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CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment for the active substance pinoxaden in light of confirmatory data submitted

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State Austria, for the pesticide active substance pinoxaden are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory information in the areas of environmental fate, mammalian toxicology and residues. The conclusions were reached on the basis of the evaluation of the representative uses of pinoxaden as a herbicide in winter and spring cereals. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and/or literature in the dossier peer reviewed, are presented. Concerns are identified.

KEYWORDS

confirmatory information, herbicide, peer review, pesticide, Pinoxaden, risk assessment

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SUMMARY

Pinoxaden was included in Annex I to Directive 91/414/EEC on 1 July 2016 by Commission Implementing Regulation (EU) 2016/370 and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. A specific provision of the approval required the applicant to submit to the European Commission further studies on:

1. a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in groundwater;
2. the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child, Repro 2).

In accordance with the specific provision, the applicant, Syngenta, submitted an updated dossier in August 2018 (addressing confirmatory data under point 1) and in April 2019 (addressing confirmatory data under point 2), which was evaluated by the designated rapporteur Member State (RMS), Austria, in the form of two addenda to the draft assessment report. In compliance with guidance document SANCO 5634/2009-rev.6.1, the RMS distributed the addenda to Member States, the applicant and EFSA for comments on 16 November 2018[1] and on 17 May 2022.[2] The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 30 June 2023. EFSA added its scientific views on the specific points raised during the commenting phase, in column 4 of the reporting table, in the form of a technical report issued in February 2024.

Following consideration of the comments received, the European Commission requested EFSA to organise a peer review of the evaluation by RMS of the confirmatory data and to deliver its conclusions on:

– the relevance of groundwater metabolites – in particular whether the general approach to consider data from metabolite M3 to address the relevance of metabolites M11, M54, M55 and M56 is acceptable and whether metabolite M3 is not relevant since divergent views were expressed on the outcome of the developmental toxicity study in rabbits (NOAEL setting in the developmental toxicity study on M3 in rabbits; as well as of the comparison to a threshold of concern of 0.02 µg/kg body weight per day at groundwater relevance assessment Step 4). In case step 4 of the relevance assessment according to European Commission guidance document Sanco/221/2000 would be triggered for one or more of the metabolites, an assessment of the exposure of consumers to the metabolites from sources other than drinking water (i.e. food) should also be performed to enable comparison to the threshold of concern of 0.02 µg/kg body weight per day.
  Moreover, the consultation process also revealed divergent views on the differences in toxicity of groundwater metabolites containing a chiral centre (i.e. all of them except M3 and M11) and additional ACCase (acetyl-CoA carboxylase) inhibition activity by pinoxaden metabolites.
– The residue definition for monitoring in groundwater.
– The modelling endpoints to be used at different tiers for the groundwater exposure assessment – in particular, the modelling for metabolite M55 degradation, possible pH dependence, kinetic formation fractions between metabolites M2 and M3, plus the approach for deriving KFoc values in particular for the Marsillargues soil and metabolite M52.
– The use of groundwater monitoring data, in particular scaling groundwater concentrations measured in the monitoring studies to account for differences between farmer practice at monitored sites and the intended uses that need to be assessed as well as the appropriate practice regarding temporal sampling and temporal practice for expressing concentrations when using them to compare to parametric limits, in the context of edge of field sampling wells, for samples from the saturated zone.

The following conclusions are derived.

The information available on **environmental fate and behaviour** was sufficient to complete the necessary groundwater exposure assessment for the representative uses assessed. Information from the highest tier of assessment indicated groundwater exposure by relevant metabolites above the parametric drinking water limit of 0.1 µg/L occurred in 5 of the 70 vulnerable sites monitored. This was the case for 4 of the 21 sites assessed as being representative of the Thiva FOCUS (FOrum for Co-ordination of pesticide fate models and their Use) climate zone and 1 of the 33 sites assessed as being representative of the Hamburg FOCUS climate zone.

Information available on **mammalian toxicology** allows to conclude that metabolite M3 is not relevant based on hazard assessment according to step 3b and 3c of the European Commission guidance document Sanco/221/2000 (screening for toxicity). This was not the case for metabolites M2, M52 and M11, M54, M55 and M56, which are considered relevant.

EFSA reviewed the available data on M3 **residues in food and feed**, provided an exposure assessment and a refined assessment of the potential toxicological significance of M3 for consumers according to the European Commission guidance document Sanco/221/2000. Although the dietary intake assessment for M3 is provisional due to incomplete data availability and the need for conservative assumptions, combined chronic dietary exposure from both food and water is reasonably expected to remain well below the ADI set for M3 for all population groups.

[1]Addendum 1 containing the RMS assessment of the confirmatory data set under point 1 (Austria, 2018).

[2]Addendum 2 containing the RMS assessment of the confirmatory data set under point 2 (Austria, 2022).

BACKGROUND

Pinoxaden was included in Annex I to Directive 91/414/EEC[3] on 1 July 2016 by Commission Implementing Regulation (EU) 2016/370,[4] and has been deemed to be approved under Regulation (EC) No 1107/2009,[5] in accordance with Commission Implementing Regulation (EU) No 540/2011,[6] as amended by Commission Implementing Regulation (EU) No 541/2011.[7] EFSA previously published a Conclusion on this active substance on 16 August 2013 (EFSA, 2013) and the Technical Report outlining the outcome of the consultation with Member States, the applicant and EFSA on the pesticides risk assessment in light of confirmatory data published on 20 February 2024 (EFSA, 2024).

