, the monitoring study of Pleasants and Oberhauser (2013)¹² might provide some insights on the potential indirect effects of NTAs populations due to the loss of their host plants. However, the study presents several limitations and uncertainties that should not be disregarded. Open points RMS to update the RAR: i) By considering the general open points made for the terrestrial vertebrates (where applicable); ii) By revising the relevance of the publications used for the biodiversity assessment and reporting all strengths and limitations of the study by Pleasants and Oberhauser (2013). Soil organisms The available evidence in Dennis et al. (2018)¹³ would also be informative for soil microorganisms. Based on the agreed updated criteria (see 'Relevance of peer-reviewed open literature to inform the biodiversity risk assessment', above), the relevance assessment should be revised accordingly (relevant for all studies considered). Open points RMS to update the RAR: i) The relevance classification of the studies should be revised according to the general agreement (see 'Relevance of peer-reviewed open literature to inform the biodiversity risk assessment', above); ii) To reflect that Dennis et al. (2018) might also be considered relevant for soil microorganisms.

¹² Pleasants JM and Oberhauser KS, 2013. Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population. *Insect Conservation and Diversity*, 6: 135-144. <https://doi.org/10.1111/j.1752-4598.2012.00196.x>

¹³ Dennis PG, Kukulies T, Forstner C. et al., 2018. The effects of glyphosate, glufosinate, paraquat and paraquat-diquat on soil microbial activity and bacterial, archaeal and nematode diversity. *Scientific Reports*, 8: 2119. <https://doi.org/10.1038/s41598-018-20589-6>



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	Non-target terrestrial plants (NTTPs) <u>The experts agreed to revise the relevance of the studies considered for the biodiversity assessment of NTTPs (unanimous agreement).</u> Open points i) <u>RMS to update the RAR appendix on biodiversity (Vol. 3 B.9-CP) by including all relevant studies on NTTPs;</u> ii) <u>The relevance classification of the NTTP studies should be revised according to the general agreement (see 'Relevance of peer-reviewed open literature to inform the biodiversity risk assessment', above);</u> iii) RMS to better clarify the classification of Boutin et al. (2014)¹⁴ in a revised RAR; iv) RMS to revise the study evaluation of Damgaard et al. (2014)¹⁵ and its relevance assessment; v) RMS to revise the relevance assessment of Strandberg et al. (2012¹⁶ and 2021¹⁷) considering that it was confirmed that they used the formulation for representative uses. <u>Uses where less than 50% of the surface is treated (i.e., including band and spot applications) and railway uses</u> The experts agreed that uses where less than 50% of the surface is treated (i.e., including band and spot applications) and railway uses might be needed for safety and phytosanitary reasons. For such uses, a risk-benefit analysis should be considered by risk managers. Open points RMS to ensure that the additional points on the biodiversity assessment for uses where the treated area is less than 50% and railway uses are reflected in the RAR, e.g.: i) The effectiveness in terms of exposure reduction of the uses, such as spot treatments or strip applications, where the treated area is

¹⁴ Boutin C. et al., 2014. Herbicide impact on non-target plant reproduction: What are the toxicological and ecological implications? Environmental Pollution, 185: 295-306.

¹⁵ Damgaard C, Strandberg B, Mathiassen SK and Kudsk P, 2014. The effect of glyphosate on the growth and competitive effect of perennial grass species in semi-natural grasslands. Journal of Environmental Science and Health, Part B, 49(12): 897-908. DOI: 10.1080/03601234.2014.951571

¹⁶ Strandberg, B. et al., 2012. Effects of herbicides on non-target plants: How do effects in standard plant test relate to effects in natural habitats? Danish EPA, Pesticide Research, 137: 1-115.

¹⁷ Strandberg B. et al., 2021. Effects of glyphosate spray-drift on plant flowering. Environmental Pollution, 280: 116953



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	less than 50%, was not demonstrated (see discussion point on birds & mammals under 5.7); ii) The effectiveness of unsprayed strips to reduce potential risk to biodiversity in band application situations is questionable and would depend on the quality of those strips. Considering that the strips are managed, they cannot be considered equivalent to MFFM; The treatment of less than 50% of the area (i.e., including band and spot applications) and railway uses was not considered <i>per se</i> sufficient to exclude effects on biodiversity.
New experts' consultation point 5.26 proposed by EFSA for completeness of discussion (October 2022): Experts to consider some potentially relevant newly available publications arisen after the public consultation/ reporting table stage. EFSA identified a number of publications that might be considered potentially relevant and therefore it was agreed to share these selected studies with MSs to allow a peer review and further consideration in the expert meetings. In particular, MS experts are asked to share their views whether these potentially relevant articles might be considered more critical or may alter the weight of evidence in the current assessment and to determine	Systematic literature searches The literature searches performed by the applicants were generally in line with the EFSA (2011) guidance (EFSA Journal 2011;9(2):2092). However, it was noted that several peer-reviewed publications identified after the public consultation, and which were seemingly published within the timeframe covered by the literature search (January 2010 - June 2020), were not originally captured by the applicant's literature searches. Therefore, there were some concerns about the sensitivity of the searches. These concerns had not been addressed by the applicants following a data requirement after the public consultation. During the discussions on the individual topics (individual non-target organisms, ED assessment), it was discussed and agreed that the RMS will reassess the relevance and reliability of all the available studies from the scientific literature considering the agreement reached under experts' consultation points 5.10 and 5.12. For the assessment on biodiversity and the assessment on microbiome, some specific considerations were agreed; those agreements are included under experts' consultation point 5.25 and expert consultation point 5.1 identified following comments by public. These agreements and considerations are equally relevant for studies captured by the literature search conducted by the applicants, studies highlighted during the public consultation on the RAR and for newly available papers identified subsequently. Open point RMS to further reflect on the sensitivity of the literature search performed by the applicants for the EU assessment, in light of the



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if any eventual follow up would be needed.	presence of relevant studies not having been captured by the literature searches. <u>Newly available publications identified up to the expert consultations</u> Formally, in line with the legislation, there is no legal obligation to consider newly available data submitted outside of the dedicated public and targeted consultations or after the deadline of the window for providing the additional information within the clock stop period, unless they constitute adverse data (cf Article 56 of Regulation (EC) No 1107/2009 regarding information on potentially harmful or unacceptable effects). For this reason, although a systematic review of the literature has not been carried out by EFSA or the RMS, EFSA has identified newly available papers on glyphosate even outside of the legal requirements and collected a list of studies as a result. For the discussion related to the only study found as potentially relevant for the risk assessment for aquatic organisms (Tartu et al. 2022), please refer to expert consultation point 5.11. For the discussion related to the studies identified as potentially relevant for the assessment on the potential effect on microbiome/microbiota in relation to non-target organisms (Ruuskanen et al. 2022; Almasri et al. 2022; Motta and Moran, 2022), please refer to expert consultation point 5.1 identified following comments by public. For the ED assessment for non-target organisms, the only relevant study identified in the above exercise for the assessment of the endocrine disrupting properties of glyphosate is Verderame <i>et al.</i>, (2022). See open point under expert consultation point 5.24 It was acknowledged that there were publications identified at a later timepoint which were not discussed by the experts. The following publications were brought to the attention of the experts for further consideration: Ames et al. (2022) and Wathsala et al. (2022). Open points - RMS to ensure that all relevant publications identified up to the expert consultations are included in the RAR.



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	- RMS to consider and, if needed, to include in the RAR the publications by Ames et al. (2022) and Wathsala et al. (2022) identified additionally. Cited references Almasri et al., 2022. Mild chronic exposure to pesticides alters physiological markers of honey bee health without perturbing the core gut microbiota. <i>Scientific Reports</i>, 12(1):4281; Ames J, Miragem AA, Cordeiro MF, Cerezer FO, Loro VL, 2022 Effects of glyphosate on zebrafish: a systematic review and meta-analysis. <i>Ecotoxicology</i>, 31(8):1189-1204. doi: 10.1007/s10646-022-02581-z Motta EVS, Powell JE and Moran NA, 2022. Glyphosate induces immune dysregulation in honey bees. <i>anim microbiome</i> 4: 16. https://doi.org/10.1186/s42523-022-00165-0 Ruuskanen S, Fuchs B, Nissinen R, Puigbò P, Rainio M, Saikkonen K, Helander M, 2022. Ecosystem consequences of herbicides: the role of microbiome. <i>Trends Ecol Evol.</i>, 13:S0169-5347(22)00229-4. doi: 10.1016/j.tree.2022.09.009. Epub ahead of print. PMID: 36243622; Tartu S, Renoirt M, Cheron M, Gisselmann L-L, Catoire S and Brischoux F, 2022. Did decades of glyphosate use have selected for resistant amphibians in agricultural habitats? <i>Environ Pollut</i>, 310:119823. doi: 10.1016/j.envpol.2022.119823 Verderame M, Chianese T, Rosati, L, Scudiero R, 2022. Molecular and Histological Effects of Glyphosate on Testicular Tissue of the Lizard <i>Podarcis siculus</i>. <i>International Journal of Molecular Sciences</i>, 23(9), 4850 Wathsala RHGR, Folgueras EC, Iuffrida L, Candela M, Gotti R, Fiori J, et al., 2022. Glyphosate and its breakdown product AMPA elicit cytoprotective responses in haemocytes of the Mediterranean mussel (<i>Mytilus galloprovincialis</i>). <i>Environmental Toxicology and Pharmacology</i> 2022 Vol. 96 Pages 103997. DOI: https://doi.org/10.1016/j.etap.2022.103997
Experts' consultation 5.1 identified following comments by public Experts to consider the evidence provided on effects on microbiota and microbiomes in relation to non-target organisms.	For the current peer review process, studies were identified (both submitted via literature search and during the consultation phases) on the potential effects of glyphosate, and its formulation, on the microbiome of non-target organisms. Studies on microbial communities were provided for animals, plants and soil. The relevance and reliability criteria used for assessing the literature provided during the consultation phase were discussed in the context of the current assessment for glyphosate. It was agreed that the relevance evaluation should be consistent with the scheme used for other areas of the current assessment (see expert consultation point 5.10). Specific



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See also expert consultation identified in the mammalian toxicology section for effect on microbiota and impact on animal health (mainly livestock).	reliability criteria to address the unstandardised methodologies across the provided literature studies were identified and agreed. It was recognised that no regulatory endpoint could be derived from any of the microbiome studies identified for the current glyphosate assessment, and no known link is possible between the potential effects on microbiome and the protection goals for non-target organisms. The impact of glyphosate on the microbiome was also discussed in the mammalian toxicology expert meeting TC 80 (expert consultation point 2.30). Open points - RMS to revise in the updated RAR the relevance and reliability status of studies on microbiome considering the agreed criteria; - RMS to include in the assessment the three publications on microbiome identified by EFSA additionally: • Ruuskanen S, Fuchs B, Nissinen R, Puigbò P, Rainio M, Saikkonen K, Helander M. Ecosystem consequences of herbicides: the role of microbiome. Trends Ecol Evol. 2022 Oct 13:S0169-5347(22)00229-4. doi: 10.1016/j.tree.2022.09.009. Epub ahead of print. PMID: 36243622 • Almasri, H., Liberti, J., Brunet, JL. et al. Mild chronic exposure to pesticides alters physiological markers of honey bee health without perturbing the core gut microbiota. Sci Rep 12, 4281 (2022). https://doi.org/10.1038/s41598-022-08009-2 • Motta, E.V.S., Powell, J.E. & Moran, N.A. Glyphosate induces immune dysregulation in honey bees. Animal microbiome 4, 16 (2022). https://doi.org/10.1186/s42523-022-00165-0 - EFSA to report in the EFSA Conclusion for glyphosate in a narrative way the outcome of those studies categorised as relevant and reliable/reliable with restrictions.
Experts' consultation 5.2 identified following comments by public	'MON 0139' is the actual salt form that is present in the formulation for representative uses. This salt form was used for the chronic studies on honey bees (adult and larva) and for the available non-<i>Apis</i> studies (only acute), therefore those studies are representative for the active substance. All available dossier studies with the active substance and



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Experts to discuss and agree on the use of the studies for bees where the test item was neither the active substance nor the formulation for representative uses 'MON 52276'.	the formulation for representative uses indicate low toxicity towards bees with no indication of higher toxicity of the formulation for representative uses. Moreover, chronic exposure to the formulation as such is unlikely. The experts at the meeting agreed that no further data are needed; the effects are well represented by the existing data. Nevertheless, during the discussions some information in the RAR was identified as potentially erroneous; therefore, the following open point for corrections was identified: Open point RMS to correct the reference for the EFSA Technical Report¹⁸ and reflect in the revised RAR that the conclusion in this report for bumble bees and solitary bees is in relation to the tier-1 risk assessment of EFSA, 2013¹⁹.

¹⁸ DOI: <https://doi.org/10.2903/sp.efsa.2015.EN-924>

¹⁹ EFSA (European Food Safety Authority), 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295



REPORT OF PESTICIDE PEER REVIEW TC 91

METALAXYL-M – Amendment of approval conditions

Rapporteur Member State: BE

5. Ecotoxicology

Date: 22 September 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health, Food Chain Safety and Environment	BE
Federal Environmental Agency (UBA)	DE
Benaki Phytopathological Institute	GR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Hearing expert	CH

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

Please note that information part of this report may have been masked by EFSA in accordance with Article 63 of Regulation (EC) No 1107/2009 as well as EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009, or EFSA's Practical Arrangements concerning transparency and confidentiality as a consequence of confidentiality requests submitted by the applicant on application dossiers for pesticides active substances or Maximum Residue Levels, respectively. Please note that information disclosed in this report is without prejudice to pre-existing intellectual property rights and data exclusivity clauses set out in Union law, and particularly in Article 62 of Regulation (EC) No 1107/2009.

Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the reproductive toxicity of metalaxyl-M for birds and to derive the most appropriate endpoint for use in the long-term risk assessment. The following information should be considered: i) Reproductive toxicity to the bobwhite quail (IIA 8.1.3/01). ii) Reproductive toxicity to the mallard duck (IIA 8.1.3/02). iii) Reproductive toxicity to the bobwhite quail (IIA 8.1.3/03). This should include consideration of the historical control data for the reproductive toxicity (hatchling survivorship) to the bobwhite quail (including further information requested under data requirement 5(2)).	- Bobwhite quail (metalaxyl, IIA 8.1.3/01) Considering the biological relevance and significance of the reduction of the ratio of 14-day old survivors of hatchlings reared (10%) at 900 mg/kg feed, the endpoint (NOEC) was set at 300 mg/kg feed. Experts acknowledged the shortcomings of the study (i.e., use of metalaxyl in place of metalaxyl-m, shortened egg collection phase, not detailed report) - Mallard duck (metalaxyl, IIA 8.1.3/02) The endpoint was proposed to be 300 mg metalaxyl/kg feed, based on several effects at 900 mg metalaxyl/kg feed (eggshell thickness, chick BW, live 3-week embryos). Experts acknowledged the shortcomings of the study (i.e., use of metalaxyl in place of metalaxyl-m, shortened egg collection phase, age of birds) - Bobwhite quail (metalaxyl-m, IIA 8.1.3/03) Concerns were raised about the control performance in this study, which the applicant attempted to address by submitting historical control data (HCD). Concerns were raised that the newly submitted HCD assessment was considered to be insufficient to address the concern, despite some experts noting that the HCD data may confirm the control performed close to other controls in the same lab at a similar time. Based on the available evidence, the meeting could not conclude that the control performed sufficiently well, noting that the 4 studies in the HCD set provided by the applicant were of the lower end of the performance criteria in the OECD TG. The majority of the experts agreed that, owing to the poor performance of the control, a reliable endpoint cannot be obtained



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iv) Reproductive toxicity to the mallard duck (IIA 8.1.3/04). Please also refer to the conclusion of the Pesticides Peer Review Meeting 119 (23 – 25 September 2014 – Experts' consultation 5.1).	from this study. Some supportive evidence may be obtained from the study, considering endpoints such as eggshell thickness. Mallard duck (metalaxyl-m, IIA 8.1.3/04) It was agreed that the endpoint (NOEC) from this study was 300 mg/kg feed considering the biological relevance of the differences between the control and the treatment at 900 mg a.s./kg feed for several reproductive parameters. This study was considered more relevant, considering the test item was metalaxyl-m and the overall study quality was considered higher than IIA 8.1.3/01 and 02 The meeting agreed that the endpoint from the mallard duck study (metalaxyl-m, IIA 8.1.3/04) should be used in Risk assessment. Open points - RMS to include additional details of the long-term study with the bobwhite quail IIA 8.1.3/01 and its assessment in the RAR, reporting on the outcome of the meeting discussion (including the endpoint selection). The LoEP should be amended accordingly. - RMS to include additional details on the evaluation of the long-term study with the bobwhite quail IIA 8.1.3/03, reporting on the outcome of the meeting discussion (including the endpoint selection). Specifically, by acknowledging that owing to the poor performance of the control, a reliable endpoint cannot be obtained from this study. Similarly, RMS to reflect that the majority of endpoints obtained from the reproductive toxicity study on the bobwhite quail were not reliable. Some supportive evidence may be obtained from the study, considering endpoints such as eggshell thickness. The LoEP should be amended accordingly. - RMS to include additional details on the evaluation of the long-term study with the mallard duck IIA 8.1.3/04, reporting on the outcome of the meeting discussion (including the endpoint selection). RMS to recalculate the NOEL from this study, considering the biologically relevant effects observed at 900 mg a.s./kg feed, and to present the calculation in a revised RAR. The LoEP should be amended accordingly. - For all long-term studies, RMS to include all the calculations to NOEL in the RAR and to update the LoEP accordingly. - RMS to update the risk assessment and LoEP using the endpoint from the study on reproductive toxicity on the mallard duck (42 mg a.s./kg bw per day to be confirmed).



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Experts' consultation 5.2 Experts to discuss the refined risk assessment for birds (acute and long-term): - The bird focal species selection for risk assessment for the sunflower and spinach uses. - PD refinement for the acute and long-term risk assessment for birds consuming spinach and sunflower seeds. - The proposed residue refinement for the long-term RA of birds consuming seeds, including consideration of the i) modelling details for DT50 derivation; ii) ftwa averaging period; iii) extrapolation across crops, iv) geographical representativeness of the available data; v) use of unprotected seeds for residue investigations. - The proposed residue refinement for the long-term RA of birds consuming seedlings (residue refinement). - The weight of evidence for the acute and chronic RA, including i) the number of treated seeds required to reach LD50 and the foraging	a. <u>Acute risk to small granivorous birds in sunflower</u> Focal species Based on the available data the RMS selected the following focal species: - magpie, carrion crow, red-legged partridge, wood pigeon, ciril bunting and crested lark. The meeting considered the focal species reasonable for Southern Zone areas but it was a major uncertainty as to whether these focal species also cover the central zone. FIR/bw refinement The applicant proposed to refine the energy content of sunflower seeds which is used to refine the FIR. The experts agreed that the energy content and moisture content could be refined in principle, however, the values presented in the RAR could not be relied upon (had not been demonstrated to be done in an unbiased manner). Overall, the experts agreed that the values for moisture and energy content are not reliable on the basis of what is presented. PD the PD refinement proposed by the applicant was based on the following studies - Study in freshly drilled sunflower fields in Spain: - Diet composition of ciril bunting and crested lark, faeces samples - Published literature investigating wildlife mortalities following imidacloprid use Based on the available information, for the crested lark, the PD values were considered suitable for a WoE consideration pending on the considering the foraging area required to reach the LD50/10. The experts did not accept the refinement of PD = 0 for the ciril bunting as either the site selection was not suitable, or it questions the appropriateness of the ciril bunting as a focal species. WoE - Number of treated seeds required to reach toxicity - Foraging area required to reach toxicity - De-husking - Avoidance - PD values in a qualitative manner



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area approach (including consideration of the seed weight and types of sowing machinery); ii) the avoidance of treated seeds; iii) de-husking; iv) the assumption that seeds may be dug-up by birds - The refined FIR/bw.	It was acknowledged that the data used to consider the number of seeds on the soil surface seemed to be worse case (10 per m2) relative to the sowing rate given in the GAP table (i.e., only 8 seeds per m2). However, some of the species needed small areas to reach the LD50/10. Overall, a low acute risk to the selected focal species was not demonstrated considering the available lines of evidence Open points RMS to update the acute risk assessment for granivorous birds in sunflower. The updated assessment should consider the following: - The uncertainties regarding the selection of the focal species and their relevance to areas where sunflowers are grown in central EU. - The fact that the proposed refine energy content and moisture content were not supported by data collected in an unbiased manner and therefore they are only considered as illustrative. The quantitative risk assessment should be recalculated using the default values for crops seeds as given in EFSA (2009). The RMS may also keep the refined assessment using the proposed values in the RAR but clearly indicating that the assessment is included for purely illustrative purposes - The PD values for the ciril bunting were not considered reliable - The PD values for the crested lark could only be considered in a WoE for the acute RA - The foraging area refinements alone were not considered sufficient to exclude a high risk. - The arguments regarding de-husking and avoidance did not bring evidence to suggest a low acute risk. b. Acute risk spinach seeds – small granivorous birds Focal species Information has been submitted by the applicant and accepted by the RMS. This information was related to freshly drilled fields with spinach and onion: - spinach and onion in UK - onion in NL Based on the available evidence, a refinement of focal spp for was proposed based on the following species: - CEU: rook, wood pigeon, red-legged partridge and skylark.



