REPORT OF PESTICIDES PEER REVIEW TC 132

PROQUINAZID – AIR IV

Rapporteur Member State: SE

4. Environmental fate and behaviour

Date: 7 March 2024

List of participants:

Status	**Name of institution/attendee**
EFSA statutory staff members	EFSA
National Expert 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 FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
National Experts nominated by MS HR	Croatian Agency for Agriculture and Food (HAPIH) - HR
National Expert nominated by MS NL	Ctgb - NL
National Expert nominated by MS SK	Water Research institute - SK
Observer	Federal Office for the Environment - CH

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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

4. Environmental fate and behaviour

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 4.1 Experts to discuss and agree on the acceptability of the aerobic degradation (2000) and consequently on the degradation endpoints derived from this study for proquinazid and metabolites IN-MM671, IN-MM991 and IN-MM986.	In the non-labelled soil aerobic degradation study dosed with proquinazid, IN-MM671, IN-MM986 and IN-MM991 no significant deviations of the test design as compared to OECD 307 Test Guideline were observed for proquinazid. However, concerns were raised regarding the derivation of the persistence and modelling endpoints in particular for the metabolites. The experts discussed the RMS assessment reported in the updated RAR and presented during the meeting. For the parent compound, the RMS proposed to consider acceptable only the persistence endpoint at 10°C. Normalisation to 20°C is not needed in this case as other data on the same soil at 20°C incubation are available. For the metabolites, large variability and scattering of the data was observed. Some experts considered the fits of the degradation patterns are described quite well for some soils for some metabolites and could be retained. Other experts were not in favour to accept this variation of data for laboratory incubations and endpoints for metabolites should not be derived from this study. Overall, the majority of the experts agreed that no reliable endpoints can be derived for metabolites IN-MM671, IN-MM986 and IN-MM991 from the non-labelled soil aerobic degradation study. **Open point**: RMS to update the RAR and the LoEP by excluding the endpoints derived for metabolites IN-MM671, IN-MM986 and IN-MM991 from the non-labelled soil aerobic degradation study, and to update the overall geometric mean DegT50 accordingly.

Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 4.2 Experts to discuss and agree on the acceptability of the field study (1999) and to agree if it can be used to derive modelling endpoints for proquinazid and metabolite IN-MM986.	The EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 (2014) values states that multiple applications should not be used when designing new field studies to obtain degradation rates. However, it was noted that this field dissipation study should not be rejected as the kinetic fitting (from parent to metabolite) from the last application can be conducted overcoming the issue of having multiple applications. Regarding the results of the Data requirement 4.5 on DFOP-SFO pathway fit for the non-normalized data, it was noted that the kinetic fitting non-normalised HS-SFO for metabolite IN-MM986 is very poor and cannot be accepted. All the other kinetic assessments as proposed by the RMS were agreed by the experts. Overall, the experts agreed with the updated RMS' assessment as presented in the RAR, and then this field dissipation study should not be rejected as the kinetic fitting (from parent to metabolite) from the last application can be conducted overcoming the issue of having multiple applications. No persistence endpoints could be derived for metabolite IN-MM986 from this field study. **Open point:** RMS to update the RAR with the conclusion that DFOP-SFO and HS-SFO pathway fit for the non-normalized data for metabolite IN-MM986 from the field study are considered as not reliable.
Experts' consultation 4.3 Experts to discuss and agree on the acceptability of the new irradiated water/sediment study (2023) and to agree on how to use the study in the aquatic exposure assessment.	The new aerobic biotransformation of [^{14}C]Proquinazid under irradiation was studied in two US river water/sediment systems following OECD TG 308 Test Guideline. The RMS accepted the endpoints derived only from one of the two systems investigated (Taunton River), and a conservative DT50 of 18.8 days (derived from slow phase in the HS fit) could be used in the exposure assessment. This value is 2 times faster respect to the degradation in water/sediment under dark conditions. These results confirm that photolysis may play a significant role in the degradation of proquinazid under natural conditions. However, it remained unclear to what extent the irradiated system (each vessel contained 10 g sediment (dry weight equivalent) flooded with 30 mL of corresponding overlying water, resulting in a sediment/water ratio of 1/3 (w/v)) mimics natural field conditions. No novel metabolites that would trigger further exposure assessment were identified in the irradiated water/sediment study. The experts discussed whether the results from this study could be used for modelling purposes.

Subject	Conclusions Pesticides Peer Review Meeting
	Taking into consideration that proquinazid is strongly sorbed and considering the approach of the FOCUS modelling regarding sediment partitioning, the experts concurred that employing endpoints from this study would not be suitable. The RMS also explained that the study was not intended to derive modelling endpoints but to address some requirements in the ecotoxicology section (i.e. information on the whole system DT90 vs the trigger of 100 days). In conclusion, the experts agreed that the new irradiated water/sediment study is considered acceptable but the modelling endpoints to be used in the aquatic exposure assessment are those derived from the water/sediment under dark conditions. RMS and EFSA will inform the ecotoxicology experts that the whole system DT90 (i.e. dissipation in the two water and sediment phases) derived for proquinazid in this new irradiated water/sediment study is lower than 100 days but the fate experts' view is that the irradiated study design did not accurately mimics natural field conditions.
Experts' consultation 4.4 Experts to agree on the degradation endpoints to be used for PECsoil calculations for proquinazid and metabolites IN-MM671, IN-MM986 and IN-MM991.	New PECsoil calculations were provided by the Applicant for the parent and its soil metabolites. The endpoints used in these calculations were agreed by the experts. However, it was noted that PECsoil for the parent were based on the longest lab SFO DT50 (=201 days) in view that a sufficient margin of safety in the risk assessment for soil dwelling organisms for all representative uses was reached. Nevertheless, PECsoil calculations based on the longest field DT50 could be necessary/useful for the residue colleagues for rotational crops assessment. The experts agreed that the PECsoil for the parent compound should be calculated based on the longest field dissipation rates derived from the UK field trial Alconbury (k1 = 0.252, k2 = 0.010, tb = 0.863). **Open point**: RMS to update the PECsoil calculations for proquinazid using the kinetic parameters of the biphasic degradation modelling endpoints derived from the UK field trial Alconbury. The RAR and the LoEP should be updated accordingly.
Experts' consultation 4.5 Experts to agree on the degradation endpoints to be used for PECgw calculations for proquinazid and	The Applicant provided new PECgw calculations based on input parameters mostly in line with the tier I input as recommended by RMS and the max doses in the GAP table. The degradation endpoints used for PECgw calculations for proquinazid and metabolites IN-MM671, IN-MM986 and IN-MM991 were discussed considering the outcomes of Expert's consultations 4.1 and 4.2.

Subject	Conclusions Pesticides Peer Review Meeting
metabolites IN-MM671, IN-MM986 and IN-MM991.	The experts agreed with the modelling endpoint for the parent, i.e. the geomean from the field data. Also the inputs for metabolites (both soil degradation and adsorption) as proposed by the RMS in the updated RAR were considered as appropriate for GW modelling. Experts agreed on the following degradation endpoints to be used for PECgw calculations: Parent: DegT50 = 23.4 days (geomean from field studies) IN-MM671: DegT50= 155.5 days (f.f. 0.94 from parent) IN-MM986: DegT50= 59.2 days (geomean from lab + field studies) (f.f. 1 from parent derived in the field dissipation study) IN-MM991: DegT50 = 31.8 days (0.58 from IN- MM671) The formation fraction IN-MM986 → IN-MM991 should be 1 (from the laboratory studies). The adsorption endpoints for parent and the metabolites are those indicated in the current LoEP. **Open point**: RMS to update the groundwater exposure assessment for parent and metabolites with the endpoints agreed in the Peer Review Meeting TC 132. The representative uses with the highest doses as indicated in the GAP should be considered in this assessment. The RAR and the LoEP should be updated accordingly.
Experts' consultation 4.6 Experts to agree on the degradation endpoints to be used for PECsw,sed calculations for proquinazid and metabolites IN-MM671, IN-MM986 IN-MM991 and IN-MT884.	Degradation endpoints to be used for PECsw,sed calculations for proquinazid and metabolites IN-MM671, IN-MM986, IN-MM991 and IN-MT884 were discussed considering the outcomes of Expert's consultations 4.1, 4.2 and 4.3. The Applicant provided new PECsw,sed calculations for proquinazid and for metabolites IN-MM671, IN-MM986 IN-MM991 and IN-MT884. The applicant used a formation of 1 for all the metabolites as worst case. Experts agreed with the input parameters presented by the RMS at the meeting, including the lab DegT50 value for the parent as discussed under point 4.5 for PECgw calculations. Experts agreed on the following endpoints to be used for PECsw,sed calculations: Formation fraction (soil): Proquinazid to IN-MM991 = 1 (worst case)

Subject	Conclusions Pesticides Peer Review Meeting
	Formation fraction (water, sediment): Proquinazid to all metabolites =1 (worst case) DT50 water = 1000 d (FOCUS default value to be used for proquinazid and all metabolites) DT50 sediment = 68.2 d (FOCUS default value to be used for proquinazid) DT50 sediment = 1000 d (FOCUS default value to be used for all metabolites) Plant uptake factor = 0 (worst case value to be used for proquinazid and all metabolites). **Open point** RMS to update PECsw,sed calculations for proquinazid (up to FOCUS Step 4) and metabolites IN-MM671, IN-MM986 IN-MM991 and IN-MT884 (up to FOCUS Step 3 or Step 4 if needed) with the agreed endpoints. RMS might consider presenting an exposure and risk assessment for the lower risk GAPs so that a comprehensive conclusion can be reached. The RAR and the LoEP should be updated accordingly.

REPORT OF PESTICIDES PEER REVIEW TC 132

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

Rapporteur Member State: PL

4. Environmental fate and behaviour

Date: 7 March 2024

List of participants:

Status	**Name of institution/attendee**
EFSA statutory staff members	EFSA
National Expert nominated by RMS PL	E-V-A Sp. z o.o. - PL
National Expert nominated by MS AT	Austrian Agency for Health and Food Safety (AGES) - AT
National Expert nominated by MS DE	Federal Environment Agency (UBA) - DE
National Expert nominated by MS FR	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - FR
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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticides Peer Review Meeting
Experts' consultation 4.1 Member States experts to discuss and agree on: • the approach proposed to address the route of aerobic degradation in soil and if further soil degradation data are necessary, considering also the Applicant's proposal of an additional study with new degradation tests for Terpinen-4-ol in three further soils (Data requirement in comment 4(2)); • the possible dependency of degradation from the soil pH considering the behaviour in soil of some minor components tested; • the most suitable DT50soil to be used for the PEC	Experts discussed the route and rate of degradation of the main TTO constituents in soil, based on the outcomes of the two aerobic degradation studies originally reported in the RAR and the additional interim report in the amended RAR. The assessment proposed by the RMS in the RAR was agreed. Moreover, it was highlighted that with a vapour pressure >2 Pa, the majority of constituents will volatilise before they are quickly degraded by soil microorganisms. Experts discussed and agreed on the need to perform an exposure assessment for the major metabolite of Terpinene-4-ol, UK-14.5 (M2), found at max. 22.5 % after 12 h. Although it showed a quick disappearance, it was formed at > 10 % in relation to Terpinene-4-ol, but also when the max. specified amount of Terpinene-4-ol is considered in relation to the whole mixture. A finalisation of the new provided study is required, including the identification of the major metabolite UK-14.5 (M2). Updated RAR indicated the possible presence of methyl-eugenol. No information on its potential contamination of groundwater has been provided. Experts agreed that even pH dependence trends may be observed for some of the tested components, the difference between the DT50 values were minor (in the range of hours), so considering a pH dependence in modelling would not lead to major differences in the PEC estimation. The geometric mean DT50 of the available values can sufficiently represent the soil degradation at various pH. Experts agreed on the RMS proposal to use the longest actual DT50 soil of 10.9 days derived for Globulol for PEC soil calculations. For PECgw, according to the agreed „virtual compound" approach, the longest normalised geometric mean DT50 in soil of 7.70 days derived for Globulol is proposed. For surface water / sediment

Subject	Conclusions Pesticides Peer Review Meeting
calculations considering the different approaches proposed for soil, groundwater and surface water/sediment compartments.	exposure, decision was postponed with the discussion of the last experts‘ point (see Conclusion of the Experts‘ consultation 4.3). A **data gap** was identified for the finalisation of the new aerobic degradation study for Terpinen-4-ol in three further soils, including the identification of the major metabolite UK-14.5 (M2). A further **data gap** is set for more detailed information on the expected presence and potential contamination of groundwater by the impurity methyl-eugenol to ensure there is not exposure to consumers through groundwater. For the RMS the following **open points** were identified: • to update the RAR according to the discussions reported in the Experts' meeting report; • to update the RAR and include the conclusions on the pH dependence in soil degradation of TTO components in the LoEP, taking also into account the results of the Kendall test; • to provide updated PECgw for TTO using the „virtual compound", i.e., the longest normalised geometric mean DT_{50soil} of 7.70 days derived for Globulol; • to report in the RAR the DT50soil endpoints to refine PECgw at a national level, if needed, based on the specific compound assessment grouping (structure similarity).
Experts' consultation 4.2 Member States experts to discuss and agree: • on the approach proposed to address the degradation in water/sediment systems considering that only the study with Terpinene-4-ol was conducted with radiolabelled test item; • if the route of degradation of the relevant TTO constituents was sufficiently	Results from the water and sediment study originally reported in the RAR and from the new interim report on aqueous photolysis provided with the amended RAR were discussed by the experts. Experts considered that the water/sediment study performed was sufficient to demonstrate the rapid decline of the investigated compounds in aquatic sysyems, although the only radiolabelled compound examinated in the study was Terpinene-4-ol. The new aqueous photolysis study was considered reliable and the formation of two photodegradation products detected for >10 % AR in the irradiated system (i.e., UK-12.6 at 10 %AR and UK-15.2 at 11.5 %AR) was confirmed. However, considering the % represented by Terpinene-4-ol in TTO, their formation in relation to the whole mixture would result in < 10 %. A finalisation of the study is required, including the identification of these two major metabolites in the study as proposed by the Applicant.

Subject	Conclusions Pesticides Peer Review Meeting
investigated or if further aquatic degradation data are necessary.	A **data gap** was identified for the finalisation of the new aqueous photolysis study for Terpinen-4-ol, including the identification of the two major metabolites UK-12.6 and UK-15.2. Besides this data gap, experts considered that no further data was considered necessary at this stage to address the route of degradation of TTO in water and sediment.
Experts' consultation 4.3 Member States experts to discuss and agree on: • the most suitable approach to be used in the surface water exposure assessment for TTO between the five potential solutions proposed by the RMS; • the relevant endpoints to be selected for the respective PECsw and PECsed calculations; • possible refinement calculations to demonstrate acceptable risk to aquatic organisms; • the proposed calculations (PECsw) for the exposure assessment of the representative formulation. New surface water exposure assessment will be performed using the correct version of the software, once the decision on the most suitable approach is taken during the expert consultation.	Experts discussed the five different approaches proposed by the RMS in the RAR for the determination of the exposure in the aqueous compartments. The Applicants' approach to consider the application rate expressed as the whole active substance together with input parameters for Terpinene-4-ol as the leading component of TTO was considered appropriate for the exposure assessment in aquatic systems. Evidences are based on the fact that Terpinene-4-ol is the most persistent component in aquatic systems among all tested compounds, the most stable in aquatic toxicity studies, the one with the highest water solubility and one of the least adsorbed in soil/sediment. The following parameters of Terpinene-4-ol were agreed to calculate PECsw/sed of TTO: • geometric mean normalised DT50soil of 0.39 days derived from the 4 tested soils; • geometric mean DT50 whole water/sediment system of 5.9 days , DT50 water of 5.9 days and DT50 sediment of 1000 days (due to low Koc of Terpinene-4-ol). • Koc of 89 mL/g (derived from the HPLC method). For the soil metabolite UK-14.5 (M2) assessed as major metabolite in soil, it is acknowledged that once identified it can be grouped by structure similarity to other components. Until identity is not available, there is a data gap on how to consider this metabolite in surface water exposure assessment. It is noted that Applicant cannot provide new information at this stage but, in case they manage to identify the metabolite, such information can be mentioned in the updated RAR and RMS can provide a grouping of metabolite UK-14.5 (M2) for national level assessments. The experts also agreed that the assessment provided in the amended RAR for the PECsw/sed calculations of the product formulation due to spray drift entries is acceptable. A **data gap** was set in relation to the soil metabolite UK-14.5 (M2) that, once identified, needs to be assessed for the surface water and sediment compartments. For the RMS an **open point** was identified to provide updated PECsw/sed calculations using the most recent versions of the

Subject	Conclusions Pesticides Peer Review Meeting
	models and considering the approach of the lead component concept, i.e., using the properties of Terpinene-4-ol for further risk assessment. For STEP 4 calculations, mitigation measures should not exceed 95 % spray drift reduction and run-off should not be mitigated above the FOCUS Landscape ceilings (FOCUS, 2007). Atmospheric deposition should be calculated according to EVA speadsheet and implemented in the SWAN model.

REPORT OF PESTICIDES PEER REVIEW TC 127

BENSULFURON-METHYL – AIR IV Rapporteur Member State: IT

4. Environmental fate and behaviour

Date: 24 January 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 Germany	Federal Environment Agency (UBA) - DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute - EL
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 RMS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) – NL
Observer	Federal office for the environment (BAFU) - CH

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to discuss and agree whether the substance properties selected by the applicant to obtain the updated **PEC_S** calculations for the representative use on **rice** for bensulfuron-methyl and its major metabolites are in line with the relevant guidelines and guidance documents.	Experts discussed the fulfilment of all the data requirements linked to relevant studies and endpoints used to update PECsoil calculations for the representative use on rice for bensulfuron-methyl and its major metabolites. All the new studies were considered acceptable. However, RMS was asked to perform minor updates, such as the change of kinetic fitting in the data from the new soil tested under OECD 307, and the reporting in the LoEP of irradiated and dark condition degradation results from the new soil photolysis study. Experts identified the need for a reliable flooded aerobic soil degradation study and two additional adsorption endpoints for bensulfuron-methyl which would cover acidic soil conditions. Considering that a reliable flooded aerobic soil degradation study is still pending (definition of residue for rice unknown), the majority of the experts agreed to set a data gap for PECsoil calculations for the representative use of bensulfuron-methyl on rice. **Open Points:** 1. RMS to update the RAR and LoEP with results of the new aerobic soil metabolism study (OECD 307) to be used for deriving modelling endpoints of bensulfuron-methyl, considering a pseudo SFO of FOMC DT90/3.32 (DT50 35.2 d) and consequently to update the overall geomean DegT50 value. 2. RMS to add in the LoEP the DT values of degradation and the formation amount of the metabolites calculated in the dark control of the new soil photolysis study. 3. RMS to indicate in the LoEP that the residue definition for the soil compartment for the use on rice is still open for the lack of a reliable flooded aerobic soil degradation study.