It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on:

1. a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in groundwater;
2. the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child).

In accordance with the specific provision, the applicant, Syngenta, submitted an updated dossier in August 2018 (addressing confirmatory information under point 1), and in April 2019 (addressing confirmatory data under point 2), which was evaluated by the designated rapporteur Member State (RMS), Austria, in the form of addenda to the draft assessment report (Austria, 2018, 2022). In compliance with guidance document SANCO 5634/2009-rev.6.1 (European Commission, 2013), the RMS distributed the addenda to Member States, the applicant and the EFSA for comments on 16 November 2018 and on 17 May 2022. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 30 June 2023. EFSA added its scientific views on the specific points raised during the commenting phase, in column 4 of the reporting table, in the form of a technical report issued in February 2024 (EFSA, 2024).

Following consideration of the comments received, the European Commission requested EFSA to organise a peer review of the evaluation by RMS of the confirmatory data and to deliver its conclusions on:

- The relevance of groundwater metabolites - in particular whether the general approach to consider data from metabolite M3 to address the relevance of metabolites M11, M54, M55 and M56 is acceptable and whether metabolite M3 is not relevant since divergent views were expressed on the outcome of the developmental toxicity study in rabbits (NOAEL setting in the developmental toxicity study on M3 in rabbits; as well as of the comparison to a threshold of concern of 0.02 µg/kg body weight per day at groundwater relevance assessment Step 4). In case step 4 of the relevance assessment according to European Commission guidance document Sanco/221/2000 would be triggered for one or more of the metabolites, an assessment of the exposure of consumers to the metabolites from sources other than drinking water (i.e. food) should also be performed to enable comparison to the threshold of concern of 0.02 µg/kg body weight per day.
  Moreover, the consultation process also revealed divergent views on the differences in toxicity of groundwater metabolites containing a chiral centre (i.e. all of them except M3 and M11) and additional ACCase (acetyl-CoA carboxylase) inhibition activity by pinoxaden metabolites.
- The residue definition for monitoring in groundwater.
- The modelling endpoints to be used at different tiers for the groundwater exposure assessment - in particular, the modelling for metabolite M55 degradation, possible pH dependence, kinetic formation fractions between metabolites M2 and M3, plus the approach for deriving KFoc values in particular for the Marsillargues soil and metabolite M52.
- The use of groundwater monitoring data, in particular scaling groundwater concentrations measured in the monitoring studies to account for differences between farmer practice at monitored sites and the intended uses that need to be assessed as well as the appropriate practice regarding temporal sampling and temporal practice for expressing concentrations when using them to compare to parametric limits, in the context of edge of field sampling wells, for samples from the saturated zone.

The addenda to the revised RAR were discussed at the Pesticides Peer Review Experts' teleconferences (TC) 148 and 149 on environmental fate and behaviour, and mammalian toxicology, respectively, in September 2024. Details of the issues discussed, together with the outcome of these discussions were recorded in the respective meeting reports.

[3]Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

[4]Commission Implementing Regulation (EU) 2016/370 of 15 March 2016 approving the active substance pinoxaden, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 70, 16.3.2016, p. 7–11.

[5]Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[6]Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[7]Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

A final consultation on the conclusions arising from the peer review took place with Member States via a written procedure in June – July 2025.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS's evaluation of the confirmatory data submitted in relation to the risk assessment of groundwater metabolites. A key supporting document to this conclusion is the peer review report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the compilation of comments in the reporting table to the conclusion. The peer review report (EFSA, 2025) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the reports of the scientific consultations with Member State experts
- the comments received on the draft EFSA conclusion

Given the importance of the DAR including the final addendum to it (with reference to confirmatory information point 2) (Austria, December 2024) and the peer review report, these documents are considered as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATION FOR REPRESENTATIVE USES

Pinoxaden is the ISO common name for 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate (IUPAC) (following the 1979 IUPAC rules it had been 8-(2,6-diethyl-*p*-tolyl)-1,2,4,5-tetrahydro-7-oxo-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate).

The formulation for representative uses of the new active substance evaluation was 'Axial' (code A-12303 C), an emulsifiable concentrate (EC) containing 100 g/L pinoxaden. It should be noted that this formulation always needs to be used with the adjuvant coded A-12127R.[8]

The representative uses evaluated comprise applications by foliar broadcast spraying against grassweeds in crops of winter and spring cereals including durum wheat. Full details of the GAPs can be found in the list of end points in Appendix B.

CONCLUSIONS OF THE EVALUATION

1 | ENVIRONMENTAL FATE AND BEHAVIOUR

Pinoxaden was discussed during the Pesticides Peer Review Experts' meeting 101 (March 2013) and the confirmatory information on groundwater metabolites in TC 149 (September 2024).