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	- No focal species could be identified for NEU and it was further noted that the extrapolation of onion to spinach is not straightforward. In addition, the only available study with spinach was conducted in UK (CEU); thus, it shall not be used for refinement in the NEU. - Overall, experts agreed on the focal species selection for SEU; however, the available evidence did not allow to exclude small granivorous birds as focal species for CEU. In addition, there was agreement - rook, wood pigeon, red-legged partridge and skylark can be used as large focal species for the CEU. FIR/bw refinement The experts agreed with the FIR/bw refinement as proposed by the RMS (i.e., to consider the worst-case energy and moisture content value proposed by EFSA (2009) or both cereals and weed seeds). PD refinement CEU The data supporting the PD refinement were presented. Following the written procedure of the peer-review, further information on the quantitative refinement were presented. The diet of skylarks was determined by faecal analysis based on a study conducted in 3 arable farmland areas in UK, where dominating crops were cereals and sugar beet. The study showed the proportion of the main food items in the diet of skylarks per month divided in 6 categories: invertebrates, grass flowers and seeds, cereal grain, dicotyledonous weed seeds, monocotyledonous leaves and dicotyledonous leaves. It was highlighted that the refinement based on PD/PT are generally unacceptable for in the acute risk assessment for granivorous birds. Therefore, consistent with the use in sunflower, the quantitative use of the PD in the acute risk assessment for granivorous birds was considered unacceptable. The PD values were considered suitable for a WoE consideration pending on the additional lines of evidence. WoE - Number of treated seeds required to reach toxicity - Foraging area required to reach toxicity - Avoidance based on laboratory trials Avoidance was not considered to provide sufficient evidence of low risk, because of the uncertainties related to the extrapolation to wild species under field conditions. The number of seeds needed to reach the LD₅₀/10 was calculated for spinach seeds in analogy to what was done for sunflower. The



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	foraging area approach was presented by the RMS. Experts considered that for small granivorous birds, the margin of safety for reaching LD₅₀/10 was considered very limited. Experts noted that the foraging area approach presented in the RAR assumed precision drilling. Overall, experts considered that consideration of the calculation provided on the number of treated seeds required to reach the LD50 or LD50/10 was not sufficient to conclude low risk. Concerning the foraging area approach, uncertainties were highlighted related to the assumption of precision drilling in the calculations (i.e., its representativeness across EU and the potential for seasonal variation in the availability of seeds on the soil surface). Consideration of the PD for skylark would likely not influence this conclusion. Open points: Focal species selection: RMS to update the risk assessment for small granivorous birds considering that for the uses in spinach and the acute risk assessment of granivorous birds: - A relevant focal species for NEU was not selected. - The focal species selection for SEU (linnet, greenfinch and crested lark) was agreed by the meeting. - The available weight of evidence did not allow to exclude small granivorous birds as focal species for CEU. - There was agreement that rook, wood pigeon, red-legged partridge and skylark can be used as large(r) focal species for the CEU. PD: RMS to reflect that the proposed PD refinement for CEU was only deemed suitable for WoE consideration pending on the additional lines of evidence. WoE: The RMS is requested to update the WoE by providing calculations of the foraging area to reach toxicity assuming both precision and standard drilling techniques. Additionally, RMS to acknowledge the meeting conclusions: - when precision drilling is assumed, the risk for linnet was considered high - Assuming standard drilling, the meeting considered unlikely that foraging area approach would be considered sufficient to conclude low acute risk for any of the focal spp.



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	Consideration of the PD for skylark would likely not influence this conclusion. - Assumption of avoidance by birds was insufficient to conclude low risk, considering the uncertainties related to the extrapolation to wild species under field conditions. c. <u>Long-term risk to granivorous birds small in sunflower (seeds)</u> Residue (relevant for both uses) The residue decline studies were presented by the RMS: Maize: 3 sites in UK, early, mid-season, late sowing of crop TREC tool calculating 21-d ftwa values, geomean=0.149 Spinach: 4 trials in PL, DE and northern FR, 4 trials in ES and northern PT, TREC tool calculating 21-d ftwa values, geomean=0.384 Oilseed rape: 4 trials in DE, TREC tool calculating 21-d ftwa values, geomean=0.102 Based on these studies the RMS agreed on the following: ftwa of 0.218 (geomean from all field studies for the refinement of sunflower, calculated by TREC tool). ftwa = 0.384 (geomean from all spinach field studies) The representativeness of the dataset to the NEU was questioned since only data were from CEU and SEU were submitted. Maize: several uncertainties were identified: - Meteorological information - Independence of the trial locations - Use of surrogate crop - Use of different formulation - The use of residue information for unprotected seeds Overall, experts considered that, due to the drawbacks and uncertainties identified above, the study shall not be used for risk assessment. OSR: the following uncertainties were identified: - Use of a different formulation - Independence of the trial location - Different seed loading than in GAP - Use of surrogate crop



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	- Meteorological data - The statistical fit of some of the trials Overall, experts considered that, due to the drawbacks and uncertainties identified above, the study shall not be used for risk assessment. Spinach: - The sites were generally considered independent - The seed loading was not entirely compliant with the GAP - A different formulation was used - For two trials uncertainties related to the meteorological conditions were identified Overall, experts agreed: - to discard the maize and OSR studies and the trial in PT where rain might have influenced the dissipation of the active ingredient; - not to extrapolate from spinach seed to sunflower seed (considering the uncertainties of the spinach dataset and the morphological difference of the 2 seeds types). - for spinach not to pool the DT₅₀ data from CEU and SEU; - to consider the dataset relevant for the residue refinement of spinach seeds. - For spinach the ftwa should be based on the geomean DT₅₀ for the CEU and the maximum value for the SEU, considering the lower number of valid trials in the South. Focal species and FIR/BW See discussion above PD The RMS presented the proposed PD refinement for magpie, crested lark and ciril bunting. - Magpie: considering the uncertainties (the lack of confirmation on the relative presence of sunflower in the landscape; the lack of transparency related to the PD calculation; it was unclear if the study observation period was the same as the sowing period of sunflower), the PD refinement for magpie was only considered suitable for qualitative consideration in a WoE. - Ciril bunting and crested lark: - the geographical representativeness of the study for the CEU was questioned



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Subject	Conclusions Pesticide Peer Review Meeting
	- The relevance of smaller granivorous species such as goldfinch and red-legged partridge could not be dismissed - Another study investigating the diet of skylarks on freshly drilled spring cereal fields in Germany was considered suitable for WoE consideration/experts' judgement), suggesting that a PD=1 would be worst-case. WoE: De-husking and avoidance did not provide sufficient evidence of a low risk, because of the uncertainties such as the extrapolation to wild species under field conditions. Open points. Residues: the RMS is requested to: - update the assessment of the residue decline data in the RAR by taking into consideration EFSA (2019, Supporting publication 2019:EN-167) and the outcome of the meeting discussion - to clarify in a revised RAR the use of the data in RA, considering the outcome of the meeting discussion: i.e., i) that no acceptable refinement is possible based on the maize study in UK (2012) and the oilseed rape study in DE (2016) (i.e., to update the RA for sunflower accordingly); ii) that trial RPR20-087-037FR should be excluded from the DT₅₀ calculation for spinach. That the DT₅₀ dataset from CEU and SEU in spinach should not be pooled (i.e., the maximum spinach seed DT₅₀ value should be used for SEU and the geomean should be used for CEU). Therefore, the residue refinement for spinach seeds should be updated accordingly. The RAR should be updated by clearly identifying the graphs and statistics for each residue trials in spinach that will be considered for the DT₅₀. Please, RMS to include information on the occurrence of rainfall across trials and to transparently assess the geographical representativeness and independence of the trial locations. In Table B.9.1.9.4.11, please RMS to report the DT₅₀ in addition to the 21-ftwa calculation. - RMS to reflect in a revised RAR that based on the available evidence, it can't be excluded that seeds below the soil surface would not be consumed by birds. - RMS to reflect that the available refinements (including those on residue decline) do not cover NEU.



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Subject	Conclusions Pesticide Peer Review Meeting
	FIR / bw: concerning the refinement based on focal species and energy content of seed, RMS to align the long-term risk assessment with the conclusions drawn for the acute. PD: RMS to update the risk assessment in the revised RAR by deleting the quantitative PD refinement for magpie and to include qualitative consideration of the PD refinement in a WoE. RMS to update the risk assessment by considering the following: - The PD value of 0 for ciril bunting was not accepted (see acute RA for further details). - the PD value of 0.2 for crested lark could be suitable for long-term risk assessment for the spinach uses in SEU. However, the PD refinement for this species for the CEU was dismissed due to the lack of geographical representativeness of the data. The study investigating the diet of skylarks on freshly drilled spring cereal fields in Germany (2014) might be useful for a qualitative consideration of the PD in CEY (i.e., based on experts' judgement in a WoE). WoE: RMS to reflect in a revised RAR that the available lines of evidence was insufficient to demonstrate low long-term risk for granivorous birds foraging on treated sunflower seeds. d. <u>Long-term risk to birds consuming sunflower seedlings</u> Residue (relevant for both uses) they submitted residue decline study in protected conditions and a justification for the use of these data (which lacked measurements in seed/seed cap and root), stating that metalaxyl-m is not phloem mobile, not present in roots. This justification was accompanied by a study measuring radiolabelled residues in seeds and soil matrixes. All the experts agreed that that the roots and seed casing should have been assessed in the residue study (i.e., that the justification of the applicant was not sufficiently substantiated by the available data and was insufficient to dismiss the consumption of contaminated plant parts below ground). For this reason, the experts disagreed with the quantitative use of the proposed residue refinement. Focal species: Based on literature data RMS considered that the risk from consumption of treated seedlings needed additional refinement for the focal species wood pigeon and magpie.



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Subject	Conclusions Pesticide Peer Review Meeting
	The experts agreed that the proposed specific focal species are in principle reasonable- However, the available data did not allow demonstrating that that they are sufficiently worst-case to cover all bird species potentially consuming germinating seedlings. Overall, the meeting dismissed the focal species selection. Open points, the RMS is requested to: i) RMS to update the RAR (including the LoEP) by deleting the higher tier residue refinement in seedlings, acknowledging the reasons why the meeting disagreed with their use (i.e., lack of measurements in roots, seed and seed casing). RMS to update the evaluation of studies investigating the residue decline in shoots by reflecting the meeting conclusion (i.e., that the lack of measurement in seed, seed casing and root is a major source of uncertainty) ii) update the risk assessment for the larger herbivorous species using default Tier 1 assumptions. iii) concerning the proposed focal species selection, the RMS should reflect in a revised RAR that smaller omnivorous species were not considered addressed e. <u>Long-term risk to small granivorous birds in spinach (seeds)</u> Residue See discussion point above Focal species See acute RA Refined FIR / bw CEU and SEU See acute RA PD refinement CEU The data were the same as for the acute RA. However, the meeting considered necessary to review the use of PD in the long term risk assessment. Data were on cereals, which were expected to be more attractive than spinach seeds. The experts considered that the PD values were reasonable for the refined risk assessment for the skylark in the CEU.



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Subject	Conclusions Pesticide Peer Review Meeting
	Overall, the experts confirmed that the proposed PD refinement for skylark was acceptable for use in the long-term risk assessment of birds consuming spinach seeds in CEU. However, they acknowledged that smaller granivorous species, which were not addressed by the focal species studies, will not be covered by this refinement. PT refinement SEU The refinement was based on a study investigating the PT for greenfinch, linnet and crested lark in freshly drilled spinach fields in ES. It was noted that the study was an interim report albeit a detailed version including the results. Therefore, a formal data gap will need to be identified for the final report. The PT refinement was not questioned by the meeting WoE: - Number of treated seeds required to reach toxicity - Foraging area required to reach toxicity - Avoidance based on laboratory trials The experts agreed that the WoE approach was not sufficient to exclude a high long-term risk to birds consuming treated spinach seeds. The risk assessments presented by the applicant assume precision drilling and therefore the RMS should reflect that the risk would be even greater in the case if seeds were not precision-drilled (sometimes known as standard drilling). Open point PD: RMS to update the long-term risk assessment for birds consuming spinach seeds in CEU considering the following: i) small granivorous bird species were not addressed by the focal species studies and are therefore not addressed by the PD refinement ii) The PD refinement for the skylark in CEU was considered acceptable. However, the TERIt calculation in the RAR/LoEP will need to be updated considering the newly agreed long-term endpoint and decision concerning the residue refinement. PT:



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Subject	Conclusions Pesticide Peer Review Meeting
	- EFSA to reflect that the conclusion has been reached on the basis of an interim report and also to identify a (formal) data gap for the final report. - RMS: The PT refinement was not questioned by the meeting. RMS to reflect the uncertainty related to the lack of information on the drilling method used in the PT study. WoE: - RMS to update the RAR ensuring that all the calculations done using the NOEL value are updated which include those presented for the 'number of seeds to reach the NOEL/5' and foraging area. Since the outcome of the Tier 1 risk assessment for the lower and medium seed loading will no longer result in a low risk. Therefore, the RMS may also provide calculations for the 'number of seeds to reach the NOEL/5' and foraging area for the lower seed loadings in the GAP. f. <u>Long-term risk assessment for birds consuming spinach seedlings</u> Residue See discussion above on residue in seedlings Open point RMS to update the risk assessment for birds consuming germinating seedlings, reflecting that the measured residues values were not acceptable. The RMS may want to clarify in the uncertainty analysis that the assumption of a fTWA = 1 was considered a worse case and, in reality, there will be a reduction in the residues as the plant grows resulting in dilution (this can also be mentioned for sunflower). g. <u>Metabolites (relevant for birds and wild mammals)</u> It was questioned whether the information in the RAR was sufficient to exclude a risk from plant metabolites in the palatable growth stage. It was noted that in the EFSA (2015) Conclusion a data gap was identified but it was not clear whether the applicant has provided information to address this data gap. The RMS confirmed that no new information was available. Experts noted that the information available seemed to suggest that the risk to metabolites was not of great concern. Nevertheless, a



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Subject	Conclusions Pesticide Peer Review Meeting
	robust assessment (considering the residue and metabolism studies and the human toxicology dataset) needs to be presented to cover all of the relevant metabolites. Open point: RMS to present a more detailed risk assessment of metabolites in the B.9 Section of the RAR considering the residue and metabolism studies and the data presented in the human tox section. The RMS is asked to check whether all plant metabolites occurring at >10% are addressed by the available toxicological data. An assessment from plant metabolites should be done for both wild mammals and birds. General open point: The RMS is requested to reflect in a revised RAR that the proposed refinements of the risk assessment for birds and mammals were not considered by the meeting to cover the Northern EU Zone.
Experts' consultation 5.3 Experts to discuss the refined risk assessment (Acute and long-term) for mammals. Particularly the following refinements might require further discussion and agreement: - The focal species selection for risk assessment for the sunflower and spinach uses. - PD refinement for the acute and long-term risk assessment for mammals consuming spinach and sunflower seeds. -The refined FIR/bw. - The proposed residue refinement for the long-term	a. <u>acute RA for wild mammals consuming sunflower seeds</u> Focal species (relevant for both uses): The RMS and previous assessment used the wood mouse as a focal species. Concern was raised during the commenting phase and therefore the applicant submitted 2 new field studies in spinach fields. Based on the newly submitted studies the focal species was a wood mouse (CEU) and Algerian mouse (SEU). The RMS considered that extrapolation from spinach fields to sunflower seeds was reasonable but acknowledged that the attractiveness of the drilled seed itself was not accounted for. Overall, the experts agreed that the wood mouse was a suitable focal species for sunflower in CEU. Additionally, the experts agreed that the data and assessment identified the Algerian mouse as a suitable focal species for granivorous mammals in SEU in sunflowers. The experts noted that they would prefer to have a field study to confirm the focal species in both crops, but accepted the proposed crop extrapolation based on experts' judgement. PD refinement (relevant for the acute and reproductive risk assessment) the diet of wood mouse was investigated in three studies. The following concerns were raised:



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Subject	Conclusions Pesticide Peer Review Meeting
RA of birds consuming seedlings. - The weight of evidence, including: - o De-husking. - o PT.	- o suitability of the studies for the assessment. Specifically, the meeting commented on the age of the study; the timing relative to the GAP; the way the data were extracted. - o based on arable farmland in general - o it is not clear whether the wood mice which were caught were living close to freshly sown sunflower/spinach fields or freshly sown cereal seeds (as a surrogate for the crops under assessment). It was agreed that the data were not suitable for a quantitative PD refinement for wood mouse in sunflower. However, the experts decided that the data do indicate that PD for wood mouse in sunflower (seeds) will be less than 1. This should be reflected in the final uncertainty assessment. - For the Algerian mouse the applicant referred to 2 literature studies to propose a PD refinement. These studies could not be considered by the meeting to be directly relevant for the diet of the mice living in close proximity to freshly sown sunflower fields. Therefore, the experts did not consider the proposed PD values were suitable for the refine risk assessment for Algerian mice in SEU. PD values were considered generally unsuitable for the acute assessment. The experts considered that they may use the PD values in a WoE assessment. WoE - The RMS presented the calculations for the number of seeds needed to reach the LD50 (no assessment factor) and the foraging area. The meeting noted that the margin of safety shown by the proposed calculation was low. - It was acknowledged that woodmouse are likely to de-husk seed such as sunflowers. However, it was acknowledged that the de-husking studies do not account for the residue intake the animals will take during handling and de-husking of the seed. However, in this case, given the magnitude of failure in the Tier 1 and the level of reduction needed to reach a low risk, de-husking alone was not considered sufficient to reach a conclusion of low risk. It was suggested also that the Algerian mouse may also de-husk seeds but again this could only be considered in a WoE assessment. Overall, it was not possible to conclude low risk based on the WoE.



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Subject	Conclusions Pesticide Peer Review Meeting
	Open point - PD: RMS to update the RAR reflecting that the experts considered that the proposed PD values were not suitable for use in a quantitative assessment and also to reflect (e.g., in the uncertainty analysis) that it is likely that PD for the sunflower seeds is less than 1. - WoE: RMS to acknowledge that de-husking may be qualitatively considered in a WoE assessment (wood mouse, sunflower) but the level of required reduction in exposure meant that a low risk cannot be concluded (relevant for SEU and CEU). - RMS to update the RAR/LoEP by reporting the outcome of the meeting discussion b. <u>acute RA for wild mammals consuming sunflower seedlings</u> Residues in germinating seedlings The discussion held previously for birds is also relevant and therefore an open point is identified for the RMS to remove the assessment for the acute risk to mammals consuming sunflower seedlings. c. <u>acute RA for wild mammals consuming spinach seeds</u> Focal species see discussion above Refined FIR / bw see discussion for birds PD The RMS proposed that the PD values for the two focal species can be extrapolated from those discussed for sunflowers. However, it was noted that the proposed values for sunflowers were not accepted in a quantitative assessment. Therefore, the proposed PD values were not considered acceptable for the acute RA in spinach. WoE (Foraging area and number of seeds to reach the LD50, de-husking) The margin of safety indicated in the calculation for the foraging area and number of seeds to reach toxicity was considered low. The experts noted that they considered that de-husking for spinach seeds is not comparable to sunflower and therefore there is more uncertainty regarding de-husking.