Subject	Conclusions Pesticide Peer Review Meeting
	Data gap: Reliable adsorption endpoints for bensulfuron-methyl in two additional soils (including soils in acidic conditions) are missing. **Data gap:** A reliable flooded aerobic soil degradation study for bensulfuron-methyl is missing. **Data gap:** Updated PECsoil calculations for representative uses on rice for bensulfuron-methyl (and metabolites) are missing, pending on the data gaps for a reliable flooded aerobic soil degradation study and reliable adsorption endpoints for bensulfuron-methyl in two additional soils.
Experts' consultation 4.2 Experts to discuss and agree whether the substance properties selected by the applicant to obtain the updated **PEC_S** calculations for the representative use on **spring cereals** for bensulfuron-methyl and its major metabolites are in line with the relevant guidelines and guidance documents.	Experts discussed the fulfilment of all the data requirements linked to relevant studies and endpoints used to update PECsoil calculations for the representative use on spring cereals for bensulfuron-methyl and its major metabolites, if not covered already by the Experts' Consultation 4.1. The compound methyl 2-hydrosulfonylmethyl benzoate was considered not to require further assessment, as it was formed only after four months of anaerobic conditions. On the other hand, it was confirmed that the anaerobic metabolite IN-DAT97 triggered assessment, for being detected at initial sampling points after flooding the soil. Experts discussed the max. observed formation of major metabolites and the highest persistence DT50 values of major metabolites to be used in the exposure assessment. Experts identified the need for a reliable field dissipation study on bensulfuron-methyl. Experts agreed that RMS should provide the required PECsoil calculations for the use in spring cereal in the revised RAR and LoEP, considering the details specified in the related open points. **Open points:** 1. RMS to update the RAR (CP volume) and the LoEP with the PEC soil for spring cereals calculated considering the updated endpoints agreed by the experts, i.e., using for IN-J0290 the worst-case DT50 of 9.7 d (HS fit); for IN-R9419 the worst-case DT50 of 84.7 d; and the max. observed formation of 21% AR for IN-J0290, 25.7% AR for IN-R9419 and 24.8% AR for IN-N5297. 2. RMS to update the LoEP with the PECsoil calculations for the major metabolite found in anaerobic conditions (IN-DAT197). **Data gap**: A reliable field dissipation study for bensulfuron-methylis missing.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.3 Experts to discuss and agree whether the substance properties selected by the applicant to obtain the updated **PEC_{GW}** calculations for the representative use on **rice** for bensulfuron-methyl and its major metabolites based on revised endpoints and the standard MED-rice guidance (2003).	Experts discussed that the applicant did not provide updated PECgw calculations for bensulfuron-methyl and for the major metabolites due to the lack of available studies. With no reliable flooded aerobic soil degradation study, the definition of residues triggering further assessment in rice fields is unknown. The majority of the experts agreed to set a data gap for PECgw calculations for the representative use of bensulfuron-methyl on rice. **Open point:** RMS to indicate in the LoEP that the residue definition for the groundwater compartment for the use on rice is still open for the lack of a reliable flooded aerobic soil degradation study. **Data gap:** Updated PECgw calculations for representative uses on rice for bensulfuron-methyl and its soil metabolites are missing. To obtain reliable PECgw calculations, the pending flooded aerobic soil degradation study and reliable adsorption endpoints for bensulfuron-methyl in two additional soils should be provided.
Experts' consultation 4.4 Experts to discuss and agree whether the substance properties selected by the applicant to obtain the updated **PEC_{GW}** calculations for the representative use on **spring cereals** for bensulfuron-methyl and its major metabolites are in line with the relevant guidelines and guidance documents.	Based on the meeting discussion stated in the Experts' consultations 4.1 and 4.2, experts discussed the endpoints to be used for PECgw calculations for the use of bensulfuron-methyl in spring cereals. Experts agreed that RMS should provide the required PECgw calculations for spring cereal use, considering the endpoints specified in the related open points. Experts highlighted that these updated PECgw will only cover alkaline conditions and may need to be recalculated once new Koc values for acidic soils are provided and the pH dependency situation related to Koc becomes clear. Based on these PECgw calculations, the leaching potential of metabolites that may occur under acidic conditions is under-estimated by the results at alkaline pH because of likely lower metabolite formation in alkaline conditions. **Open points:** 1. RMS to update the RAR (CP volume) and the LoEP with the PECgw of bensulfuron-methyl for the use on spring cereals calculated considering the updated endpoints agreed by the experts, i.e., a geometric mean soil DTeg50 of 56.9 d; and Koc value of 75.8 mL/g as worst-case (from n=2); and default water solubility (if data gap is confirmed). 2. RMS to update the RAR (CP volume) and the LoEP with the PECgw of major soil metabolites for the use on spring cereals calculated considering the updated endpoints agreed by the experts, i.e., consolidated degradation and adsorption endpoints for IN-J0290; new adsorption endpoints for IN-R9419, IN-N5297, IN-D1R84 and IN-DAT97; and the max. observed formation in soil of 21%

Subject	Conclusions Pesticide Peer Review Meeting
	AR for IN-J0290, 25.7% AR for IN-R9419 and 24.8% AR for IN-N5297. **Data gap:** PECgw for bensulfuron-methyl and its metabolites in acidic soil conditions are currently not available. Current PECgw only cover alkaline conditions and may need to be recalculated once new Koc values for acidic soils are provided and the pH dependency situation related to Koc becomes clear (pending on the data gap for reliable adsorption endpoints for bensulfuron-methyl in two additional (acidic) soils). The leaching potential of metabolites that may occur under acidic conditions is underestimated by the results at alkaline pH because of likely lower metabolite formation in alkaline conditions.
Experts' consultation 4.5 Experts to discuss and agree whether the substance properties selected by the applicant to obtain the updated **PEC_{SW} and PEC_{SED}** calculations for the representative use on **rice** for bensulfuron-methyl and its major metabolites are in line with the relevant guidelines and guidance documents.	Experts discussed that the applicant did not provide updated PECsw and PECsed calculations for bensulfuron-methyl and for the major metabolites due to the lack of available studies. With no reliable flooded aerobic soil degradation and water/sediment studies, the definition of residues triggering further assessment for the use on rice is unknown. The majority of the experts agreed to set a data gap for PECsw and PECsed calculations for the representative use of bensulfuron-methyl on rice. **Open point:** RMS to indicate in the LoEP that the residue definition for the surface water and sediment compartments for the use on rice is still open for the lack of a reliable flooded aerobic soil degradation and water/sediment study. **Data gap:** Updated PECsw and PECsed calculations for representative uses on rice for bensulfuron-methyl and its metabolites are missing. To obtain reliable PECsw and PECsed calculations, the pending flooded aerobic soil degradation and water/sediment studies and reliable adsorption endpoints for bensulfuron-methyl in two additional soils should be provided.
Experts' consultation 4.6 Experts to discuss and agree whether the substance properties selected by the applicant to obtain the updated **PEC_{SW} and PEC_{SED}** calculations for the representative use on **spring cereals** for bensulfuron-methyl and its major metabolites are in line with the relevant	Experts discussed the fulfilment of all the data requirements linked to relevant studies and endpoints used to update PECsw and PECsed calculations for the representative use on spring cereals for bensulfuron-methyl and its major metabolites, if not covered already by the Experts' Consultations 4.1, 4.2 and 4.4. Experts discussed the formation of two unknown peaks in the available photodegradation study of bensulfuron methyl in natural water. Experts concluded that no new aqueous photolysis study was required but agreed to set a data gap for an appropriate identification of the radioactivity of the two unidentified peaks. Experts highlighted the need for a reliable water/sediment study, which lead to a data gap in PECsw/sed calculations for potential metabolites only formed in water/sediment systems.

Subject	Conclusions Pesticide Peer Review Meeting
guidelines and guidance documents.	Experts discussed inconsistencies in the 1/n values in the consolidated list of endpoints of the aqueous photolysis metabolite IN-T5831 and discussed the Koc values to be used for bensulfuron-methyl and the aqueous photolysis metabolite IN-YY142 for the surface water and sediment exposure assessment. Experts agreed that RMS should provide the required PECsw and PECsed calculations for spring cereal use, considering the endpoints specified in the related open points. Experts highlighted that these updated PECsw and PECsed will only cover alkaline conditions and may need to be recalculated once new Koc values for acidic soils are provided and the pH dependency situation related to Koc becomes clear. **Open points:** 1. RMS to add the results from the sterile buffer at pH 7 of the available aqueous photolysis study in the revised LoEP. 2. RMS to update the RAR and the LoEP with the correct 1/n values for the common metabolite IN-T5831 coming from the study reported in the most recent RAR of rimsulfuron. RMS to recalculate the arithmetic mean of 1/n. 3. RMS to update the RAR (CP volume) and the LoEP with the PECsw/sed of bensulfuron-methyl for the use on spring cereals calculated considering the updated endpoints agreed by the experts, i.e., a geometric mean soil DegT50 of 56.9 d; Koc values of 75.8 mL/g for surface water and 136.6 mL/g for sediment, being worst-case values from the data available (n=2); default DT50 water/sediment of 1000 d; and default water solubility (if data gap is confirmed). 4. RMS to update the RAR (CP volume) and the LoEP with the PECsw/sed (Step 1 & 2) of major soil metabolites for the use on spring cereals calculated considering the updated endpoints agreed by the experts, i.e., consolidated degradation and adsorption endpoints for IN-J0290; new adsorption endpoints for IN-R9419, IN-N5297, IN-D1R84 and IN-DAT97; the max. observed formation in soil of 21% AR for IN-J0290, 25.7% AR for IN-R9419 and 24.8% AR for IN-N5297; and default DT50 water/sediment of 1000 d. 5. RMS to include in the RAR (CP volume) and the LoEP the calculated PECsw/sed (Step 1 & 2) of major aqueous photolysis metabolites considering the updated endpoints agreed by the experts, i.e., consolidated degradation and adsorption endpoints for IN-T5831; the updated 1/n arithmetic mean value for IN-T5831; max. occurrence in water of 14% AR for IN-T5831 and 14.7% AR for IN-YY142;

Subject	Conclusions Pesticide Peer Review Meeting
	Koc values of 10 mL/g for surface water and 10000 mL/g for sediment for IN-YY142; and default DT50 water/sediment of 1000 d. **Data gap:** An appropriate identification of the radioactivity of the two unidentified peaks (RT=14min, R=15 min) detected in the available aqueous photolysis study is missing. **Data gap:** A reliable water/sediment study is missing. **Data gap:** PECsw and PECsed for bensulfuron-methyl and metabolites in acidic soil conditions are not available. Current PECsw and PECsed only cover alkaline conditions and may need to be recalculated once new Koc values for acidic soils are provided and the pH dependency situation related to Koc becomes clear (pending on the data gap for reliable adsorption endpoints for bensulfuron-methyl in two additional (acidic) soils). **Data gap:** PECsw/sed for potential metabolites only formed in water/sediment systems are not available (pending on the data gap for a water/sediment study).

REPORT OF PESTICIDES PEER REVIEW TC 127

BIXLOZONE – NAS 1107 Rapporteur Member State: NL

4. Environmental fate and behaviour

Date: 24 January 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 Germany	Federal Environment Agency (UBA) - DE
National Experts nominated by MS Greece	Benaki Phytopathological Institute - EL
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 Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) - IT
National Experts nominated by RMS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) – NL
Observer	Federal office for the environment (BAFU) - CH

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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

4. Environmental fate and behaviour

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 4.1 MSs to discuss in a meeting of experts the relevance of the inclusion of the DegT50 values derived from the field dissipation studies where bixlozone was applied on bare soil (i.e. not-incorporated immediately after the application) to derive the overall geometric mean value.	In the available field dissipation trials, bixlozone was sprayed at the same trial site, at the same time on both "surface" bare soil plots without incorporation (i.e. legacy field trials) and "incorporated" plots (tailored field trials, i.e. sprayed onto bare soil and then incorporated into the first centimetres of the top soils just after application). There was a discussion among experts regarding whether DegT50 values derived from the legacy field trials should be consider for modelling purposes taking into consideration that tailored field dissipation studies according to the EFSA DegT50 guidance are available. "Surface" not-incorporated plots, in this view, would only be used to determine DisT50 and calculate Predicted Environmental Concentration (PEC) in soil. The t-test provided by the RMS confirmed that the difference between the two populations is statistically different with DegT50 values longer in "incorporated" plots compared to "surface"-applied plots although the legacy DegT50 were derived according to the recommendation of EFSA DegT50 GD (2014) to exclude the potential influence of surface processes. The consensus among the majority of experts was to exclusively utilize results from field "incorporated" plots to derive DegT50 for FOCUS modelling. **Open point** RMS to: - Submit the statistical analysis of the available field DegT50 datasets presented during the TC 127 - Update the DAR by indicating that only DegT50 endpoints for bixlozone derived from tailored field dissipation studies (i.e. sprayed onto bare soil and then incorporated into the first centimetres of the top soils just after application) should be used in exposure modelling and to update the overall geomean to be used for modelling purposes

Subject	Conclusions Pesticide Peer Review Meeting
	- Update the list of endpoints by removing from the "Rate of degradation field soil dissipation studies – Modelling endpoints" box for bixlozone the results from the "Bare soil – product NOT incorporated after spraying", and to update the overall geomean value. **Post meeting Note**: After the fate TC 127 meeting, following an internal (EFSA) discussion with colleagues of the PREV Residues Team, it was noted that the current PECsoil/PECaccumulation calculations are based on the worst-case laboratory DFOP DT50 of 358 days. Taking into consideration that this soil exposure assessment is considered more conservative and that the resulting soil dwelling risk assessment does not raise any concern, the experts in TC 127 concluded that no new PECsoil/PECaccumulation calculations are required to address the risk to soil organisms. However, more realistic PEC soil would be needed for rotational crops assessment. Therefore, another open point is set. **Open point** RMS to provide new PECsoil/PECaccumulation calculations for bixlozone based on the new agreed soil DegT50 endpoints to address the rotational crops assessment. Specifically, the new calculations should use the longest not incorporated persistence field endpoint (= 181 days from the SC trial GE01) in the first year and then for subsequent accumulation calculation the longest incorporated persistence field endpoint (= 247 days from the SC trial IT02) for the subsequent years of accumulation.
Experts' consultation 4.2 MSs to discuss in a meeting of experts the validity of the aerobic degradation in soil, [redacted] (2015a, amended 2018) to investigate the route and rate of degradation of bixlozone in soil. In particular, the experts should consider if the incubation period of 120 days was appropriate and if metabolite unknown RRT:0.81 (2,4-dichlorobenzyl alcohol?) could have been formed at levels that would trigger further assessment if a	The possibility that a prolonged testing period of the route aerobic degradation of bixlozone in soil would have resulted in higher (i.e. > 5% AR) amounts of the unknown radioactivity RRT:0.81 was discussed by the experts taking into consideration all the available information. Examining data from other soils at the same retention time did not reveal a consistent pattern of increasing residues. Most experts agreed that, in this instance, the unknown residue is unlikely to reach the 5% AR level that triggers identification and further assessment.

Subject	Conclusions Pesticide Peer Review Meeting
longer incubation period was used. EFSA note: according to Table 8.1.1.1-12 the mean max occurrence of unknown RRT 0.81 in the RefeSol 02-A soil ([carbonyl-14C]-labelled bixlozone) is 2.69 % AR which was measured at the end of the study (120 days), while at 76 day was 2.43 % AR and at 30 day was 1.4 % AR. A clear trend of increasing formation (mean of the two replicates) within the incubation time for unknown RRT 0.81 is also evident in the Lufa 2.2 soil according to Table 8.1.1.1-11. In addition, in OECD 307 it is indicated (par. 39): "The rate and pathway studies should normally not exceed 120 days, because thereafter a decrease of the soil microbial activity with time would be expected in an artificial laboratory system isolated from natural replenishment. Where necessary to characterise the decline of the test substance and the formation and decline of major transformation products, studies can be continued for longer periods (e.g. 6 or 12 months). Longer incubation periods should be justified in the test report and accompanied by biomass measurements during and at the end of these periods."	

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.3 Member States to discuss in a meeting of experts the suitability of the field dissipation study [redacted] (2018a) to derive persistence and modelling endpoints for bixlozone. In particular, the experts should consider: - The potential contribution of soil photodegradation to the dissipation of bixlozone in the bare soil plots - The dissipation rate for bare soil vs incorporated plots - The reliability of the DT50 value obtained from the test trial IT03 where the mean procedural recovery was only about 60 %.	The general discussion over the different field tests design ("surface" vs "incorporated" trials) conducted under experts' consultation 4.1 has been specifically resumed for the field study conducted in Southern Europe (FR01, IT02 and IT03). Based on the RMS assessment, it was agreed that photolysis was likely not significant in trial FR01 but could have played a role in IT02. While dissipation was faster in summer trials, increased volatilization might be a factor, especially in non-incorporated plots. However, for persistence assessment, longer dissipation times are considered. In trial IT03, despite spatial variability, consistent recovery on Petri dishes was observed, deemed insignificant for degradation endpoints due to immediate incorporation after application. Overall, the experts confirmed the conclusions already made under discussion point 4.1 (i.e. given the differences between the "surface" and "incorporated" plots, the potential contribution of soil photodegradation to the dissipation of bixlozone in soil cannot be excluded and that only the DegT50 from the tailored plots should be used for modelling purposes). See open point under experts' consultation 4.1.
Experts' consultation 4.4 Member States to discuss in a meeting of experts the adequacy of the application rate of 250 g a.s./ha used in the field dissipation studies [redacted], 2018b (trials GE01 and FR02) and [redacted] (2018), which is lower than the maximum application rate for the representative uses in maize and winter oilseed rape, to address the rate of dissipation of bixlozone in soil and to detect quantifiable residue levels of soil metabolites of bixlozone.	Although in two field studies with GE01 and FR02 trials and with UK trial, an application rate of 250 g a.s./ha was used, there are sufficient trials from three sites where bixlozone was applied at the max application rate of 375 g a.s./ha. The two studies are also considered valid to address the route of dissipation in soil of bixlozone as in all field trials the metabolites 2,4-dichlorobenzoic acid F9600-3-OH-propanamide were analysed with a sufficiently low LOD. Experts agreed that the field dissipation studies conducted with an application rate lower than the max dose rate indicated in the GAP for the representative uses on winter OSR and maize can be retained in the exposure assessment.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.5 MSs to discuss in a meeting of experts the approach that should be used to derive the overall geometric mean DegT50 value for bixlozone when field dissipation data from trials with SC and CS formulation at the same trial site (i.e. applied at the same site, at the same time on plots in close proximity of each other).	The discussion focused on determining the approach for deriving the overall geometric mean field DegT50 value for bixlozone in exposure modelling, specifically whether to combine data from trials with SC and CS formulations. RMS proposed separate kinetic endpoints for SC and CS formulations, emphasizing the different behaviour in soil. T-tests showed a significant difference between DegT50 values from CS and SC formulations when paired. Experts considered various options but agreed not to use results from the CS formulation in the EU assessment due to potential differences in behaviour. The chosen overall geomean DegT50 of 76.6 d closely aligned with the 74.9 d derived for "incorporated" trials with SC formulation, indicating minimal impact on exposure modelling results. It was agreed to retain the calculations already done using the overall geomean DegT50 of 76.6 d and no new PECgw calculations are necessary. A note will be added in the LoEP indicating that for new calculations the DegT50 of 74.9 d derived for SC formulation should be used. In case CS formulation would be used at national level, it was proposed to have the different endpoints separated for CS and SC formulations in the LoEP. **Open point:** RMS to update the DAR and the LoEP with the information provided during the meeting and with the conclusions agreed by the experts of the Pesticide Peer Review TC 127. **Open point**: EFSA to make clear in the EFSA conclusion for bixlozone that in case an assessment with CS formulation would be needed at national level, agreed endpoints are available for an example of CS formulation.
Experts' consultation 4.6 MSs to discuss in a meeting of experts the potential pH dependency of the adsorption properties of metabolite 2,4-dichlorobenzoic acid and to agree on the adsorption endpoints for modelling purposes.	Several discussions were made regarding the assessment of the adsorption behaviour of 2,4-dichloro benzoic acid taking into consideration data available from dossiers for spirodiclofen and bixlozone. Experts observed similar limitations in data quality between the two dossiers, particularly regarding low adsorption percentages. They decided not to rely on the batch adsorption study from the spirodiclofen dossier due to identified deficiencies and requested an evaluation of these shortcomings for transparency. It was collectively agreed that the acid's adsorption is influenced by pH, with significant adsorption expected primarily at low soil pH values.

Subject	Conclusions Pesticide Peer Review Meeting
	To model metabolite 2,4-dichloro benzoic acid leaching conservatively across varying environmental pH levels, it was agreed to utilize the geomean Kfoc value from the bixlozone dossier for soils above pH 7, consistent with the original DAR of 2021, as it provides low adsorption endpoints accompanied by 1/n values greater than 1. **Open point:** RMS to evaluate in an amended DAR the batch adsorption study of 2,4-dichloro benzoic acid that is available in the spirodiclofen dossier to assess and conclude on its deficiency. In addition, RMS is asked to clearly indicate the reversion to the 2021 assessment in line with the conclusions of the experts' discussions and the action completed to address open point 4(22) in the evaluation table. This includes the PEC calculations that should also be reinstated in the list of endpoints. A note should be added that the correct 2,4-dichloro benzoic acid DT50 to be used in future assessments should be 6 days (the 2021 assessment used a value of 5.4 days).
Experts' consultation 4.7 MSs to discuss in a meeting of experts if metabolite F9600-3-OH-propanamide, measured at ≥ 10% applied radioactivity (mean maximum of 14.8% of applied radioactivity) after 122 days of anaerobic soil incubation (laboratory study [redacted], 2015b) trigger further exposure assessment	The experts discussed the formation of F9600-3-OH >5%AR under anaerobic conditions, noting it occurred after 90 to 122 days. They reasoned that crops like oilseed rape and cereals, although tolerant to some anaerobic conditions, are unlikely to be cultivated in fields with such prolonged anaerobic periods. Metabolite F9600-3-OH-propanamide does not warrant additional exposure assessment and it should not be included in the residue definition for risk assessment. **Open point:** RMS to remove the metabolite F9600-3-OH from the list of metabolites triggering assessment in the list of endpoints and in an amended DAR.