Route and rate of degradation of pinoxaden under dark aerobic conditions was investigated at 20–25°C in twelve soils with the substance ^{14}C labelled in one of the rings (phenyl ring, pyrazole ring or oxadiazepine ring). In all these experiments pinoxaden exhibited very low to low persistence and it was quickly hydrolysed to pivalic acid and M2 (max. 89.7% applied radioactivity (AR)) that subsequently underwent oxidation at the pyrazole ring to form M3 (30.6% AR). Initial degradation of pinoxaden seemed to be abiotic since it was also quickly degraded under sterile conditions. Single first-order (SFO) DT_{50} and formation fractions of metabolites M2 and M3 were derived with a multicompartmental kinetic analysis (FOCUS, 2006). In these experiments, M2 exhibited low to moderate persistence and M3 exhibited moderate to high persistent. Due to the fact that degradation of M3 was expected to be pH dependent and the 12 soils in which pinoxaden was incubated did not include the lower end of the acidic soil conditions for agricultural soils, an ad hoc study of the dark aerobic degradation of M3 in acidic soils was included in the dossier. In the three more acidic soils investigated, M3 exhibited high to very high persistence. In aerobic dark soil incubations where metabolites identified in lysimeter leachate (see 4 paragraphs below) M11, M52, M54, M55 and M56 were dosed, the metabolites exhibited: low to moderate, low, low, low to medium and moderate to high persistence respectively. A pH dependence of degradation was identified as needing to be accounted for in predicted environmental concentration (PEC) calculations for M3 and M55. In incubations where pinoxaden was dosed, unextractable residues accounted for 32.0%–63.4% AR after 100–120 days depending on the soil and moiety labelled. Mineralisation to CO_2 accounted for 4.3%–47.6% AR after 100–120 days.

The route of degradation of pinoxaden under aerobic (3 h)/anaerobic (119 days) dark conditions at 20°C was investigated in one soil. Pinoxaden still degraded rapidly to M2 (max 94.4%), which then remained stable under these conditions. Mineralisation was negligible (CO_2 = 0.1% AR) and very minor amounts of unextractable residue were formed.

[8]For the confirmatory information submission, based on the information in the GAP table (available in the latest list of endpoints update provided by the RMS (see Appendix B)), the formulation for the representative uses (A13814D) is a different formulation to the one previously peer reviewed (A-12303 C) (EFSA, 2013). Detailed information on its composition has not been included in an updated volume 4 to the draft assessment report by the RMS.

Photolysis of pinoxaden on soil was investigated in two microbially active soils with either the ^{14}C phenyl or ^{14}C pyrazole labelled pinoxaden at 20 or 25°C under simulated sunlight. Photolysis may contribute to the degradation of soil metabolites M2 and M3. A novel major photolysis metabolite was identified in one of the studies SYN 515622 (max. 20.4% AR after 6 days continuous irradiation). Some unidentified components reached 5% in two consecutive sampling points or at the study end. In another experiment metabolite NOA 437397 reached a maximum of 6.7% AR at the study end. During the peer review it was concluded that, in agreement with the RMS assessment, for the representative use proposed (post emergence autumn and spring applications) it is unlikely that these metabolites will reach levels that would need to be considered with respect to the groundwater exposure assessment. However, Member States may need to consider them for the authorisation of other pinoxaden products with different GAPs.

Field soil dissipation studies were carried out with formulated pinoxaden in Italy (four studies, three sites), Spain (four studies, two sites) and Germany (two studies, two sites) and two studies with ^{14}C labelled pinoxaden in the phenyl ring were performed in Switzerland (one site). Different application patterns were used in these studies following the proposed representative uses. Kinetic parameters derived for the metabolite M2 from field studies were considered acceptable during the experts' consultation of its use for environmental modelling. Field dissipation studies at trial sites one each in Spain, Germany and France where treated plots had acidic pH where metabolite M3 was dosed were also used to derive kinetic parameters for environmental modelling. Under these field conditions M3 exhibited moderate to medium persistence. Field persistence endpoints for metabolite M2 have not been derived.

Two lysimeter studies were carried out with ^{14}C-phenyl labelled pinoxaden in Switzerland and Germany. In the Swiss study the principal metabolite found in the leachate in each experimental year was M3 (max. annual average concentration = 0.07–0.15 µg/L in the first year). In the German study, a number of metabolites exceeded the 0.1 µg/L trigger during the second and/or third experimental years: M3, M52, M11 (SYN 504574), M54, M55, M56. The annual average leachate concentrations can be found in Table 13. Batch adsorption studies in a total of 9 soils for pinoxaden, 12 soils for M2, 8 soils for M3 and 3 soils each for M11, M52, M54, M55 and M56 were available in the dossier. According to these studies, pinoxaden exhibited high to medium mobility and metabolites M2, M3, M11, M54, M55 and M56 exhibited very high soil mobility. M52 exhibited high mobility. None of the compounds was identified as needing pH dependent adsorption to be taken into account in the modelling of PEC concentrations.

Hydrolysis of pinoxaden and metabolite M3 was investigated in buffered sterile solutions at pHs between 4 and 9. Hydrolysis of pinoxaden and metabolite M3 was pH dependent, being faster at alkaline pH values. The main hydrolysis metabolite of pinoxaden was M2 that was stable to hydrolysis under all the conditions tested. As surface water exposure and risk was not the topic of confirmatory data, EFSA Conclusion (2013) is where information on aqueous photolysis, natural sediment water systems and predicted surface water and sediment concentrations consequent to the representative uses, can be found.