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Subject	Conclusions Pesticide Peer Review Meeting
	Overall, the WoE (including consideration of the PD) was considered insufficient to conclude low risk. Open point for the RMS to update the RAR reflecting the outcome of the discussions for each of the refinement steps (point c.) proposed for the assessment. d. <u>Long-term RA for wild mammals consuming sunflower seeds</u> Residue refinement: refer to long-term risk birds Focal species: refer to the acute assessment PD refinement: refer to the acute assessment The expert considered that the PD values should not be used in a quantitative manner but were sufficient to indicate that PD for the seeds is likely to be less than 1. The concerns discussed for sunflower seeds above in the acute assessment are also relevant here. WoE - PT Additional information by the applicant included a PT refinement based on Monte Carlo simulations, which were not quantitatively used by the RMS in RA. Several concerns were raised by the experts: - the PT studies were performed in cereal fields and not sunflower fields. - Concerns were raised around the use of 21-day PT values given that this methodology has been questioned previously (EFSA, 2019). - It was questioned why standard PT values were not derived from the submitted data, but the RMS indicated that this was not done by the applicant (possibly because the applicant assumed that the refined assessment using PD would be sufficient). The experts considered the two PT studies which were performed in cereals in DE (and not sunflower/spinach). The experts discussed whether suitable PT values could be obtained for cereals based on the available studies. Extrapolation to



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Subject	Conclusions Pesticide Peer Review Meeting
	sunflower fields could then be discussed. However, this was not considered appropriate in the context of an experts meeting where what is presented should be peer-reviewed since it would be necessary to check the original reports and use the raw data. However, the meeting acknowledged that some of the studies (e.g, IIIA 10.3/02) were already considered in the previous assessment. Two additional PT studies (IIIA 10.3/01 and 02) in Sunflower were evaluated and several shortcomings were identified: - The crop phenology in the study IIIA 10.3/02 did not represent the freshly sown fields - For IIIA 10.3/01 the location was DE: - o no mention of the type of driller, although data were available on the number of seeds remaining on the surface. - o a key short coming was that only a few animals were radio tracked A DEFRA report was also acknowledged/discussed which was considered for the derivation of a 90th percentile PT value in the last assessment. However, it seemed it was not included in the new dossier. - Overall, the experts considered the available PT studies in the context of the meeting but this could not be considered as a complete and transparent assessment of the data. The Experts agreed that no quantitative value should be derived with the information available at the meeting. Nevertheless, it was acknowledged that a PT of 0.51 was applied in the previous assessment and therefore the expert considered that this may be used in a qualitative manner to conclude that it is likely that PT for the wood mouse in sunflowers will be less than 1. For SEU (Sunflowers) no PT data are available for the Algerian mouse. It was agreed that the above conclusion for wood mice was also applicable but with more uncertainty. - De-husking: see previous discussions Overall, the WoE was considered insufficient to conclude a low long-term for wild mammals consuming sunflower seeds. Open points: - General: for the RMS to update the RAR reflecting the outcome of the discussions for each of the refinement steps (point d.) proposed for the assessment. - WoE (PT): RMS to reflect in the RAR that the Monte Carlo approach as proposed by the applicant was not suitable to



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Subject	Conclusions Pesticide Peer Review Meeting
	obtain a 21-day PT value (wood mice, CEU, sunflowers). The RMS may reflect that the data indicate that the PT for wood mice in sunflowers is likely to be less than 1. RMS to reflect that no PT value is available for Algerian mouse in SEU sunflowers. e. <u>Long-term RA for wild mammals consuming sunflower seedlings</u> Residue refinement: See previous discussion and open point for residues in seedlings f. <u>Long-term risk to granivorous mammals consuming spinach seeds</u> Focal species: See previous discussion PT: the RMS presented the 2 new field studies submitted by the applicant: - use of freshly drilled spinach fields by wood mouse in Germany, PT (90th percentile) = 0.172 - use of freshly drilled spinach fields by Algerian mouse in Spain, PT (90th percentile) = 0.017 The type of drilling technique was not specified. Therefore, the experts considered that it would be more appropriate to assume that the seeds were precision drilled with few seeds remaining on the surface. It should be reflected that the assessment does not cover all drilling techniques and communicate this to risk managers. - Algerian mouse: Overall, the experts agreed to use the maximum PT value of 0.194 from this study, considering the uncertainties related to the distribution of data. - For wood mouse (CEU): the experts agreed with the 90th percentile PT value for the wood of 0.172. WoE: - De-husking: see previous discussion Open points: - General: RMS to update the RAR reflecting the outcome of the discussions for each of the refinement steps (point f.) proposed for the assessment. - PT/WoE: RMS to update the risk assessment for the Algerian mouse using a maximum PT value of 0.194. Furthermore, the RMS should reflect in the uncertainty analysis that PT



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Subject	Conclusions Pesticide Peer Review Meeting
	values (for both species) may be higher in the case of standard drilling techniques. The RMS may also add a reflection regarding the fact that de-husking is not considered to bring much evidence of low risk/exposure to the assessment.
Experts' consultation 5.4 Experts to agree on the long-term fish endpoint considering the available new data submitted as part of the updated literature search	The applicant submitted an update literature search covering the 10 years prior to submission. This update included studies on fish which were deemed potentially relevant for the risk assessment for aquatic organisms (i.e., IIA 8.2.2/01; IIA 8.2.2/02; IIA 8.2.2/03). Consequently, the meeting was requested to further discuss i) the relevance of these studies for risk assessment ii) whether a reliable endpoint could be derived from any of these studies iii) whether the available evidence triggered a reconsideration of the previously agreed fish endpoint. The study IIA 8.2.2/02 was considered invalid (upon consideration of the most appropriate OECD TG), because of the low hatching success and survival in the control, the test temperature of 28°C and the lack of a positive control group in the test design. Studies IIA 8.2.2/01 and IIA 8.2.2/03 were not considered to challenge the current endpoint selection. Overall, the meeting agreed that the new evidence was insufficient to challenge the previously selected endpoint for fish. Open points: - the RMS is requested to provide a complete evaluation of the available literature studies (with particular reference to the fish studies) relative to the most equivalent test guideline. A clear and transparent assessment, acknowledging the meeting discussion is needed, especially since the study appeared to give a potentially lower endpoint than the one currently being used for the risk assessment. RMS to acknowledge that it would be recommended that any further studies performed with fish also consider the potential higher sensitivity of zebra fish. The RMS is requested to check whether an update of the risk assessment for aquatic organisms and soil organisms is needed based on the outcome of the revised exposure assessments. If updated PEC values are available, then the risk assessments in the RAR and LoEP should be updated accordingly.



REPORT OF PESTICIDE PEER REVIEW TC 89

FAT DISTILLATION RESIDUES – AIR IV

Rapporteur Member State: CZ

5. Ecotoxicology

Date: 8 September 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Central Institute for Supervising and Testing in Agriculture	CZ
National Institute of Public Health	CZ
Federal Environmental Agency (UBA)	DE
Federal Institute for Risk Assessment (BfR)	DE
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
University of Veterinary Medicine and Pharmacy in Kosice	SK

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Pesticide Peer Review TC 89 (6– 8 September 2022)
Fat distillation residues

Discussion points / Outcome

5. Ecotoxicology

Please note that information part of this report may have been masked by EFSA in accordance with Article 63 of Regulation (EC) No 1107/2009 as well as EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009, or EFSA's Practical Arrangements concerning transparency and confidentiality as a consequence of confidentiality requests submitted by the applicant on application dossiers for pesticides active substances or Maximum Residue Levels, respectively. Please note that information disclosed in this report is without prejudice to pre-existing intellectual property rights and data exclusivity clauses set out in Union law, and particularly in Article 62 of Regulation (EC) No 1107/2009.

Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the proposed waiver for the endocrine disruption (ED) assessment and the toxicological studies for birds.	All the experts agreed on the waiver for ED assessment and the toxicological studies for birds based on the following considerations: • the active substance is a mixture of natural low risk substances (i.e. palmitic, stearic, oleic acids); • Toxcast data on palmitic, stearic and oleic acids are available and are essentially negative; • the representative uses of the substance (repellent against browsing by the game, applied by brush or hand coating); • similarities with other substances (i.e. fish oil and sheep fat) for which a waiver was accepted due to the nature of these substances and their representative uses; • taking into account the toxicology conclusions (for more information please refer to the mammalian toxicology Peer Review meeting report TC 89). Open point: RMS to update the RAR to reflect the discussions including the mammalian toxicology discussion point (see Mammalian Toxicology Peer Review Experts' Meeting TC 89).



REPORT OF PESTICIDE PEER REVIEW TC 88

ETHEPHON– AIR III

Rapporteur Member State: NL

5. Ecotoxicology

Date: 2 August 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
4leaves S.C.	PL
Hearing expert	CH
External expert	DE

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts should discuss the validity and relevance of the XETA assay in relation to: - The concentration setting in the XETA, and the highest concentration tested vs the MTC - The pertinence of the choice of the XETA for a weak TPO inhibitor (see comment above) and if the conclusion for human health can be extrapolate to amphibian	The experts discussed all the available evidence justifying the selection of the concentration in the newly submitted studies. The experts also considering the overall evidence and weight of evidence for drawing a conclusion on whether the criteria were met or not for the T-modality in non-mammalian species. Overall, the experts agreed that it is unlikely that ethephon meets the ED criteria for the T-modality and non-mammalian species. An uncertainty analysis associated to this conclusion will be presented. Open point: RMS to revise the uncertainty analysis for the conclusion for the T-modality.
Experts' consultation 5.2 Experts should discuss the validity of the REACTIV assay in relation to: - The concentration setting in the REACTIV, and the highest concentration tested vs the MTC	The experts discussed all the available evidence justifying the selection of the concentration in the newly submitted studies. The experts discussed the available assessment for validity. The experts agreed that the available REACTIV can only be considered as additional information at this stage considering the validation status of the assay. Open point: RMS to reflect the outcome of the discussion in the revised RAR and amend it as needed.



Pesticide Peer Review TC 88 (2 August 2022)
Ethephon

Subject	Conclusions Pesticide Peer Review Meeting
- The validity of the test (no agreed validity criteria at the time of the submission)	
Experts' consultation 5.3 Experts should discuss the validity of the RADAR assay in relation to: - The validity of the test (no agreed validity criteria at the time of the submission)	The experts discussed all the available evidence justifying the selection of the concentration in the newly submitted studies. The experts discussed the available assessment for validity. Based on the validity criteria that were not met, all the experts agreed that the study is partially reliable (is invalid for androgenicity and valid for anti-androgenicity). Open point: For the RMS to amend the evaluation based on the outcome of the discussion.
Experts' consultation 5.4 Expert to discuss the FSTRA assay based on a more complete reporting of the other parameters, i.e., histopathology.	The experts discussed the findings in the available FSTRA and in particular the changes in the gonad histopathology. Although the overall dataset was not suggesting a clear pattern, the majority of the experts (not the RMS) agreed that there is positive (but weak) evidence of ED activity for EAS modalities (increase testes mineralization, decrease gonad stage scoring) and therefore it cannot be concluded whether Ethephon meets the ED criteria. According to the ECHA EFSA ED Guidance, level 5 studies would be needed as requested to the applicant in case of positive findings in level 3 studies. However, in this case it was agreed that a level 4 (OECD TG 234 - FSDT) could be sufficient to confirm or dismiss the concerns identified.



REPORT OF PESTICIDE PEER REVIEW TC 87

SULFUR – AIR IV

Rapporteur Member State: FR

5. Ecotoxicology

Date: 19 July 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Hearing expert	CH

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Pesticide Peer Review TC 87 (18-19 July 2022)
Sulfur

Discussion points / Outcome

5. Ecotoxicology

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Minutes might be revised due to pending data gaps at the time of the meeting and /or eventual need for further follow up consultation after the meeting. If needed, the final agreement will be made available in the meeting report published at the end of the peer review process.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the refined assessment for the risk to granivorous, omnivorous, small insectivorous and frugivorous birds (ripening) resulting from the intended uses on grapevine.	For the refinement of the RUD values, it is acknowledged that it is not possible to check the robustness and the validity of the derivation of the proposed RUD value of 2.9 mg/kg. In addition, it is not possible to use the RUD value of 5.33 mg/kg, since it is extracted from a un-noted document. It was discussed whether information from a literature search on toxic effects provided by the applicants could be used in a WoE approach. It was acknowledged that (i) it is unclear whether sulfur was one of the substances for which the analyses were conducted, (ii) the reporting was very limited (e.g. animals not correctly identified), and (iii) it is not clear whether sulfur has been measured. Thus, it is not possible to consider this study in a WoE approach. For the use of updated deposition factors, it was acknowledged that the newly selected deposition factors are reliable and allow for a robust refinement of the risk assessment. It should also be noted that (i) the specific exposure condition of sulfur (i.e., high background exposure, long history of safe use including pharmaceutical uses, low additional burden originating from crop protection uses, and being sulfur an essential element needed at high level), and (ii) the extrapolated LD₅₀ coming from a study where no mortality was reported. A low acute risk can be expected for birds for all uses.
Experts' consultation 5.2 The experts should discuss:	The approach to the surface water risk assessment for sulfur. It was considered that (i) organisms were exposed to both soluble and non-soluble forms of sulfur, (ii) that there was no effect observed in organisms up to the highest concentrations tested, (iii) the low solubility



Pesticide Peer Review TC 87 (18-19 July 2022)
Sulfur

Subject	Conclusions Pesticide Peer Review Meeting
- The approach to the surface water risk assessment for sulfur. - The risk assessment for sediment dwelling organisms - The information provided by the concern raised by the RMS regarding the potential buffering capacity of water bodies to neutralize acid inputs from sulfate ions	of sulfur in the water column, and (iv), sulfate is one of the main nutrients for aquatics organisms It was agreed to use a WoE approach to conclude on the risk assessment for organisms in the water column The risk assessment for sediment dwelling organisms For sulfur Dust, the lowest ratio for step2 is 6.48 and for the sulfate there is no PEC/RAC calculation available for the time being however after the e-fate meeting (TC86) the PECs for sulfate were agreed to be calculated. It is proposed to update the RAR considering that with 100% drift risk is identified. Although drift 100% might be an overestimation, it is unknown whether a lower drift value could indicate a high risk or not. In absence of further information, the risk could not be refined for sediment-dwelling organisms. The information provided by the concern raised by the RMS regarding the potential buffering capacity of water bodies to neutralize acid inputs from sulfate ions A statement to waive sulfate in the aquatic risk assessment was provided. The fact that sulfate is a main nutrient might not be sufficient to waive the risk assessment. If there is a significant contribution of sulfate, it could contribute to eutrophication of the water bodies. The contribution from the pesticide use of sulfur is not negligible. The majority of experts acknowledge this particular concern and suggest paying particular attention to potential risk of eutrophication of water bodies at member state level.
Experts' consultation 5.3 Experts to discuss the risk assessment for bees.	Higher tier studies were necessary to address the risk for adult bees and larvae. Data from a semi-field study conducted with the formulation Sulfur 80% WG was included in the RA. The location is considered less influential compared to field studies. Although the application in the tunnel study does not mimic the maximum seasonal use pattern as reported in the GAP, where multiple applications are intended, it was recognised that one application can be considered realistic due to the living period of the adult bee (i.e., up to 3 weeks). Multiple applications could build up, increasing the exposure of the honeybee. For contact exposure, adult honeybees are unlikely to be exposed more than once over their lifetime. The oral exposure will occur during the flowering



Pesticide Peer Review TC 87 (18-19 July 2022)
Sulfur

Subject	Conclusions Pesticide Peer Review Meeting
	period, which in vineyards can occur up to 3 weeks. Multiple exposure can be considered as possible for both adults and larvae. Since the two products are considered different it is noted that it is not possible to pull all evidence together for a WoE approach. The available tunnel study was conducted with a higher application rate than the intended uses in cereals. Cereals as reported in the GAP are deemed not attractive for nectar and low attractive for pollen collection. The treated crop scenario in cereals may not be the most relevant while the flowering weeds scenario may contribute higher to the overall exposure. The higher tier study is not considered fully appropriate to conclude on the low risk to honeybees for the use on cereals and grapevine.
Experts' consultation 5.4 Experts to discuss the risk to non-target arthropods. The discussion should include the following: - Correction for off-field risk assessment - The need for a correction factor of 0.5 for the study of Röhlig, U., 2016 (KCP1 10.3.2.2/05) - DT₅₀ for MAF calculation - Any new data and risk assessment provided by the applicant. - Off-field risk assessment for the representative dust formulations - In-field risk the foliar-dwelling arthropods <i>C. carnea</i>. - The possible wash-off of sulfur due to rain	Correction for off-field risk assessment In ESCORT 2 it is stated that the correction factor can be lowered from 5, but it does not give an indication to what extent and how this correction factor may be reduced. A correction factor of 5 should be used to ensure a higher rate is tested, and to cover the inter-species variability in sensitivity of off-field non-target arthropod species to plant protection products. DT₅₀ for MAF calculation No robust data was provided to support the selection of a MAF of 2.6 and 2.2 for the in-field risk assessment assuming a DT₅₀ of 10 days. According to ESCORT2, a MAF of 3.5 for more than 8 applications and 2.7 for 4 applications should be used to perform the risk assessment. Any new data and risk assessment provided by the applicant. None. The off-field risk assessment for the representative dust formulations. No suitable drift value available to conduct the off-field risk assessment. Off field risk assessment for Sulfur Dust was not available. In-field risk the foliar-dwelling arthropods <i>C. carnea</i>. An extended laboratory test with treated bean leaves has been provided by the applicant for <i>C. carnea</i>.



Pesticide Peer Review TC 87 (18-19 July 2022)
Sulfur

Subject	Conclusions Pesticide Peer Review Meeting
and its effects on the aging residue study (KCP2 10.3.2.2/05)	The study is considered valid. The new endpoint allows to conclude a low in- and off field risk for grapevines and cereals, respectively. The possible wash-off of sulfur due to rain and its effects on the aging residue study (KCP2 10.3.2.2/05) The studies are considered not reliable to be used for the risk assessment since it could not be excluded that wash-off of the pesticides from the leaves may influence the outcome of the studies. In the case of <i>T. cacoeciae</i>, some concerns over the recovery and recolonization of the organism. Based on the biology and ecology of the species, the intended application patterns, and taking into account the results of the aged residue studies, it appears that establishing new in-field populations is not likely within one year for use in grapes. Concerns on the design of the study are noted as well, such as influencing /confounding effects. Toxicity effects could be observed up to 61 and 69% of effects at 56 and 70 days after treatment. It was discussed that effects observed could be higher in a classical aged residue study where no wash-off events would be included. For the Sulphur Dust, the in-field risk for NTAs remains as high. The off-field risk could not be finalized. For the Sulfur 80% WG the off-field was considered as low, with mitigation measures applied, while the in-field risk remains as high for <i>A. rhopalosiphi</i> and <i>T. cacoeciae</i>
Experts' consultation 5.5 Experts to discuss the higher tier assessments for earthworms and other soil macro-organisms	The applicant provided only interim reports for three field studies. noted that it is not possible to concluded the RA since several details are missing from the interim reports (e.g. no material and methods provided only a study plan, no information about pesticide application history), thus impeding the assessment of reliability and relevance for the studies. Biological relevant effects seem to be observed in both collembola studies although deemed not statistically significant. It is noted that the final reports are at the time of the expert meeting available but could not be taken into consideration as they were not submitted withing the permitted time-period. The high risk for collembola for all the representative uses could not be resolved. For earthworm, high risk cannot be resolved for Sulfur Dust.
Experts' consultation 5.6 Expert to discuss if the information available substantiate the arguments	Expert agreed that further data are not necessary to assess the ED potential of sulfur. The waiver of the ED assessment has been agreed at the meeting. It is unlikely that sulfur meets the ED criteria for non-target organisms.



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Sulfur

Subject	Conclusions Pesticide Peer Review Meeting
for waiving the need of the ED assessment of sulfur.	Open point: RMS to update the RAR including the reference that substantiate each of the arguments and the cross reference to other sections in the RAR as well as other EFSA/official publications (e.g., use as food supplement). RMS to include the position paper in the meeting folder.