REPORT OF PESTICIDES PEER REVIEW TC 121

CHLOROTOLURON – AIR III

Rapporteur Member State: BG

4. Environmental fate and behaviour

Date: 15 November 2023

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 Bulgaria	Risk assessment centre on food chain - BG
National Experts nominated by MS Germany (2)	Federal Environment Agency (UBA) - DE
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 Croatia	Croatian Agency for Agriculture and Food - HR
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) – NL
Observer	Federal office for the environment (BAFU) - CH

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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

4. Environmental fate and behaviour

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 4.1 Experts to agree on the acceptability of the aerobic degradation in soil study Vol. 3 B.8 (AS) Data point. B.8 .1.1.1/02 to derive rate of degradation endpoints for chlorotoluron and desmethyl chlorotoluron.	A study investigating the degradation of chlorotoluron in four German soils was considered possibly acceptable for the rate of degradation. However, several deficiencies were highlighted such as some soil recoveries of the applied radioactivity were below 90%, there were extraction problems with the soils (quantified results being unavailable for all the solvents used for the extraction). Overall, the experts considered that the draw backs with the study were sufficient to exclude the study and not rely on it for both the route and rate of degradation of chlorotoluron. **Open point:** RMS to remove (strike through) from the list of endpoints the lab rate of degradation endpoints for chlorotoluron and desmethyl chlorotoluron derived from study investigating the degradation of chlorotoluron in four German soils.
Experts' consultation 4.2 Experts to agree on the degradation endpoints to be used for the exposure assessment of chlorotoluron and desmethyl chlorotoluron considering the updated kinetic evaluation of the Rate of aerobic degradation in laboratory study Vol. 3 B.8	For chlorotoluron the updated kinetic assessment was discussed to derive DegT50 from field studies in line with the relevant EFSA DegT50 guidance (2014) considering that the trial sites were located in both Northern and Southern areas of France. The pH dependency of degradation for chlorotoluron was also discussed. For desmenthyl chlorotoluron the updated kinetic assessments of the reliable lab studies and field studies were discussed. The experts discussed if considering the laboratory and field kinetic endpoints together that degradation of desmenthyl chlorotoluron would be considered pH dependent. For chlorotoluron the updated kinetic assessment was agreed to be relied on to derive DegT50 from field studies in line with the

Subject	Conclusions Pesticide Peer Review Meeting
(AS) Data point. B.8.1.1.4/05.	relevant EFSA DegT50 guidance (2014). It was confirmed that the degradation of chlorotoluron was not pH dependent. For desmenthyl chlorotoluron the updated kinetic assessments of the reliable lab studies and field studies were accepted, though at field trial site 3 (Picardie) the maximum formation and later time points can be seen to be underestimated by the metabolite fitting and the formation fraction was the lowest. On balance the experts agreed the kinetic endpoints for desmenthyl chlorotoluron for the remaining three trial sites. The experts concluded that considering the laboratory and field kinetic endpoints together the degradation of desmenthyl chlorotoluron is pH dependent. The experts agreed to split the dataset for desmenthyl chlorotoluron (lab and field) DegT50 using the data above pH 6.5 (in water) and below pH 6.5 (in water, in practice this means that for soils < pH 6.5 only lab data are available in this case due to the small reliable dataset of field endpoints). The geomean DegT50 for values above pH 6.5 (water) is 38 days. For pH below 6.5 (water) it is 123 days. It was agreed to use the arithmetic mean of the field and lab kinetic formation fractions independent of the soil pH in this case with this dataset. This value is 0.3457. **Open point:** RMS to use the EFSA DegT50 endpoint selector to compare the lab and field endpoints for chlorotoluron and desmenthyl chlorotoluron excluding the degradation endpoints derived from the four German soils (see Experts' consultation 4.1) and update the RAR consequently. RMS to update the list of endpoints modelling endpoints for desmenthyl chlorotoluron splitting the data set (lab and field) with pH above and below 6.5 (in water) as indicated in the discussion above.
Experts' consultation 4.3 Experts to agree on the degradation endpoints to be used for the exposure assessment of chlorotoluron benzoic acid considering the new terrestrial field dissipation study.	Experts discussed the new field dissipation study of chlorotoluron benzoic acid from bare soil at four different locations in Northern and Southern Europe and its kinetic evaluation. Experts noted that the available PEC groundwater for chlorotoluron benzoic acid had been calculated using the soil kinetic formation fraction from the laboratory incubations (as formation fraction values from field investigations are not available). However, experts questioned if the lab kinetic formation fractions might be used in this case, as they may be underestimating the formation of chlorotoluron benzoic acid that will happen in the field. It was noted that PEC soil accumulation for chlorotoluron benzoic acid should in principle be calculated using the longest DT50 and DT90 and the one that leads to the highest PEC soil accumulation should be used. But this was not needed as accumulation will not occur in this case as the longest DT90 is below 1 year and the GAP for the representative use only includes a single application per year.

Subject	Conclusions Pesticide Peer Review Meeting
	Experts agreed to rely on the new field dissipation study of chlorotoluron benzoic acid from bare soil at four different locations in Europe and its kinetic evaluation. Experts concluded that the degradation of chlorotoluron benzoic acid was not pH dependent. In the absence of information on formation potential in the field it was agreed that it might be assumed, as a conservative estimate, that in the field chlorotoluron benzoic acid might have a kinetic formation fraction of 1 minus the formation fraction of desmethyl chlorotoluron (i.e., 1 - 0.3457 = 0.6532). PEC soil accumulation for chlorotoluron benzoic acid are not needed as accumulation will not occur in this case as the longest DT90 is below 1 year and the GAP for the representative use only includes a single application per year. **Open point:** RMS to update the list of endpoints highlighting that the formation fraction of chlorotoluron benzoic acid is derived from 1 minus the formation fraction of desmethyl chlorotoluron (i.e., 1 - 0.3457 = 0.6532).
Experts' consultation 4.4 Experts to discuss and agree on the acceptability of the adsorption study Vol. 3 B.8 (AS) Data point. B.8.1.2.2/01 for metabolite desmethyl chlorotoluron and to agree on the adsorption endpoints to be used for this metabolite in the exposure assessment.	The study on the adsorption of desmethyl chlorotoluron and its deviation from OECD TG 106 and EFSA OECD 106 checklist were discussed. The applicant provided additional calculations considering the correction for the non-extractable residues content, determined in the preliminary test at the highest concentration (5 mg/L), to all the tested fractions. The indirect method was used. It was discussed that the LOQ of the analytical method used to measure the concentration of the supernatant was not provided in the study report, but it is assumed low enough since the recovery of radioactivity is around 100%. The RMS assessment that the adsorption of desmethyl chlorotoluron was discussed by the experts. Experts agreed that non-extractable residues should not be regarded as parent substance and therefore are to be excluded from the sorbed fraction. It was discussed that this correction related to the same non-extractable residues content for all the tested concentrations can lead to uncertainty especially considering a possible underestimation of 1/n value. Even a large impact on the PECgw calculations applying this correction is not expected, the majority of the experts proposed and agreed on the use of the default value of 1/n of 0.9 as alternative. The RMS assessment that the adsorption of desmethyl chlorotoluron was not pH dependent was agreed by the experts due mainly to the chemical structure of the metabolite.

Subject	Conclusions Pesticide Peer Review Meeting
	Open points: RMS to update the environmental exposure assessment using the proposed 1/n = 0.9 for the PECgw and PECsw/sed calculations of metabolite desmethyl chlorotoluron. The calculations should be repeated considering also the outcomes from open point in the experts' consultation 4.2 on the rate of degradation and formation fraction of desmethyl chlorotoluron. The aquatic exposure assessment for desmethyl chlorotoluron should be performed in line with the discussion held during the TC 123 on ecotoxicology.
Experts' consultation 4.5 Experts to discuss and agree on the acceptability of the study Vol. 3 B.8 (AS) Data point. B.8.1.2.2/02 on the adsorption of metabolite chlorotoluron benzoic acid and to agree on the endpoints to be used for this metabolite in the exposure assessment considering the update assessment on its pH dependence of adsorption and the new adsorption study.	Experts discussed the reliability of the adsorption study for the metabolite chlorotoluron benzoic acid already available during the commenting phase. Experts took into account that not only adsorption in soil LUFA 6S did not fulfill some of the quality criteria according to the OECD 106 checklist, but total recovery was also < 90% for the two soils LUFA 2.1 and LUFA 2.3 and also the criteria Kd x (soil:solution ratio) was partly < 0.3 and KfE/Kf indicates high uncertainty. For LUFA 2.3, visual fit of the Freundlich isotherm was not satisfactory with r2 < 0.975. Experts discussed the reliability of the new adsorption study for the metabolite chlorotoluron benzoic acid and noted that the currently stated pH values in the LoEP for this study do not agree with the pH values reported in the soil characteristics in the RAR. These two sets of values supposedly correspond to the pH measured before and after the addition of the active substance in the soil. Considering that the test material was chlorotoluron benzoic acid but no decrease in the pH was observed after the addition of the active substance, experts concluded that this difference could be due to the effect of the buffer solution. The experts discussed the pH dependence in the adsorption of chlorotoluron benzoic acid. Based on the agreed pH values in Table B.8.1.2.2-20, the pH range (in water) covered in the new adsorption study is 4.8 to 8.32. Higher adsorption was observed at the two soils with pH ≤ 5 (KFOC 22.7 and 45.0 mL/g), while the three soils with pH > 6 had KFOC in the range of 1.77 to 4.67 mL/g. Experts discussed the cutoff point to separate the two datasets of adsorption endpoints for modelling in either pH 5 or pH 6, since there is a gap of adsorption data between these pH. The pKa of this metabolite was not provided by the applicant but an estimate was calculated by DE as pKa of 3.14. Based on this, a turning point of adsorption properties may be theoretically expected around pH 6. However, some member states preferred selecting a pH of 5 as a more conservative approach, since more pH values would be modelled with a lower geometric mean of KFOC values. Some experts also indicated that soils at pH < 5 are not representative of European agricultural soils (pH between 5.1 and 8).

Subject	Conclusions Pesticide Peer Review Meeting
	The majority of the experts were of the view that the adsorption study for the metabolite chlorotoluron benzoic acid already available during the commenting phase should be rejected. Experts agreed to consider only the results of the new adsorption study available in the amended RAR to derive adsorption endpoints for the metabolite chlorotoluron benzoic acid. Experts agreed to use the pH in water given in the soil characterisation table (Table B.8.1.2.2-20). Experts agreed that the adsorption of chlorotoluron benzoic acid was pH dependent. The majority of the experts agreed that the exposure assessment should be performed considering two sets of PECgw calculations, for pH ≤ 5 and pH > 6, clearly pointing to risk managers that there is a gap of adsorption information between pH 5 and 6 so the applicability of these PEC calculations for pH between 5 and 6 are uncertain. For the two sets of calculations, experts agreed to use the geometric mean of the KFOC values and the arithmetic mean of the 1/n values of each dataset (for pH ≤ 5, KFOC of 32.0 mL/g and 1/n of 0.9005; for pH > 6, KFOC of 3.35 mL/g and 1/n of 0.9537). Experts agreed that there was no need for PECsw and PECsed calculations, considering that calculations for this metabolite were provided up to Step 2 and the relevant endpoints needed for these calculations did not change significantly. **Open points**: RMS to indicate in the revised RAR that the adsorption study for the metabolite chlorotoluron benzoic already available during the commenting phase is not acceptable and delete from the list of endpoints the adsorption endpoints coming from this study. RMS to amend the list of endpoints updating the pH values (in CaCl2 and in water) coming from the new adsorption study for the metabolite chlorotoluron benzoic, so that they are in line with the values provided in Vol. 3 CA B.8 Table B.8.1.2.2-20. RMS to provide new PECgw calculations for the metabolite chlorotoluron benzoic acid considering two sets of calculations, for pH ≤ 5 and pH > 6, clearly pointing that there is a gap of adsorption information between pH 5 and 6 so the applicability of these PEC calculations for pH between 5 and 6 are uncertain. RMS to use the geometric mean of the KFOC values and the arithmetic mean of the 1/n values of each dataset (for pH ≤ 5, KFOC of 32.0 mL/g and 1/n of 0.9005; for pH > 6, KFOC of 3.35 mL/g and 1/n of 0.9537). The calculations should be repeated considering also the outcomes from open points in the experts' consultations 4.2, 4.3 and 4.4.

REPORT OF PESTICIDES PEER REVIEW TC 115

1-METHYLCYCLOPROPENE – Amendment of approval conditions

Rapporteur Member State: NL

4. Environmental fate and behaviour

Date: 05 September 2023

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 France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) - FR
National Experts nominated by RMS Netherlands (2)	Board for the Authorisation of Plant Protection Products and Biocides (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

4. Environmental fate and behaviour

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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 4.1 MSs experts to agree on the assessment of the new proposed studies to address the fate and behaviour in soil in light of the additional information requested to the Applicant and taking into account the intrinsic properties of the 1-MCP being released in gas phase during the application. Moreover, MSs to discuss the proposed endpoints for PEC modelling calculations in the soil and groundwater compartments.	• It was agreed that the aerobic soil metabolism study submitted by the applicant can be considered in a weight of evidence approach but not to derive reliable kinetic parameters. • It was agreed that the study investigating soil deposition, cannot be used for the exposure assessment of 1-MCP in soil. In particular, the experts agreed that the study cannot be used to refine the PEC calculations (as proposed by the applicant). • In the aerobic metabolism study, the unextracted residues reach levels above the 70 % trigger, while mineralisation is also less than 5 % at the end of the study (study is finalised after 7 d). It is up to the consideration of residues and ecotoxicology experts to assess if there may be harmful effects for the environment and or residues in succeeding crops (as stated in the unless clause of the uniform principles). Alternatively, applicant could provide a longer study (lasting at least the 100 d) or information demonstrating that under field use the levels of NER in soil will be below the trigger of 70 % (e.g., by a reliable deposition investigation). • Taking into account, the uncertainties identified, it was agreed that the metabolite methallyl alcohol should be considered a major metabolite in the soil compartment and a data gap should be identified for the applicant to address it. • For PECsoil and PECsw calculations the use of a default value for 1-MCP, DegT50 = 1000 d, is agreed. • For PECgw calculations a default value of 1-MCP of DegT50 = 14.1 d (20°C) is agreed, based on the ready biodegradability

Subject	Conclusions Pesticide Peer Review Meeting
	study results and ECHA guidance on Biocidal Products Regulation (ECHA 2017). • For the metabolite methallyl alcohol the following default parameters are agreed for PEC calculations: Maximum amount formed: 100 % of parent on molar amount; Koc = 10 mL/g, 1/n =1; DegT50 = 1000 d; Vapour pressure = 0 Pa; Water solubility = 1000 mg /L. **Open point**: RMS to ensure that the calculations performed according to the agreed endpoints are clearly reported in the RAR and the list of endpoints. RMS to produce new PEC_{GW} calculations using the DegT50 = 14.1 d (20°C). **Data gap**: applicant to address the formation of the metabolite methallyl alcohol in the soil compartment as, with the available information, experts agreed it is needed to be considered a major metabolite in this compartment. **Open point**: RMS to provide PEC_{soil} and PEC_{GW} for the metabolite methallyl alcohol using the default agreed endpoints. For PEC_{GW} the experts agreed the metabolite should be modelled as if it was applied as parent. The list of endpoints should be updated accordingly.
Experts' consultation 4.2 MSs experts to discuss and agree on the validity of the CA 7.2.2.3/01 study and in particular on the identification and quantification of the metabolite methallyl alcohol in the two water/sediment systems tested. The discussion will include the degradation pathway proposed by the Applicant and, if no further studies and updated kinetic fit are submitted, the proposal to use the conservative DT50	Taking into account the uncertainties identified in the available water/ sediment studies (high volatilisation, sediment extracted with only water, presence of methallyl alcohol in these residues, but quantification not reported), the experts agreed the metabolite methallyl alcohol should be considered a major metabolite in the water and sediment compartments and a data gap should be identified for the applicant to address it. Since from the kinetic analysis provided it is not possible to derive reliable kinetic parameters, for the surface water modelling exposure the experts agreed that the default parameters below could be used. For 1-MCP (see also considerations from the experts' consultation point 4.1): - DT50 in the whole system = 1000 d;

Subject	Conclusions Pesticide Peer Review Meeting
of 1000 days for the PECsw/sed modelling considering the intrinsic properties of the active substance, which is a gas.	- DT50 in water = 1000 d; - DT50 in sediment = 1000 d. For the metabolite methallyl alcohol: • Maximum amount formed: 100 % of parent on molar amount; • DT50 in the whole system = 300 d (worst-case default for the metabolites based on aquatic RA guidance); • DT50 in water = 300 d (worst-case default for the metabolites); • DT50 in sediment = 300 d (worst-case default for the metabolites); • Koc = 10 mL/g to address worst-case for surface water compartment and Koc = 10000 mL/g for sediment, with and 1/n = 1. **Data gap**: applicant to address the formation of the metabolite methallyl alcohol in the surface water and sediment compartments as with the available information experts agreed it needs to be considered a major metabolite in these compartments. **Open point**: RMS to provide PECsw/sed using the agreed default end points up to FOCUS Step 2 and to update the List of endpoints accordingly. **Open point**: RMS to update the list of endpoints according to the conclusions of the meeting (e.g., the residue definition in the different compartments).

REPORT OF PESTICIDE PEER REVIEW TC 111

QUINOLIN-8-OL (8-HYDROXYQUINOLINE) – AIR IV Rapporteur Member State: ES

4. Environmental fate and behaviour

Date: 22 June 2023

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 Spain	National Institute for Agricultural and food research and technology (INIA) – (ES)
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 Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) – (NL)

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 MSs experts to discuss and agree: - on the proposed approach to include the % of bound residues to the extracted amount of radioactivity for the calculation of the modelling endpoints in the [redacted] (2004a) soil degradation study; - consequently on the proposed kinetic assessment of the 4 tested soils; - on the endpoints to be used for the exposure assessment of the a.s. considering the chelating properties of 8-hydroxyquinoline and the proposed use in permanent greenhouse.	Experts discussed that quinolin-8-ol dissipates by rapidly forming unextractable residues and that the formation of unextractable residues is essentially considered a transformation of the active substance. Overall, the experts considered that the unextracted residues should be excluded from the DegT50 used for FOCUS modelling, while for PEC soil calculation other approaches might be considered. The experts considered the approach proposed in the RAR would not necessarily cover the accumulated complexed material coming from the active substance that is operationalised as being represented by the unextractable radioactivity. Therefore, the experts agreed that PEC soil should be calculated accounting for accumulation of unextracted radioactivity. Experts also discussed and agreed on the endpoints derived from the updated kinetic fits. **Open point:** RMS to calculate PEC soil considering the soil with the longest available DT90 where unextractable residues were added to the measured extractable active substance. This will be a PEC soil accumulation due to the DT90 being longer than a year. Both soil accumulation and PEC soil boxes should be completed in an amended RAR and updated list of endpoints. **Open point:** RMS to update the list of endpoints to indicate the triggering (currently labelled regulatory) endpoints as modelling endpoints, and which were previously the modelling endpoints as triggering endpoints. The normalisations for moisture need revising, i.e.: normalised for modelling, not normalised for persistence.

Subject	Conclusions Pesticide Peer Review Meeting
	FOMC fit to continue to be selected as the modelling endpoint in the Soest soil and then for modelling FOMC/3.32 to be indicated in the list of endpoints table. New triggering endpoint for the Soest soil to continue to be the SFO fit. Kinetics for the other 3 soils as assessed by the RMS to also be retained (i.e., now DFOP for modelling and for triggering DFOP for LUFA 2.2 and HS for the other 2 soils). All modelling endpoints with biphasic fits to use DT90/3.32, and not the k2. DT90 values to always be included in the list of endpoints. Finally, RMS to also update the RAR according to these decisions.
Experts' consultation 4.2 MSs experts to discuss and agree on the approach proposed by the Applicant to consider the % of bound residues as part of the adsorbed mass in equilibrium sorption in the [redacted] (2004c) study. Moreover, experts to agree on the endpoints to be used for the exposure assessment of the a.s. considering the chelating properties of 8-hydroxyquinoline and the proposed use in permanent greenhouse.	The adsorption study provided by the Applicant for quinolin-8-ol was conducted with the indirect method and the extractable+non-extractable test substance was used for calculating the parental mass balance and for the determination of the Freundlich adsorption isoterms. Following the OECD guideline and OECD 106 evaluators checklist, experts agreed that the direct method needed to have been used because of a mass balance less than 90%. The only usable endpoints that can be derived from the available study are to use measured active substance in both the soil pellet extract and the supernatant from the pre-test to determine new Kd and Kdoc values. **Open point:** RMS to recalculate Kd and Kdoc values for quinolin-8-ol using the results from the pre-test and to update RAR and amend the list of endpoints. The updated RAR and list of endpoints have to indicate that in this case a 1/n of 1 should be used with the available Kdoc values, considering also the Frendlich results from the indirect method determined with total radioactivity. **Data gap:** An OECD 106 guideline Freundlich adsorption study for quinolin-8-ol using the direct method was not available, but it is still considered needed.
Experts' consultation 4.3 MSs experts to agree on the approach used for PEC calculations in the different compartments considering the clarification of intended use in permanent greenhouses.	The overall approach discussed by experts at the points 4.1 and 4.2 on how to consider unextractable residues in the soil degradation and in the soil adsorption studies has led to update considerations on the PEC calculations. For the soil compartment, as the DT90 relevant for soil PEC is now > 1 year, PEC soil should be calculated, and a soil organisms risk assessment was considered relevant. For PEC surface water, sediment and groundwater, in this case the experts agreed that, for drip irrigation application directly to soil in

Subject	Conclusions Pesticide Peer Review Meeting
	permanent greenhouses, FOCUS groundwater modelling with the standard scenarios and the D6 scenario for surface water can be sufficient to identify a safe situation for the EU process for active substance approval and the uses assessed at EU level for the representative formulation. An open point for an updated PEC soil calculation that accounts for accumulation has been already included at expert discussion point 4.1. **Open point:** RMS to indicate, in the list of endpoints and an amended RAR for the PEC surface water and groundwater, the quinolin-8-ol substance properties endpoints that should be used for future modelling, i.e. the geomean DegT50 and Kdoc resulting from completing the open points at expert consultation points 4.1 and 4.2, including the use of a 1/n value of 1.