Potential groundwater contamination for pinoxaden and metabolites M2, M3, M11, M52, M54, M55 and M56 was addressed by calculation of the 20 years 80th percentile annual average leachate concentrations at 1m depth with PEARL v4.4.4 for the representative uses and using the input parameters agreed during the peer review (see Pesticides Peer Review Experts' meeting 101 report[9] and Teleconference 149 report for further details (EFSA, 2025)). According to these calculations pinoxaden and metabolite M2 would not be expected to exceed the limit of 0.1 µg/L. Metabolites M11, M55 and M56 will exceed the limit of 0.1 µg/L on this basis in all simulated scenarios with M55 and M56 also exceeding 0.75 µg/L at all scenarios except for Okehampton winter cereals, whilst M11 was exceeding 0.75 µg/L at just the Jokioinen (winter and spring cereals) and Hamburg (spring cereals) scenarios. Metabolites M3 and M54 will exceed the limit of 0.1 µg/L in all simulated scenarios and uses except for winter cereals at the Sevilla scenario, with just M3 exceeding 0.75 µg/L in the majority of them (the M3 exceptions being winter cereals at Thiva and spring cereals at Chateaudun and Porto). For Metabolite M52 concentrations only exceeded 0.1 µg/L at the Hamburg (winter and spring cereals) and Okehampton (winter cereals) scenarios.

The applicant implemented a targeted edge of field groundwater monitoring programme, across five European countries (France, Germany, Italy, Lithuania and the UK) to investigate the leaching potential of pinoxaden soil metabolites M2, M3, M11, M52, M54, M55 and M56 in vulnerable settings where farmer product use records were available under realistic use conditions.

The objectives stated for the monitoring programme were to:

- Install a new groundwater monitoring network in representative cereal land use areas defined as vulnerable according to environmental models (representing Tier 4 in the tiered assessment scheme for groundwater exposure assessment according to European Commission, 2014).
- Determine the concentrations of the seven pinoxaden soil metabolites M2, M3, M11, M52, M54, M55 and M56 in EU groundwater at vulnerable field sites across the EU, with an understanding of the vulnerability of the site in an EU context.
- Contextualise groundwater monitoring sites across the vulnerability distribution of the EU through extrapolation across EU FOCUS groundwater scenarios for other EU Member States.
- Demonstrate whether the use of pinoxaden on highly vulnerable areas might result in these metabolites being present in groundwater at levels above a parametric value of 0.1 µg/L, with indications of the extent to which this may occur.

[9]See it in the Pinoxaden peer review report available in OpenEFSA (under supporting documents) at the following link: https://open.efsa.europa.eu/questions/EFSA-Q-2009-00329.

The Pesticides Peer Review Experts' TC 149 report provides an overview of the experts views on the: (i) selection of the candidate areas for monitoring; (ii) selection of the sites where monitoring wells were installed and samples taken; (iii) characterisation of the soil column and climate at the sites; (iv) well installation, instrumentation and maintenance; (v) storage stability of pinoxaden metabolites in chilled and frozen groundwater; (vi) use history at the monitoring sites; (vii) hydraulic connectivity assessment between field of known treatment history and sampling wells; (viii) assessment of the monitoring sites' leaching vulnerability, contextualisation of the monitoring sites, the best ways to report and analyse the concentration results for each site and across sites including temporal considerations. That is, considerations that any percentile concentration accounts for spatial aspects when considering all time high concentrations of a given number of wells and for spatial/temporal aspects when considering maximum concentrations of individual years of a given number of wells. The experts' views on the uncertainties that exist related to these eight aspects can be found in the TC 149 report (EFSA, 2025).

The experts[10] concluded that all time high and/or annual maximum sample concentration (measured and dose rate-normalised) for the pinoxaden metabolites over the entire monitoring period at some spatial assessment levels (whole EU, FOCUS climate zones) were appropriate to be used for calculating temporal percentiles and presenting the number of sites above 0.1 µg/L, to be considered for decision making. Annual mean sample concentrations were not considered sufficiently robust for use in decision making. Some experts considered the other spatial assessment levels available (central and southern EU regulatory zones, individual member states) might also have utility in combination with the aforementioned temporal percentiles.

It was clarified that at sites with multiple sampling wells at each sampling date only the maximum value was taken into account in the RMS presentation of the detailed results tables. It was highlighted that as protection goals when using targeted monitoring data have not been defined for EU level decision making, it is difficult to find the best way to present the results in a unique way. The use of any spatial (considering all time high concentrations of a given number of wells) or spatial/temporal percentile (considering maximum concentrations of individual years of a given number of wells) was discussed. It was discussed that the percentile from lower tiers, when leaching concentrations in the unsaturated zones are estimated by modelling (annual average recharge concentrations leaving the top 1m of the soil column), is more understood as an operational protection goal to ensure a higher level of protection in the groundwater. Therefore, the experts did not consider a 90th percentile defensible for actual groundwater (i.e. the saturated zone), considering also that only quarterly sampling had been carried out in the monitoring programme. The use of a temporal percentile above the 90th (e.g. the 95th, 97th or 99th percentile) when monitored samples are taken from actual (shallow) groundwater (i.e. the saturated zone) was supported as appropriate by the experts. Therefore, the results as follows (Tables 1–12 which present results for the whole EU and the FOCUS climate zones (Hamburg and Thiva) for which more than 20 sites were available) have been presented here in the main conclusion. Results for the central and southern EU regulatory zones and individual member states[11] are however available in Appendix B. The experts agreed[12] that it was appropriate to use non-linear scaling on the monitored results (accounting for the phenomenon of concentration dependent soil adsorption), so that risk managers had data that better reflected the representative good agricultural practices (GAPs) regarding the dose rates being assessed and not just the farmer practice at the monitored sites, where dose rates and application frequency were typically lower than the GAP. Note that the scaling approach has not accounted for the aspect of lower application frequency (which at the monitored sites was typically triennial application, with at best a few sites representing biennial application). As risk managers may have interest in the not scaled (as measured) results, these have also been provided (Tables 1, 3, 5, 7, 9 and 11 and in Appendix B).