Pesticide Peer Review TC 79 (28 June 2022) - Follow up meeting from TC 72 on assessment of aquatic organisms
Dimoxystrobin

REPORT OF PESTICIDE PEER REVIEW TC 79

Follow up meeting from TC 72 on assessment of aquatic organisms

DIMOXYSTROBIN – AIR III

Rapporteur Member State: HU

5. Ecotoxicology

Date: 28 June 2022

List of participants:

Institute	Member States Country code
Federal Environmental Agency (UBA)	DE
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
National Food Chain Safety Office	HU
External expert	DE
Hearing expert	CH

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Pesticide Peer Review TC 79 (28 June 2022) - Follow up meeting from TC 72 on assessment of aquatic organisms
Dimoxystrobin

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss the aquatic risk assessment for dimoxystrobin, in particular: - The toxicokinetic-toxicodynamic (TKTD) model for fish and its potential use in the fish risk assessment; - The additional mesocosm assessment provided by the applicant during the clock stop (including exposure profile comparison). (Follow up discussion from TC 72 (January 2022) following updated RAR with revised assessment of the additional information submitted by the applicant during the clock stop, not yet considered in the January 2022 TC). See revised RAR and Applicants overview of findings and relevant documents submitted during the clock stop.	<i>Discussion on the mesocosm study:</i> <i>Assessment whether the exposure in the test system is a realistic worst case with respect to the exposure predicted for the representative uses under assessment:</i> Since the agreed endpoints were not used, the experts agreed that the comparison submitted was not correct and could not be used for the risk assessment. In addition, the experts agreed that no ETO-RAC and no overall ERO-RAC could be derived from the mesocosm study that could have been used in the comparison of the exposure in the test system and the exposure predicted to demonstrate a worst-case. Open point: RMS to update the RAR according to the discussions. <i>Further consideration of the species and species groups representation:</i> The experts agreed that emergence of chironomid species could be assessed and the minimum detectable difference (MDD) determined. The experts agreed that there are no surrogate representative taxa covering the marine species <i>Crassostrea virginica</i> with a sufficiently high abundance to conclude on the absence of effects on molluscs. In addition, there are only three sampling points, with no sampling before the start of exposure. The expert agreed that <i>D. longispina</i> data can be used as a surrogate representative species for mysids. However, this approach might not be



Pesticide Peer Review TC 79 (28 June 2022) - Follow up meeting from TC 72 on assessment of aquatic organisms
Dimoxystrobin

Subject	Conclusions Pesticide Peer Review Meeting
	adequate for other macrocrustaceans that may have a longer reproductive/life cycle (i.e. Gammarus). All experts agreed with the RMS that the mesocosm study was not suitable for the derivation of a reliable ETO/ERO RAC value for phytoplankton, since it did not properly address the risk for algae, because the most sensitive taxa (diatoms) were not well represented. Based on all the above, it is confirmed that an ETO-RAC cannot be derived since a class 3A effect is observed on daphnids at the lowest concentration; and an overall endpoint (ERO-RAC) from the mesocosm study could not be derived since there is still uncertainty over the mollusc, crustaceans with long reproductive cycle (i.e. Gammarus) and the most sensitive phytoplankton taxa (diatoms). Open point: RMS to reflect the outcome of the discussion in the RAR and in the List of end points (LoEP). <i>The test item used in the mesocosm study:</i> The RMS agreed with the applicant that the endpoints that were derived from the mesocosm study with the solo formulation 'BAS 505 01 F' represents a worst-case scenario for the representative formulation 'BAS 540 01 F'. The RMS has added the evaluation of this other formulation to the revised RAR. All the experts agreed with the RMS opinion. Open point: RMS to reflect the outcome of the discussions in the RAR and in the LoEP. <i>Discussion on the TKTD model (General Unified Theory of Survival – GUTS Red) used to refine the fish chronic risk assessment:</i> The experts agreed that the study was comprehensively reported, had a solid application, and used a standard GUTS software. It relied on a large experimental dataset which, overall, was of suitable quality. However, the calibration and the interpretation of the validation of the model presented some issues that were discussed, and which decrease the overall reliability of the model application. In addition, GUTS model address lethal effects and the calibration/validation was carried out for rainbow trout whereas the Tier 1 risk assessment is driven by sublethal effects on the fathead minnow. Interspecies extrapolation is not agreed



**Pesticide Peer Review TC 79 (28 June 2022) - Follow up meeting from TC 72 on
assessment of aquatic organisms
Dimoxystrobin**

Subject	Conclusions Pesticide Peer Review Meeting
	in EFSA (2018)³. Therefore, the experts agreed that the study cannot be used for refining the chronic fish risk assessment for dimoxystrobin. Open point: RMS to reflect the outcome of the discussions in the RAR.

³ EFSA (2018). Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD) effect models for regulatory risk assessment of pesticides for aquatic organisms. EFSA Journal 2018;16(8):5377 DOI: <https://doi.org/10.2903/j.efsa.2018.5377>



REPORT OF PESTICIDE PEER REVIEW TC 77

UREA – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 06 May 2022

List of participants:

Institute	Member States Country code
Federal Environmental Agency (UBA)	DE
National Institute for Agricultural and food research and technology (INIA)	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Benaki Phytopathological Institute	GR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL

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Pesticide Peer Review TC 77 (05 – 06 May 2022)
Urea (AIR IV)

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the ED potential of the active substance during the experts' meeting.	For non-target organisms, neither data nor a robust justification for waiving were submitted by the applicant. Therefore, the experts agreed that additional data should be submitted to allow drawing a conclusion. The experts agreed to give the applicant both the possibility of: - demonstrating that an ED assessment according to the ECHA/EFSA (2018) ED guidance is not scientifically justified OR - submitting further data in line with the ECHA/EFSA (2018) ED guidance (i.e. level 3 studies: FSTRA for EAS-modalities and XETA for T-modality). In the first case, one possibility could be to quantitatively compare the exposure from the application of urea as PPPs to the natural background level or urea end-products in fish. Additionally, the use of urea in other regulatory areas could be considered.
Experts' consultation 5.2 Expert consultation is required to discuss the reliability and validity of the studies for aquatic organisms and the choice of the endpoint for the acute aquatic organism's risk	-The endpoints from the information from ECHA, SIDS and the IUCLID database for which a proper evaluation of the studies/endpoints was not possible were disregarded -For the studies from the open literature, the information is lacking regarding the analytical measurements and/or control performance



Pesticide Peer Review TC 77 (05 – 06 May 2022)
Urea (AIR IV)

Subject	Conclusions Pesticide Peer Review Meeting
assessment, considering the following: -Additional studies for fish, daphnia and algae acute aquatic toxicity with the formulation ENTOMELA 50 SL to be submitted by the applicant, and bridging between the formulations ENTOMELA 50 SL and ENTOMELA 75 SL -Clarification on the ECHA and OECD endpoints submitted -Discuss the validity of the available studies for fish (Vol. 3 CA, B.9.2.1), invertebrate (B.9.2.4.1), algae (B.9.2.6) and aquatic macrophyte (B.9.2.7) and their use for the risk assessment.	therefore experts agreed that those studies can be considered only as supportive information. - Based on the data submitted, expert agree that the bridging between both formulations is acceptable, since only urea content is different; the other co-formulants are the same and have no toxicity classification. - All regulatory studies with ENTOMELA 50 SL were considered valid and reliable. Since for daphnia, the nominal recovery goes below 80% recovery, the endpoint should be expressed in term of measured concentrations and the RA amended accordingly. In addition, for the algae study, only 5 replicates instead of 6 are available and a preliminary range finding test was conducted; however, this information was not available and should be added in the RAR. - All regulatory studies with ENTOMELA 50 SL are limit test and the endpoints were established as greater than values ($LC_{50} > 29$ mg urea/L; RAC worst-case: 0.29). Considering the margin in the RA that would lead to high risk, the experts would agree to consider the endpoints from ENTOMELA 50 SL in the RA of ENTOMELA 75 SL. Using these values for RA, low acute risk was concluded to aquatic organisms. -It was noted that ENTOMELA 50SL is also the representative formulation for hydrolysed proteins (HP), i.e., the formulation is a mixture. All experts agreed that a mixture toxicity assessment should be conducted to clarify if the a.s. urea is more toxic when formulated with HP. Open point: RMS to include information additional information on the bridging between formulations. Open point: RMS to include in the RAR the mixture toxicity assessment to confirm that when formulated with HP, urea does not pose higher toxicity. Open point: RMS to remove the endpoints from literature studies and the pertinent risk assessment from the LoEP. Open point: RMS to recalculate the formulation endpoint for daphnia and to express it in terms of measured concentrations; consequently, RMS to amend the risk assessment to aquatic invertebrates accordingly in RAR and LoEP. Open point: RMS to include the information of the limitations of the algae formulation study and the info of the range finding test. Open point: RMS to reflect the outcome of the discussion in the revised RAR



REPORT OF PESTICIDE PEER REVIEW TC 77

HYDROLYSED PROTEINS– AIR IV

Rapporteur Member State: ES

5. Ecotoxicology

Date: 06 May 2022

List of participants:

Institute	Member States Country code
Federal Environmental Agency (UBA)	DE
National Institute for Agricultural and food research and technology (INIA)	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Benaki Phytopathological Institute	GR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL

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Pesticide Peer Review TC 77 (05 – 06 May 2022)
Hydrolysed Proteins (AIR IV)

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 To assess the studies that will be submitted by the applicant and reviewed by the RMS with particular attention to the analytical methods used for Nitrogen determination and the related point raised by the member state DE.	The analytical verification of the test items in the newly submitted studies were considered acceptable by the experts. Overall, experts agreed with the RMS' evaluation and further data were not considered needed. In addition, since the formulated product ENTOMELA 50 SL is a mixture of hydrolysed proteins and urea, a mixture toxicity assessment was considered necessary. Open point: RMS to check if an evaluation of the analytical method was included in the RAR (Vol 3, B.5.) and if this was not done, include it. Open point: RMS to acknowledge that ENTOMELA 50 SL is a mixture formulated product containing more than one active substance and to demonstrate in the updated RAR that hydrolysed proteins are not more toxic when formulated with urea in ENTOMELA 50 SL.
Experts' consultation 5.2 Experts to discuss the ED properties of hydrolysed proteins.	Based on the physicochemical and ADME properties of the hydrolysed proteins, the fact that hydrolysed proteins are widely used for several purposes and approved in different jurisdictions, and available evidence from the literature review, experts agree that sufficient evidence is available to conclude, based on the weight of evidence, that it is unlikely that hydrolysed proteins meet the ED criteria for humans and non-target organisms.



Pesticide Peer Review TC 77 (05 – 06 May 2022)
Hydrolysed Proteins (AIR IV)

Subject	Conclusions Pesticide Peer Review Meeting
	All the experts agreed that further data are not needed. An expert noted that REACH registration as a source of information for the WoE should be taken with caution because check for the reliability of the information in the dossier is not required for these substances. EFSA noted that REACH dossiers could be considered as a source of information, but the assessment of reliability and relevance has to be done independently by RMS and through the Peer Review process. It was also noted that for this purpose the data has to be accessible in the dossier and that the level of details could be a matter of discussion. All of the experts agreed with the waiver.



REPORT OF PESTICIDE PEER REVIEW TC 77

BENFLURALIN– ART. 31

Rapporteur Member State: NO

5. Ecotoxicology

Date: 06 May 2022

List of participants:

Institute	Member States Country code
German Environment Agency (UBA)	DE
Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA)	ES
French Agency for Food, Environmental and Occupational Health & Safety (ANSES)	FR
Benaki Phytopathological Institute (BPI)	GR
Board for the Authorisation of Plant Protection Products and Biocides (CtbG)	NL
Norwegian Food Safety Authority	NO
MERIT MARK Sp. z o. o.	PL

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Pesticide Peer Review TC 77 (05 – 06 May 2022)
Benfluralin – Art. 31

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the refinement of the long-term risk assessment for birds and mammals, including the risk from secondary poisoning to earthworm-eating birds and mammals, e.g., by means of portion of food items in the diet (PD), portion of food obtained in the treated area (PT), risk assessment with focal species, residue per unit dose (RUD) and mechanical incorporation into the soil immediately after application to a depth of 15 cm.	Bioconcentration factor for earthworms Overall, the experts agreed on using the available BCF of 2.4 for the risk assessment calculations while acknowledging the uncertainties identified (high organic content of the artificial soil used in the study and lack of information of the lipid content) in the quantitative risk assessment. Open point: RMS to reflect the discussion in the revised RAR and amend the risk assessment accordingly. Refined RUD values for seeds and arthropods While it is reasonable to assume that RUD values for seeds and arthropods are lower than the default RUDs, most of the experts considered that refined RUDs should be obtained experimentally and related to the proposed use, in line with the recommendations given in the EFSA guidance document for birds and mammals (EFSA, 2009). Therefore, the proposed refinements were not accepted. Open point: RMS to reflect the outcome of the discussion in the revised RAR and amend the risk assessment accordingly. Song thrush as focal species for earthworm-eating birds and PT of 0.8



Pesticide Peer Review TC 77 (05 – 06 May 2022)
Benfluralin – Art. 31

Subject	Conclusions Pesticide Peer Review Meeting
	None of the proposals to refine the risk to earthworm-eating birds were accepted by the experts since they were not based on experimental data. Open point: RMS to reflect the outcome of the discussion in the revised RAR. <u>Wood mouse as focal species for bare soils in the secondary poisoning risk assessment for earthworm-eating mammals</u> A field study justifying the selection of wood mouse as the most suitable species was not available. The information submitted was not sufficient to consider the wood mouse as the only specific focal species for earthworm-eating mammals. Also, it was unclear whether the potentially relevant report “Higher Tier Reproductive Mammal Risk Assessment for the Active Substance Benfluralin” (Report No. R12284)” was made available by the applicant. Open points: - RMS to reflect the outcome of the discussion in the revised RAR; - RMS to clarify with the applicant if the report “Higher Tier Reproductive Mammal Risk Assessment for the Active Substance Benfluralin” (Report No. R12284) was submitted. If the study was submitted within the deadline for further data submission, an evaluation should be included in the revised RAR. Comments and positions papers which may be provided by the applicant can also be taken into account, as appropriate.
Experts’ consultation 5.2 Experts to discuss the long-term risk assessment for aquatic organisms, the assessment of exposure mitigation measures such as a 20 m no-spray buffer zone, a vegetative buffer, use of 90% drift reduction nozzles and any combination thereof, while considering that, according to the supported uses, benfluralin is	Low risk for aquatic organisms can be concluded for the representative uses of benfluralin only when several mitigation measures are combined. However, the level of spray drift reduction by combining such measures is more than that indicated in the FOCUS landscape and mitigation guidance (FOCUS, 2007). It was considered that this high level of mitigation would often not be achieved in practice. Open point: EFSA to explore how to make available the requested information for decision making in the conclusion.



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Benfluralin – Art. 31

Subject	Conclusions Pesticide Peer Review Meeting
mechanically incorporated into soil immediately after application at a depth of 15 cm.	
Experts' consultation 5.3 Experts to discuss the long-term risk assessment to aquatic organisms, the possibility to derive specific toxicity endpoints for metabolites 371R and 372R for use in the risk assessment. The current (renewal) assessment, due to the lack of data on their toxicity, uses the default assumption that the two metabolites are 10 times more toxic than the parent compound (benfluralin) to aquatic organisms. However, their structures are very similar to trifluralin's metabolite TR-15 (ethyl-benzimidazole) which is far less acutely toxic to aquatic organisms than benfluralin. Therefore, in order to ensure consistency across assessments, the conclusion on trifluralin should be considered.	The experts considered the screening risk assessment assuming the metabolites 371R and 372R to be ten times more toxic than the parent compound as rather conservative. In addition to the lines of evidence presented by the applicant in the position paper, the RMS checked the available chronic and acute data for fish and invertebrates with the pesticide group benzimidazoles since the structural formula of both transformation products seemed to be very similar to the toxophore of this pesticide group. By taking into account all available data and lines of evidence, the RMS considered that toxicity to benfluralin is sufficiently protective for the metabolites 371R and 372R. The experts agreed with the assessment performed by the RMS. Open points: - RMS to reflect the outcome of the discussion in the revised RAR; - RMS to update the RAR by listing/summarising all lines of evidence considered in the weight of evidence assessment to address the risk for metabolites 371R and 372R, indicating how the available evidence was weighed and integrated as well as all sources of uncertainty that were identified and what their impact on the assessment outcome was.

REPORT OF PESTICIDE PEER REVIEW TC 73

FLUTIANIL – confirmatory data

Rapporteur Member State: BE

5. Ecotoxicology

Date: 29 April 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health, Food Chain Safety and Environment	BE
Federal Institute for Risk Assessment (BfR)	DE
Federal Environmental Agency (UBA)	DE
Ministerio de Sanidad	ES
National Institute for Agricultural and food research and technology (INIA)	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Benaki Phytopathological Institute	GR
State Plant Protection Service	LV
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL

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Pesticide Peer Review TC 73 (29 April 2022)
Flutianil – confirmatory data

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Peer Review as a follow up to the EFSA confirmatory data Technical Report (EFSA Supporting publication 2022:EN-7217): Experts should discuss the available Fish Short-Term Reproduction Assay (FSTRA) study. In particular it should be discussed whether the MTC (maximum tolerable dose) was reached in the study and if based on the available evidence, a conclusion on the ED properties of flutianil for the EAS-modalities for non-mammalian species could be drawn. The arguments provided in column 3 of reporting table	The lack of effects in the Fish Short-Term Reproduction Assay (FSTRA) gave an indication that the highest tested concentration was not close to the MTC and this indicated that the doses selected in the study were low to trigger the potential identification on whether the ED criteria could be met for non-target organisms other than mammals for the EAS-modalities. Considering all available information (e.g. information from the performance of other test designs in aquatic system, the recoveries obtained and the solvents used), the experts at the meeting agreed that the applicant should demonstrate that it is not possible to perform a test in similar conditions as the ones in the OECD TG 229 using higher concentrations (with the same or any other solvents). If this is not possible, and it is concluded that higher tested concentrations are not possible to be reached even using solvents, no further testing would be required. However, if on the contrary, it is possible to test higher concentrations, a test in line with OECD TG 229 should be performed to reach a conclusion on the ED properties of the substance for the EAS-modalities for non-target organisms other than mammals. In the case that a new study is conducted and shows positive findings, further testing would be required in line with the ECHA/EFSA ED



Pesticide Peer Review TC 73 (29 April 2022)
Flutianil – confirmatory data

Subject	Conclusions Pesticide Peer Review Meeting
point 5(1) in the EFSA Technical Report are referring to the solubility of the active substance in water while in the study a solvent was used. The solvent has normally the purpose of increasing the solubility of the active substance as demonstrated by the data on solubility in organic solvents reported in the list of endpoints (LoEP). This should be considered further for the test design and the decision on the doses to be tested. Moreover, results of the available acute toxicity studies demonstrated the LC50 to be at much higher concentrations. In addition, it must be noted that in general, the use of solvent is not recommended but if necessary, the selection of the solvent should be properly justified. Particular attention should be given to those solvents that may interact with the endocrine system of aquatic organisms (Hutchinson T.H., et al., 2006a. Acute and chronic effects of carrier solvents in aquatic organisms: A critical review. Review. Aquatic Toxicology, 76 ; pp.69–92.).	guidance (ECHA/EFSA, 2018) (i.e., a level 5 study with fish such as a test according to OECD TG 240 (Medaka Extended One Generation Reproductive Test (MEOGRT))). Data gap: Applicant to demonstrate that it is not possible to perform a test in similar conditions as the ones in the OECD TG 229 using higher concentrations (with the same or any other solvents) OR a test in line with OECD TG 229 where there should be indications on whether the MTC was reached. In the case that a new study is submitted (because it was possible to test higher concentrations by using a pertinent solvent) and it shows positive findings, further testing would be required in line with the ECHA/EFSA ED guidance (ECHA/EFSA, 2018) (i.e., a level 5 study with fish such as a test according to OECD TG 240 (Medaka Extended One Generation Reproductive Test (MEOGRT))). Open point: RMS to revise the DAR reflecting the outcome of the discussion.
Experts' consultation 5.2 Peer Review as a follow up to the EFSA confirmatory data	The lack of effects in the Amphibian Metamorphosis Assay (AMA) gave an indication that the highest tested concentration was not close to the MTC and this indicated that the doses selected in the study were low to trigger the potential identification on whether the ED criteria could be met for non-target organisms other than mammals for the T-modality.