REPORT OF PESTICIDE PEER REVIEW TC 107

BUPROFEZIN – AIR IV

Rapporteur Member State: IT

4. Environmental fate and behaviour

Date: 23 May 2023

List of participants:

Status	**Name of institution/attendee**
EFSA statutory staff member	EFSA
National Experts nominated by MS Germany	Federal Environmental Agency (UBA) – (DE)
National Experts nominated by RMS Italy	International Centre for Pesticides and Health Risk Prevention (ICPS) – (IT)
National Experts nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) – (NL)
Observer	Federal Office for the Environment – (CH)

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to discuss and agree on the degradation endpoints to be used for the exposure assessment of buprofezin.	Reliable degradation endpoints for buprofezin are available only for 3 soils, with no DT50 available at pH below 6.4. A new soil degradation study for buprofezin in acidic soil is currently ongoing. DT50 values form field dissipation studies are also available for buprofezin, with a soil pH range from 5 to 7.8. Based on the results from field dissipation studies, no pH dependence was observed. When plotting lab and field data, no clear indication of pH dependence was shown either. The comparability of the sites from a US field dissipation study to the EU conditions was assessed using ENASGIPS. The Fresno (California) soil was considered representative of European conditions, but the Pikeville (North Carolina) soil was representative of European conditions only for soil properties and not climate. Therefore, the endpoints from the soil Pikeville (North Carolina) were proposed to be excluded by the applicant. The Member State considered that if the soil at the trial site is representative of EU soils and the climate conditions during the study are in the range that a FOCUS reference condition normalisation would be valid, ENASGIPS database values for locations should not be a reason to exclude the soil. Therefore, experts agreed to the endpoints from the soil Pikeville (North Carolina) should not be excluded. The Kendall test was repeated adding this soil to the entire dataset of lab and field values, and no pH dependence was observed. The experts concluded that until the missing laboratory soil degradation study was provided, a geomean normalised field DegT50 of 29 days is the appropriate endpoint for any future FOCUS modelling of buprofezin.

Subject	Conclusions Pesticide Peer Review Meeting
	The experts agreed that the existing PECgw and PECsw/sed calculations using a DegT50 of 31.5 days for buprofezin could be retained in this case. For PEC soil calculations, it was agreed that an SFO DT50 value of 99 days for buprofezin should be used considering the current dataset. **Open point**: RMS to include Kendall test results for pH dependence also including the Pikeville (North Carolina) soil in an amended RAR. **Open point**: RMS to add a footnote in the LoEP to the PECgw and PECsw/sed calculations to indicate that in future modelling for buprofezin a geomean normalised field DegT50 of 29 days would be the most appropriate endpoint (considering the current dataset). **Data gap**: A new soil degradation study on buprofezin in acidic soil (pH < 6) (Experts confirmed this, which was already present in the Evaluation Table).
Experts' consultation 4.2 Experts to discuss and agree on the adsorption endpoints to be used for the exposure assessment of buprofezin.	Following the OECD 106 evaluators checklist several deviations were identified by the RMS in the old adsorption study on buprofezin (e.g.; only 4 concentrations were used, Kd * soil/solution ratio was > 0.3 in all soils, KfE/Kf ratio exceeded the factor of 1.2 in all soils, etc…) The RMS proposed to consider the old adsorption study not acceptable and that no reliable Freundlich adsorption parameters could be obtained for any of the soils in this study, because significant validity criteria of the OECD 106 evaluators checklist were not met for all soils. A new adsorption study was considered to be acceptable by RMS, as no major deviations were found, and the validity criteria of the OECD 106 evaluators checklist were met for all soils. No pH dependence was observed within the pH range tested. The Member State experts agreed that the endpoints derived from the old adsorption study should not be relied on. The Member State experts agreed to consider the new adsorption study acceptable and to use a geometric mean Kfoc of 4923 mL/g and an arithmetic mean 1/n of 1.02 in the exposure assessment of buprofezin.

REPORT OF PESTICIDE PEER REVIEW TC 101

PARAFFIN OIL CAS 8042-47-5 – AIR IV **Rapporteur Member State: EL**

4. Environmental fate and behaviour

Date: 21 April 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 Germany (2)	Federal Environmental Agency (UBA) (DE)
National Expert nominated by RMS Greece (2)	Benaki Phytopathological Institute (BPI) (EL)
National Expert nominated by MS France (2)	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) (IT)
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)
Observer	Federal Office for the Environment (CH)

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 **MSs experts to consider the outcomes of the new proposed water/sediment study that should include an exhaustive method development and optimization phase to overcome the technical challenges encountered in prior studies. MSs experts to agree on the kinetic fit endpoints proposed and on the DT50 to be used for further PECsw and PECsed calculations.** **Additionally, experts to consider the assessment of the soil degradation study (2022) and consequent update of the related endpoints necessary for the exposure assessment (DT50soil).**	**1) No new OECD 308 study has been submitted by any of the Applicants. They claim technical difficulties to perform a standard OECD 308 study due to the properties of the substance (high adsorption, volatilization, low density, immiscibility with water…). These difficulties seem to be encountered even when the formulated product (with [redacted] is used. These properties are also key to the mode of action of this substance that is physically and not metabolic. Another difficulty is to distinguish the applied product from natural background compounds. Experts agreed that route of degradation can be described by the transformation to alkanes with shorter carbon chain and CO_2 as the final degradation product. However, even acknowledging the difficulties to perform a standard OECD 308 study, the experts agreed that further information would be necessary to address the rate of degradation of paraffin oil in the aquatic environment, particularly in the sediment compartment.** **New PECsw/PECsed calculations (2D and 3D up to Step 2) have been submitted based on worst-case endpoints for the three representative products. Spray drift mitigation measures (non-spray buffer zones + drift reduction nozzles) have been applied to Step 2 (sometimes resulting in mitigation exceeding the FOCUS trigger of 95 % reduction).** **2) No additional degradation in soil study was provided by Applicant PTQ. However, reliable soil degradation endpoints are available for eight soils and therefore the data gap is not essential to finalise the exposure assessment.** **3) It was noted that the PECgw results based on a Vp value of 0.003 Pa with the PEARL model (e.g. Vol 3 B (CP) p. 17 for the**

Subject	Conclusions Pesticide Peer Review Meeting
	BCP405D/CCL742 product) and exceeding 0.1 µg/L were struck-through in the updated RAR, but it is considered that the input parameters on which these calculations are based on are still representative for some of the components of the mixture and the calculations need to be re-instated. Data gap. Data on the rate of degradation of paraffin oil in the aquatic environment, particularly in the sediment compartment is needed. To obtain these a sediment saturated incubation type study dosed with radiolabelled (if practical) paraffin oil, is proposed. In this study the collection of CO_2 would be needed to track the degradation process. In addition, the applicants should consider providing sound justifications for the extrapolation of the results between products. The data gap applies to all the applicants. Open point: RMS to remove from the LoEP Step 2 PECsw/ PECsed with RMM exceeding the 95% overall reduction. Open point: RMS to provide further clarifications on the procedure followed for the new submitted 2D Step 2 PECsw/PECsed calculations for BCP405D/CCL742 and NEU 1130 I EW products. Open point: PECgw results based on a Vp value of 0.003 Pa with the PEARL model (e.g. Vol 3 B (CP) p. 17 for the BCP405D/CCL742 product) should re-instated in the updated RAR.
Experts' consultation 4.2 (jointly discussed with the Ecotoxicology experts): MSs experts to agree on the outcomes of the PEC calculation proposed for the surface water/ sediment exposure assessment, both in field and greenhouse, with modified Step 2 and considering only the spray drift with the application of appropriate mitigation measures. This approach was proposed because	(This point was discussed in Peer Review meeting on ecotoxicology TC 102. The discussion is reproduced here for completeness) <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

Subject	Conclusions Pesticide Peer Review Meeting
paraffin oil will not go to the ditch surface water via run off or drainage due to the considerable low water solubility and high K_{OC}. This consultation should consider also the outcomes from the experts' consultation 4.1 and should be jointly done with ecotoxicology experts to take into account how toxicity studies for aquatic organisms are performed considering the FOCUS exposure profile of the mesocosms studies.	(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: (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 µg a.s./m²) 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).

REPORT OF PESTICIDE PEER REVIEW TC 101

PICLORAM – AIR III

Rapporteur Member State: PL

4. Environmental fate and behaviour

Date: 21 April 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) (AT)
National Expert nominated by MS Germany	Federal Environmental Agency (UBA) (DE)
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) (IT)
National Expert nominated by MS Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (NL)
National Expert nominated by RMS Poland	Institute of Environmental Protection – National Research Institute (PL)
Observers	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

4. Environmental fate and behaviour

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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 4.1 Experts, for the study related to kinetic assessment of the rate of degradation in aerobic conditions, to discuss and agree on: 1) the reliability of the kinetic evaluation for ATCP in RefeSol 02-A soil using a top-down fit; 2) the selection of degradation endpoints for the picloram and the metabolite ATCP that should be used for the calculation of PECsoil, PECgw, PECsw and PECsed calculations; 3) the need of a field dissipation study conducted for the metabolite ATCP. The definition of the residue for risk assessment should be then updated, accordingly.	**1)** The meeting agreed that not reliable kinetic end points can be derived for metabolite ATCP in RefeSol 02-A soil (laboratory study from 2019). Among other drawbacks only three data points describe the decline of the metabolite in this soil. In addition, methodology to derive a formation fraction using the top-down approach deviates from agreed methods and was considered not acceptable. **2)** For parent picloram the experts agreed that recent (2021) field study and its kinetic evaluation are reliable and should be used to derive soil end points. For PECsoil the SFO DT50 value of 89.81 days derived from the Ohrensen soil should be used. For PECgw, PECsw and PECsed calculations, an evaluation if soil laboratory and field data should be combined (based on the endpoint selector of the EFSA DegT50 Guidance Document) needs to be conducted. **3)** The data gap on soil lab incubations for ATCP (see1) would need to be addressed before the requirement for field soil kinetic endpoints for ATCP could be concluded on. 1) **Data gap** confirmed for reliable soil degradation endpoints to be derived for metabolite ATCP from laboratory soil aerobic incubation tests for at least two more soils. 2) **Open point**: RMS to calculate new PECsoil for picloram based on the field agreed DT_{50} endpoint. **Open point:** RMS to assess for if soil laboratory and field data should be combined (based on the endpoint selector of the EFSA DegT50 Guidance Document) and to update PECgw, PECsw and PECsed accordingly.

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to update PEC calculations for metabolite ATCP using worst-case default soil DT_{50} value of 1000.
Experts' consultation 4.2 Experts to discuss the 2010 soil photolysis study and agree on: 1) the acceptability of the study design and its results; 2) the metabolite 4-amino-5,6-dichloropicolinic acid that is still increasing at the end of the study and if its level is triggering further assessment under realistic conditions; 3) the kinetic analysis of irradiated samples. The definition of the residue for risk assessment should be then updated, accordingly.	1) Overall experts agreed that the photolysis in soil study from 2010 complies with applicable guidelines and is reliable and acceptable. 2) Based on the available data and currently applicable triggers, experts agreed that metabolite 4-amino-5,6-dichloropicolinic acid is reaching levels triggering assessment based on the HPLC analysis. 3) The kinetic analysis using mixed HPLC+TLC analytical results was not considered acceptable. New kinetic analysis of the irradiated and dark control samples using only HPLC results is to be performed by the RMS. 4) Metabolite 4-amino-5,6-dichloropicolinic acid reaches level in soil that trigger the need for exposure assessment for soil, groundwater and surface water from his formation in soil as a result of photolysis. Therefore, environmental end points need to be identified. **Open point:** RMS to provide HPLC results of the irradiated samples in an amended RAR. **Open point:** RMS to perform a new kinetic analysis of the irradiated and dark control samples using only HPLC results. **Open point:** RMS to provide an amended RAR including metabolite 4-amino-5,6-dichloropicolinic acid in the residue definition for risk assessment in soil, groundwater and surface water compartments. The LoEP should be amended accordingly. **Open point:** RMS to update the RAR with the outcome of the experts' discussion to indicate the data gaps related to degradation and adsorption endpoints for metabolite 4-amino-5,6-dichloropicolinic acid. **Open point:** RMS to provide PEC soil, ground water and surface water calculations for metabolite 4-amino-5,6-dichloropicolinic acid using an application rate equivalent to the max observed formation in soil (converted from mass to molar) using the average of the two duplicates at the last time

Subject	Conclusions Pesticide Peer Review Meeting
	point which 9.9 %. Furthermore, a Kfoc = 1 mL/g (for PECgw and PECsw calculations) or Kfoc = 1000 mL/g (for PECsed calculations) and 1/n of 1 should be used. The LoEP should be amended accordingly. **Data gap:** degradation in soil and adsorption in soil endpoints for metabolite 4-amino-5,6-dichloropicolinic acid should be set to derive this metabolite.
Experts' consultation 4.3 Experts to agree on the adsorption endpoints for picloram proposed in the 2010 study and the completeness of the study according to the OECD 106 evaluators' checklist (EFSA Supporting publication 2017: EN-1326). The final agreed endpoints should be used for the calculation of the PECsoil, PECgw, PECsw and PECsed.	Despite the claim by the applicant that the direct method had been used in the adsorption experts in the meeting were not able to verify it as it is uncertain whether the sorption values obtained are for picloram or sum of picloram and its transformation products. **Data gap:** reliable adsorption study for the active substance with at least four soils. The soils in the study should be selected in order to cover different ranges of pH to conclude on the possible pH dependency. **Open point:** RMS to amend the RAR and LoEP, including the conclusion that there is no reliable soil adsorption data, though it can be concluded that picloram is expected to be mobile in soil. **Open point:** RMS to delete the PECgw calculations for picloram from the LoEP. Note: the production of PEC GW using default adsorption end points is not required as it is considered not helpful to characterize a realistic worst-case situation with respect to potential GW contamination, Therefore, the issue of ground water exposure remains as not finalized.
Experts' consultation 4.4 Experts to agree on the adsorption endpoints for the metabolite ATCP and eventually the acceptance of the results from the SAR/QSAR estimation.	No batch equilibrium sorption study is available for metabolite ATCP, a new OECD 106 batch equilibrium study is ongoing but not yet available. Only estimation of the sorption parameters using QSAR is available for metabolite ATCP. The majority of the experts concluded that default values should be used for metabolite ATCP (Kfoc = 1 mL/g (for PECgw and PECsw calculations) or Kfoc = 1000 mL/g (for PECsed calculations) and 1/n of 1).

Subject	Conclusions Pesticide Peer Review Meeting
	Data gap: a batch equilibrium sorption study for metabolite ATCP with at least three soils is needed. **Open point:** RMS to update the RAR with the outcome of the experts' discussion to indicate the data gap related to batch equilibrium sorption study for metabolite ATCP. **Open point:** RMS to perform FOCUS Step 1 and 2 calculations using for picloram using Kfoc = 1 mL/g (for PECsw calculations) or Kfoc = 1000 mL/g (for PECsed calculations) and 1/n of 1. According to experts' consultation 4.1 an evaluation if soil lab and field data should be combined to derive modelling endpoints (based on the endpoint selector of the EFSA DegT50 Guidance Document) should be conducted and the results used in surface water and sediment calculations. The LoEP should be amended accordingly. **Open point:** RMS to perform FOCUS Step 1 and 2 calculations for metabolite ATCP using Kfoc = 1 mL/g (for PECsw calculations) or Kfoc = 1000 mL/g (for PECsed calculations) and 1/n of 1. According to experts' consultation 4.1 for ATCP the worst-case default soil DT_{50} value of 1000 days and a f.f. of 1 should be used for PEC calculations. The LoEP should be amended accordingly.

REPORT OF PESTICIDE PEER REVIEW TC 101

PENOXSULAM – AIR IV

Rapporteur Member State: IT

4. Environmental fate and behaviour

Date: 21 April 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 Germany (2)	Federal Environmental Agency (UBA) (DE)
National Expert nominated by MS Greece (2)	Benaki Phytopathological Institute (BPI) (EL)
National Expert nominated by MS France (2)	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 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)
Observers (2)	Federal Office for the Environment

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to discuss the validity of the study CA 7.1.1.1/1 (2001) for the assessment of the route and rate of degradation of penoxsulam in aerobic soil. If considered valid, the persistence and modelling endpoints should be agreed upon.	A soil aerobic degradation study investigated the degradation of penoxsulam in four European soils. The study was conducted to an older test guideline which preceded OECD 307 and presented different deviations related to the pre-incubation storage conditions, microbial biomass measurements, solvent concentrations, oxygen supply, lower temperature at the rear of the incubator at day 120 (for the 20 °C incubations) and lack of replicates, among others. After reviewing the additional information provided by the applicant, some Member States' experts were in favour of keeping all soils from this study, as the issues on storage, lack of replicates and biomass were not enough to exclude the soils, and the DT_{50} values obtained from this study were on the same range of DT_{50} ranges obtained in other studies. The acceptability of this study implied that the metabolite BST had to be considered a major soil metabolite. The majority of the experts agreed that the soil aerobic degradation study of penoxsulam in four European soils should be relied on, but the available kinetic assessment would need to be carried out excluding the last sampling point at 120 days for the 20°C incubations due to the reasons discussed above. **Open point**: RMS to carry out a new kinetic assessment of the results from the soil aerobic degradation study of penoxsulam in four European soils excluding the last sampling point at 120 days for the 20°C incubations.

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to add the metabolite BST to the residue definition for exposure and risk assessment in soil. See also open point in Experts' consultation 4.6.
Experts' consultation 4.2 Experts to discuss the validity of the study CA 7.1.1.1/2 (2002a) to address the route and rate of degradation of penoxsulam in aerobic soils. In particular, for the route of degradation, results on the formation of metabolites SFA and sulfonamide should be discussed to conclude if these metabolites trigger further assessments by the other disciplines and/or requiring consideration for groundwater. For the rate of degradation, the modelling endpoints for penoxsulam and its metabolites should be discussed and agreed upon.	A soil aerobic degradation study investigated the degradation of penoxsulam in five soils (three US soils and two Japanese soils). The study was conducted to an older test guideline which preceded OECD 307 and presented different deviations related to the pre-incubation storage conditions, OC levels, microbial biomass measurements, incubation temperature and test duration, among others. Overall Member State experts agreed to consider these deviations minor and accept the study. Experts did not agree with the applicant's proposal to reject the Arkansas soil based on ENASGIPS results. Experts agreed to consider the Japanese non-volcanic, North Dakota, California and Arkansas soils as representative of EU agricultural soils, and to consider the volcanic Japanese soil as not representative. The relevance of the two major metabolites only found in the Arkansas soil (SFA and sulfonamide) were discussed. SFA fulfilled the criteria to be considered a major soil metabolite, while the relevance of sulfonamide was questionable, since it was found at levels > 5% only after 179 days. However, at 91 days it was present at 4.8% AR. Overall, the data indicated that the metabolite sulfonamide triggers the need for an assessment. Based on the results of the three reliable soil aerobic degradation studies, the experts agreed that there is not enough evidence to confirm a pH dependency on degradation for penoxsulam. Experts also agreed to consider the new soil aerobic degradation study for the metabolites 5-OH-XDE-638, BSTCA and BST acceptable and agreed with the kinetic evaluation performed by RMS (SFO kinetics). The majority of the experts agreed that the soil aerobic degradation study of penoxsulam in three US soils and two Japanese soils should be relied on. Experts agreed to consider

Subject	Conclusions Pesticide Peer Review Meeting
	the Japanese non-volcanic, North Dakota, California and Arkansas soils as representative of EU agricultural soils, and to consider the volcanic Japanese soil as not representative. Member State experts agreed to consider both SFA and sulfonamide as soil metabolites reaching level triggering the assessment except for the representative uses on rice. See also open point in Experts' consultation 4.6. It was agreed that no pH dependency on degradation for penoxsulam should be considered, and that the results and kinetic assessment of the new soil aerobic degradation study for the metabolites 5-OH-XDE-638, BSTCA and BST were acceptable. **Open point**: RMS to provide an amended RAR reflecting the conclusion on the acceptability of the soil aerobic degradation study of penoxsulam in three US soils and two Japanese soils, highlighting the inclusion of the endpoints derived from the non-volcanic Japanese soil and the US California, North Dakota and Arkansas soils and the rejection of the endpoints derived from the volcanic Japanese soil. **Open point**: RMS to add metabolites SFA and sulfonamide in the residue definition triggering furthers assessment in soil except for the representative uses on rice. See also open point in Experts' consultation 4.6. **Open point**: RMS to provide an amended LoEP correcting for the Japanese non-volcanic soil the normalized DT_{50}, which should be 19.7 d instead of 24.9 d.
Experts' consultation 4.3 Experts to discuss the suitability of the assignment of identity of metabolite BST formed in the soil photolysis study CA 7.1.1.3/1 (2002) and to agree if metabolite BST is formed at levels that trigger further assessment by other disciplines and/or requiring consideration for groundwater exposure.	In a soil photolysis study for penoxsulam on an EU soil and a USA soil, the identification of BST questionable, since it was not confirmed by LC/MS method. Based on new data provided, applicant proposed to re-classify BST as a multi-component region and to no longer consider it as a major soil photolysis metabolite. Member States experts agreed to not consider metabolite BST as a soil photolysis metabolite triggering the assessment. Note: BST reached levels triggering assessment in the dark aerobic soil incubation in the soil aerobic degradation study of penoxsulam in four European soils.