A. Sample based assessment

TABLE 1 EU (all 70 sites) – as measured (in the below table and following ones, cells are highlighted in grey when concentration values are above 0.1 µg/L).

	M2	M3*	M11	M52	M54	M55[a]	M56
n samples[b]	1589	1589	1589	1589	1589	1589	1589
n ≤ LOD	1549	1350	1511	1528	1560	1519	1340
% ≤ LOD	97.5	85.0	95.1	96.2	98.2	95.6	84.3
n > LOD	40	239	78	61	29	70	249
% > LOD	2.5	15.0	4.9	3.8	1.8	4.4	15.7
n > LOQ	4	72	11	32	5	20	70
% > LOQ	0.3	4.5	0.7	2.0	0.3	1.3	4.4
n > 0.1 µg/L	0	17	1	2	0	1	0
% > 0.1 µg/L	0.0	1.1	0.1	0.1	0.0	0.1	0.0

(Continues)

[10]See experts' consultation points 4.6 and 4.7 at the Pesticides Peer Review Experts' TC 149 (EFSA, 2025).

[11]That can be considered more pertinent for zonal or national assessments.

[12]See experts' consultation points 4.6 and 4.7 at the Pesticides Peer Review Experts' TC 149 (EFSA, 2025).

TABLE 1 (Continued)

		M2	M3*	M11	M52	M54	M55[a]	M56
Max. (µg/L)		0.064	0.361	0.108	0.162	0.051	0.107	0.095
All time high concentration ($n=70$)	99th perc.[c]	0.045	0.222	**0.102**	**0.139**	0.045	0.084	0.078
	97th perc.[c]	0.022	0.086	0.076	0.093	0.039	0.061	0.058
	95th perc.[c]	0.021	0.082	0.058	0.080	0.035	0.055	0.054
Annual max. concentrations ($n=70\times5=350$)[d]	99th perc.[c]	0.021	0.149	0.058	0.080	0.035	0.055	0.061
	97th perc.[c]	0.012	0.059	0.026	0.059	0.017	0.029	0.041
	95th perc.[c]	0.009	0.031	0.022	0.044	0.012	0.021	0.032

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).

LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).

Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.

Abbreviations: LOD, limit of detection; LOQ, limit of quantification.

[a]Corrected to account for limited sample storage stability ($DT_{50}=9.2$ days).

[b]Sampling occasions; in case of multiple results at a single sampling occasion (due to multiple *sampling* wells installed) only the maximum concentration at each sampling occasion has been considered.

[c]MS EXCEL's quantil.incl() function.

[d]On basis of annual max. concentrations of 2015, 2016, 2017, 2018 and 2019; occasional samples in 01/2020 considered to represent 2019 samples.

*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 2 EU (all 70 sites) – rate-normalised (non-linear scaling approach).

		M2	M3*	M11	M52	M54	M55[a]	M56
n samples[b]		1589	1589	1589	1589	1589	1589	1589
n ≤ LOD		1549	1350	1511	1528	1560	1519	1340
% ≤ LOD		97.5	85.0	95.1	96.2	98.2	95.6	84.3
n > LOD		40	239	78	61	29	70	249
% > LOD		2.5	15.0	4.9	3.8	1.8	4.4	15.7
n > LOQ		8	109	22	35	12	33	107
% > LOQ		0.5	6.9	1.4	2.2	0.8	2.1	6.7
n > 0.1 µg/L		2	24	2	5	1	2	6
% > 0.1 µg/L		0.1	1.5	0.1	0.3	0.1	0.1	0.4
Max. (µg/L)		0.129	0.483	0.154	0.261	0.151	0.122	0.122
All time high concentration ($n=70$)	99th perc.[c]	0.091	0.388	**0.146**	**0.186**	**0.102**	**0.122**	**0.111**
	97th perc.[c]	0.029	0.177	0.098	**0.138**	0.070	0.077	0.076
	95th perc.[c]	0.025	0.113	0.081	**0.110**	0.058	0.063	0.069
Annual max. concentrations ($n=70\times5=350$)[d]	99th perc.[c]	0.025	0.215	0.082	**0.110**	0.069	0.062	0.079
	97th perc.[c]	0.015	0.079	0.038	0.065	0.030	0.038	0.054
	95th perc.[c]	0.011	0.042	0.026	0.041	0.016	0.027	0.039

LOD = 0.0075 µg/L (0.015 µg/L from 06/2015–01/2016).

LOQ = 0.025 µg/L (0.05 g/L from 06/2015–01/2016).

Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.

Abbreviations: LOD, limit of detection; LOQ, limit of quantification.

[a]Corrected to account for limited sample storage stability ($DT_{50}=9.2$ days).

[b]Sampling occasions; in case of multiple results at a single sampling occasion (due to multiple *sampling* wells installed) only the maximum concentration at each sampling occasion has been considered.

[c]MS EXCEL's quantil.incl() function.

[d]On basis of annual max. concentrations of 2015, 2016, 2017, 2018 and 2019; occasional samples in 01/2020 considered to represent 2019 samples.

*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 3 FOCUS climate zone Hamburg (33 sites) – as measured.