Pesticide Peer Review TC 73 (29 April 2022)
Flutianil – confirmatory data

Subject	Conclusions Pesticide Peer Review Meeting
Technical Report (EFSA Supporting publication 2022:EN-7217): Similarly, as for the FSTRA, for the Amphibian Metamorphosis Assay (AMA), the experts should discuss whether the concentrations chosen for conducting the study are appropriate to reach the MTC and if based on the available evidence it is possible to conclude on the ED properties of flutianil for non-mammalian species for the T-modality.	The selection of the highest tested dose in the AMA was in line with what was done in the FSTRA above. Therefore, the experts at the meeting agreed that the applicant should demonstrate that it is not possible to perform a test in similar conditions as the ones in the OECD TG 231 using higher concentrations (with the same or any other solvents). If this is not possible, and it is concluded that higher tested concentrations are not possible to be reached even using solvents, no further testing would be required. However, if on the contrary, it is possible to test higher concentrations, a test in line with OECD TG 231 should be performed to reach a conclusion on the ED properties of the substance for the T-modality for non-target organisms other than mammals. In the case that a new study is conducted and it shows positive findings, further testing would be required in line with the ECHA/EFSA ED guidance (ECHA/EFSA, 2018) (i.e., a study according to OECD TG 241 (Larval Amphibian Growth and Development Assay (LAGDA))). Data gap: Applicant to demonstrate that it is not possible to perform a test where higher concentrations are tested (with the same or any other solvents) OR a test in line with OECD TG 231 where there should be indications on whether the MTC was reached. In the case that a new study is submitted (because it was possible to test higher concentrations by using a pertinent solvent) and it shows positive findings, further testing would be required in line with the ECHA/EFSA ED guidance (ECHA/EFSA, 2018) (i.e., a study according to OECD TG 241 (Larval Amphibian Growth and Development Assay (LAGDA))). Open point: RMS to revise the DAR reflecting the outcome of the discussion.



REPORT OF PESTICIDE PEER REVIEW TC 73

QUARTZ SAND – AIR IV

Rapporteur Member State: LV

5. Ecotoxicology

Date: 29 April 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Institute for Risk Assessment (BfR)	DE
Ministry of Environment and Food of Denmark, Environmental Protection Agency	DK
Ministerio de Sanidad	ES
Benaki Phytopathological Institute	GR
State Plant Protection Service	LV

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Pesticide Peer Review TC 73 (27 – 29 April 2022)
Quartz sand

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the ED properties of the active substance quartz sand	In line with ECHA/EFSA guidance, a waiver was proposed with the following justifications: - Evidence of poor solubility and poor absorption; it is not bioavailable after oral, dermal and inhalation exposure. - Available evidence from similar substances, does not show any concern for ED. In the available short term and long-term including reprotoxicity studies, there is no evidence of effects in the endocrine organs. - No evidence of ED activity based on the available data in ToxCast. - There are no known physiological mechanisms that allow large quartz sand particles such as those prevalent in the active substance, to cross intestinal membranes and enter the blood or lymphatic circulation. The same is true for dermal absorption. Therefore, oral or dermal exposure to quartz sand is not expected to result in systemic absorption. Based on those, the waiver was accepted by all experts. Open point: RMS to align the arguments for the ED waiver in both toxicity and ecotoxicity sections of the RAR.



REPORT OF PESTICIDE PEER REVIEW TC 73

(3E) 3-DECEN-2-ONE – NAS

Rapporteur Member State: NL

5. Ecotoxicology

Date: 29 April 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Public Service Health, Food Chain Safety and Environment	BE
Federal Environmental Agency (UBA)	DE
Federal Institute for Risk Assessment (BfR)	DE
Ministerio de Sanidad	ES
National Institute for Agricultural and food research and technology (INIA)	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Benaki Phytopathological Institute	GR
State Plant Protection Service	LV
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Pesticide Peer Review TC 73 (27 – 29 April 2022)
(3E) 3-decen-2-one (NAS)

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the ED properties of (3E) 3-decen-2-one	According to the ECHA/EFSA Guidance a justification for waiving a full ED assessment was proposed and agreed by the RMS. The main justifications for waiver are: - A 3-decen-2-one is a naturally occurring (fruits, juices, spices, vegetables, coffee and tea) acyclic aliphatic ketone that is also used as a food flavouring ingredient. - Rapid metabolism (known to metabolize rapidly and extensively to innocuous substances). - Highly unlikely that any potential adverse effects on endocrine system following respiratory exposure would occur at dose levels not causing excessive local toxicity. Available data demonstrated that adverse effects are limited to local irritation effects following inhalation administration. - The substance is classified as GRAS (generally regarded as safe) according to the US FDA and it has been evaluated by EFSA as acceptable for use as a structural class II food flavouring (not genotoxic). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has also evaluated it as a food flavouring. - It is readily biodegradable. - The DT₅₀ in air is 2h. - The threshold for human intake of a structural class II food flavouring is 540 µg/person/day. Although the waiver was considered robust enough and agreed by all the experts, additional data were performed but completed outside the regulatory deadline. Those were therefore not eligible and not reviewed



Pesticide Peer Review TC 73 (27 – 29 April 2022)
(3E) 3-decen-2-one (NAS)

Subject	Conclusions Pesticide Peer Review Meeting
	in the context of the peer review process. These will be considered as data gap in the EFSA conclusion.



REPORT OF PESTICIDE PEER REVIEW TC 72

DIMOXYSTROBIN – AIR III

Rapporteur Member State: HU

5. Ecotoxicology

Date: 28 January 2022

List of participants:

Institute	Member States Country code
External expert	DE
Federal Environmental Agency (UBA)	DE
Julius Kuehn-Institute (JKI)	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
National Food Chain Safety Office, Directorate of Plant Protection, Soil Conservation and Agri-Environment	HU
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
University of Veterinary Medicine and Pharmacy in Kosice	SK
Observer	CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the endpoint from the subchronic study KCA 8.1.1.3/3 on the mallard duck (<i>Anas platyrhynchos</i>).	The selection of the ecotoxicologically relevant endpoint from the long-term reproduction study KCA 8.1.1.3/3 on the mallard duck (<i>Anas platyrhynchos</i>) was considered to require further discussion, in relation to the biological relevance of effects observed for a number of reproductive endpoints, including i) the number of fertile eggs/group; ii) the number of 14-day old embryos/group; iii) the number of 21-day old embryos/group and iv) the number of eggs laid/female bird/week. Based on the available information and considering that the observed effects on eggs at 300 mg a.s. /kg diet were not reflected in the final reproductive output, the majority of experts agreed with the RMS evaluation and supported setting the endpoint from this study at 300 mg a.s./kg diet (i.e., the NOAEL from this study was confirmed to be 36 mg a.s./kg bw per day). Open point RMS to reflect the outcome of the discussion in the updated RAR.
Experts' consultation 5.2 Experts to discuss the ecotoxicologically relevant endpoint to be used for the	The 2-generation study with rats (KIIA 5.6.1/1) was considered for the selection of a long-term endpoint for use in the risk assessment for wild mammals. The RMS originally proposed a NOEL of 5 mg a.s./kg bw per day, based on effect on bodyweight of the F2 generation at 150 ppm.



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Dimoxystrobin

Subject	Conclusions Pesticide Peer Review Meeting
chronic risk assessment for mammals.	A number of effects were observed in this study, the most relevant being the reduction of bodyweight (g) in the F2 generation of pups (males and females) observed at 150 ppm. Based on the available conversion, this corresponds to a NOAEL of 12.1 mg a.s./kg bw per day for the F2 generation. Based on the available data, the meeting agreed on a NOAEL of 12.1 mg a.s./kg bw per day for the F2 generation, which was considered protective of effects observed across other studies presented in the mammalian toxicology section. Open point RMS to update the RAR by reporting the conclusions drawn by the meeting. RMS to update the risk assessment in a revised RAR and LoEP by considering the NOAEL of 12 mg a.s./kg bw per day (i.e., by using the dose conversion relevant for the F2 generation).
Experts' consultation 5.3 Experts to discuss the available residue trials and the calculated DT50 to be used in the refined risk assessment for wild mammals. In particular the experts should discuss: The representativeness of the residue trials against the representative uses in the GAP (e.g. in terms of BBCH and zone). The assessment of the residue trials in terms of statistical evaluation, visual fit, etc.	The refined long-term risk assessment for wild mammals included a DT50 refinement based on studies KCA 8.1/1, KCA 8.1/2 and KCA 8.1/3 in wheat and pea. The use of a refined DT50 from these studies was questioned during the commenting phase, in relation to their representativeness to the GAP (i.e., crop phenology and location) and statistical fit. Overall, a number of uncertainties were identified, such as the crop phenology (i.e., low BBCH); the low number of independent trial locations; the lack of a quantification of the active substance in roots; the statistical fit of a subset of trials and the geographical representativeness of the dataset. Therefore, it was not considered appropriate to use the residue data to replace the default DT50 in the refined risk assessment for small herbivorous mammals. Open points: - RMS to update the RAR by aligning the evaluation of the residue decline data (including the evaluation of degradation kinetics) to EFSA, 2019 (see EFSA Supporting publication 2019:EN-1673); - RMS to revise the RAR reflecting the outcome of the discussion on the residue dataset.



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Dimoxystrobin

Subject	Conclusions Pesticide Peer Review Meeting
	- RMS to update the refined long-term risk assessment for wild mammals by discarding the use of a refined DT50.
Experts' consultation 5.4 Experts to discuss the following studies on aquatic organisms: Acute toxicity studies to fish, RAR Vol. 3CA B.9.2.1.: i-on the active substance: - first acute toxicity study on rainbow trout - second acute toxicity study on rainbow trout ii-on the solo formulation: - Acute toxicity study on rainbow trout (2000b) iii) Acute toxicity of BAS 507 00F to fish (2001): - on common carp - on zebrafish - on Bluegill sunfish - on Fathead minnow In particular, reliability of the studies should be discussed in relation to the additional information on the analytical measurements provided by the applicant and the cross-contamination of controls.	Acute toxicity studies to fish, RAR Vol. 3CA B.9.2.1.: i-on the active substance: -first acute toxicity study on rainbow trout: (1998): Overall, although the results can be reliable, due to the uncertainties the experts classified this study as valid and reliable with certain limitations for regulatory purposes. -second acute toxicity study on rainbow trout (2000): the endpoint from this study is more robust (and provided confidence intervals) than the first acute toxicity study on rainbow trout and the LC₅₀ is noted to be in the same range. The experts at the meeting agreed that the endpoint from this second acute toxicity study on rainbow trout is reliable/valid and should be used for fish tier 1 risk assessment. ii-on the solo formulation: Acute toxicity study on rainbow trout, (2000b): The study is valid but the LC50 is interpolated. iii) Acute toxicity of BAS 507 00F to fish (2001): -on common carp -on zebrafish -on Bluegill sunfish -on Fathead minnow Overall, the studies were considered reliable since the validity criteria were met for all of them. The experts agreed to express the endpoint based on nominals for the studies on <i>D. rerio</i> and <i>P. promelas</i>, and to recalculate the endpoints for <i>C. carpio</i>, and <i>L. macrochirus</i> based on the recovery of epoxiconazole, for which the deviations from nominal are much lower than for dimoxystrobin. Open point: RMS to update the risk assessment considering the agreement in the meeting. The endpoint from the second acute toxicity study on rainbow trout carried out with the active substance should be used for the fish tier 1 risk assessment. Open point: RMS to revise the calculations conducted in the experts' meeting and to confirm the values. Open point: RMS to harmonize the values across the RAR where necessary. Pay attention to the experts' consultation 5.8.



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Dimoxystrobin

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to reflect the discussion in the revised RAR and amend the LoEP accordingly.
Experts' consultation 5.5 Experts to discuss: 1. - The validity of ELS study with rainbow trout. - The endpoints of the ELS study with fathead minnow. In addition, experts should discuss the modified ELS: - with rainbow trout (CA 8.2.2.1/1). - with golden orfe with the solo formulation. 2. Their use in the risk assessment and the assessment factor (AF) to be applied.	B.9.2.2.1 Fish early life stage toxicity test i) with the active substance: ELS study with rainbow trout: the hatching success is 66%. Therefore according to the new OECD guidelines 210 (2013) validity criteria, the study is not considered valid. The experts agreed to disregard the ELS study with rainbow trout. ELS study with fathead minnow: The experts agreed that the statistically not significant tendency towards inhibition in growth from 8 µg a.s./L based on mean wet weight was biologically significant. Therefore, they agreed with the proposal to set the NOEC at 8 µg/L in order to cover effects on growth. Modified ELS study with rainbow trout (CA 8.2.2.1/1): The experts agreed that the uncertainty with regard to the reliability of the study is due to the exposure profile that does not cover part of the FOCUS scenario and whether the exposure profile matches the sensitive life stages. The experts agreed that, based on the uncertainties above, this study should not be considered in the risk assessment. ii- Modified ELS with golden orfe with the solo formulation: The experts agreed to express the endpoint from the study in TWA and to derive a NOEC. Due to the uncertainties in the study (species sensitivity, single dose exposure, dosing regime) it is not considered possible by the experts to lower the assessment factor below 10. Open point: RMS to update the RAR with regard to the assessment of the ELS study on rainbow trout (ELS-1999) and to remove the endpoint from the study from the LoEP. Open point: RMS to update the RAR and the LoEP with regard to the ELS study on fathead minnow study, and the tier-1 risk assessment using the endpoint set during the expert meeting (NOEC = 8 µg/L). Open point: RMS to update the RAR considering the discussion in the meeting on the modified ELS study on rainbow trout. Open point: RMS to update the RAR considering the discussion on the modified ELS study with golden orfe during the meeting.



Pesticide Peer Review TC 72 (25 – 28 January 2022)
Dimoxystrobin

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.6 Experts to discuss the aquatic invertebrate endpoints from the available studies on <i>Asellus aquaticus</i> (CA 8.2.4.2/1) and on <i>Americamysis bahia</i> (CA 8.2.4.2/3)	The experts agreed to use the endpoint at 96h for both additional aquatic invertebrate toxicity studies on <i>Asellus aquaticus</i> (CA 8.2.4.2/1) and on <i>Americamysis bahia</i> (CA 8.2.4.2/3), since the endpoint should be set at the onset of effect. All available information has already been considered in the RAR.
Experts' consultation 5.7 Experts to discuss: - The mesocosm study and its reliability on the basis of the provided re-analysis. - Coverage of chironomid species and most sensitive species (i.e. marine and <i>C. virginica</i>) from the available data. - The RACs that can be derived from the available data on aquatic invertebrates (ETO and/or ERO-RAC) and the risk assessment of aquatic invertebrates.	It was recognised that despite the high number of MDD1 taxa, several sensitive groups were not well covered due to a low abundance (algae, macro-crustacean). There is uncertainty regarding the assessment of an effect on chironomids and other groups, for which there was no sampling before exposure. The experts agreed that an overall endpoint (ETO or ERO) could not be derived for aquatic organisms. Nevertheless, a specific provisional ERO-RAC could be derived for daphnia. However, the ERO-RAC for daphnia was not considered protective of species with a longer reproductive cycle. Furthermore, since it has not been demonstrated that the exposure in the mesocosm covers the predicted exposure profile, currently the experts agreed that the provisional ERO-RAC for daphnia could not be used for the risk assessment. Open point: RMS to update the RAR in line with the discussion on the mesocosm study during the meeting.
Experts' consultation 5.8 Experts to discuss: - The available toxicity data. - The Geomean-based & the SSD-based RACacute, the related AF and acute fish risk assessment.	It was agreed that only data on the active substance and the solo formulation should be included in the calculation of the geomean. It was agreed that also in the calculation of the SSD, data from formulation with other active substance should not be included since the presence of another active substance would add uncertainty in the calculation of the sensitivity distribution, and adding lower endpoints does not necessarily lead to a more conservative endpoint. Therefore, the number of species necessary for an SSD-calculation is not satisfactory and this approach should be removed from the RAR. The AF applied in the geomean-RAC calculation should be in line with the EFSA (2013) guidance, i.e. 100.



Pesticide Peer Review TC 72 (25 – 28 January 2022)
Dimoxystrobin

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to update the RAR in line with the discussion during the meeting. RMS also to revise calculation for the endpoints and for the geomean (see also point 5.4). The RMS should also remove the SSD approach from the RAR and update the LoEP accordingly.
Experts' consultation 5.9 Experts to discuss the higher tier studies on bees. In particular, experts should discuss the studies by KCP 10.3.1.5/1; KCP 10.3.1.6/1 and KCP 10.3.1.6/2.	The available information was not considered sufficient to resolve the chronic risks to bees. Overall, the experts agreed with the assessment of the RMS and that further data would be needed. The deficiencies of the residue studies should be considered at Member state level for the product authorisation. Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.10 Experts to discuss: - the reliability of the field studies on earthworms (KCP 10.4.1.2/1, KCP 10.4.1.2/2 and KCP 10.4.1.2/3) for use in risk assessment, and in particular: -if the GAP is sufficiently reflected; -the study design (exposure conditions, pesticide application, species representation). - The risk assessment for earthworms considering the exposure assumptions.	Due to the severe limitations identified, the study KCP 10.4.1.2/1 was considered not acceptable for the risk assessment of dimoxystrobin for earthworms. Based on the less severe shortcomings noted, the experts agreed to study KCP 10.4.1.2/2 as supporting information only. The experts considered that the earthworm field study KCP 10.4.1.2/3 can be used to address the risk arising from the intended uses of dimoxystrobin (up to 2×0.5 L/ha) since the effects observed on one earthworm species are not treatment related but most likely due to natural variability. Overall, the experts concluded that the risk to earthworms resulting from the intended uses of dimoxystrobin is low. Open point: The RMS should reflect the outcome of the discussion in the updated RAR.



Pesticide Peer Review TC 72 (25 – 28 January 2022)
Dimoxystrobin

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.11 Experts to discuss the endocrine disrupting (ED) properties of dimoxystrobin.	T-modality: Considering the information in the mammalian toxicity section, and in line with the XETA Annex³ of the EFSA/ECHA ED Guidance, the appropriateness of the XETA (Xenopus Eleutheroembryo Thyroid Assay) to investigate T-activity has been confirmed by the experts. Since the XETA was negative, the experts agreed with the RMS conclusion that dimoxystrobin does not meet the ED criteria for the T modality for non-target organisms. However, since an interim report was submitted, the applicant is requested to provide the full definitive report with the final results. EAS-modalities: In line with the ECHA/EFSA ED guidance, the experts agreed that a test according to OECD TG 229 or TG 230 is requested. In addition, it was agreed that this test should include gonad histopathological investigations. In case of positive result, further data might be requested (i.e. Medaka Extended One Generation Test (MEOGRT), OECD TG 240). Open point: RMS to update the RAR reflecting the discussion held in the meeting.

³ <https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2018.5311&file=efs25311-sup-0002-Annex.pdf>



REPORT OF PESTICIDE PEER REVIEW TC 72

ALUMINIUM SILICATE – AIR IV

Rapporteur Member State: EL

5. Ecotoxicology

Date: 28 January 2022

List of participants:

Institute	Member States Country code
External expert	DE
Julius Kuehn-Institute (JKI)	DE
Federal Environmental Agency (UBA)	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
University of Veterinary Medicine and Pharmacy in Kosice	SK
Observer	CH

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² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Pesticide Peer Review TC 72 (25 – 28 January 2022)
Aluminium silicate

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the risk assessment for bees and the proposed weight of evidence approach: Several high contact and dietary risk scenarios were identified using EFSA (2013) and SANCO/10329/2002. Current dietary risk assessment schemes may be very conservative for inorganic substances. Supplementary data are available (including field studies on honeybee foraging and laboratory studies in bumblebees). Effects were observed across several field studies in NTAs. New information may be submitted by the applicants.	High acute contact risk and high chronic and larval risks were identified for a number of uses. Additionally, the acute oral risk assessment could not be addressed due to the lack of a valid endpoint (relevant for all representative uses). Therefore, a data gap was formally identified according to Reg. 283/2013-2014. The toxicity dataset, risk assessment and WoE proposed by the RMS were discussed and the meeting concluded the following: Despite acknowledging that the available Tier-1 assessment is potentially a worst-case, the meeting agreed that there was not enough evidence from the submitted valid data to conclude a low risk for bees (acute, chronic and larval). Additionally, the majority of experts considered that in the field the risk might be lower than indicated by the calculated Tier-1 assessment. Appropriate data would be needed to conclude on a low risk (e.g., higher-tier semi-field or field studies). Overall, the weight of evidence was not considered sufficient to conclude low risk from the intended uses. Open point: RMS to revise the weight of evidence by acknowledging the discussion and overall conclusions of the meeting.