Subject	Conclusions Pesticide Peer Review Meeting
	No actions for RMS.
Experts' consultation 4.4 Experts to discuss representativeness of the soils used to investigate the adsorption properties of penoxsulam in the study CA 7.1.3.1.1/1 (2000).	The soil adsorption study provided for penoxsulam assessed in 17 soils and one sediment from different geographic locations where rice and wheat are grown. Experts discussed the reliability of the Japanese soils and soil M572 (Marcham, alkaline soil, pH 8). Member State experts agreed to include the results from Japanese non-volcanic soils (M559, M561) and to exclude the results from volcanic Japanese soils (M558, M560), for the same reasons explained in Experts' consultation 4.2. The only alkaline soil M572 had been excluded by RMS due to low R_2 value in Freundlich isotherm and low % adsorption. The reason for the low R_2 value was probably due to an experimental error in one of the aliquots of the 5-ppm concentration. Member State experts agreed to keep the results of soil M572 in the dataset excluding the results coming from replicate M572-F-5.0a as the linear fit of the Freundlich slope was better than when excluding replicate M572-F-5.0b. The inclusion of the alkaline soil M572 confirmed the pH dependency of the adsorption properties of penoxsulam. It was agreed that, for the exposure assessment, a K_{Foc} of 68.2 mL/g and 1/n of 1.01 was used for acidic soils and a K_{Foc} of 7.8 mL/g and 1/n of 0.837 was used for alkaline soils. Member State experts noted that should penoxsulam be renewed in zonal and national assessments, the results of a new adsorption study started by applicant to investigate adsorption in alkaline conditions (not yet available) might be considered for product authorisations. Member State experts agreed to include the soil adsorption endpoints of penoxsulam from the Japanese non-volcanic soils and the alkaline soil M572 (excluding M572-F-0.5a) and to exclude the results from volcanic Japanese soils. Experts agreed that a pH dependency of the adsorption properties of penoxsulam had to be considered for the exposure assessment: a KFoc of 68.2 mL/g and 1/n of 1.01

Subject	Conclusions Pesticide Peer Review Meeting
	for acidic soils and a KFoc of 7.8 mL/g and 1/n of 0.837 for alkaline soils. **Open point**: RMS to amend the RAR and the LoEP in line with the conclusion of the experts' meeting and to add Kendall test results for all the soils and the selected endpoints including soil M572.
Experts' consultation 4.5 Experts to discuss the reliability of the direct photochemical degradation study CA 7.2.1.2/1 (2000).	The direct photochemical degradation study of penoxsulam presented several deviations compared to the OECD guideline 316, such as no traps for organic volatiles, no monitoring of pH variation, use of single replicates and no information on LOD and LOQ. RMS concluded that the results demonstrated that penoxsulam photodegraded very rapidly in both pH 7 buffered water and natural water systems and proposed that the study could be considered acceptable. Member State experts agreed to consider the photochemical degradation study acceptable. Experts agreed to include metabolites 2-amino-TP, 5-OH-2-amino-TP, TPSA and BSA in the definition of residues requiring further assessment in surface water and sediment. **Open point**: RMS to amend the LoEP including metabolites 2-amino-TP, 5-OH-2-amino-TP, TPSA and BSA in the definition of residues requiring further assessment in sediment. See also open point in Experts' consultation 4.6.
Experts' consultation 4.6 Experts to discuss the new PEC calculations provided.	**Definition of residues requiring further assessment:** Considering the outcomes of the Experts' consultation 4.1 to 4.5, Member State experts agreed on the list of residues requiring further assessment for the representative uses on chicory and on rice. Chicory (and other crops except rice): Soil: Penoxsulam, 5-OH-XDE-638, BSTCA, BST, SFA, sulfonamide, BSA*, 2-amino-TP* Ground water: Penoxsulam, 5-OH-XDE-638, BSTCA, BST, SFA, sulfonamide, BSA*, 2-amino-TP*

Subject	Conclusions Pesticide Peer Review Meeting
	Surface water: Penoxsulam, 5-OH-XDE-638, BSTCA, BST, SFA, sulfonamide, BSA**, 2-amino-TP**, 5-OH-2-amino-TP***, TPSA*** Sediment: Penoxsulam, 5-OH-XDE-638, BSTCA, BST, SFA, sulfonamide, BSA**, 2-amino-TP**, 5-OH-2-amino-TP***, TPSA*** Air: Penoxsulam * soil photolysis / ** soil and aqueous photolysis / *** aqueous photolysis Rice: Soil: Penoxsulam, 5-OH-XDE-638, BSTCA, BST Ground water: Penoxsulam, 5-OH-XDE-638, BSTCA, BST Surface water: Penoxsulam, 5-OH-XDE-638, BSTCA, BST, BSA*, 2-amino-TP*, 5-OH-2-amino-TP*, TPSA* Sediment: Penoxsulam, 5-OH-XDE-638, BSTCA, BST, BSA*, 2-amino-TP*, 5-OH-2-amino-TP*, TPSA* Air: Penoxsulam * aqueous photolysis Considering the specific agronomic practices in paddy fields, soil photolysis metabolites (BSA and 2-amino-TP) and soil metabolites formed at later sampling times in soil degradation studies (SFA and sulfonamide) were excluded from the list of residues requiring further assessment for representative uses on rice because they will be formed at <5% at the time of flooding (at 2-5 days after application). **PEC for representative uses on rice**: The new flooded aerobic soil degradation study dosed with penoxsulam was considered acceptable by experts. DFOP kinetic model was selected to derive modelling and triggering endpoints for penoxsulam from the flooded aerobic degradation study. Experts agreed with RMS proposal, presented during the meeting, to re-calculate modelling endpoints considering DFOP DT90/3.32 instead of using DFOP k2, considering that residue levels were <10% AR in both soils for the total system, water and soil phases. New Tier 1 MED-rice calculations are required.

Subject	Conclusions Pesticide Peer Review Meeting
	It was agreed that pH dependency on adsorption of penoxsulam did not need to be considered for PEC calculations for representative uses on rice, since flooded paddy fields are generally acidic pending to neutral pH (around 6.5 to 7). Experts requested higher tier MED-rice calculations (RICEWQ/RIVWQ) using the new kinetic endpoints agreed in the meeting and to also include calculations of applications to dry soils. Experts also agreed with RMS' proposal to calculate higher tier exposure assessment considering the draft rice guidance with the new clustered scenarios. **PEC for representative uses on chicory**: Experts agreed that it was also needed to re-calculate PEC values for the representative uses on chicory considering the new definition of residues requiring further assessment, the pH dependent sorption for penoxsulam and the agreed persistence and modelling endpoints for penoxsulam and metabolites. For BST, new PECsoil calculations were needed, changing the default DT_{50} of 1000 days to the experimental DT_{50} of 71.6 days, the value obtained in the new soil aerobic degradation study for metabolites 5-OH-XDE, BSTCA and BST. - Member State experts agreed on the definition of residues requiring further assessment, having a special definition of residue for rice. Experts agreed that new 1 MED-rice calculations were required for penoxsulam, using the endpoints from the new flooded aerobic soil degradation study dosed with penoxsulam (DFOP DT90/3.32 as modelling endpoints) and considering no pH dependence on adsorption. Higher tier MED-rice calculations (RICEWQ/RIVWQ) were requested for penoxsulam and its metabolites. Experts agreed that it was also needed to re-calculate PEC values for the representative uses on chicory considering the new definition of residues requiring further assessment, the pH dependent sorption for penoxsulam and the agreed persistence and modelling endpoints for penoxsulam and metabolites.

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to update the RAR and the LoEP with the agreed list of residues requiring further assessment for the representative uses on chicory and rice. **Open point**: RMS to update the RAR and the LoEP with the agreed list of residues requiring further assessment for the representative uses on chicory and rice. **Open point**: RMS to include the agreed persistence and modelling endpoints for flooded soils in the amended RAR. For penoxsulam, modelling endpoints for flooded soils should be re-calculated using DFOP DT90/3.32. The LoEP should be amended accordingly. **Open point**: RMS to provide PEC sediment calculations for the representative uses on rice for metabolites BSA, 2-amino-TP, TPSA, and 5-OH-2-amino-TP. The RAR and the LoEP should be amended accordingly. **Open point**: RMS to provide new Tier 1 MED-rice calculations for penoxsulam for soil, groundwater, surface water and sediment with the new kinetic endpoints agreed in the meeting for uses on and using a 5-day closure time. The RAR and the LoEP should be amended accordingly. **Open point**: RMS to provide higher tier (RICEWQ/RIVWQ) calculations for penoxsulam and its metabolites using MED-Rice scenario with the new kinetic endpoints agreed in the meeting for uses on rice and to consider applications to dry soils using a 5-day closure time. The RAR and the LoEP should be amended accordingly. **Open point**: RMS to perform higher tier exposure assessment for uses on rice using the new clustered scenarios as described in the draft rice guidance "Update and harmonization of rice pesticide risk assessment and revision of European guidelines" using both 5- and 10-day closure times. The RAR should be amended accordingly, however results should not be included in the LoEP. In the EFSA conclusion, EFSA can indicate that these calculations are available in the RAR. **Open point**: RMS to update PEC calculations for the representative uses on chicory considering pH dependent sorption for penoxsulam and the agreed persistence and

Subject	Conclusions Pesticide Peer Review Meeting
	modelling endpoints for penoxsulam and metabolites. See also open points in Experts' consultations 4.1, 4.2 and 4.4. **Open point**: RMS to amend the LoEP correcting the formation percentages for all metabolites in the sections related to water/sediment and PEC calculations to ensure that the formation percentages are the averages of the replicates with the highest mean values. **Open point**: RMS to indicate in a footnote in the LoEP as appropriate that for future PEC calculations the values of formation percentages for metabolites 5-OH-XDE-638 (15.7% in surface water), BSTCA (7.8% in sediment and 48.3% in soil), and BST (7.6% in soil) would be those to use. **Open point**: RMS to update PEC calculations for BST in the RAR and the LoEP changing the default DT_{50} of 1000 days to the experimental DT_{50} of 71.6 days and to leave only the initial PEC_{Soil} values. **Open point**: RMS to provide PEC calculations for soil, groundwater, surface water and sediment for SFA and sulfonamide. The RAR and the LoEP should be amended accordingly. **Open point**: RMS to provide PEC sediment calculations for metabolites BSA, 2-amino-TP, TPSA, and 5-OH-2-amino-TP. The RAR and the LoEP should be amended accordingly.

REPORT OF PESTICIDE PEER REVIEW TC 94

FENPROPIDIN – AIR III

Rapporteur Member State: CZ

4. Environmental fate and behaviour

Date: 19 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
Federal Environment Agency (UBA)	DE
Benaki Phytopathological Institute	EL
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)	FR
Ctgb	NL
External expert - chair	CH
Observer	CH
Observer	EL

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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

4. Environmental fate and behaviour

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 4.1 Experts to discuss and agree on the acceptability of the lab aerobic degradation study on fenpropidin done with sandy loam and loam soils.	Several shortcomings were identified in an aerobic soil degradation study such as: mass balance, and uncharacterised polar metabolites reaching levels that triggered assessment. Regarding the uncharacterised polar metabolites, a read across was proposed based on another aerobic soil degradation study where polar metabolites were identified. However, the study proposed for the read across was assessed as also having shortcomings and during the commenting phase it was agreed that the study was not acceptable and should not be used. Other soil incubations were valid for determining rate of degradation but did not have the required mass balance to exclude that other metabolites may be being formed at levels that triggered assessment. Member state experts concluded that the available evidence from the soil incubations was insufficient, and then a data gap had to be identified for a valid route of degradation study with the test substance appropriately radiolabelled to cover the fate of fenpropidin in soil. Data gap: A valid route of degradation study with the test substance appropriately radiolabelled to cover the fate of fenpropidin in soil was not available. Open point:

Subject	Conclusions Pesticide Peer Review Meeting
	RMS to update the list of endpoints to indicate a data gap in the aerobic route of degradation in soil for metabolites triggering assessment box.
Experts' consultation 4.2 Experts to discuss on the acceptability of the lab aerobic degradation studies on fenpropidin done with soil Lufa 2.2 and soils Lufa 6S, Lufa 5M and Lufa 3A and to agree on the endpoints to be used in the exposure assessment.	In one lab degradation study done with one soil (Lufa 2.2) the additional analytical procedure to obtain "clean-up extract" was questioned. The comparison of the "raw extract" and "cleaned-up extract" showed lower concentrations of fenpropidin in the "cleaned-up extract" at all sampling points. However, the residual radioactivity fraction losses after cleaning procedure resulted in the range of 1.2 – 12.5 % AR. Therefore, the RMS concluded that the two datasets did not differ significantly and that the additional analytical procedure did not affect the reliability of the study. The experts agreed that the study can be used to derive rate of degradation endpoint for fenpropidin. In another lab degradation study done with three soils (LUFA 6S, LUFA 5M and LUFA 3A) no volatile compounds were trapped, bound residues and metabolites were not analysed, therefore a mass balance was not completed. However, recovery was in the recommended range for unlabelled test items (70 – 110 %). Experts discussed that fenpropidin might have volatilised as the volatiles were not trapped. However, in another study where volatiles were trapped, significant volatilisation (other than CO_2) had not occurred. The experts agreed that the study can be used to derive rate of degradation endpoints for fenpropidin. Overall the experts agreed that the soil incubations in Lufa 2.2, LUFA 6S, LUFA 5M and LUFA 3A be used to derive rate of degradation endpoints for fenpropidin with the SFO fits selected for modelling endpoints. Open point: RMS to remove the results from soils Dielsdorf Sandy loam (1.4 mg/kg), Dielsdorf Sandy loam (10 mg/kg), Steinmaur Loam (1.4 mg/kg), and Steinmaur Loam (10 mg/kg) from the list of endpoints and to update the geomean DT50 value for fenpropidin to 89.6 days.
Experts' consultation 4.3 Experts to discuss and agree if it is acceptable deriving modelling	It was argued that considering the lack of information in all the field studies, the kinetic fits might not be representative of the degradation of fenpropidin in soil, and then modelling endpoints could not be derived as normalisation of the data cannot be performed in an appropriate way.

Subject	Conclusions Pesticide Peer Review Meeting
endpoints from the field dissipation studies on fenpropidin.	In particular, for Dielsdorf (Waisenhof), Dielsdorf (Ried), Steinmaur and Valésia soils the distance of weather station from field site was not reported, and then the daily weather data cannot be used for normalisation. In Motterwitz soil the low procedural recoveries of fortified samples invalidated the results of analysis. In Ölbronn-Dürrn, Meistrazheim and Stratton Audley soils two applications were performed, which precludes calculating a DegT50 in line with the relevant guidance. Experts agreed that results from soils Dielsdorf (Waisenhof), Dielsdorf (Ried), Steinmaur Valésia, Ölbronn-Dürrn, Meistrazheim, and Stratton Audley should not be used for deriving modelling endpoints for fenpropidin from the field dissipation studies. Furthermore, results from Motterwitz soil should not be used for deriving both persistence and modelling endpoints from the field dissipation studies. Open point: RMS to update the RAR in line with conclusion of expert meeting. RMS to update the list of endpoints to exclude modelling endpoints for Dielsdorf (Waisenhof), Dielsdorf (Ried), Steinmaur, Valésia, Ölbronn-Dürrn, Meistrazheim and Stratton Audley soils and to exclude persistence and modelling endpoints for Motterwitz soil and to update the conclusion on amalgamating the lab data and field data consequently. Open point: RMS to calculate PECsoil for fenpropidin using kinetic endpoints from Meistrazheim and Dielsdorf (Ried) soils in an amended RAR and add to the list of endpoints the one giving the highest initial PECsoil.
Experts' consultation 4.4 Experts to discuss on the acceptability of the adsorption studies on fenpropidin and on metabolite CGA289267 and to agree on the endpoints to be used in the exposure assessment.	The OECD 106 evaluators checklist was used to assess batch adsorption studies on fenpropidin and metabolite CGA289267. For fenpropidin: in soils Steinmaur, BBA 2.1, BBA 2.2, BBA 2.3, and Dielsdorf the experts noted that the adsorption endpoints had deficiencies related to mass balances, high adsorbed amounts in combination with the use of the indirect method and the fact that the LOQ was not reported. In addition only four concentrations were investigated and less than two orders of magnitude were achieved by the study set up;

Subject	Conclusions Pesticide Peer Review Meeting
	for the soils LUFA Speyer 2.2 and LUFA Speyer 5M it was considered that results might be relied on, while for 5 Borstel, 4 Ebbinghof and LUFA 3A soils there were problems related with the concentration range and mass balance issues for 5 Borstel, 4 Ebbinghof and LUFA 3A soils; the LOQ was reported and was low enough to rely on the available isotherms in soils Gartenacker, East Anglia and Seven Springs; for soil Capey, the lowest concentration measured was below the LOQ, the isotherm was not relied on and the mass balance was borderline acceptable; for the 18 Acres soil the mass balance was poor being significantly below that required in one of the replicates. For metabolite CGA289267: the stability of the metabolite in two soils LUFA 2.2 and LUFA 6S included in the pre-test was demonstrated. In these two soils the soil solution ratio between the pre and definitive tests was different when the mass balance had been determined. Experts agreed that the results from soils LUFA 2.2 and LUFA 6S might be relied on, but not for the other three soils (LUFA 2.1 Sand, LUFA 2.3 Loamy sand and LUFA 5M Loamy sand), where stability of the test substance was not known. Also test substance purity was an issue considered more problematic when the mass balance had not be determined; stability of the metabolite in the two soils - Speyer 2.2 and Gartenacker -included in the pre-test was demonstrated. Senozan, Welde, Bretagne 1 soils did not have a mass balance and stability confirmed to have more uncertainty in their reliability than the other soils considering that the indirect method had been used. Overall the majority of the experts agreed to consider that all these five soils might be relied on. The experts agreed that the results in soils LUFA Speyer 2.2, LUFA Speyer 5M, Gartenacker, East Anglia and Seven Springs can be considered reliable to derive adsorption endpoints for fenpropidin. The experts agreed that the results in soils LUFA 2.2, LUFA 6S, Speyer 2.2, Gartenacker, Senozan, Welde and Bretagne 1 can be considered reliable to derive adsorption endpoints for metabolite CGA289267. Open point: RMS to update the list of endpoints deleting the adsorption endpoints for fenpropidin derived from soils LUFA Speyer soil 3A, 5 Borstel, 4 Ebbinghof, 18 Acres and Capay. The overall geomean Koc and arithmetic mean 1/n for fenpropidin should be recalculated being the new values 2042.6 ml/g and 0.752, respectively.

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to update the list of endpoints deleting the adsorption endpoints for metabolite CGA289267 derived from soils LUFA 2.1 Sand, LUFA 2.3 Loamy sand, LUFA 5M. The overall geomean Koc and arithmetic mean 1/n for metabolite CGA289267 should be recalculated being the new values 90.8 ml/g and 0.946, respectively. Open point: RMS to update the RAR in line with conclusion of expert meeting on batch equilibrium adsorption of fenpropidin and metabolite CGA289267 and to add plots of Freundlich isotherms to the RAR. Open point: RMS to update the reference list indicating studies relied on to include the study where the applicant had reported the outcomes of applying the OECD 106 evaluators checklist.
Experts' consultation 4.5 Experts to discuss and agree on the acceptability of the results of one water/sediment study considering the low recoveries in Eslohe-Wenholthausen system and the volatile losses.	The acceptability of a water/sediment study was questioned as recovery decreased below 90% AR (minimum value of 80%) in Eslohe-Wenholthausen system at 4 out of 10 sampling times. This is outside the range of acceptable values specified in the OECD 308 test guideline. Furthermore, in the first test series substantial losses through volatilisation were observed. Experts considered that the study design had a number of deficiencies. Considering that there were low recoveries in the Eslohe-Wenholthausen system the experts considered that endpoints from this incubation should not be relied on. Open point: RMS to update the RAR with the conclusion not to rely on the results of the Eslohe-Wenholthausen water/sediment system and to remove the results for this system from the list of endpoints and update geomean values consequently. The RMS to also clarify in the RAR that the change in the volatile trap system resulting in two series of results being produced was done for both the systems.
Experts' consultation 4.6	The vapour pressure of fenpropidin is 0.019 Pa, therefore dry deposition of fenpropidin following volatilisation was included at Step 4 calculations. Dry deposition was calculated using the EVA

Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss and agree on the acceptability of the semi field trials for refining the dry deposition rate of fenpropidin.	model and the field volatilisation studies. A buffer distance of 50 m was assumed in all simulations for the purpose of calculating dry deposition loadings. Three new semi field trials were conducted to determine the redeposition of fenpropidin following volatilisation in wind tunnel tests. The acceptability of these semi field trials for refining the dry deposition rate of fenpropidin was questioned as several deficiencies were found in the studies. The experts noted that the experiments on sugar beet might not be representative of the representative uses. Also that only winter cereals (and not spring cereals) might be covered by the available experiments. Furthermore, it seemed that dose rates used were not comparable to the representative uses assessed. Phenological growth stages of the crops had not been reported so were not known. It was also noted that the experiments were not carried out with the representative formulation. The number of experiments is relatively limited given the number of environmental conditions and intended use practices needing assessment. Also temperature ranges in the tunnels did not always seem relevant for the representative uses. Therefore, the percentiles calculated by the applicant were considered to not have an understandable context. The above considerations apply to all the experimental short range atmospheric deposition information included in the RAR. Overall the experts considered that results from the semi field trials should not be used and short range deposition for fenpropidin be considered in the usual manner using the EVA tool. Open point: RMS to remove the PECsw using experimental short range deposition values from the list of endpoints and include the outcome of this discussion in an amended RAR. Open point: RMS to update PEC groundwater, surface water and sediment considering new DegT50 and adsorption endpoints as agreed in the meeting of experts (see Experts' consultations 4.2, 4.3, 4.4 and 4.5) also using a kinetic formation fraction for CGA289267 from fenpropidin of 1, considering the data gap identified for a reliable route of degradation study (see Experts' consultation 4.1). PEC in surface water to address short range transport and deposition using FOCUS landscape and mitigation guidance (2007) with the EVA tool when spray drift is mitigated, considering that maximum 95% reduction in exposure via spray drift and 90%

Subject	Conclusions Pesticide Peer Review Meeting
	reduction in exposure via runoff are allowed. Updated assessment to be included in the amended RAR and list of endpoints.