	M2	M3*	M11	M52	M54	M55[a]	M56
n samples[b]	893	893	893	893	893	893	893
n ≤ LOD	862	741	840	874	875	850	693
% ≤ LOD	96.5	83.0	94.1	97.9	98.0	95.2	77.6
n > LOD	31	152	53	19	18	43	200
% > LOD	3.5	17.0	5.9	2.1	2.0	4.8	22.4
n > LOQ	2	38	1	11	4	10	50

TABLE 3 (Continued)

		M2	M3*	M11	M52	M54	M55[a]	M56
% > LOQ		0.2	4.3	0.1	1.2	0.4	1.1	5.6
n > 0.1 µg/L		0	0	0	0	0	1	0
% > 0.1 µg/L		0.0	0.0	0.0	0.0	0.0	0.1	0.0
Max. (µg/L)		0.037	0.086	0.031	0.072	0.051	0.107	0.071
All time high concentration (*n* = 33)	99th perc.[c]	0.032	0.085	0.029	0.066	0.048	0.088	0.067
	97th perc.[c]	0.022	0.083	0.024	0.055	0.043	0.051	0.059
	95th perc.[c]	0.020	0.082	0.023	0.043	0.041	0.042	0.056
Annual max. concentrations (*n* = 33 × 5 = 165)[d]	99th perc.[c]	0.020	0.082	0.023	0.057	0.040	0.041	0.056
	97th perc.[c]	0.014	0.057	0.021	0.027	0.025	0.029	0.046
	95th perc.[c]	0.011	0.032	0.014	0.018	0.016	0.026	0.034

LOD = 0.0075 µg/L (0.015 µg/L from 06/2015–01/2016).

LOQ = 0.025 µg/L (0.05 g/L from 06/2015–01/2016).

Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.

Abbreviations: LOD, limit of detection; LOQ, limit of quantification.

[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).

[b]Sampling occasions; in case of multiple results at a single sampling occasion (due to multiple *sampling* wells installed) only the maximum concentration at each sampling occasion has been considered.

[c]MS EXCEL's quantil.incl() function.

[d]On basis of annual max. concentrations of 2015, 2016, 2017, 2018 and 2019; occasional samples in 01/2020 considered to represent 2019 samples.

*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 4 FOCUS climate zone Hamburg (33 sites) – rate-normalised (non-linear scaling approach).

		M2	M3*	M11	M52	M54	M55[a]	M56
n samples[b]		893	893	893	893	893	893	893
n ≤ LOD		862	741	840	874	875	850	693
% ≤ LOD		96.5	83.0	94.1	97.9	98.0	95.2	77.6
n > LOD		31	152	53	19	18	43	200
% > LOD		3.5	17.0	5.9	2.1	2.0	4.8	22.4
n > LOQ		4	69	7	12	10	19	79
% > LOQ		0.4	7.7	0.8	1.3	1.1	2.1	8.8
n > 0.1 µg/L		0	4	0	0	1	1	1
% > 0.1 µg/L		0.0	0.4	0.0	0.0	0.1	0.1	0.1
Max. (µg/L)		0.074	0.182	0.046	0.075	0.151	0.121	0.106
All time high concentration (*n* = 33)	99th perc.[c]	0.059	0.160	0.046	0.071	**0.128**	**0.100**	0.096
	97th perc.[c]	0.028	0.117	0.046	0.062	0.083	0.058	0.077
	95th perc.[c]	0.025	0.112	0.035	0.048	0.074	0.053	0.073
Annual max. concentrations (*n* = 33 × 5 = 165)[d]	99th perc.[c]	0.025	0.112	0.034	0.062	0.076	0.052	0.072
	97th perc.[c]	0.017	0.076	0.026	0.035	0.064	0.041	0.066
	95th perc.[c]	0.014	0.046	0.022	0.020	0.030	0.033	0.045

LOD = 0.0075 µg/L (0.015 µg/L from 06/2015–01/2016).

LOQ = 0.025 µg/L (0.05 g/L from 06/2015–01/2016).

Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.

Abbreviations: LOD, limit of detection; LOQ, limit of quantification.

[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).

[b]Sampling occasions; in case of multiple results at a single sampling occasion (due to multiple *sampling* wells installed) only the maximum concentration at each sampling occasion has been considered.

[c]MS EXCEL's quantil.incl() function.

[d]On basis of annual max. concentrations of 2015, 2016, 2017, 2018 and 2019; occasional samples in 01/2020 considered to represent 2019 samples.

*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 5 FOCUS climate zone Thiva (21 sites) – as measured.

		M2	M3*	M11	M52	M54	M55[a]	M56
n samples[b]		375	375	375	375	375	375	375
n ≤ LOD		370	351	362	348	367	367	367
% ≤ LOD		98.7	93.6	96.5	92.8	97.9	97.9	97.9
n > LOD		5	24	13	27	8	8	8
% > LOD		1.3	6.4	3.5	7.2	2.1	2.1	2.1
n > LOQ		2	2	6	15	1	2	0
% > LOQ		0.5	0.5	1.6	4.0	0.3	0.5	0.0
n > 0.1 µg/L		0	1	1	1	0	0	0
% > 0.1 µg/L		0.0	0.3	0.3	0.3	0.0	0.0	0.0
Max. (µg/L)		0.064	0.160	0.108	0.162	0.034	0.073	0.013
All time high concentration (*n* = 21)	99th perc.[c]	0.053	0.136	0.098	**0.148**	0.032	0.068	0.013
	97th perc.[c]	0.030	0.089	0.077	**0.121**	0.028	0.058	0.013
	95th perc.[c]	0.008	0.042	0.057	0.094	0.024	0.048	0.013
Annual max. concentrations (*n* = 21 × 5 = 105)[d]	99th perc.[c]	0.009	0.041	0.057	0.094	0.024	0.047	0.013
	97th perc.[c]	0.008	0.017	0.046	0.073	0.014	0.017	0.010
	95th perc.[c]	0.008	0.013	0.026	0.064	0.012	0.013	0.009

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).

LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).

Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.

Abbreviations: LOD, limit of detection; LOQ, limit of quantification.

[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).

[b]Sampling occasions; in case of multiple results at a single sampling occasion (due to multiple *sampling* wells installed) only the maximum concentration at each sampling occasion has been considered.

[c]MS EXCEL's quantil.incl() function.

[d]On basis of annual max. concentrations of 2015, 2016, 2017, 2018 and 2019; occasional samples in 01/2020 considered to represent 2019 samples.

*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 6 FOCUS climate zone Thiva (21 sites) – rate-normalised (non-linear scaling approach).

		M2	M3*	M11	M52	M54	M55[a]	M56
n samples[b]		375	375	375	375	375	375	375
n ≤ LOD		370	351	362	348	367	367	367
% ≤ LOD		98.7	93.6	96.5	92.8	97.9	97.9	97.9
n > LOD		5	24	13	27	8	8	8
% > LOD		1.3	6.4	3.5	7.2	2.1	2.1	2.1
n > LOQ		3	3	9	17	2	4	0
% > LOQ		0.8	0.8	2.4	4.5	0.5	1.1	0.0
n > 0.1 µg/L		2	1	1	4	0	0	0
% > 0.1 µg/L		0.5	0.3	0.3	1.1	0.0	0.0	0.0
Max. (µg/L)		0.129	0.345	0.142	0.152	0.038	0.069	0.015
All time high concentration (*n* = 21)	99th perc.[c]	**0.104**	0.281	**0.129**	**0.150**	0.037	0.066	0.015
	97th perc.[c]	0.056	0.154	**0.103**	**0.145**	0.034	0.060	0.013
	95th perc.[c]	0.008	0.026	0.076	**0.140**	0.032	0.054	0.012
Annual max. concentrations (*n* = 21 × 5 = 105)[d]	99th perc.[c]	0.018	0.026	0.075	**0.139**	0.032	0.053	0.012
	97th perc.[c]	0.008	0.023	0.054	**0.105**	0.020	0.025	0.009
	95th perc.[c]	0.008	0.018	0.028	0.071	0.014	0.012	0.008

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).

LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).

Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.

Abbreviations: LOD, limit of detection; LOQ, limit of quantification.

[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).

[b]Sampling occasions; in case of multiple results at a single sampling occasion (due to multiple *sampling* wells installed) only the maximum concentration at each sampling occasion has been considered.

[c]MS EXCEL's quantil.incl() function.

[d]On basis of annual max. concentrations of 2015, 2016, 2017, 2018 and 2019; occasional samples in 01/2020 considered to represent 2019 samples.

*Concluded as not relevant, see Sections 2, 3 and 4.

B. Site based assessment

TABLE 7 EU (all 70 sites) – as measured.

	M2	M3*	M11	M52	M54	M55[a]	M56
n sites	70	70	70	70	70	70	70
n ≤ LOD	57	19	40	38	49	49	43
% ≤ LOD	81.4	27.1	57.1	54.3	70.0	70.0	61.4
n > LOD	13	51	30	32	21	21	27
% > LOD	18.6	72.9	42.9	45.7	30.0	30.0	38.6
n > LOQ	2	13	10	19	5	10	10
% > LOQ	2.9	18.6	14.3	27.1	7.1	14.3	14.3
n > 0.1 µg/L	0	2	1	2	0	1	0
% > 0.1 µg/L	0.0	2.9	1.4	2.9	0.0	1.4	0.0

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).
LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).
Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.
Abbreviations: LOD, limit of detection; LOQ, limit of quantification.
[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).
*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 8 EU (all 70 sites) – rate-normalised (non-linear scaling approach).

	M2	M3*	M11	M52	M54	M55[a]	M56
n sites	70	70	70	70	70	70	70
n ≤ LOD	57	19	40	38	49	49	43
% ≤ LOD	81.4	27.1	57.1	54.3	70.0	70.0	61.4
n > LOD	13	51	30	32	21	21	27
% > LOD	18.6	72.9	42.9	45.7	30.0	30.0	38.6
n > LOQ	4	20	19	21	9	14	12
% > LOQ	5.7	28.6	27.1	30.0	12.9	20.0	17.1
n > 0.1 µg/L	1	5	2	5	1	2	2
% > 0.1 µg/L	1.4	7.1	2.9	7.1	1.4	2.9	2.9

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).
LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).
Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.
Abbreviations: LOD, limit of detection; LOQ, limit of quantification.
[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).
*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 9 FOCUS climate zone Hamburg (33 sites) – as measured.