Pesticide Peer Review TC 72 (25 – 28 January 2022)
Aluminium silicate

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.2 Experts to discuss the risk assessment for NTAs and to cover the following points: - Additional information provided by the applicant - Standard test species were not directly addressed at the lower tier. - A number of open-literature laboratory studies were not relied upon. Their use in risk assessment may be discussed. - Field studies (i.e., old and new studies) and their use to address the in- and off-field risk assessment. - Possible mitigation measures	A number of open-literature laboratory studies were available, but could not be relied upon, as the test design did not follow recognised guidelines. These laboratory toxicity studies included glass-plate and leaf-disc bioassays on representative NTA species (including the ESCORT 2 indicators <i>Typhlodromous pyri</i> and <i>Chrysoperla carnea</i>). Some effects were observed across studies, which included: reduction in the number of laid eggs, reduced larval ability to grasp leaf surface, mobility issues, changing in feeding preferences, mortality and changes in life span. However, the experts agreed that the available open literature laboratory studies were not suitable to derive a robust endpoint for the first tier RA for NTAs. A number of studies (i.e., KCA 8.3.2/01 and KCP 10.3.2.4/01 to 08) were considered invalid by the RMS because of severe limitations related to the test design and sampling. Overall, the meeting agreed not to consider them sufficiently robust to address the risks to NTAs. Additionally, a total of 11 open literature field studies, including one new field study (KCP 10.3.2-19) were available. These studies presented several limitations, including e.g., unreported dose verification, issues with sampling methods and absence of a valid toxic reference. Given the uncertainties related to these drawbacks, these studies were considered reliable with restrictions and were used qualitatively in a weight of evidence. These studies (i.e., those accepted with restrictions) showed a number of adverse effects – often severe - on soil- and foliar-dwelling NTAs, such as reduced abundance and species richness for a wide variety of taxa. In some instances, adverse effects were recorded after a single application. Recovery was not considered demonstrated and the risk in the off-field areas was not considered addressed based on the available information. The experts agreed that given the current data available, unreliability and limitations of the individual studies a comprehensive in- and off-field RA could not be performed. However, there were clear indications of adverse effects on NTA communities across the open literature field studies. Thus, high risk cannot be excluded. Additionally, it was not considered possible to determine appropriate and effective risk mitigation measures. The meeting suggested that further tests may be needed to further characterise the in- and off-field risk for NTAs (e.g., with new studies performed according to latest guidance). Open point:



Pesticide Peer Review TC 72 (25 – 28 January 2022)
Aluminium silicate

Subject	Conclusions Pesticide Peer Review Meeting
	- RMS to reflect to outcome of the discussion in the RAR and update, whether necessary the conclusion of the risk assessment accordingly. - RMS to delete studies which were not considered fully valid and reliable from the list of endpoints.

REPORT OF PESTICIDE PEER REVIEW TC 68

METIRAM – AIR III

Rapporteur Member State: IT

5. Ecotoxicology

Date: 12 January 2022

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
Federal Institute for Risk Assessment (BfR)	DE
National Institute for Agricultural and food research and technology (INIA)	ES
TRAGSATEC	ES
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
University of Milan, Department of Pharmacological and Biomolecular Sciences	IT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
National Institute of Public Health	RO
Hearing Expert	CH

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.15 identified following consideration of comments received during the MS/APPL/public consultation on the assessments following the ED clock stop: An experts' consultation is needed to re-discuss the ED properties of metiram through the T-modality for non-target organisms other than mammals. Additionally, experts should discuss the endpoint setting from the available studies on amphibians.	The experts considered the available data and assessment following the 3-month ED clock stop. No new data were submitted by the applicant for the ED assessment. Only an uncertainty analysis of the conclusion drawn at the Pesticides Peer Review Experts' meeting 192 in February 2019. Adversity based on thyroid histopathology was identified and confirmed in the available mammalian studies both for metiram and ETU. The population relevance of the identified adversity could not be confirmed for wild mammals. Neither studies for investigating endocrine adversity nor endocrine activity were available on non-mammalian species with metiram. A number of studies of different duration were available with amphibians and ETU. All the studies showed a consistent pattern of adversity and endocrine activity. ETU is demonstrated to be formed in all the available vertebrate studies but below 10%. No metabolism studies were available with amphibians. However, it is well known that metabolism is qualitatively conserved across vertebrates, although the level of formation may vary in different species. The major sources of uncertainty in the dataset were presented and discussed as follow: • Reliability of the available studies with ETU; • Metabolism study in amphibians and cross species extrapolation • Level of ETU formed in metabolism studies



Subject	Conclusions Pesticide Peer Review Meeting
	• Concentrations where ED-mediated effects and endocrine activity was observed with ETU • Available endpoints for fish and possible maximum tolerated concentration (MTC). Metiram was not considered to meet the ED criteria according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 for wild mammals. For non-mammalian species, the experts agreed that based on the available evidence and uncertainty, a firm conclusion on metiram cannot be drawn. ETU was considered an endocrine disruptor. Open points: - RMS to update the RAR by including the assessment of the individual studies with amphibians from the open literature as presented at the meeting. RMS to pay attention to the reference dates. It was noted that especially for the 90-day study (2006) an assessment of reliability seems to be missing in the RAR. The evaluation of the other studies seems to be in line with the EFSA assessment, although not very detailed. - RMS to update the LoEP and pertinent volumes in the RAR to delete endpoints from screening studies and add a footnote in the endpoint form the 90-day study (2006) highlighting that the study is supportive, only. - RMS to update in the revised RAR and LoEP the ED assessment in line with the outcome of the discussion at the peer-review meeting.



REPORT OF PESTICIDE PEER REVIEW TC 69

Follow up meeting of TC 26 on ecotoxicology

(28 September – 2 October 2020)

PROTHIOCONAZOLE – AIR III

Rapporteur Member State: PL

5. Ecotoxicology

Date: 11 January 2022

List of participants:

Institute	Member States Country code
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	France
Federal Environmental Agency (UBA)	Germany
E-V-A Sp. z o.o.	Poland
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	The Netherlands
National Institute of Public Health	Romania
Hearing expert	Switzerland

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**Pesticide Peer Review TC 69 (11 January 2022) - follow up meeting of TC 26
Prothioconazole**

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 The experts to discuss the assessment and agree on the final endpoint from the study on reproductive toxicity of prothioconazole to mallard duck.	The meeting reviewed the long-term bird studies KCA 8.1.1.3/02 and KCA 8.1.1.3/03 and discussed the statistical and biological relevance of the observed effects across relevant response variables (i.e., with focus on reproductive performances). The meeting considered the following body of evidence: - previous review by the former RMS - the discussion which took place during TC26 - the written procedure on additional information - the statistical methods and results presented by study authors and reviewed by the EPA - raw data Based on this body of evidence the meeting concluded that no statistically significant or biologically relevant effect was demonstrated across studies. Therefore, the NOEL values were revised as follows: - toxicity of prothioconazole for mallard duck (KCA 8.1.1.3/02) -> NOEL: 190 mg a.s./kg bw/d - toxicity of PTZ-desethio metabolite to northern bobwhite quail (KCA 8.1.1.3/03) -> NOEL: 43 mg /kg bw/d Open points: i. RMS to update the RAR with the conclusion of the meeting (including the additional information included in the RMS presentation e.g., raw data which was used for interpretation) for the studies with mallard duck (KCA 8.1.1.3/02) and northern



Pesticide Peer Review TC 69 (11 January 2022) - follow up meeting of TC 26
Prothioconazole

Subject	Conclusions Pesticide Peer Review Meeting
	bobwhite quail (KCA 8.1.1.3/03) (a.s. and desthio metabolite respectively). ii. Therefore, risk assessment for prothioconazole should be performed with the endpoint from the other available study (86 mg a.s./kg bw per day). iii. Additionally, the RA for the desthio metabolite should be performed with the NOEC of 43 mg a.s./kg bw per day from KCA 8.1.1.3/03. iv. The LoEP should be updated accordingly. This open point is relevant for both representative products.
Experts' consultation 5.2 The experts to discuss the weight-of-evidence assessment for birds as presented by RMS in the RAR revised after TC 26 and agree on the final outcome of the risk assessment.	TWA (time weighted average) factor should not be used for acute assessments. No refined DT50 value was available for seedlings in winter sown cereals. However, the evidence from the data for spring sown cereals was considered sufficient to assume a DT50 of 10 days. A DT50 of 10 days for prothioconazole is reasonable for winter cereals based on the evidence from the available data on spring cereals showing notably faster degradation. Insufficient evidence was available to support the use of a 10-day DT50 for the metabolite. A 7-day averaging period should be assumed for cereal seed considering the germination time. For the current assessment it was agreed that the PT values should be used for reaching the final outcome of the quantitative assessment. The argument regarding dehushing and overlap of the breeding season was not considered sufficiently supported to provide reliable evidence to the weight-of-evidence assessment. Overall a low risk to bird was indicated for spring down cereals whereas the risk from winter sown cereal remains high. Open points: i. RMS to correct the acute assessment removing the TWA factor. The RMS should also add a justification for the use of a DT50 of 10 days for the parent and metabolites for the seedling germinating from winter sown cereals. ii. For spring cereals, the RAR should be updated also using an averaging period of 7 days for the fTWA value.



**Pesticide Peer Review TC 69 (11 January 2022) - follow up meeting of TC 26
Prothioconazole**

Subject	Conclusions Pesticide Peer Review Meeting
	iii. For the metabolite to remove the fTWA for the tier 1 risk assessment for metabolite PTZ-desthio for winter sown cereals. iv. The RMS should acknowledge the risk to linnet in the revised risk assessment. v. RMS to revise the risk assessment, acknowledging the decisions taken above and highlighting that ecological refinement were not applicable to linnet.
Experts' consultation 5.3 Experts to discuss the combined risk assessment for birds and mammals accounting for the parent and the metabolite PTZ-desthio as presented in the RAR revised after TC 26 and agree on the final outcome of the risk assessment.	The RMS suggested to consider the combined risk from the parent and toxic metabolite by the use of combined Toxicity-Exposure Ratios (TERs). Other approaches were discussed but overall the approach by the RMS was considered suitable. The experts agreed with the assessments performed by the RMS noting that they were conservative. Open point: i. Since the endpoints for birds were revised (see discussion point 1), the RMS needs to update the combined RA for birds with the revised endpoints for birds.



REPORT OF PESTICIDE PEER REVIEW TC 67

CYMOXANIL – AIR IV

Rapporteur Member State: LT

5. Ecotoxicology

Date: 25 November 2021

List of participants:

Institute	Member States Country code
Federal Environmental Agency (UBA)	DE
Julius Kuehn-Institute (JKI)	DE
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
External expert	FR
The State Plant Service under the Ministry of Agriculture of the Republic of Lithuania	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
University of Veterinary Medicine and Pharmacy in Kosice	SK

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the appropriateness of the endpoint used in the risk assessment based on the geomean of endpoints with greater than values. Any newly submitted information from the applicants should also be considered.	Several acute and short-term toxicity studies with birds were available. Both the geomean of the available acute studies and short-term toxicity studies were presented. All the available endpoints were unbound values. The geomean calculated using unbound values is considered conservative as all the available endpoints are considered in the geomean calculation as absolute values. The geomean of the short-term toxicity studies was lower than the geomean of the acute studies. Overall, the experts agreed to use the geomean of the available short-term toxicity studies with birds for acute risk assessment. Open point: RMS to check and amend risk assessment in the RAR And LoEP, as needed, based on the outcome of the discussion. The RMS should also check if in the LoEP the correct endpoints for both acute and short-term toxicity studies with birds are reported.
Experts' consultation 5.2 Experts to discuss: - The refined risk assessment to frugivorous birds considering the information provided by the applicants.	- The risk assessment for the representative uses on tomato failed for the representative formulation Dauphin 45 WG and Cymoxanil 45WG. The only available refinement was a refined DT50 based on plant metabolism studies or on residue decline studies in lettuce (Dauphin 45 WG) or tomatoes (Cymoxanil 45 WG).



Pesticide Peer Review TC 67 (22 – 25 November 2021)
Cymoxanil

Subject	Conclusions Pesticide Peer Review Meeting
- If the risk to birds and mammals of the metabolite IN-U3204 can be addressed with the information provided by the applicants.	Metabolism studies in tomato foliage are not considered suitable to derive a DT50 as those studies are not designed for that purpose and it is not possible to extrapolate from foliage to fruit. The available residue studies in lettuce were not available in the RAR and were not re-submitted. The available residue studies in tomato missed many details, e.g. meteorological data, and therefore they cannot be used to derive a reliable DT50. - QSAR data were submitted on the toxicity of the metabolite IN-U3204 to birds and mammals. Those data were used to indicate that it is not expected the metabolite to be more toxic than the parent. However, it was noted that the metabolite has functional groups not present in the parent compound and therefore a comparative assessment cannot be done. - Overall, the available refined risk assessment based on a refined DT50 was rejected by the experts. High risk to frugivorous birds for the representative uses on tomato is therefore concluded. - Overall, the newly submitted data on the metabolite IN-U3204 were not considered suitable that additional information is needed to further address the toxicity of the metabolite IN-U3204 to birds and mammals. Open point: for the RMS to reflect the outcome of the discussion in revised RAR and revise the risk assessment, as needed.
Experts' consultation 5.3 Experts to discuss the relevant long-term endpoint for the risk assessment for mammals. The outcomes of the expert consultation on ED for histopathological findings should be considered. Experts to discuss if the toxicity observed in the acute data is gender-driven or if a geometric approach could be used.	- As long-term endpoint for mammals, the RMS proposed the use of a NOAEL from developmental studies with rat based on increased incidence of skeletal variations and delayed ossification. The NOAELs from available developmental studies with rabbits were lower. However, the lower endpoints from developmental studies with rabbit were not considered to be ecotoxicologically relevant because either based on non-relevant maternal effects or based on effects observed in very few animals in a study with a higher dose spacing if compared to the other developmental studies with rabbits or considered too conservative and based on a poor reporting when considering the overall dataset. - As acute endpoint for mammals, the RMS proposed to use LD50 485 mg/kg (lowest combined endpoint) for both sexes. Two acute studies with mammals were available which do not show a similar pattern in terms of sensitivity of males and females. - The experts agreed with the long-term endpoint selected by the RMS: 10 mg/kg bw/d from developmental studies with rats based on increased incidence of skeletal variations and delayed ossification. - The experts agreed with the selected acute endpoint for mammals.



Pesticide Peer Review TC 67 (22 – 25 November 2021)
Cymoxanil

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.4 Experts to discuss: - The refined risk assessment to herbivorous and frugivorous mammals for all representative uses considering the information provided by the applicants. - The relevant focal species for small herbivorous mammals	The Tier 1 risk assessment for mammals failed for all the uses. A refined risk assessment based on measured DT50 was proposed. The available studies and reliability of the derived DT50 was discussed. For Cymoxanil 45 WG, overall 2 residue trials in wheat and 3 in peas were considered as providing a reliable DT50. The proposal to use vole as a focal species was also discussed. However, no data were available in support of this selection. For Rival Duo, the available residue trials were discussed. Overall, the experts considered that only the trials in Poland and Hungary gave a reliable DT50 for both wheat and oilseed rape. For Dauphin 45 WG, the available refined DT50 was based on residue decline studies in lettuce which were, however, not re-submitted for renewal and therefore not re-evaluated. Overall, the experts agreed that data on monocot and dicot should not be merged in line with EFSA (2019). The experts agreed that the number of sites on both monocot and dicot is not sufficient (EFSA, 2019) to use the measured DT50 in the refined risk assessment at the EU level. However, when considering all the available data from different applicants, four sites per monocot (wheat) and five for dicot (pea and OSR) for CEU are available and suitable to be used for risk assessment for those uses intended to be in CEU. For Cymoxanil 45 WG, the experts agreed that vole cannot be considered the focal species without data supporting this choice. Post-meeting note According to the conclusion reported above, i.e. overall dataset for cymoxanil, and following an internal discussion, it was agreed that the available data should be pooled together and used for all the relevant representative uses and scenarios, i.e. the data should be used independently of the data submitter and owner. As recommended during the meeting, data on monocot and dicot should be kept separated. Although, the majority of the uses in the GAP are for all EU or CEU and SEU, it is noted that there is one use on potatoes at 0.10 Kg a.s./ha for Dauphin 45 WG which is only intended for CEU. Open point RMS to revise the RAR by pooling all the available and reliable residue decline data together and use them in the revised risk assessment for those uses which are limited to CEU.



Pesticide Peer Review TC 67 (22 – 25 November 2021)
Cymoxanil

Subject	Conclusions Pesticide Peer Review Meeting
	The risk assessment should be revised by deleting the use of the refined DT50 when not suitable, i.e. representative uses for SEU and all EU.
Experts' consultation 5.5 Experts to discuss the endpoint setting with particular focus on the comparison with historical control data.	To support the endpoint setting from one of the available Early-life cycle tests (ELS), the applicant has provided a dataset covering larval length and wet weight in rainbow trout in control groups from a number of studies in order to explain the suitability of the available study that showed statistically significant difference in these 2 parameters in comparison with the control group at all tested concentrations. This historical control data (HCD) were obtained from the same facilities where the test was conducted and it covers approx. a time frame of 1 year. The suitability of these data was considered in the overall endpoint setting from this study. The majority of the experts agreed with the proposal of using a NOEC of 0.044 mg/L by considering only the information and the actual controls from the ELS test with rainbow trout and disregard the use of HCD due to a number of limitations (e.g. only data from 3 studies, limited timeframe, not detailed information). Open point: for the RMS to reflect the outcome of the discussion in the revised RAR.
Experts' consultation 5.6 Experts to discuss the validity of the honeybee larval studies CA 8.3.1.3-01 and CA 8.3.1.3-01 for the risk assessment of cymoxanil. The following aspects should be considered: the use of a solvent control, the comparison of the results to the solvent control group, the use of Abbott correction for mortality, the fulfilment of the validity criteria for larval mortality and adult emergence across all replicates, the differences observed between the resulting endpoints from both studies, and the dates of the in-life phases.	The study was considered appropriate in terms of design and validity criteria to address the possible effects in honey bee larvae. A detailed assessment of the percentage of effects and the statistical analysis lead to the selection of the endpoint from the study was conducted during the meeting. The experts agreed the initially proposed NOED of 0.241 µg a.s./larvae. This endpoint was used to conduct the risk assessment for honey bee larvae. Open point: for the RMS to reflect the outcome of the discussion in the revised RAR.