REPORT OF PESTICIDE PEER REVIEW TC 81

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

4. Environmental fate and behaviour

Date: 21 November 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
Umweltbundesamt / 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
National Food Chain Safety Office (NÉBIH)	HU
Pesticide Registration Division, Department of Agriculture, Food and the Marine Laboratories	IE
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Swedish Chemicals Agency (KemI)	SE
External experts (3)	EFSA
External expert - Chair (1)	CH
Observers (2)	CH

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to discuss and agree on: - the use of trigger/modelling endpoints for testing pH-dependence of glyphosate and AMPA - the way to handle pH dependence of the biphasic degradation rates of glyphosate (use of DT50/DT90/kinetic parameters) - the selection of modelling endpoints for glyphosate, when pH-dependence is confirmed, including endpoints derived from field dissipation studies. This discussion to take into account the RMS assessment	On balance the experts agreed with the RMS conclusion that pH dependent degradation in soil of glyphosate and its metabolite AMPA cannot be excluded considering the available soil DT90 values, the fast phase DT50 values and the slow phase DT50 values for glyphosate. For AMPA the pH dependency was indicated on the basis of SFO DT50 values. The experts agreed that the approach of the RMS for modelling endpoints at the first tier was appropriate and can be used for the approval / RAR exposure assessment. However, they agreed that for uses where refinement would be needed (future assessments), geomeans for acidic and alkaline soils be used. The experts agreed that the available dataset of kinetic values should be split in relation to soils having a pH above or below 6.5, measured in water. They also agreed that the kinetic formation fraction from glyphosate to AMPA from the available dataset should be the arithmetic mean of all soils independent of their pH. **Open point** RMS to correct the distance to the weather station indicated on page 485 of the amended RAR to 42 km and update the conclusion to indicate that it was concluded as correct to use the information (regarding temperature) as it had been erroneously indicated on page 429 and 585 that the data from the distant weather station should not

Subject	Conclusions Pesticide Peer Review Meeting
of the additional information submitted by the applicants.	be considered reliable. RMS to add a note that for the other weather data (precipitation) there was on-site information available. **Open point** RMS to amend the RAR page 674 to correct the Kendall test results for the pathway fit. **Open point** RMS to update the RAR including the CP product Vol3 and list of endpoints (LoEP) to include the soil geomean DegT50 results for glyphosate and AMPA when the dataset is split for soils with a pH in water above and below 6.5. **Data gap** Reliable AMPA soil DegT50 endpoints from at least 3 field trial sites were not available.
Experts' consultation 4.2 Experts to discuss and agree on the definition of the residue for exposure/risk assessment taking into account the RMS evaluation of the information provided consequent to the data requirements. In particular whether the definition for sediment needs to include "chromatographic fraction P1a" and/or 1-oxo-AMPA / M3.3.	The RMS proposed the inclusion of the metabolites P1a and M3.3 in the residue definition for sediment based on a rough estimation of max. occurrence of each unknown fraction in the related AMPA-dosed study, considering that AMPA is formed up to 27% of the applied radioactivity (AR) in glyphosate dosed study. The rough estimation showed that in sediment P1a has a max. estimated occurrence of 14.4% AR and M3.3 has a max. estimated occurrence of 6.2% AR from glyphosate. The applicants provided a kinetic approach to determine the max. occurrence of fractions P1a and M3.3 using the entire metabolic pathway from glyphosate, showing similar results and demonstrating that both metabolites would trigger their inclusion in the residue definition for risk assessment in the sediment compartment. It was discussed whether the fractions P1a and M3.3 should be included also in the residue definition for the risk assessment in the surface water compartment. Since metabolite HMPA was clearly appearing only in the water compartment, but was quantified in the glyphosate-dosed water/sediment study, the experts discussed also the inclusion of metabolite HMPA in the residue definition for sediment.

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	Both PEC surface water and PEC sediment were calculated for HMPA using a default Koc value of 10 mL/g, resulting in potentially not appropriate PEC for the sediment compartment. The experts agreed on the inclusion of P1a and M3.3 in the residue definition for risk assessment in the sediment compartment. The experts agreed on the PEC sediment calculated by the RMS using the max occurrence of 14.4%, considered as worst-case occurrence between P1a and M3.3. The experts agreed to not include the two unknown fractions P1a and M3.3 in the residue definition for risk assessment for the surface water. The experts agreed on the inclusion of metabolite HMPA in the residue definition for sediment and on the need for PEC sediment calculated with a default Koc value of 10000 mL/g. The experts also agreed on the RMS conclusion that the unknown fraction M3.3 cannot be formally identified as 1-oxo-AMPA and that both fractions P1a and M3.3 cannot be identified as the same compound. The final agreed **definition for residues requiring further assessment** is: Soil (Glyphosate, AMPA), Groundwater (Glyphosate, AMPA), Surface Water (Glyphosate, AMPA, HMPA), Sediment (Glyphosate, AMPA, HMPA, P1a, M3.3). **Open point:** RMS to delete from the LoEP the PEC surface water calculated using a default Koc value of 10000 mL/g for the fractions P1a and M3.3. RMS to indicate in the RAR that only the PECsed are acceptable and required. **Open point:** RMS to update the PEC sediment calculations for HMPA using a default Koc value of 10000 mL/g and to include the metabolite HMPA in the residue definition for sediment in both an update to the RAR and the list of endpoints.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.3 MSs to discuss in a meeting of experts the groundwater monitoring data from public survey reported in the public monitoring data assessment and interpretation study CA 7.5/002 (2020) in light of the additional information required to the applicants, and to agree if/how to use these data for EU regulatory purpose. MS to also discuss the published groundwater monitoring information associated with railway sites in Sweden and, as for the other groundwater monitoring information, to agree if/how to use these data for EU regulatory purpose.	Overall, for the period 1995-2020, a total of 251755 data for glyphosate analysed samples and 228453 data for AMPA analysed samples from 40031 and 35909 sampling sites, respectively, were assessed from groundwater monitoring in the updated RAR. The experts discussed and agreed with the RMS assessment of the outlier analysis and although the method applied appeared robust, it was considered not adapted to the specific case. The comparison against the threshold values, reported as exceedances of glyphosate concentration of drinking water standards resulted in only few cases, mostly sampled once. The RMS assessment that the results of the applicant's vulnerability evaluation should be taken with caution was endorsed by the experts for the reasons identified by the RMS in their assessment in the RAR. The experts discussed the topic of surface water becoming groundwater as a result of bank infiltration / the connectivity of surface water bodies to groundwater aquifers. In the published groundwater monitoring exercise carried out in Sweden from use on railways, the monitored levels provide reassurance that groundwater exposure above the parametric value generally did not occur in the monitored situations. However, for limited durations, concentrations above the parametric value can occur in individual samples. These monitoring results confirm that for the representative use of a single application per year to railways, groundwater exposure above the parametric limit of short duration under the Swedish conditions monitored is possible (1% exceedance in the down gradient wells, 6% (glyphosate) 4% (AMPA) exceedance of 0.1 µg/L in wells beneath the tracks where preferential connection to groundwater might have occurred). But for longer temporal exposure assessment goals, exposure above the parametric limit was not indicated. Overall, the experts agreed with the conclusion of the RMS that this groundwater monitoring dataset for glyphosate and AMPA was insufficient to use for regulatory groundwater exposure assessment and results need to be taken with caution. In relation to the bank infiltration / the connectivity of surface water bodies to groundwater aquifers, the experts acknowledged that the large proportion of agricultural land treated with glyphosate may make this a more important issue than for other active substances and their

Subject	Conclusions Pesticide Peer Review Meeting
	metabolites, but the route of entry to groundwater from surface water is in practice common to all uses of substances that have significant surface water exposure potential. In the published groundwater monitoring exercise carried out in Sweden from use on railways, the representative use of two applications per year was not covered by the monitoring exercise. The results of the monitoring would not be representative of conditions in the whole of the EU. However, it was concluded that this information is useful for the exposure assessment for the single use application pattern and Swedish conditions monitored. **Open point** The applicant's latest aquifer type analysis (one aspect of the applicant's vulnerability assessment) to be added to the amended RAR as this information is currently missing. **Open point** RMS to add references to publications and databases referenced in the updated groundwater public monitoring data assessment and interpretation study (2022) that are not in the RAR to the Vol. 3CA B.8 (AS) monitoring addendum at the end of the RMS study summary on page 145. **Open point** RMS to update Volume 1 of the RAR to discuss the issue of connectivity of surface water and groundwater and the potential for bank infiltration of glyphosate, AMPA and HMPA, considering the information in the study Sanchis *et al.* (2012)[3] and their conclusion on it. **Open point**

[3] Sanchís, J., Kantiani, L., Llorca, M. et al. Determination of glyphosate in groundwater samples using an ultrasensitive immunoassay and confirmation by on-line solid-phase extraction followed by liquid chromatography coupled to tandem mass spectrometry. Anal Bioanal Chem 402, 2335–2345 (2012). https://doi.org/10.1007/s00216-011-5541-y; (ERRATUM) Sanchís, J., Kantiani, L., Llorca, M. et al. Erratum to: Determination of glyphosate in groundwater samples using an ultrasensitive immunoassay and confirmation by on-line solid-phase extraction followed by liquid chromatography coupled to tandem mass spectrometry. Anal Bioanal Chem 404, 617 (2012). https://doi.org/10.1007/s00216-012-5992-9

Subject	Conclusions Pesticide Peer Review Meeting
	EFSA to present in its conclusion the issue of connectivity of surface water to groundwater (including so called bank infiltration) and indicate in its conclusion that information to further address this route for groundwater exposure is a data gap. I.e. in a way comparable to what had been done in the previous peer review at EU level of glyphosate. **Open point** RMS to provide a summary and assessment of the groundwater monitoring associated with the use of glyphosate on railways in Sweden (publication Cederlund, 2022)[4] considering the discussion in the expert meeting in an amended RAR and include the results in the list of endpoints.
Experts' consultation 4.4 MSs to discuss in a meeting of experts if the general methodology of data collection of public monitoring data and the minimum quality criteria based on existing guideline documents for groundwater monitoring programs are applicable to surface water (SW) and sediment monitoring data. Experts also to agree if/how to use these data for EU regulatory purpose also in light of the additional information required to the applicants. In addition, the approach used by the RMS in the	For the period 1995-2020, a total of 308134 data for glyphosate analysed samples and 270813 data for AMPA analysed samples from 15004 and 12689 sampling sites, respectively, from public monitoring data were assessed for surface water in the updated RAR. The experts discussed and agreed that the general methodology of data collection proposed by the applicants, including the minimum quality criteria, were of limited applicability for the assessment of the data for regulatory purposes. The experts discussed and agreed with the RMS assessment of the outlier analysis and although the method applied appeared robust, it was considered not adapted to the specific case. The comparison against the threshold values, reported as exceedances of glyphosate concentration against the regulatory acceptable concentration (RAC) resulted in only few cases, mostly sampled once, while only two sites had consecutive exceedances. The RMS assessment that the results of the applicant's vulnerability evaluation should be taken with caution was endorsed by the experts for the reasons identified by the RMS in their assessment in the RAR. Above all, due to the very limited number of exceedances provided with the analysis, the experts concluded that there is no need in carefully scrutinising the factors used in the applicant's analysis.

[4] Cederlund, 2022. Environmental fate of glyphosate used on Swedish railways — Results from environmental monitoring conducted between 2007–2010 and 2015–2019. Science of The Total Environment Volume 811, 10 March 2022, https://doi.org/10.1016/j.scitotenv.2021.152361

Subject	Conclusions Pesticide Peer Review Meeting
assessment of SW monitoring data against the Drinking Water Directive (DWD) threshold for raw SW should be discussed.	Regarding the sediment monitoring data provided, the experts agreed with the RMS conclusion that the spatial/temporal distribution of the dataset is limited (i.e., 1272 samples for glyphosate and 1224 samples for AMPA from three EU MSs and for the period 2003-2019). The experts also agreed that the minimum quality criteria set in the FOCUS Groundwater Report (European Commission, 2014)[5] cannot be directly applicable to the sediment compartment. Overall, the experts agreed with the conclusion of the RMS that the surface water monitoring dataset for glyphosate and AMPA was insufficient to use for regulatory surface water exposure assessment and the results need to be taken with caution. Monitoring results from public survey cannot be assimilated to concentrations that can be used for regulatory exposure assessment and be assessed against a regulatory exposure assessment goal without additional information. For the sediment monitoring, the experts agreed that the limited dataset provided is not representative of the EU and a comparison of sediment concentrations with the RAC values is of limited use. **Open point** RMS to add references to publications and databases referenced in the updated surface water public monitoring data assessment and interpretation study (2022) that are not in the RAR to the Vol. 3CA B.8 (AS) monitoring addendum at the end of the RMS study summary on page 347.
Experts' consultation 4.5 MSs to discuss in a meeting of experts the available information on the drinking water monitoring data in light of the additional information requested to the applicants, and to agree if/how to use	Unaggregated drinking water monitoring data were only available from 4 member states regarding glyphosate and 3 for AMPA and the data were limited. The experts noted that a proportion of the data reported are not recent. No information was available in the study regarding the origin of raw data for drinking water. The experts noted that the findings of glyphosate exceeding the pesticide standard for drinking water of 0.1 µg/L in some samples, reflects a legal breach of the drinking water regulation.

[5] European Commission, 2014. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 3, 613 pp.

Subject	Conclusions Pesticide Peer Review Meeting
these data for EU regulatory purpose.	Overall, the experts considered that the available data from individual drinking water samples were of limited value for assessment for the whole EU, as unaggregated values only originated from a few countries. The member state experts agreed with the RMS statement in the RAR that the data discussed here should be considered with caution and further information might be requested at MS level for product registration. **Open point** RMS to carry out the action that was indicated at open point 4.125 in the evaluation table.
Experts' consultation 4.6 MSs to discuss in a meeting of experts the relevance of the available monitoring data for glyphosate in the air compartment and to agree if/how this information can be used in the EU regulatory exposure assessment.	The experts discussed the assessment of the monitoring data for glyphosate and the metabolite AMPA that was reported in the updated RAR in relation to the air compartment. In particular, the discussion focused on the public monitoring raw data originated only from France covering the period 2018-19 (381 samples from 8 sites) and the additional information provided from literature review with monitoring studies in Germany and France. The experts noted that despite the few data available and the intrinsic properties of glyphosate and AMPA, there is a high frequency of quantified samples with values > the limit of detection (LOD) for glyphosate, with the frequency for AMPA being lower. The experts agreed that for the design of the studies, the concentrations detected are proposed to mainly be related to the particulate-bound concentration, as a result of wind-eroded particle transportation, rather than volatilisation. Overall, the experts agreed with the conclusion of the RMS that this very limited air monitoring dataset for glyphosate and AMPA was insufficient to use for regulatory air exposure assessment and the results need to be taken with caution.
New experts' consultation point 4.7 proposed by EFSA for completeness of discussion (October 2022):	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

Subject	Conclusions Pesticide Peer Review Meeting
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 if any eventual follow up would be needed.	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 RMS, EFSA has identified newly available papers on glyphosate even outside of the legal requirements and collected a list of studies as a result. As an outcome of this exercise, after a preliminary assessment, EFSA identified a publication on groundwater monitoring associated with railway sites in Sweden as potentially relevant: Cederlund, H. (2022) Environmental fate of glyphosate used on Swedish railways results from 2007-2010 and 2015-2019. Science of the Total Environment 811 (2022) 152361. Conclusions from the discussion on this paper can be found earlier in this meeting report at experts' consultation point 4.3.

REPORT OF PESTICIDE PEER REVIEW TC 90

METALAXYL-M – Amendment of approval conditions Rapporteur Member State: BE

4. Environmental fate and behaviour

Date: 20 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	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
Hearing expert	CH

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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

4. Environmental fate and behaviour

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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 4.1 Member state experts to agree the most appropriate degradation pathway to be used for kinetic fitting and forward groundwater modelling and the DT50 and kinetic formation fractions to be used in FOCUS groundwater simulations considering the already available information and the RMS evaluation of the information provided to address the data requirements.	In the past peer review it was agreed that 0.1 was a conservative formation fraction to be used for modelling metabolite SYN546520 from NOA409045 (based on lysimeter data where racemic metalaxyl was dosed). In the present assessment regarding the formation fraction of SYN546520 from NOA409045 three values are available from additional aerobic laboratory soil incubations dosed with metalaxyl-M, not available before. The fitting of the kinetics in laboratory soil incubations that was provided for pathways alternative to Metalaxyl-M goes to NOA409045 goes to SYN546520 as terminal metabolite was poor. Experts agreed that the arithmetic mean of the three available formation fractions derived using the laboratory soil incubation studies, excluding the value derived from inverse modelling a lysimeter study dosed with racemic metalaxyl, should be used for PECgw calculations. Therefore, a formation fraction of 0.013 should be used for the formation of metabolite SYN546520 from NOA409045. It was also agreed that the second degradation pathway investigated and presented in the updated RAR should not be used in the present assessment. **Open point**: RMS to add in the list of endpoints the arithmetic mean value of formation fractions derived using the laboratory soil incubation studies for metabolite SYN546520.

Subject	Conclusions Pesticide Peer Review Meeting
	Open point: RMS to correct the list of endpoints DegT50 aerobic degradation for parent metalaxyl-M to report the value as a geomean rather than it being indicated as a median value (though the value is correct and does not need to be changed).
Experts' consultation 4.2 Member state experts to consider the RMS evaluation of the information provided to address the data requirements for updated PEC calculations. To consider if the available results might be relied on or if further calculations are necessary.	It was discussed whether to keep the PECgw calculations done using a conservative value of 0.1 for the formation fraction of metabolite SYN54652 from NOA409045 or new PEC groundwater calculations would be needed considering the formation fraction of 0.013 that had been agreed. Overall experts agreed that new groundwater modelling is needed, considering the agreed average formation fraction of 0.013 for metabolite SYN546520 from NOA409045. PEC soil and PEC surface water calculations are not triggered for metabolite SYN546520. Experts agreed the available PEC calculations with the exception of the groundwater modelling because of the formation fraction used in for metabolite SYN54652 from NOA409045 as discussed above. **Open point:** RMS to provide an amended RAR adding updated PEC groundwater calculations for metabolite SYN546520 using the agreed average formation fraction of 0.013 for SYN546520 from NOA409045. All other substance parameters to be the same as those used by the RMS in the amended RAR dated 22/07/2022. The use patterns simulated to be the same as those used by the RMS in that amended RAR. The list of endpoints should be amended accordingly.

REPORT OF PESTICIDE PEER REVIEW TC 86

SULFUR – AIR IV

Rapporteur Member State: FR

4. Environmental fate and behaviour

Date: 12 July 2022

List of participants:

Institute	**Member States Country code**
Austrian Agency for Health and Food Safety (AGES)	AT
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

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Member States to discuss in a meeting of experts the PECsoil calculations approach for both formulations by including the sulfur/sulfate background levels.	For both the formulations, the FOCUS (1997) guidance was used to derive PECsoil for sulfur, without considering transformations rate between the applications. A crop interception of 0% was used for the SULPHUR DUST, while values from EFSA (2014) guidance were used for SULFUR 80% WG. More reliable total sulfur concentrations in agriculture soils were provided as background level, but it was proposed to not add it to the PECsoil. Sulfur is not persistent and no accumulation of sulfur in soil is expected. However, sulfate ions levels are highly variable, prone to fast dissipation and can result from other sources then the use of sulfur as pesticide. Experts agreed to compare the background level without adding the concentrations to the PECsoil. Experts agreed with the RMS approach for calculating PECsoil and on the decision to not include sulfates in the PECsoil calculations.
Experts' consultation 4.2 Member States to discuss in a meeting of experts the approach to be used for PEC groundwater calculations.	Estimation of PECgw represents only the newly added sulfur in soil following the application of PPPs, the background level of sulfur in soil was not considered for the groundwater exposure assessment. Two approaches were proposed: the Flux method (already used in the assessment in 2008) and the FOCUS modelling (submitted in the present assessment). The PECgw using the two approaches resulted in similar values and were both quite conservative considering the substance parameters used.