Pesticide Peer Review TC 67 (22 – 25 November 2021)
Cymoxanil

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.7 Experts to discuss the weight of evidence paper CP 10.2.1-01 focusing on the presence or absence of nectar in grapevines, the attractiveness to honeybees, residues of cymoxanil found in grape nectar and/or pollen, and the implications for higher/refined risk assessment for grapevines.	The submitted position paper used a number of studies to support the relevance of nectar in grapevines in the overall exposure to bees; however, the literature search wasn't transparently reported. In addition, a number of reports with monitoring data and bee poisoning incidents were available. However, the information those documents provided is of scarce value for issuing the regulatory question. Overall, the majority of the experts agreed that the information provided in the WoE was not sufficient and exposure through nectar can't be excluded. Further data would be needed to address the chronic risk to bees (adults and larvae). Open point: for the RMS to reflect the outcome of the discussion in the RAR. Open point: for the RMS to amend the risk assessment considering that the exposure through nectar should not be disregarded.
Experts' consultation 5.8 Considering the provided data by the applicants, experts to discuss: - The risk assessment for non-target arthropods considering the severe effects on reproduction observed in glass-plate. - If the higher tier risk assessment covers the representative uses and the application rates.	- For Cymoxanil 45 WG, the experts agreed to consider the effects observed on reproduction for the tier 1 risk assessment. The experts also considered following a weight of evidence approach to refine the risk for non-target arthropods that considered the fast dissipation of cymoxanil and the results of an aged-residue study on <i>Typhlodromus pyri</i>. - For Rival Duo, a field study on potatoes showing recovery of non-target arthropod populations within one year was used to refine the in-field risk. No mitigation measures were proposed by the applicant for the off-field risk assessment. - For Dauphin 45, it could not be confirmed whether this formulation is equivalent to Cymoxanil 45WG. Therefore studies performed on the latter cannot be used to assess the risk for non-target arthropods for the representative uses on grapes, tomatoes and potatoes with Dauphin 45. - For Cymoxanil 45 WG, the experts agreed to also present the Tier I risk assessment using both LR₅₀ and ER₅₀. The experts agreed that when using the results of the aged residue studies with <i>Typhlodromus pyri</i>, low risk in-field is concluded on grapes. The experts agreed to use the available data on residue decline studies in a qualitative way to conclude also a low risk to potatoes and tomatoes. - For Rival Duo, the majority of the experts agreed with the conclusion of the RMS; i.e., that a low in-field risk can be concluded based on the available field study. A high off-field risk was concluded as no mitigation measures were proposed by the applicant. - For Dauphin 45, the experts agreed that, the presented Tier 1 risk assessment cannot be accepted without further data confirming that the



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Cymoxanil

Subject	Conclusions Pesticide Peer Review Meeting
	two formulations are comparable. If data are further submitted at MS level on the equivalence of the two formulations, then the conclusion drawn for Cymoxanil 45 WG also applies to this formulation. Open point: - Cymoxanil 45W: RMS to revise the current RAR by reflecting the outcome of the discussion and to strikethrough the quantitative RA presented using the refined DT₅₀ from the current RAR and LoEP. - Rival Duo: RMS to revise the risk assessment by reflecting the outcome of the discussion and the fact that the results of the field study cannot be used for refining the off-field risk. - Dauphin 45: • RMS to delete the available risk using data from CTF on Cymoxanil 45 WG and reflect the outcome of the discussion; • RMS to assess whether information is available on the comparability of the two formulations and in case inform EFSA.
Experts' consultation 5.9 Experts to discuss the ED potential of cymoxanil.	In line with the ECHA/EFSA ED guidance, the dataset for NTOs for EATS - modalities wasn't complete neither for adversity nor for endocrine activity. Further data are needed to draw a conclusion of the ED properties of cymoxanil on non-target organisms other than mammals. According to ECHA/EFSA Guidance, the following tests are considered necessary: • An AMA test according to OECD TG 231 (for T-modality); a XETA according to OECD TG 248 would also be considered suitable in this case. • A FSTRA test according to OECD TG 229 including gonad histopathology. If one of those level 3/4 assays is positive, further data might be needed to investigate adversity (e.g. LAGDA according to OECD TG 241 and/or MEOGRT according to TG OECD 240). Open point: RMS to revise the Vol. 3 B9 by clarifying which type of studies are the 2 studies mentioned by the applicant CTF and state its suitability for the ED assessment. Open point: RMS to reflect the outcome of the discussion in the revised RAR.



REPORT OF PESTICIDE PEER REVIEW TC 67

RAPE SEED OIL – AIR IV

Rapporteur Member State: NL

5. Ecotoxicology

Date: 25 November 2021

Institute	Member States Country code
Federal Environmental Agency (UBA)	DE
Julius Kuehn-Institute (JKI)	DE
External expert	FR
Agence nationale de sécurité sanitaire, de l'alimentation, de l'environnement et du travail (ANSES)	FR
The State Plant Service under the Ministry of Agriculture of the Republic of Lithuania	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL

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Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.2 (Environmental fate and Behavior experts' consultation point to be jointly discussed with the Ecotoxicology experts) Experts to discuss and agree on the approach to be used for the surface water/sediment exposure assessment for rape seed oil both in field and greenhouse uses, as the FOCUS models cannot properly describe the behaviour of oils in natural water/sediment systems. This consultation should be done jointly with ecotoxicology experts to consider how toxicity studies for aquatic organisms are performed.	It was discussed that FOCUS Step 3 and 4 cannot properly describe the behaviour of oils in natural water/sediment systems, as the FOCUS TOXSWA model is based on the assumption of instantaneous partitioning to the sediment for very high sorbing substances, which is the case for rape seed oil, and this assumption will underestimate the water column exposure that can occur via spray drift. It was noted that at FOCUS Step 2 partitioning of spray drift to sediment only occurs at 2 days, so this can be a better estimation of what may occur. It was considered that FOCUS Step 2 calculations might be completed using the option of no runoff or drainage (considering the high adsorption to soil that will occur in this case) and that buffer distances can be applied at Step 2 when required. A risk assessment cannot be done with PEC_{sw} expressed in mg/m². If the rape seed oil is emulsified in water, the endpoint from the studies can be expressed in mg/l, and if there is an emulsifier, the substance can be expected to stay longer in the water column, and then PEC_{sw} expressed in µg/L can be used in the RA. It was agreed to use FOCUS Step 2 to calculate PEC_{sw}, in µg/L, considering only spray drift. When required, buffer distances can be applied at Step 2 to mitigate spray drift. Open point: RMS to provide PEC_{sw} calculations at FOCUS Step 2 considering only spray drift and buffer distances for spray drift mitigation, if needed.



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Rape seed oil

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the available data for aquatic invertebrate and algae to address the data requirements.	The RMS is of the opinion that, considering the low solubility of rape seed oil in water, data requirements are sufficiently addressed with the data on the formulation and that these data can be used for the risk assessment of the active substance. The experts agreed on the RMS' proposal to use the representative formulation data to perform the risk assessment for the renewal rape seed oil and indicate that this conclusion is only valid for this representative formulation and equivalent or comparable formulations. Open point: RMS to update the aquatic risk assessment with the new PEC_{sw} values calculated by e-fate.
Experts' consultation 5.2 Experts to discuss: - The studies: - Chronic oral toxicity test on honey bee adults - Larval toxicity test (repeated exposure) - Semi-field (tunnel) study). - The acute risk via contact exposure for all intended uses. - Any new studies/scientific evidence submitted by the applicant.	Chronic oral toxicity study: The applicant submitted a study demonstrating by chemical analysis that stock solutions of the same concentrations as those used in the chronic adult study are stable and homogeneous for 10 days when stored at the same conditions. Larval toxicity study: The available 8-day larval study shows limitations as it did not cover the full development. At day 8, effects on larval mortality were observed at the two highest tested concentrations. Semi-field (tunnel) test: By using the results on mean coverage of eggs, larvae, capped brood on the brood comb from the tunnel test, no impact on bee brood was seen with two applications of rape seed oil at 19.3 kg a.s./ha. The colony strength in the test item group at the end of the assessment period (day 21) was not statistically significantly different from the control colonies. Chronic oral toxicity study: The experts agree that the endpoint can be estimated based on the nominal concentration of rape seed oil. Larval test: The Tier 1 RA for brood development will not be formally conducted with the endpoint derived from the 8-day study as it does not cover the full development of bees. Semi-field (tunnel) test: All MS experts agreed to use the results of the semi-field (tunnel) study to assess the effect of rape seed oil on honey bee brood for this particular case.



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Rape seed oil

Subject	Conclusions Pesticide Peer Review Meeting
	Acute risk via contact exposure: It was agreed to use the endpoint derived from the contact laboratory study for the acute risk assessment of rape seed oil. Open points: - RMS to revise the RAR reflecting the outcome of the discussions on the chronic oral toxicity test, the tunnel test and the acute risk via contact exposure. - RMS to revise the Tier 1 risk assessment for honey bee larvae based on the endpoint derived from the 8-day study but indicating that the risk assessment is only indicative. The tier 1 calculation based on the 8-day honeybee larval should be removed from the List of Endpoints.
Experts' consultation 5.3 Experts to discuss the additional studies with <i>Typhlodromus pyri</i> and their used in the risk assessment for non-target arthropods.	No additional higher tier data were provided to refine the risk for non-target arthropods. Since no additional data was submitted, there was no discussion; the experts agreed with the risk assessment performed by the Rapporteur Member State with the available data.
Experts' consultation 5.4 Experts to discuss any additional scientific lines of evidence that could be used in a weight-of-evidence approach to assess the risk of rape seed oil for collembolans.	The Technical Report on recurring issues in ecotoxicology (EFSA, 2015³) indicated that a correction factor of 2 should be applied to collembolan and soil mite studies where 5% organic matter is used in the test guideline. No lethal or sub-lethal effects were observed in the chronic laboratory study on <i>Folsomia candida</i> even at the highest concentration tested. The resulting endpoint for <i>F. candida</i> is a higher than value. There is uncertainty around the correction factor considering that the toxicity study was conducted using 5% organic matter. The experts agreed to apply the correction factor of 2 for Tier 1 risk assessment for Collembola and to further refine the risk following a weight-of-evidence approach, which would include TER values based

³ EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA Supporting Publication 2015; 12(12):EN-924. 62 pp. doi:10.2903/sp.efsa.2015.EN-924



Pesticide Peer Review TC 67 (22 - 25 November 2021)
Rape seed oil

Subject	Conclusions Pesticide Peer Review Meeting
	on the NOEC for <i>Folsomia candida</i> and to consider a low risk for all representative uses of rape seed oil except for the field use in woody ornamentals. Open point: RMS to update the risk assessment according to the outcome of the discussion and to update the endpoints in the List of Endpoints.



REPORT OF PESTICIDE PEER REVIEW TC 67

ISOFLUCYPRAM (NAS 1107/2009)

Rapporteur Member State: FR

5. Ecotoxicology

Date: 25 November 2021

List of participants:

Institute	Member States Country code
Julius Kuehn-Institute (JKI)	DE
Federal Environmental Agency (UBA)	DE
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
The State Plant Service under the Ministry of Agriculture of the Republic of Lithuania	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL

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Pesticide Peer Review TC 67 (22 – 25 November 2021)
Isoflucypram

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to decide whether the substance under assessment meets the ED criteria for non-target organisms.	A XETA and a modified AMA were considered in the RAR for the T-modality and a REACTIV, a RADAR and a FSTRA for EAS-modalities. These studies were, however finalised after the closure of the stop of the clock for additional information and thus are not eligible in the course of this process. Nevertheless, since a transparent evaluation was provided by the RMS in the revised DAR, the reliability of the studies and possible concern were discussed during the meeting. T-modality: The available XETA included 2 tests. One of the tests was positive at the highest tested concentration. The modified AMA only showed effects on Hind limb length at day 7 and a slight change in histopathology. EAS-modality: The REACTIV gave positive evidence for endocrine activity. The RADAR was not considered valid. In males, a statistically significant highest tubercle score and a slight increase in mean testicular stage scores was detected in males at the highest tested concentration. This seems to indicate a slightly advanced development stage of male fish, however no androgenic effects were seen on females. The available Modified AMA (modified OECD TG 231) and FSTRA (OECD TG 229) were not eligible as finalised after the closure of the 3-month stop of the clock period provided for in the legislation for submission of additional information. Moreover, for the other available relevant studies for the ED assessment of non-target organisms, only interim results were submitted on time, i.e. with the 3-month stop of the clock. Nevertheless, the RMS provided a transparent evaluation of the data in the revised DAR. Based on the information presented in the revised RAR isoflucypram was considered not to meet the ED criteria through EAS-modalities due to the lack of endocrine activity. For the T-modality, considering the information available (i.e. XETA positive and some positive evidence in the modified AMA) and the



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Isoflucypram

Subject	Conclusions Pesticide Peer Review Meeting
	uncertainty in the available dataset, experts considered that a MoA should be conducted to contextualize the available evidence as first step and consider the need of further information on adversity (i.e., a LAGDA).
Experts' consultation 5.2 Experts to discuss the endpoint selected for the risk assessment of wild mammals. In particular, it should be discussed whether the endpoint selected by the RMS (reduction of bodyweight gain after 12 months of exposure) should be used for selecting the endpoint. Any additional information provided by the applicant should also be considered under this expert consultation point.	The experts considered the available data in toxicology. It was agreed that only effects on absolute values on bodyweight should be considered as relevant for the risk assessment of wild mammals. The off-spring NOEL based on a delay in vaginal opening from the rat multi-generational study was considered to be relevant for the assessment. All experts agreed that the relevant endpoint for the assessment of wild mammals should be 34.1 mg/kg bw/d. RMS to update the list of endpoints, with the agreed end point for the assessment of wild mammals, and the RA in the RAR.
Experts' consultation 5.3 Experts to discuss the reliability of the endpoints derived from the early-life stage toxicity to fish. It should be noted that the aquaria used in the study was only 4 L. OECD 210 indicates that the aquaria should be large enough to allow for proper growth of the control (e.g. for small fish 7 L). It should be noted that the RMS reported that there were several underdeveloped/undernourished fish during study days 6-13 in the solvent control (1 in replicate B on day 6, 1 in replicate C on day 6 and 7 and 2 on day 8). It should be noted that the NOEC derived from this study	The experts considered that the small size of the aquaria was not a critical issue since the fish loading criteria was not exceeded and the growth/health of the fish in the water control was not affected. The experts also considered that the pump failure during the study was not a critical issue since the endpoint was expressed in terms of mean measured concentrations. The experts considered that the available TK/TD modelling has not been validated and calibrated appropriately. The endpoint from the fish ELS study was NOEC = 13.28 µg a.s./L based on geometric mean calculations. Open point: RMS to include more details of their evaluation of the TK/TD modelling in the RAR (e.g., checklist from EFSA, 2018).



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Isoflucypram

Subject	Conclusions Pesticide Peer Review Meeting
(13.28 µg a.s./L) is based on growth as well as larval survival. Therefore, the argumentation regarding the survival of the larvae in the controls does not resolve this issue.	
Experts' consultation 5.4 Experts to discuss the higher tier chronic risk assessment for fish. Please note that this discussion is not needed if the applicant does not provide any further information.	Point closed. No discussion was necessary as no data additional data/ risk assessment was provided.
Experts' consultation 5.5 Experts to discuss the risk assessment for bees and whether overall a low risk can be concluded. The discussion should include a consideration of whether the data are sufficient to exclude a risk from potential metabolites.	The experts agreed that the honeybee larvae toxicity study was valid. The screening assessment indicated a low risk to honeybees. Three of the semi-field studies were considered reliable noting the limitations of semi-field conditions. The results of the 4th semi-field study was considered to be inconclusive for the bee endpoints. The three reliable semi-field studies were considered to support the conclusion of low risk to bees through sublethal and accumulative effects. The assessment of plants metabolites was also considered to show a low risk to honeybees. The experts agreed that the ED10 value for honeybee larvae was reliable and can be used for the risk assessment. The available data and risk assessments were considered to demonstrate a low risk to honeybees. Open points: RMS to update the List of endpoints, the study summary for the honeybee larvae study and the RA accordingly. A footnote should be added to explain that the differences in adult emergence were calculated on raw data. RMS to reflect the outcome of the discussion regarding the semi-field studies, sublethal and accumulative effects in the RAR and the list of endpoints.



REPORT OF PESTICIDE PEER REVIEW TC 64

HEPTAMALOXYLOGLUCAN – AIR IV

Rapporteur Member State: FR

5. Ecotoxicology

Date: 19 November 2021

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
National Institute for Agricultural and food research and technology (INIA)	ES
Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (ANSES)	FR
State Plant Service under the Ministry of Agriculture	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL

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Pesticide Peer Review TC 64 (15 – 19 November 2021)
Heptamaloxyloglucan

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the justification provided by the applicant for waiving the endocrine disruption (ED) assessment as recommended in the ECHA/EFSA ED Guidance.	The ECHA/EFSA ED Guidance foresees cases in which an endocrine disruption (ED) assessment is not considered justified based on the physico-chemical and (eco)toxicological properties of the substance under assessment. In line with this, a waiver of the ED assessment for non-target organisms was proposed with the following justifications: - Heptamaloxyloglucan, as unchanged molecule, is not absorbed and has no bioaccumulation potential; - Heptamaloxyloglucan has a non-toxic mode of action; - Carbohydrates, compounds similar to heptamaloxyloglucan are largely distributed in soil and fruits. - The absorbable metabolites of heptamaloxyloglucan are monosaccharides (glucose, fucose, xylose and galactose) and short-chain fatty acids (acetate, propionate and butyrate). They are naturally present in metabolic pathways of animals and humans and are known to be devoid of toxicity except when ingested in very large quantities. - No indication of EATS mediated adversity in the available mammalian studies and available literature on fish and birds. Overall, it was agreed to waive the ED assessment and therefore the ED criteria are not considered met for EATS-modalities. Open point: RMS to reflect the outcome of the discussion in the revised RAR.



REPORT OF PESTICIDE PEER REVIEW TC 63

OXAMYL – AIR III

Rapporteur Member State: IT

5. Ecotoxicology

Date: 20-22 September 2021

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Central Institute for Supervising and Testing in Agriculture	CZ
Julius Kühn- Institute	DE
Federal Environmental Agency (UBA)	DE
Ministry of Environment and Food of Denmark, Environmental Protection Agency	DK
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
International Centre for Pesticides and Health Risk Prevention (ICPS)	IT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
External expert	DE
External expert	PL
Hearing expert	CH
Hearing expert	IT

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Pesticides Peer Review TC 63 (20 – 23 September 2021)
Oxamyl

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Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the refined acute and chronic risk assessment to bird taking grit in tobacco and potato; the risk to row ends; the risk from exposure through weed seedlings and soil arthropods. Experts to also consider the mitigation measures proposed as parts of refinement.	A number of refinements were proposed by the applicant and required further discussion: 1. Granule size 2. Two field monitoring studies 3. Position paper (birds consuming granules as grit) 4. Time Weighted Average (TWA) of 0.53 (birds consuming granules as grit) 5. Risk mitigations (birds consuming granules as grit) 6. Risk assessment from exposure through weed seedlings 7. Risk assessment from exposure through soil arthropods Conclusions: - Birds consuming grit: The refinement based on granule size was dismissed because of the high level of uncertainty around this measure. The meeting considered that the G density refinement based on the 90th percentile granule count was justified for the EU risk assessment. However, separate assessment for the edge of field and mid-field were considered necessary. The weight of evidence proposed by the applicant was not considered sufficient <i>per se</i> to address the risks to birds taking granules as grit. The use of a default TWA of 0.53 was not deemed justified for this scenario. - Exposure through weed seedlings:



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Subject	Conclusions Pesticide Peer Review Meeting
	The proposal by the applicant to use residue studies to address the risk through weed seedlings was dismissed because of the high uncertainty related to proposed assessment. - Exposure through soil arthropods: It was noted that a specific risk assessment addressing this exposure scenario was not envisaged by EFSA (2009). Additionally, the risk could be considered covered by other exposure scenarios (i.e., secondary poisoning – vermivore birds and mammals) Open points: RMS to update the acute and chronic risk assessment to bird taking grit in tobacco and potato (see also Experts' consultation 5.2). Specifically, the following points should be addressed: - The risk assessment should be updated by deleting the granule size refinement. - The RMS should carefully check the appropriateness of the summary statistics reported in the RAR for the two field monitoring studies, i.e., to confirm that the correct value was reported when the 90th percentile normalised granule counts/density was averaged across all trials. If necessary, the summary tables and risk assessment will need to be updated accordingly, by using the correctly derived G density value. Note that the meeting agreed that the mean of all normalized 90th percentile counts should be used. Additionally, 90th percentile G density values for row ends should also be calculated and fed into the revised risk assessment (see point below). Separate assessments should be performed for the centre and edge of field. - The RMS should perform the acute and long-term RA separately for the mid field and end of rows - The RMS should update the risk assessment in the RAR, if necessary, by reflecting the conclusions drawn by the Experts' meeting concerning the position paper submitted by the applicant with the aim of addressing the risks to birds taking granules as grit - The RMS should update the Vol 1 and LoEP accordingly. Risk assessment from exposure through weed seedlings: - RMS to summarise the evaluation and reflect the outcome of the meeting discussion concerning the residues in weed seedlings in the updated RAR.