Subject	Conclusions Pesticide Peer Review Meeting
	The applicability of using the FOCUS modelling for inorganic compounds was discussed and it was concluded that in this case, considering the fast transformation rates, the FOCUS modelling can be acceptable. Experts agreed to present the results coming from the use of both approaches in the two Vol 3 B.8 (PPP). However, experts decided that only the results coming from the FOCUS modelling approach should be presented in the LoEP and used when drafting the EFSA conclusion. Open point: RMS to amend the LoEP deleting the PECgw calculated using the flux method.
Experts' consultation 4.3 Member States to discuss in a meeting of experts the approach for PECsw/PECsed calculations approach for both formulations, including the sulfur/sulfate background levels in surface waters and sediments.	The PECsw calculations for sulfur were not considered needed in the previous assessment and current assessment. The approach proposed was to set the PECsw to max water solubility which equals to 0.016 mg/L. However, during the commenting phase, it was suggested to derive PECsw considering the spray drift deposition rates for a single application instead of the max water solubility. RMS presented the PECsw calculations done following this approach, which reflects not only the dissolved part, but also the non-dissolved sulfur in water and sediment. A new drift study for deriving values for the dustable powder product was presented by the Applicant, but it was considered non acceptable as it was not representative of the uses in vineyard and the analytical method was considered not reliable. The PECsed were presented and compared with the background level of total sulfur in sediment. It was discussed whether to include the background level of total sulfur in sediment in the PECsed. Experts agreed that the PECsw calculations considering the spray drift deposition rates for a single application should be included in the RAR and in the LoEP. However, the approach using the max water solubility should be kept as represents the dissolved portion of the sulfur that reaches the water body. Therefore, the PECsw calculated for dissolved and total sulfur should be presented in the LoEP. Experts concluded that for the SULPHUR DUST a drift value of 100% should be used.

Subject	Conclusions Pesticide Peer Review Meeting
	Experts agreed to not add the background level in the PECsed calculations as the sulfur present and sulfates produced will flow through the water body systems. RMS and the experts agreed that FOCUS Step 3 and 4 are not acceptable for the assessment of the dustable powder uses. Consequently, PECsed for sulfates from SULPHUR DUST need to be calculated following the same approach used for the SULFUR 80% WG product. Open point: RMS to amend the RAR adding also the PECsw calculated considering the spray drift deposition rates for a single application. The LoEP should be amended accordingly. Open point: RMS to calculate PECsed for sulfates from SULPHUR DUST following the same approach used for SULFUR 80% WG. The LoEP should be amended accordingly.
Experts' consultation 4.4 Member States to discuss in a meeting of experts the residue definition for all compartments.	Sulfur is not expected to accumulate and will leach directly to groundwater after oxidation to sulfate. The sediment is a sink for sulfur and for the produced sulfates that, when formed, could flow through the water body systems. Additional information to support that the residue definition of exposure in air should be restricted to particulate sulfur was provided and assessed in the RAR. Experts agreed to not include sulfates in the residue definition for soil compartment, and to included it in the surface water and sediment compartments. For groundwater it was confirmed that sulfur and sulfates needed considering for the exposure assessment. For the air compartment, sulfur (particulate S) was proposed.

REPORT OF PESTICIDE PEER REVIEW TC 71

DIMOXYSTROBIN– AIR III

Rapporteur Member State: HU

4. Environmental fate and behaviour

Date: 19 January 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
Pesticides Registration & Control Division	IE
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
GEEST s.p.	SI
Hearing expert	CH

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to agree on the adsorption endpoints to be used in the exposure assessment for metabolites 505M001, 505M008 and 505M009. The pH dependency to adsorption for metabolites 505M008 and 505M009 should also be discussed and agreed.	Three studies on the adsorption of metabolite 505M01 were discussed. The study where the indirect method was used resulted to be not acceptable because many criteria of the OECD 106 Evaluators Checklist[3] were not met (e.g.: adsorbed percentages, the p values and the R-square values). The two studies done using the direct method were considered acceptable. Considering the structure of metabolite 505M01 and the acidic/alkaline properties of the functional groups, it was shown that no clear pH dependency on adsorption can be concluded. Three studies on the adsorption of metabolite 505M08 were discussed. In the study where the indirect method was used some of the criteria of the OECD 106 Evaluators Checklist were not met. In this case, it was decided not to bias the overall picture and considering that 505M08 is very mobile and stable substance, only the results from four soils were retained. The two studies done with the direct method were considered acceptable. Furthermore, the use of a 1/n of 1 instead of 1.22 in the Bruch West soil was discussed and the experts agreed to retain the Bruch West soil with the 1/n of 1.22 in the dataset. As regards the pH dependency, a significant correlation was identified between Kfoc and soil pH for metabolite 505M08. Three studies on the adsorption of metabolite 505M09 were discussed. In the study where the indirect method was used, based on the

[3] EFSA (European Food Safety Authority), 2017.Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326. 18pp.doi:10.2903/sp.efsa.2017.EN-1326

Subject	Conclusions Pesticide Peer Review Meeting
	evaluation against the OECD 106 Evaluator Checklist only the results from four soils were considered acceptable. The two studies done with the direct method were considered acceptable by the RMS. A statistically significant correlation between soil pH and Kfoc was identified for metabolite 505M09. The experts agreed with the RMS evaluation to derive adsorption endpoints for metabolite 505M01 from 10 soils coming only from the studies done with the direct method. The experts agreed that based on the information available, the data do not show a clear pH dependency to be considered in the exposure assessment for metabolite 505M01. An open point was set for the RMS to update the LoEP correcting the Kfoc values of metabolite 505M01 in one of the study done with direct method, as they are slightly different from the values reported in the RAR. The experts agreed with the RMS evaluation to derive adsorption endpoints for metabolite 505M08 from 4 soils coming from the study done with the indirect method and from 10 soils coming from the studies done with the direct method. An open point was set for the RMS to provide an amended LoEP correcting the 1/n value for the soil Bruch West and recalculate the arithmetic mean 1/n for soils with pH > 6.5. The experts agreed with the RMS evaluation to derive adsorption endpoints for metabolite 505M09 from 4 soils coming from the study done with the indirect method and from 10 soils coming from the studies done with the direct method. Overall, the experts agreed that adsorption of metabolites 505M08 and 505M09 is dependent on soil pH and then the geometric mean Kfoc and arithmetic mean 1/n values for soils with pH(H2O) > 6.5 and ≤ 6.5 should be used for PEC calculations for these two metabolites. See also open point under experts' consultation 4.5.
Experts' consultation 4.2 Experts to agree on the adsorption endpoints to be used in the exposure assessment for dimoxystrobin considering the updated	Adsorption of dimoxystrobin was investigated in three studies where the indirect method was used. In one of the study most of the soils did not meet many of the criteria outlined in the OECD 106 Evaluators Checklist. Therefore, the RMS considered that the results should not be relied on except for one soil. The other two studies were considered acceptable.

Subject	Conclusions Pesticide Peer Review Meeting
summary and evaluation of the adsorption studies.	In conclusion, for dimoxystrobin adsorption endpoints were derived from 7 soils. No pH dependency was identified for dimoxystrobin. The experts agreed with the adsorption endpoints presented by the RMS and with the absence of soil pH dependency for dimoxystrobin. No actions for RMS.
Experts' consultation 4.3 Experts to discuss and agree on the degradation endpoints that should be used for calculating PECsw,sed for dimoxystrobin.	The water/sediment study was questioned because the two selected sediments did not differ with respect to organic carbon content and texture. However, the RMS concluded that as the two systems showed a very different microbial activity, this deviation is not considered a non-conformity. The kinetic evaluations were presented and considered by the experts. The water/sediment degradation endpoints for dimoxystrobin as they are presented in the updated RAR and LoEP are considered appropriate and valid for PECsw,sed calculations. It was noted that the degradation rates derived from a water/sediment system done under outdoor conditions should not be used for modelling purposes. The experts agreed that the exposure assessment of dimoxystrobin should be done only on the basis of the water/sediment study conducted in the dark. An open point was set for the RMS to provide an amended LoEP deleting the results of the water/sediment study done under outdoor conditions.
Experts' consultation 4.4 Experts to discuss and agree on the degradation endpoints that should be used for calculating PECsoil for dimoxystrobin and its soil metabolites. Furthermore, experts should agree on the maximum occurrence values to be used for metabolite 505M08 in the soil and surface/water exposure assessment.	For dimoxystrobin the RMS reconsidered the kinetic model used to derive the endpoint for PECsoil calculations and selected the HS kinetic model instead of DFOP as appropriate to derive endpoints from a Swedish field trial. For metabolites 505M01, 505M08 and 505M09, considering that the formation fractions in the laboratory incubations were lower than the max occurrence under field conditions, the maximum occurrence in soil coming from field studies were considered appropriate for PECsoil calculations. The experts agreed with the RMS to derive the endpoint for PECsoil calculations for dimoxystrobin from HS kinetic model from a Swedish field trial. An open point was set for the RMS to recalculate PECsoil for dimoxystrobin using the new endpoint derived with HS kinetic model

Subject	Conclusions Pesticide Peer Review Meeting
	from the Swedish trial presented during the experts' meeting (k1 = 0.007578, K2 = 2.337E-14, and tb = 118 days). It was also agreed that for the slow phase a DT50 of 1000 days should be considered as the degradation of dimoxystrobin essentially stopped at the end of the study. The experts agreed with the RMS to use the maximum occurrence in soil coming from field studies for PECsoil calculations for metabolites, and then for metabolite 505M01 the maximum occurrence in soil =21.6%, for metabolite 505M08 maximum occurrence in soil = 14.6%, and for metabolite 505M09 maximum occurrence in soil = 14.4%. An open point was set for the RMS to provide updated PECsoil calculations for metabolite 505M09 using a maximum occurrence equal to 14.4% and g parameter equal to 0.0958, as a typo error was found in the LoEP. Furthermore, an open point was set for the RMS to update PECsw,sed calculations at Step 1 and 2 with the correct and agreed maximum occurrences in soil for metabolites 505M01, 505M08 and 505M09.
Experts' consultation 4.5 Experts to discuss and agree on the degradation endpoints that should be used for calculating PECgw for dimoxystrobin and its soil metabolites.	For dimoxystrobin the modelling endpoints to be used in PEC groundwater derived from trials coming from two legacy field studies and trails from a new "DegT50" field study were discussed and agreed. For the field trails from the two legacy studies: • Swedish trial: SFO kinetic model was selected for deriving modelling endpoints • German trial: HS kinetic model was selected for deriving modelling endpoints, as SFO visual fit was not acceptable and using DFOP the K2 was not significantly different from 0. The experts agreed to derive modelling endpoints coming from fast and slow phase HS kinetic fitting. • German trial: RMS selected SFO kinetic model for deriving endpoints for PECgw for dimoxystrobin. • German trial: the kinetic fitting with DFOP was considered acceptable and the experts agreed that the slow phase from this fitting should be used for modelling purposes. For the field trails from the new "DegT50" field study: • Spanish trial: SFO resulted in an unacceptable fit. The goodness of fit was improved using DFOP kinetic model, which was selected by the RMS, although the current guidance would recommend using the FOMC in this case (residues < 10% at the end of the study). The experts agreed that the DT90 FOMC/3.32 should be considered as a modelling endpoint.

Subject	Conclusions Pesticide Peer Review Meeting
	• Italian trial: a good fitting of the data was obtained with the slow phase of DFOP kinetic model. • UK trial: the goodness of fit with SFO was not satisfactory and therefore FOMC and DFOP fitting were investigated, but no significant improvement of the fitting was obtained. Therefore, the experts agreed that SFO DT50 can be selected. • DE trial: the experts agreed on the selection of the SFO DT50 as proposed by the RMS. • France trial: the use of the DT90 FOMC/3.32 was agreed to derive modelling endpoints. When modelling the **metabolites**, the RMS questioned the use of DT90 FOMC/3.32 (and in general pseudo-SFO DT50 from bi-phasic kinetic models) as degradation modelling endpoints. In similar cases, for other substances, where the DT90/3.32 or bi-phasic fit is selected this is considered equivalent to SFO endpoints. Therefore, the experts agreed that for metabolites modelling fast phase with truly bi-phasic fits can be combined with the SFO DT50 and pseudo-SFO endpoints. The modelling of metabolites should also be run combining the SFO and pseudo-SFO with truly bi-phasic fits as it cannot be anticipated which combination will result in higher concentrations for the metabolites. It was noted that the maximum occurrence of metabolite 505M01 from the field studies as if it was the kinetic formation fraction was used in the groundwater modelling at Tier 2. The experts agreed that the DT50 values using the approach as discussed above and the overall geomean DT50 for dimoxystrobin should be recalculated. Therefore, an open point was set for the RMS. The experts agreed that PECgw calculations should be performed using the fast phase geomean DT50 (38 days) and the slow phase geomean DT50 (113 days) for dimoxystrobin. In order to conclude on the groundwater exposure assessment for dimoxystrobin only the results generated with the slow phase DT50 should be used. The new PECgw modelling should be performed also based on the outcomes of the discussion point 4.1 on the pH dependence of adsorption of metabolite 505M08 and 505M09, and then the geometric mean Kfoc and arithmetic mean 1/n values for soils with pH(H2O) > 6.5 and ≤ 6.5 should be used for PEC calculations for these two metabolites. Therefore, an open point was set for RMS to provide new PECgw calculations based on the agreed modelling endpoints for

Subject	Conclusions Pesticide Peer Review Meeting
	dimoxystrobin and the consideration for metabolites as discussed during the meeting. An open point was set for RMS to remove the Tier 2 PECgw results for metabolite 505M01 from the LoEP.

REPORT OF PESTICIDE PEER REVIEW TC 71

RIMSULFURON – Ad hoc mandate -

Genotoxic potential of metabolite IN-E9260

Rapporteur Member State: SI

4. Environmental fate and behaviour

Date: 19 January 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
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
GEEST s.p.	SI
Hearing expert	CH

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Member state experts to discuss and agree if reliable soil DegT50 can be derived from the 2 field degradation studies in France and Italy.	Following scrutinising the visual kinetic fits and statistical parameters for the fits, the experts concluded that the kinetic endpoints that the RMS had derived can be considered reliable soil DegT50 values from the 2 field degradation studies in France and Italy that were the subject of the consultation. Open points for action by the RMS were identified to facilitate zonal and national assessments should a decision be made to renew the approval of rimsulfuron: **Open point** RMS to include in an amended RAR kinetic fitting for the parent and the two primary metabolites IN-E9260 and IN-J2090 using SFO-SFO modelling, including the day 0 values for both France and Italy field trials presenting the corresponding visual fits and statistical parameters. Results from these fits to be added to the list of endpoints **Open point** RMS to update the list of endpoints rate of degradation entries so it respects / is in line with list of endpoints template for both parent and metabolites. I.e. so that field modelling DegT50 endpoints be removed from the laboratory endpoints tables. They should just be accurately included in the relevant field data endpoint tables. The modelling values for each metabolite where the field and lab studies are concluded as

Subject	Conclusions Pesticide Peer Review Meeting
	appropriate to be combined, to be entered in the boxes in the template designed for this.

REPORT OF PESTICIDE PEER REVIEW TC 65

RAPE SEED OIL – AIR IV

Rapporteur Member State: NL

4. Environmental fate and behaviour

Date: 18 November 2021

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
State Plant Service under the Ministry of Agriculture	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
External expert	CH
Hearing expert	NL

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to discuss and agree on the adsorption endpoints for the parent and its metabolites to be used in the exposure assessment.	A QSAR Koc values was proposed for rape seed oil and its metabolites which were based on experimental Log Pow values. The QSAR adsorption estimates based on the measured log Pow, that had been selected by the RMS as presented in the RAR for the different fatty acids in rape seed oil, were agreed. No actions for the RMS.
Experts' consultation 4.2 (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.	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 PECsw expressed in mg/m^2. If the rapeseed oil is emulsified in water, the endpoint from the ecotoxicology studies can be expressed in mg/l, and if there is an emulsifier the substance can be expected to stay longer in the water

Subject	Conclusions Pesticide Peer Review Meeting
This consultation should be done jointly with ecotoxicology experts to consider how toxicity studies for aquatic organisms are performed.	column, and then PECsw expressed in µg/L can be used in the aquatic risk assessment. It was agreed to use FOCUS Step 2 to calculate PECsw, in µg/L, taking into consideration only spray drift. When required buffer distances can be applied at Step 2 to mitigate spray drift. **Open point:** RMS to provide PECsw calculations at FOCUS Step 2 considering only spray drift and buffer distances for spray drift mitigation, if needed.

REPORT OF PESTICIDE PEER REVIEW TC 65

CYMOXANIL – AIR IV

Rapporteur Member State: LT

4. Environmental fate and behaviour

Date: 18 November 2021

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
State Plant Service under the Ministry of Agriculture	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
External expert	CH

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to discuss and agree on the relevance of metabolite IN-R3274 in soil.	In a study where metabolite IN-W3595 was dosed, metabolite IN-R3274 reached a maximum of 32% AR. The experts discussed the available information and noted that in the active substance dosed studies metabolite IN-R3274 was not above 5% AR at more than one time point. It was considered that metabolite IN-R3274 would still represent < 5% AR when related to the percentage that would result from the formation of the precursor metabolite IN-W3595 in the parent dosed study. It was agreed that metabolite IN-R3274 did not reach levels in soil that warranted further assessment. No actions for the RMS.
Experts' consultation 4.2 Expert to discuss and agree on the acceptability of the degradation endpoints for metabolites IN-KQ960 and IN-T4226 in soil Cranfield 164 as only 3 data points are available for the kinetic analysis.	For the kinetic fitting of metabolites IN-KQ960 and IN-T4226 in the soil Cranfield 164, a top-down decline approach was used to determine degradation endpoints, but only two measured time points were available for the kinetic analysis. Experts agreed that only two measured time points are not sufficient to derive degradation endpoints for metabolites IN-KQ960 and IN-T4226 in the soil Cranfield 164. It was agreed to remove from the dataset the degradation endpoints for metabolites IN-KQ960 and IN-T4226 in the soil Cranfield 164. **Open point:**

Subject	Conclusions Pesticide Peer Review Meeting
	RMS to update the RAR removing degradation endpoints for metabolites IN-KQ960 and IN-T4226 in the Cranfield soil and to recalculate the geomean DT50 for these two metabolites. The list of endpoints should be amended accordingly.
Experts' consultation 4.3 Experts to discuss and agree on the degradation scheme of cymoxanil in soil.	The degradation scheme of cymoxanil in soil was questioned. However, experts noted that from the information presented in the RAR there is no reason to update the degradation scheme from that already presented in the RAR as was proposed by the task force and evaluated as appropriate by the RMS. It was agreed that it is not needed to update the degradation scheme. No actions for the RMS.
Experts' consultation 4.4 Experts to discuss and agree on the pH-dependency of adsorption and degradation of cymoxanil and its metabolites, especially relevant for metabolites IN-KQ960, IN-W3595 and IN-KP533.	For the active substance it was considered that pH dependent adsorption was not clearly indicated by the data and geomean values below pH 7 are in the range of the adsorption of the few alkaline values available. For metabolites IN-KQ960, IN-W3595, IN-R3273, IN-T4226 IN-U3204 and IN-JX915 experts agreed that the soil adsorption of metabolites do not need to be considered pH dependent considering their low adsorption. For metabolites IN-JX915 and IN-U3204 the adsorption was very low for these two metabolites the experts agreed that a KFoc of 0 should be used considering the OECD 106 checklist parameter value. For the active substance, the experts considered that pH dependent degradation was not clearly indicated. For metabolites IN-KQ960, IN-W3595, IN-T4226, IN-U3204, and IN-JX915 degradation was anyway fast, so it was agreed not to account for pH dependent degradation. For metabolite IN-R3273, though in some soil's degradation was slower, there was any pattern related to pH. Overall, it was agreed to use geomean Koc values in the exposure assessment for the active substance and all metabolites, except for metabolites IN-JX915 and IN-U3204 for which Koc values of 0 should be used. Furthermore, it was agreed that geomean DegT50 values should be used in the exposure assessment for the active substance and all metabolites. **Open point:**

Subject	Conclusions Pesticide Peer Review Meeting
	RMS to remove the soil adsorption values for metabolites IN-JX915 and IN-U3204 from the list of endpoints and indicate values of 0 mL/g for these metabolites. **Open point:** RMS to update the correlation plot Koc to pH for metabolite IN-R3273 in an amended RAR as what is currently presented is a mistake (Koc values are wrong). **Open point:** RMS to indicate that pH dependence of degradation as 'no' for cymoxanil and metabolites IN-W3595 and IN-R3273 in the list of endpoints.
Experts' consultation 4.5 Experts to discuss and agree on the input parameters to be used for the PECsoil calculations for cymoxanil and all the relevant metabolites in soil. Furthermore, expert to agree on the crop interception values to be used for the three products. Note: PECsoil calculations would be updated according to the results of the experts' consultation.	PECsoil should be calculated with the appropriate endpoints taking into account all available data for the active substance and its metabolites, and the same worst-case non-normalized DT_{50} value for the different compounds should be used for PEC calculations for all formulations. The following degradation endpoints were agreed by the experts for PECsoil calculations: cymoxanil: DT50 19.9 d, pseudo SFO, worst-case non-normalised laboratory DT90/3.32; IN-KQ960: DT50 4.19 d, SFO, worst-case non-normalised laboratory; IN-U3204: DT50 6.45 d, pseudo SFO, worst-case non-normalised laboratory DT90/3.32; IN-W3595: DT50 1.83 d, SFO, worst-case non-normalised laboratory; IN-T4266: DT50 1.13 d, pseudo SFO, worst-case non-normalised laboratory DT90/3.32; IN-JX915: DT50 0.65 d, pseudo SFO, worst-case non-normalised laboratory DT90/3.32; IN-R3273: DT50 60.8 d, SFO, worst-case non-normalised laboratory. **Open point:** RMS to provide updated PECsoil calculations using the agreed degradation endpoints for cymoxanil and all soils metabolites (IN-KQ960, IN-W3595, IN-T4226, IN-U3204, IN-JX915 and IN-R3273). The list of endpoints should be amended accordingly.
Experts' consultation 4.6	PECgw should be calculated with the appropriate endpoints taking into account all available data for the active substance and its metabolites,

Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss and agree on the input parameters to be used for the PEC groundwater calculations for cymoxanil and all the relevant metabolites in soil. Furthermore, experts to discuss and agree on the approach used for groundwater modelling, such as the formation fractions for metabolites, the degradation scheme in soil, the potential pH dependencies, and the crop interceptions, the crop uptake factor.	and the same degradation and adsorption endpoints values for the different compounds should be used for PEC calculations for all formulations. Experts agreed that in the exposure assessment the crop uptake should be 0 and the crop interception should be in line with EFSA DegT50 guidance (2014). Degradation endpoints for metabolites IN-KQ960 and IN-T4226 should be updated in line with experts' consultation 4.3. Furthermore, in line with experts' consultation 4.4 geomean DegT50 values and geomean Koc values should be used in the exposure assessment for the active substance and all metabolites, except for metabolites IN-JX915 and IN-U3204 for which Koc values of 0 should be used. The following degradation endpoints were agreed by the experts for PECgw calculations: Cymoxanil: geomean DegT50 0.896 d, geomean Koc 19.6 mL/g, 1/n 0.873 IN-U3204: geomean DegT50 0.142 d, ff 0.282, geomean Koc 0 mL/g, 1/n 1 IN-W3595: geomean DegT50 0.887 d, ff 1 (by default), geomean Koc 2.3 mL/g, 1/n 0.886 IN-JX915: geomean DegT50 0.178 d, 1 (by default), geomean Koc 0 mL/g, 1/n 1 IN-KQ960: geomean DegT50 1.55 d, ff 0.752, geomean Koc 4.04 mL/g, 1/n 0.909 IN-T4266: geomean DegT50 0.18 d, ff 0.043, geomean Koc 0.59 mL/g, 1/n 0.943 IN-R3273: geomean DegT50 3.94 d, ff 0.068, geomean Koc 13.7 mL/g, 1/n 0.840. **Open point:** RMS to provide updated PECgw calculations using the agreed degradation and adsorption endpoints for cymoxanil and all soils metabolites (IN-KQ960, IN-W3595, IN-T4226, IN-U3204, IN-JX915 and IN-R3273). The list of endpoints should be amended accordingly.
Experts' consultation 4.7	PECsw,sed should be calculated with the appropriate endpoints taking into account all available data for the active substance and its metabolites, and the same degradation and adsorption endpoints values

Subject	Conclusions Pesticide Peer Review Meeting
Experts to discuss and agree on the input parameters to be used for the PECsw/PECsed calculations for cymoxanil and all the relevant metabolites in soil and surface water/sediment. Furthermore, experts to discuss and agree on the approach used for surface water/sediment modelling, such as the formation fractions for metabolites, the degradation scheme in surface water, the potential pH dependencies, and the crop interceptions.	for the different compounds should be used for PEC calculations for all formulations. The following degradation endpoints were agreed by the experts for PECsw,sed calculations: Cymoxanil: DT50 0.248 d; IN-U3204: DT50 0.794 d; IN-W3595: DT50 13.7 d; IN-JX915: DT50 2.45 d; IN-KQ960: DT50 160 d; IN-T4266: DT50 3.03 d; IN-R3273: DT50 10.6 d; IN-KP533: DT50 6.52 d; M5/ASS999: DT50 63.5 d; IN-R3274: DT50 10.3 d. For the soil parameters refer to experts' consultation 4.6. **Open point:** RMS to provide updated PECsw,sed calculations using the agreed degradation and adsorption endpoints for cymoxanil and all metabolites (IN-KQ960, IN-W3595, IN-T4226, IN-U3204, IN-JX915, IN-R3273, IN-KP533, M5/ASS999 and IN-R3274). The list of endpoints should be amended accordingly. See also expert's consultation 4.6.

REPORT OF PESTICIDE PEER REVIEW TC 65

ISOFLUCYPRAM – NAS 1107/2009 Rapporteur Member State: FR

4. Environmental fate and behaviour

Date: 18 November 2021

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
State Plant Service under the Ministry of Agriculture	LT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
External expert	CH

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Member state experts to discuss whether the soil metabolite M10 with known structure triggers groundwater exposure assessment as it might be considered to still be increasing at study end at least in the incubation of the Laacher Hof AXXa soil in a laboratory soil degradation study. Member state experts to also discuss in this context and regarding M11 and M12 the RMS evaluation of the additional aged adsorption incubations that are expected to be submitted. Consideration also needed of new M12 soil incubations that are expected to be submitted. Consideration to also be made to other modelling submitted	In light of all data provided with the revised DAR, it was discussed whether metabolites M10 and M11 should be considered in the residue definition for groundwater exposure assessment. M10 exhibited persistency and was still increasing in concentration toward the end of the soil incubations in the soils where it had been detected but did not reach the 5% trigger in any of the reliable incubations. A small majority of the experts agreed that using the evidence from the 10 soil incubations that were accepted as reliable, metabolite M10 had not reached levels that warranted an exposure assessment for groundwater to have to be provided. For metabolite M11 it was agreed that the newly submitted data did not change the definition of residues. I.e. M11 did not need to be added because it was not detected. The reliability of the new degradation data for metabolite M12 was evaluated. The pH-dependency of both degradation rate and adsorption were concluded on. The majority of experts agreed that a pH-dependency of degradation rate could not be excluded, and the two-subset division proposed by applicant and RMS as presented in the amended DAR was accepted. All experts agreed that the pH-dependency of adsorption in soils for M12 had been clearly established. The endpoints to be used for modelling for metabolite M12 proposed by RMS in the amended DAR, including the division of data into pH related groups for degradation rate and adsorption (i.e. that resulted in: DT50

Subject	Conclusions Pesticide Peer Review Meeting
for PEC surface water and sediment. Note useful information on M10 and M11 is not possible from soil route of two degradation studies, due to the choices made in the conduct of those studies. Note the criteria in regulation 283/2013 have been respected considering the incubations already evaluated in the DAR, but those in Sanco/221/2000-rev.10-final (groundwater relevance) not.	of 116.6 days and K_{Foc} of 37.1 mL/g), were agreed as covering all soil pH situations, though might be conservative for soil pH below 5.8, where higher adsorption is indicated. Metabolites M10 and M11 were not included in the definition of residues triggering a groundwater exposure assessment. For metabolite M12, both degradation and adsorption in soil were agreed to be pH-dependent. Endpoints proposed in the amended DAR were considered adequate to be used in exposure modelling for metabolite M12, though might be conservative for soil pH below 5.8 where higher soil adsorption was indicated by the dataset. Amendments to the DAR and list of endpoints were not needed as the conclusions of the experts were in line with the evaluation of the RMS in the amended DAR and list of endpoints that had been prepared before the meeting.
Experts' consultation 4.2 Member state experts to discuss any RMS assessment of the information submitted and discuss how / if it might be used.	During the commenting phase the applicant proposed the addition to the dossier of two new TSCF (Transpiration Stream Concentration Factor) studies for the active substance isoflucypram and for metabolite M12. These studies were not provided and therefore there was nothing for the experts to discuss. No conclusion as these data (that might have had utility in higher tier modelling simulations) were not provided.

REPORT OF PESTICIDE PEER REVIEW TC 61

FENPYROXIMATE– AIR IV

Rapporteur Member State: AT

4. Environmental fate and behaviour

Date: 16 September 2021

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
Istituto Superiore di Sanità	IT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Institute of Environmental Protection – National Research Institute	PL

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to agree on the reliability and validity of the US field studies for EU risk assessment and to agree on the endpoints to be used for the exposure assessment.	A new study, investigating the ecoregion comparability with European conditions of the three soils from US field studies, was presented and discussed. Lucama and West Memphis soils resulted not comparable to EU conditions, while Porterville soil resulted representative of Southern European agricultural soils and climatic conditions. Considering the procedure adopted for minimising soil surface processes, it resulted that only five data points were available after 10 mm of rainfall/irrigation has occurred for the Porterville soil. Experts agreed that the Porterville soil is representative of Southern European conditions but considering that only few data points remained after 10 mm of rainfall/irrigation has occurred, only persistence endpoint can be derived from this soil. Open point: RMS to add more information in the RAR on the weather station used for the ecoregion comparability. Open point: RMS to update the RAR with the conclusion of the experts' consultation regarding the Porterville soil and to include the persistence endpoints derived for this soil. The LoEP should be amended accordingly.
Experts' consultation 4.2 Experts to agree on the appropriate degradation endpoint to be used in the exposure	For the sandy loam soil, experts agreed to use SFO kinetic model for deriving both modelling and persistence endpoints for fenpyroximate. For the sandy loam soil, experts agreed to use FOMC kinetic model for deriving persistence endpoints for fenpyroximate and SFO for deriving modelling endpoints.

Subject	Conclusions Pesticide Peer Review Meeting
assessment for fenpyroximate from kinetic evaluation. In particular endpoints for sandy loam, silty clay loam should be discussed.	The silty clay loam soil was rejected for deriving both persistence and modelling endpoints because the study was conducted at 10°C and not proper replicates were performed. Experts agreed that a soil geomean DegT50 of 68.4 d should be used in the exposure assessment of fenpyroximate, and the results from the silty clay loam soil should not be used to derive degradation endpoints. Open point: RMS to update the RAR with the conclusion of the experts' consultation. The LoEP should be amended accordingly.
Experts' consultation 4.3 Experts to agree on the reliability and validity of the field study and to agree on the endpoints to be used for the exposure assessment.	Some key information to assess the field study are missing and there are not enough data for a proper derivation of modelling and persistence endpoints (e.g. few data points available to perform a proper kinetic assessment, lack of storage and stability testing, missing information on sampling pattern and distribution of the compound in the soil, lack of climatic information). Experts agreed to not consider the results of the field study for deriving modelling and persistence endpoints for fenpyroximate. Open point: RMS to update the RAR including the conclusion of the experts' consultation.
Experts' consultation 4.4 Experts to agree on the update soil exposure assessment for fenpyroximate.	The outcomes from experts' consultations 4.1, 4.2 and 4.3 lead to the conclusion that in absence of a fully reliable dataset from field dissipation studies and considering that the only available field DT50 comes from the Porterville (California) soil, which is considered representative only of the Southern European conditions, the results from the laboratory studies should be used for deriving degradation endpoints to be used in the soil exposure assessment. Experts agreed that the longest DT50 value of 238 d coming from the laboratory studies should be used for the soil exposure assessment of fenpyroximate. Open point: RMS to update the RAR providing the initial PECsoil, and the full time series of the actual and weighted average values. The LoEP should be amended accordingly. Data gap: reliable soil degradation endpoints from at least three different soil field dissipation studies should be available for fenpyroximate as required by the Commission Regulation (EU) No 283/2013.

Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.5 Experts to agree on the update groundwater exposure assessment for fenpyroximate and its metabolites.	The outcomes from experts' consultations 4.1, 4.2 and 4.3 were considered to decide on the degradation endpoints to be used in the groundwater exposure assessment of the parent compound and its metabolites. For fenpyroximate experts agreed that a geomean soil DegT50 of 68.4 d (based on 5 soils from laboratory studies) should be used for the groundwater exposure assessment. For the metabolites, some small discrepancies have been noted in the geomean soil DegT50 values for metabolites M-3, M-8 and M-1. Open point: RMS to check and correct in the updated RAR the geomean soil DegT50 values for metabolites M-3, M-8 and M-1. In the LoEP the 'Rate of degradation in soil (aerobic) laboratory studies transformation products' and in the 'PEC groundwater' sections should be updated accordingly, and if necessary, a note should be added to clarify the correct values that should be used in the future groundwater exposure assessment.
Experts' consultation 4.6 Experts to agree on the update surface water and sediment exposure assessment for fenpyroximate and its metabolites.	The outcomes from experts' consultations 4.1, 4.2, 4.3 and 4.5 were considered to decide on the degradation endpoints to be used in the surface/water exposure assessment of the parent compound and its metabolites. For fenpyroximate experts agreed that a geomean soil DegT50 of 68.4 d (based on 5 soils from laboratory studies) to be used for the surface water/sediment exposure assessment. For the metabolites, some small discrepancies have been noted in the soil geomean DegT50 values for metabolites M-3, M-8 and M-1. Regarding degradation and formation fractions in surface/water sediment for fenpyroximate and its metabolites, nothing changed and then degradation endpoints to be used in the surface water/sediment exposure assessment were not discussed. Open point: RMS to check and correct in the updated RAR the soil geomean DegT50 values for metabolites M-3, M-8 and M-1. In the LoEP the 'Rate of degradation in soil (aerobic) laboratory studies transformation products' and in the 'PEC surface water and PEC sediment' sections should be updated accordingly, and if necessary a note should be added to clarify the correct values that should be used in the future surface water/sediment exposure assessment for metabolites M-3, M-8 and M-1. Open point: RMS to update the RAR providing the initial PECsw,sed, and also the full time series of the actual and weighted average values. The LoEP should be amended accordingly.

REPORT OF PESTICIDE PEER REVIEW TC 61

OXAMYL– AIR III

Rapporteur Member State: IT

4. Environmental fate and behaviour

Date: 15 September 2021

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
Istituto Superiore di Sanità	IT
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	NL
Institute of Environmental Protection – National Research Institute	PL
External expert	CH

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Discussion points/Outcome

4. Environmental fate and behaviour

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Subject	Conclusions Pesticide Peer Review Meeting
Experts' consultation 4.1 Experts to discuss and agree on the acceptability of degradation endpoints derived for metabolite IN-D2708 in soils Speyer 582 and LRAD 588 in the kinetic evaluation study [B.8.1.2.1.2/03]. Experts to discuss and agree on the endpoints to be used for the exposure assessment of metabolite IN-D2708.	The new kinetic evaluation was presented for metabolite IN-D2708 in soils Speyer 582 and LRAD 588. For soil LRA-D 558, despite some statistical shortcomings on the fitting of the precursor IN-A2213, the visual fit and the statical analysis of metabolite IN-D2708 using DFOP kinetic model was considered acceptable. For soil Speyer 582, the use of SFO kinetic model was considered acceptable for deriving the degradation endpoints for metabolite IN-D2708 from precursor IN-A2213. The majority of experts agreed to use DFOP kinetic model to derive degradation endpoints for metabolite IN-D2708 in soil LRA-D 588, resulting in a DegT50 of 53.6 d and ff=0.51 (from precursor IN-A2213), and to use SFO kinetic model to derive degradation endpoints for metabolite IN-D2708 in soil Speyer 582, resulting in DegT50 of 77 d and ff=1 (from precursor IN-A2213). Overall, experts agreed that for metabolite IN-D2708 a soil DT50 of 77 d should be used in the soil exposure assessment, and an overall geomean soil DegT50 of 8.4 d should be used in the groundwater and surface water/sediment exposure assessment. No actions for RMS.
Experts' consultation 4.2 Experts to discuss and agree on the acceptability of the	Regarding the acceptability of the Drummer soil it was considered that the soil pH is not so low to trigger an exclusion of the soil. Furthermore, in relation to the low biomass it was pointed out that the recommendations of the OECD 307 guidelines on the microbial activity

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Drummer soil in the aerobic degradation study, if this soil should be excluded or not from the pH dependency evaluation, and on the pH dependency on degradation of oxamyl. Experts to agree on the use of the DT50 values from literature studies to assess the effect of soil pH on oxamyl degradation in soil and to agree on the degradation endpoints to be used for the exposure assessment of oxamyl.	of the test soil (not <1% of the OC) are not that strict to trigger the exclusion of the Drummer soil. It was also noted that there might be different degradation pattern in Drummer compared to the other soils Overall on balance the majority of experts agreed to keep the values of Drummer soil to derive the degradation endpoints. The use of the DT50 values from soils coming from the literature in the assessment of pH dependency on the degradation of oxamyl was discussed. A qualitative analysis of these data shown a relation between pH and degradation. However, several uncertainties were highlighted, such as how the pH was measured, the influence of the soil moisture content was taken into account only in few studies, literature studies are quite old, and the origin of the soils in the literature studies is not known. Furthermore, it is not clear how the literature data were analysed and if a reliability and relevance assessment was done. Overall experts considered that the data coming from the literature studies should not be used in the assessment as a solid and transparent reliability and relevance assessment of the studies is missing. However, the trend of the regulatory lab and the literature data looks similar, but the results of the regulatory lab studies available in the RAR (coming from reliable studies) showed no clear pH dependence. In this particular case there was not a clear majority on the existence or not of pH dependency. Overall experts agreed that based on the available lab regulatory data there are not enough evidence to show a clear pH dependence. Open point: RMS to update the kinetic assessment for Drummer soil, apply the EFSA guidance endpoint selector for combining lab and field DegT50 and recalculate the overall geomean for oxamyl. Open point: RMS to update the RAR reflecting the conclusion of this experts' consultation and indicating that no clear pH dependency can be established for degradation of oxamyl. The LoEP should be amended accordingly. Open point: RMS to perform the exposure assessment using the overall soil geomean DegT50, including the Drummer soil (the final geomean value is pending from the action of the RMS on re-evaluating the kinetic

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	assessment for Drummer soil and apply the EFSA guidance endpoint selector for combining lab and field DegT50 values), and explain that the environmental exposure assumes that there is no pH-dependency. See also Experts' consultation 4.3 Data gap: the potential pH dependency of the soil degradation of oxamyl should be investigated in acid soils.
Experts' consultation 4.3 Experts to discuss and the agree on the adsorption endpoints to be used for the exposure assessment of oxamyl.	Experts agreed that it is not acceptable to include the results of the adsorption study done at 10°C as the adsorption constants associated to an equilibrium process are dependent of the temperature. The results of the OECD 106 calculation tool confirmed that the results of the soils Gross Umstadt, Nijmegen, Commerce and Mattapex are not acceptable. Therefore, since adsorption endpoints for oxamyl can be derived only using the Drummer soil experts agreed that for the exposure assessment of oxamyl two sets of calculations should be performed using the default worst case Kfoc values of 10 ml/g and 10000 ml/g and a 1/n of 1. Open point: RMS to update the RAR reflecting the results of this experts' consultation and including the results of the OECD 106 calculation tool for the soils Gross Umstadt, Nijmegen, Mattapex, Commerce and Drummer. RMS to provide an updated exposure assessment performing two sets of calculations for oxamyl using the default worst case Kfoc values of 10 ml/g and 10000 ml/g and a 1/n of 1. The LoEP should be amended accordingly. See also Experts' consultation 4.2. Open point: RMS to update the LoEP deleting the adsorption endpoints derived from the study done at 10°C. Data gap: adsorption data at 20°C should be provided for at least three additional soils for oxamyl.
Experts' consultation 4.4 Experts to discuss and agree on the use of the standard FOCUS scenarios to perform the ground and surface water exposure assessment for the	The use on solarization is done only in high technology or permanent closed greenhouses and the product is applied on bare soils with drip irrigation. The soil is covered with a plastic sheet to raise soil temperature above 40°C and no irrigation is performed. The groundwater exposure assessment was done at Tier 1 using the standard FOCUS groundwater scenarios. Calculations were performed also at Tier 2b increasing the temperature of the standard scenarios of

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use solarization for Oxamyl 10 SL.	2°C, 20 mm of irrigation was considered at the day before the application to set the soil moisture content to field capacity. It was argued that the justification of using an increase of 2°C is not clear. Additional PECgroundwater were calculated with greenhouse specific models and scenarios such as GEM, PEARL with special Pistoia scenario and PEARL with GASP-S. Overall experts agreed that the using these specific models and scenarios and the calculations performed at Tier 2b are not acceptable. Experts agreed to use only Tier 1 simulations (i.e. following an open field approach) to conclude on the groundwater exposure assessment. For the surface water exposure assessment experts agreed that the calculations done for D scenarios at Step 3a performed following an open field approach were considered acceptable to cover the representative use on solarization. Open point: EFSA to reflect in the conclusion that an attempt was done at Tier 2 for covering the ground water exposure assessment for the representative use on solarization. Open point: RMS to delete from the LoEP the results of the PEC groundwater done at Tier 2b and the additional PECgw calculated with greenhouse specific models and scenarios.