Pesticides Peer Review TC 63 (20 – 23 September 2021)
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Subject	Conclusions Pesticide Peer Review Meeting
	Risk assessment from exposure through soil arthropods: - RMS to reflect the outcome of the meeting discussion concerning the exposure through soil arthropods in the updated RAR. Reference should be made to the outcome of the Experts' consultation 5.4.
Experts' consultation 5.2 Experts to discuss the acute endpoints to birds, and especially the mallard duck.	The avian acute endpoint and the use of a geometric mean LD₅₀ were discussed by the meeting. Specifically, the single-dose oral toxicity study in mallard duck (B.9.1.1.1/02) was considered acceptable. Additionally, the meeting agreed on using the geometric mean LD₅₀ calculated using the two acute toxicity endpoints from the studies with the a.s. (i.e., mallard duck and northern bobwhite quail). Open point: RMS to update the risk assessment with the geometric mean LD₅₀ calculated using the acute toxicity endpoints from the two studies with the a.s. (i.e., mallard duck and northern bobwhite quail). The Vol. 1/LoEP and Vol 3 should be updated accordingly.
Expert consultation 5.3 Experts to discuss the ecotoxicologically relevant long-term endpoint for mammals, considering also the use of LD₅₀/10 as a long-term endpoint (and the risk assessment to mammals if needed).	A new assessment was provided by the applicant, justifying the ecotoxicologically relevant endpoint for mammals. Based on this assessment, a NOAEL_{bw} of 1.43 mg/kg bw/day was set from the rat 2-generation reproduction study. This approach was originally agreed by the RMS. However, further attention was given to the effects observed across all relevant studies (i.e., teratogenicity study in rat, multi-generation reproduction study in rat, teratology study in rabbits). This latter assessment resulted in the selection of a lower endpoint (i.e., NOAEL_{resorption} of 1 mg/kg bw/day from the rabbit developmental toxicity study). Conclusion All experts agreed on setting a chronic NOAEL of 1 mg/kg bw/day. The use of the LD₅₀/10 was dismissed, since its use is not specifically envisaged by EFSA (2009). It was further discussed that a data gap was set for a DNT (developmental neurotoxicity study) in the mammalian toxicology peer-review meeting. Therefore, the agreed endpoint may need to be reconsidered in future, in case a more adverse, ecotoxicologically relevant endpoint will be selected in the new study. Open point:



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	RMS to revise the RAR (i.e., including the Vol1/LoEP), by reflecting the outcome of this discussion point and by revising the long-term risk assessment for mammals, taking into account the newly agreed endpoint of 1 mg/kg bw/day.
Expert consultation 5.4 Experts to discuss the risk to bird and mammal from ingesting granules when eating soil-contaminated food, and the risk to earthworm-eating bird and mammal (vermivore risk assessment).	The refined risk assessment for birds and mammals ingesting granules when eating soil-contaminated food was discussed in relation to the proposed use of a shortcut value at 10 cm and a TWA of 0.53. Conclusion The meeting considered justified the use of a TWA of 0.53. However, a shortcut value at 5 cm incorporation was considered more appropriate and protective for the representative uses Open point: RMS to revise the RAR (i.e., including the Vol.1/LoEP) by reflecting the outcome of the discussion concerning the risk assessment for birds and mammals ingesting granules when eating soil-contaminated food. Accordingly, the risk assessment should be revised by using the shortcut value at 5 cm depth. The refined risk assessment for earthworms-eating birds and mammals was discussed, in relation to the proposed refinement options: 1. RUD in earthworms (for birds and mammals) 2. PD value of 0.1 (only for birds) 3. Refinement based on PT value (only for mammals) Conclusion Due to major drawbacks, all refinements were dismissed by the Experts. Open point: Whenever relevant, RMS to revise the RAR (i.e., including the Vol.1/LoEP) by reflecting the outcome of the discussion on the risk to earthworm-eating birds and mammals: - the refinement based on the RUD values in earthworms based on field study should be dismissed - PD value of 0.1 should not be used in risk assessment for birds - The PT refinement for mammals should be dismissed
Experts' consultation 5.5 Experts to discuss:	The aquatic risk assessment was discussed in relation to the following issues:



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- the validity of study with <i>Daphnia pulex</i>, and if data are sufficient for an SSD-RACacute - the acute risk assessment to aquatic invertebrate, on the basis of the available valid reliable data - the chronic risk assessment to aquatic invertebrate (if needed)	The validity of the acute toxicity study with <i>Daphnia pulex</i> was originally questioned by the RMS, because daphnids were found trapped on the surface. The suitability of the SSD approach was discussed, along with the most adequate assessment factor to be used in risk assessment The RMS did not originally perform the chronic risk assessment using the most sensitive endpoint from <i>Americamysis bahia</i>. Conclusion The meeting considered the acute toxicity study with <i>Daphnia pulex</i> valid. A valid SSD was derived, resulting in a median HC₅ of 32.6 µg/L. The meeting agreed on using this value, along with an assessment factor of 5 for risk assessment The meeting agreed that the chronic risk assessment should be performed using the lowest endpoint of the dataset for oxamyl (endpoint from <i>Americamysis bahia</i>) Open point: RMS to update the RAR and the LoEP, reflecting the outcome of the discussion: - The meeting considered the acute toxicity study with <i>Daphnia pulex</i> valid. - A valid SSD was derived, resulting in a median HC₅ of 32.6 µg/L. - The meeting agreed on using this value, along with an assessment factor of 5 for risk assessment - The meeting agreed that the chronic risk assessment should be performed using the lowest endpoint of the dataset for oxamyl (endpoint from <i>Americamysis bahia</i>) - Further attention should be given to the outcome of the discussion in the e-fate section regarding the revised PECsw values.
Expert consultation 5.6 Experts to discuss the higher-tier data and risk assessment to collembolan.	- Collembola field study: The study was considered reliable with restrictions. Considering the application rate applied, the study can only cover the uses of oxamyl on potato in Central Europe, but it does not cover the uses on tobacco in Southern Europe. - Collembola modelling study: The experts identified several uncertainties in the population modelling study. Furthermore, the



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	potential of the model was not fully exploited to assess the risk of oxamyl to Collembola. Conclusion - Collembola field study: Overall, the experts agreed that the study should be considered as reliable with restrictions. The majority of the experts considered that a low risk can be concluded for the representative use to potatoes in the Central zone. The risk assessment for tobacco in the Southern zone will remain unresolved. - Collembola modelling study: the population modelling study was not accepted for refining the high risk to Collembola. - Open point for the RMS: - o To update the RAR with the MDD values of the field study and the results in actual numbers. To reflect the outcome of the discussion on the field and the modelling study in an updated RAR.
Experts' consultation 5.7 Experts to discuss the ED potential of oxamyl.	In line with the testing strategy of the ECHA/EFSA ED Guidance, two level 3 studies according to OECD TG 229 (FSTRA) and OECD TG 231 (AMA) were available; therefore, the EATS-related endocrine activity was sufficiently investigated. The 2 studies did not show any positive finding. Conclusion Oxamyl is not an ED for NTOs for the EATS-modalities. Open point to RMS: to reflect in a revised RAR the outcome of the discussion in the peer-review meeting.



REPORT OF PESTICIDE PEER REVIEW TC 63

FENPYROXIMATE – AIR IV

Rapporteur Member State: AT

5. Ecotoxicology

Date: 23 September 2021

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Federal Environmental Agency (UBA)	DE
Ministry of Environment and Food of Denmark, Environmental Protection Agency	DK
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
International Centre for Pesticides and Health Risk Prevention (ICPS)	IT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
External expert	PL
Hearing expert	CH
Hearing expert	IT

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the participants invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Discussion points/Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the long-term endpoint for bird risk assessment, considering the mallard-study findings, that is not fully valid.	- The mallard duck study with the lowest endpoint did not meet all the validity criteria of the corresponding OECD and US EPA guidelines. - The conditions for merging the datasets of the two bobwhite quail studies were met, as indicated in the birds and mammals risk assessment guidance (EFSA, 2009). In conclusion: - The mallard duck study was invalidated and will not be used for the risk assessment. - The datasets from the two bobwhite quail studies can be merged. The resulting endpoint to be used for the long-term risk assessment is: NOAEL = 21.7 mg a.s./kg body weight/day. -
Experts' consultation 5.2 Experts to discuss the available and assessment for the ED potential of fenpyroximate. Experts should also discuss the need for further data.	In line with the ECHA/EFSA ED guidance, the dataset for EATS -modalities wasn't complete neither for adversity nor for endocrine activity. Further data are needed to draw a conclusion of the ED properties of fenpyroximate on non-target organisms other than mammals. According to ECHA/EFSA Guidance, the following tests are considered necessary: • A XETA test according to OECD TG 248 (for T-modality); • A FSTRA test according to OECD TG 229 including gonad histopathology or a FSDT according to OECD TG 234 (for EAS-modalities). If the concern for anti-androgenic activity is not confirmed based on the results of the tests requested to complete the dataset for the ED assessment for humans, a test according to OECD TG 229 test should be provided including investigation on gonad histopathology.



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Subject	Conclusions Pesticide Peer Review Meeting
	If one of those level 3/4 assays is positive, further data might be needed to investigate adversity (e.g. LAGDA according to OECD TG 241 and/or MEOGRT according to TG OECD 240). Open point to RMS: clearly report in details in the summary of the FFLC the missing parameters compared to a Medaka extended one gen. Open point to RMS: RMS to report the outcome of the discussion in the revised RAR.
Experts' consultation 5.3 Experts to discuss the refined risk assessment for small insectivorous birds (ornamentals) considering the focal species selection and extrapolation, proportion of diet obtained in the treated area (PT), and uncertainty analysis.	The applicant's argumentation in favour of the blue tit as a focal species in ornamentals was not fully substantiated. The representativeness of the study performed in orchards to refine the PT value in ornamentals cannot be confirmed based on the available data (e.g., no bridging from orchards to ornamentals). The type of ornamentals should be specified in more detail to agree on the selection of the blue tit as a relevant focal species for insectivore birds. The experts agreed that the proposed refined PT for blue tit in orchards cannot be used for ornamentals. Open point: for the RMS to reflect the outcome of the discussion in the RAR.
Experts' consultation 5.4 Experts to discuss the refined risk assessment for small and large herbivorous mammal considering focal species selection and extrapolation, PT (if needed), uncertainty analysis, and interception.	- <u>Large herbivorous mammals</u>. No other lagomorphs' species other than the hare and the rabbit are expected in Europe. According to the birds and mammals guidance document (EFSA, 2009), for strawberries, a deposition factor refinement for strawberries only relevant only from BBCH stage 40. - <u>Small herbivorous mammals</u>. Considering the representative uses and the wide distribution of the common vole in agricultural landscapes, the common vole could be considered as potentially representative for small herbivorous mammal in strawberry fields and ornamentals. Actual data should be generated to allow for refinement of the risk for lagomorphs (e.g., valid residue decline data, studies to determine PT). In conclusion: - <u>Large herbivorous mammals</u>. It was agreed to (i) use both the rabbit and hare as focal species, and (ii) to remove the refinement based on deposition factor for BBCH 10-39 for strawberries. - <u>Small herbivorous mammals</u>. It was agreed to use the common vole as the focal species in strawberries and ornamentals to address the risk to small herbivores feeding guild. However, the available evidence is not sufficient to address the long-term risk to the common vole for the intended uses of fenpyroximate in strawberries and ornamentals.



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Subject	Conclusions Pesticide Peer Review Meeting
	- Open points: RMS to: - o Remove the refinement for large herbivorous mammals based on deposition factors in strawberries for BBCH 10-39. - o Reflect the outcome of the discussion in the RAR.
Experts' consultation 5.5 (NOTE this can be altered following submission of new data) Experts to discuss: - the RAC and risk assessment for aquatic invertebrate and fish. - the BCF of fenpyroximate, the RAC based on biomagnification/ secondary poisoning and risk assessment, if provided. Experts to also pay attention to the Daphnia endpoints (chronic) derived from formulation tests are lower.	The sampling regime in two of the chronic <i>Daphnia</i> studies were considered inappropriate. Therefore, the actual exposure cannot be determined. There are indications that the representative formulation might be more toxic to <i>Daphnia</i> than the active substance. A high risk to fish was concluded for some of the relevant metabolites. A risk assessment considering the lowest application rate has not been performed. According to the data requirements, the BCF should be expressed as a function of total weight and lipid content. Section 7.6 of the aquatic guidance document (EFSA, 2013) mentions that the concentrations used to derive and report BMF values should be, where possible, lipid-normalized. In conclusion: - <u>Risk assessment for aquatic invertebrates.</u> - o The endpoints derived from two of the chronic <i>Daphnia</i> studies are considered not reliable. - o A <i>Daphnia</i> chronic study is needed to ascertain whether or not the representative formulation is more toxic than the active substance - <u>Risk assessment for fish</u> - o The experts agreed with the endpoints selected for the risk assessment performed by the RMS - o Further data are required to refine the risk for some of the pertinent metabolites. - <u>BCF</u> - o To use the BCF_K lipid-normalized value from the most recent study in the risk assessment. - <u>Open points</u> - o RMS to perform the risk assessment by considering also the lowest application rate. - o RMS to update the RAR and LoEP based on the outcome of the discussion.
Experts' consultation 5.6 Experts to discuss the chronic -toxicity to adult honeybee and the bee early-life stages data and	A new chronic toxicity study with honey bee worker was submitted following the written procedure. This study addressed key uncertainties related to the already available chronic study, and yielded a lower endpoint than the previously selected one. However, no assessment on HPG development was done in the new study.



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Subject	Conclusions Pesticide Peer Review Meeting
assessment, and the risk to bees from plant metabolites. Experts to also consider the field study on honeybees (2016) on <i>Phacelia</i> and whether can be used to address the above. The need for further data should be also discussed.	Two new studies were submitted to characterise hazards to honeybee larvae: - One was a single exposure test and, therefore, not suitable for risk assessment - One study that had a 22d duration. A higher tier study was available investigating the effects of fenpyroximate in honey bees, after controlled application in <i>Phacelia</i>. The validity of this study was not questioned, However, its suitability to address the risks for honeybees in the context of a EU assessment was discussed in relation to the sources of uncertainties identified. Finally, the need to address the risks from metabolites M1 and M12 was discussed in relation to the availability of exposure information and metabolism studies. In conclusion: Chronic toxicity (workers): the meeting agreed that, the risk assessment should be performed with the endpoint from the a.s. study, however the information on effect of HPG contained in formulation study, could be considered as supplementary. The experts agreed with the chronic RA performed by the RMS. Larval toxicity: The majority of experts agreed on using the NOED of 0.046 µg a.s. larvae/devel.period from a study with the active substance for risk assessment. Field study: The study would be considered reliable with restrictions by the majority of experts. Therefore, the study alone was not considered sufficient to address the risk for honey bees from the representative uses. Metabolites: In conclusion, the majority of experts agreed on the inclusion of the metabolite M12 and M1 in the risk assessment. Additionally, it was agreed that that the risk assessment for metabolites M1 and M12 based on a 10 times toxicity of the parents should be performed. Open points: RMS to update the RAR (including the Vol1/LoEP, whenever relevant) addressing the following points: - A footnote should be added in the LoEP acknowledging the uncertainty around the endpoint derived from the chronic adult study with the formulated product in the LoEP (i.e., that the food intake was not normalised for evaporative losses) - the endpoint on HPG from the same study should be removed from the LoEP.



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Fenpyroximate

Subject	Conclusions Pesticide Peer Review Meeting
	- Concerning the larval toxicity, a footnote in the LoEP, specifying that a slightly lower endpoint than the selected one is available for the formulation, which, however, did not follow the full brood life cycle. - The RAR (including the Vol.1/LoEP) should be updated with a revised chronic RA for larvae, based on the outcome of the discussion (i.e., the newly agreed endpoint). - The RAR (including the Vol.1/LoEP) should be updated by performing a quantitative screening risk assessment for M1 and M12, assuming 10 times higher toxicity than the parent compound. - EFSA to acknowledge the reasons behind the endpoint selection for honey bee larval toxicity in the EFSA conclusion.
Experts' consultation 5.7 Experts to discuss the higher- tier risk assessment to NTAs, in particular the off-field. Experts to pay attention to the most sensitive species of NTA that merits consideration in risk assessment, and extrapolation to different species (if needed). The need for further data should be also discussed.	- In-field risk assessment. The approach to extrapolate from the rapid decline in residual toxicity seen in the aged-residue study on <i>A. ropalosiphi</i> to <i>T. pyri</i> and <i>C. septempunctata</i> was not accepted - Off-field risk assessment. The available data on <i>A. ropalosiphi</i> was insufficient to conclude on a low off-field risk for the uses on ornamentals (e.g. no mortality assessment in the "semi-field" study). In conclusion: - In-field risk assessment. The in-field risk could not be resolved. Further data are needed to resolve the risk - Off-field risk assessment (ornamentals). Based on the available data and risk assessment, a low off-field risk for the uses on ornamentals can only be concluded with the implementation of mitigation measures. - Open points: - o RMS to reflect the outcome of the discussion in the revised RAR and LoEP. - o EFSA to reflect the outcome of the discussion in the EFSA conclusion (need of additional data to resolve the in-field risk).

REPORT OF PESTICIDE PEER REVIEW TC 63

SHEEP FAT – AIR IV

Rapporteur Member State: CZ

5. Ecotoxicology

Date: 21 September 2021

List of participants:

Institute	Member States Country code
Austrian Agency for Health and Food Safety (AGES)	AT
Central Institute for Supervising and Testing in Agriculture	CZ
Federal Environmental Agency (UBA)	DE
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
International Centre for Pesticides and Health Risk Prevention (ICPS)	IT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
External expert	PL
Hearing expert	CH
Hearing expert	IT

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Pesticides Peer Review TC 63 (20 – 23 September 2021)
Sheep fat

Discussion points / Outcome

5. Ecotoxicology

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 5.1 Experts to discuss the risk assessment for bees considering all relevant scenarios. The following issues should be discussed: - The NOED from the chronic honeybee larvae study; - The acute risk assessment following the EC (2002) and EFSA (2012) guidance documents (GD); - The chronic risk assessment for honeybee adults and larvae, and the risk assessment from exposure to contaminated water following the EFSA (2013) GD.	<u>The NOED from the chronic honeybee larvae study</u> - Almost 20% of effects on emergence was observed at the proposed NOED of 141.7 µg product/larva - Although not statistically different from the control group, such difference should be considered as biologically relevant - The lowest tested dose from the study would be considered sufficient surrogate of ED₁₀ value Conclusion - It was agreed to select the lowest dose as endpoint 26.79 µg/larvae from the available larvae study <u>The acute risk assessment following the EC (2002) and EFSA (2012) guidance documents (GD)</u> - Applicant had submitted a risk assessment only according to the not noted EFSA "Guidance Document on the risk assessment of plant protection products on bees (<i>Apis mellifera</i>, <i>Bombus</i> spp. and solitary bees)" (EFSA, 2013) Conclusion - The acute risk assessment according to SANCO was provided and low risk could be concluded



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Subject	Conclusions Pesticide Peer Review Meeting
- Any additional evidence/rationale provided by the applicant that can be used to assess the risk to bees.	<u>The risk assessment from exposure to contaminated water following the EFSA (2013) GD and the chronic risk assessment for honeybee adults and larvae</u> - The chronic oral risk to adult bees and larvae has been considered, according to EFSA/2013/3295. - There are no provisions within this guidance document for applications of pesticides in forestry conditions. - Orchards were selected as a surrogate crop for forest - The available evaluation can be considered as overconservative and unrealistic for the case under assessment - Thus the experts at the meeting evaluate the case for bees in a qualitatively - In the case of localised spot treatments trunks and/or stems, it is not expected that bees will be actively forage in these parts - Spray drift to the surrounding areas can be minimized due to the spot application - For application in terminal shoots, it is unclear whether the applications will be conducted at the time of flowering - It is not possible to determine the extent of exposure following the application in terminal branches in the case of deciduous trees - Exposure following application in coniferous terminal shoots is not considered an issue as these are deemed not attractive for pollen and nectar - For the puddle scenario the PEC run-off water should be used and not the PEC surface water Conclusion - The risk can be considered low for spot application, and terminal shoots application in coniferous trees - Low risk to bees for the uses at the terminal shoots and branches in deciduous trees could not be concluded - For the guttation water scenario, low risk was concluded based on the EFSA guidance Open point: RMS to update the RA considering the selection of the new larvae endpoint.



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Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to update the RAR considering the outcome of the discussion at this meeting. Open point: RMS to state clearly in the RAR that the risk assessment to bees based on the bee guidance is indicative and to remove the risk assessment to bees in the LoEP. Open point: RMS to update the risk assessment to bees for the puddle scenario by using the PEC run-off.