	M2	M3*	M11	M52	M54	M55[a]	M56
n sites	33	33	33	33	33	33	33
n ≤ LOD	24	9	19	23	22	22	15
% ≤ LOD	72.7	27.3	57.6	69.7	66.7	66.7	45.5
n > LOD	9	24	14	10	11	11	18
% > LOD	27.3	72.7	42.4	30.3	33.3	33.3	54.5
n > LOQ	1	8	1	5	4	6	9
% > LOQ	3.0	24.2	3.0	15.2	12.1	18.2	27.3
n > 0.1 µg/L	0	0	0	0	0	1	0
% > 0.1 µg/L	0.0	0.0	0.0	0.0	0.0	3.0	0.0

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).
LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).
Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.
Abbreviations: LOD, limit of detection; LOQ, limit of quantification.
[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).
*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 10 FOCUS climate zone Hamburg (33 sites) – rate-normalised (non-linear scaling approach).

	M2	M3*	M11	M52	M54	M55[a]	M56
n sites	33	33	33	33	33	33	33
n ≤ LOD	24	9	19	23	22	22	15
% ≤ LOD	72.7	27.3	57.6	69.7	66.7	66.7	45.5
n > LOD	9	24	14	10	11	11	18
% > LOD	27.3	72.7	42.4	30.3	33.3	33.3	54.5
n > LOQ	2	15	6	6	7	8	10
% > LOQ	6.1	45.5	18.2	18.2	21.2	24.2	30.3
n > 0.1 µg/L	0	3	0	0	1	1	1
% > 0.1 µg/L	0.0	9.1	0.0	0.0	3.0	3.0	3.0

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).
LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).
Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.
Abbreviations: LOD, limit of detection; LOQ, limit of quantification.
[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).
*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 11 FOCUS climate zone Thiva (21 sites) – as measured.

	M2	M3*	M11	M52	M54	M55[a]	M56
n sites	21	21	21	21	21	21	21
n ≤ LOD	20	5	11	8	14	15	16
% ≤ LOD	95.2	23.8	52.4	38.1	66.7	71.4	76.2
n > LOD	1	16	10	13	7	6	5
% > LOD	4.8	76.2	47.6	61.9	33.3	28.6	23.8
n > LOQ	1	2	6	10	1	2	0
% > LOQ	4.8	9.5	28.6	47.6	4.8	9.5	0.0
n > 0.1 µg/L	0	1	1	1	0	0	0
% > 0.1 µg/L	0.0	4.8	4.8	4.8	0.0	0.0	0.0

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).
LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).
Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.
Abbreviations: LOD, limit of detection; LOQ, limit of quantification.
[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).
*Concluded as not relevant, see Sections 2, 3 and 4.

TABLE 12 FOCUS climate zone Thiva (21 sites) – rate-normalised (non-linear scaling approach).

	M2	M3*	M11	M52	M54	M55[a]	M56
n sites	21	21	21	21	21	21	21
n ≤ LOD	20	5	11	8	14	15	16
% ≤ LOD	95.2	23.8	52.4	38.1	66.7	71.4	76.2
n > LOD	1	16	10	13	7	6	5
% > LOD	4.8	76.2	47.6	61.9	33.3	28.6	23.8
n > LOQ	1	2	8	11	2	4	0
% > LOQ	4.8	9.5	38.1	52.4	9.5	19.0	0.0
n > 0.1 µg/L	1	1	1	4	0	0	0
% > 0.1 µg/L	4.8	4.8	4.8	19.0	0.0	0.0	0.0

LOD = 0.0075 µg/L (0.015 µg/L from 6/2015–1/2016).
LOQ = 0.025 µg/L (0.05 g/L from 6/2015–1/2016).
Residues < LOD have neither been rate-normalised nor corrected for sample storage stability (M55); residues < LOD set to ½ LOD in all cases.
Abbreviations: LOD, limit of detection; LOQ, limit of quantification.
[a]Corrected to account for limited sample storage stability (DT_{50} = 9.2 days).
*Concluded as not relevant, see Sections 2, 3 and 4.

The PEC in groundwater covering the representative uses assessed as well as the groundwater monitoring results can be found in Appendix B. A key to the persistence and mobility class wording used, relating these words to numerical DT and Koc endpoint values, can be found in Appendix C.

2 | MAMMALIAN TOXICOLOGY

Confirmatory data on groundwater metabolites **M2, M52, M3, M11, M54, M55 and M56** were discussed during the Pesticides Peer Review Expert's TC 148 (September 2024). The assessment is based on the European Commission (EC) guidance document on the relevance of groundwater metabolites (European Commission, 2003).

Metabolite **M2** is considered already **relevant** at **step 3a** of the EC Guidance based on its biological activity comparable to that of the parent pinoxaden (see Table 13 in Section 4).

Based on experimental data, metabolites **M52**, **M3, M11, M52, M54 and M56** are unlikely to be genotoxic (step 3b of the EC Guidance).

M55 is considered **relevant** at **step 3b** of the EC Guidance based on its genotoxic potential since it showed positive results in the bacterial gene mutation assay and equivocal/positive results in the in vivo Comet assay.[13]

Metabolite **M52**[14] is considered a **relevant** groundwater metabolite since data are not available to show that M52 do not share the toxicological properties of pinoxaden that has a harmonised classification as **Repr. 2**, **H361d**, *suspected of damaging the unborn child*[15] (ECHA RAC, 2016) (**step 3c**).

M3 is not relevant according to **step 3c** of the EC guidance (screening for toxicity; see Table 13). The peer review considered that the criteria for classification for reproductive toxicity, according to Regulation (EC) No 1272/2008, may not be met as considered not sufficiently severe (i.e. delayed development) (acknowledging that classification is under ECHA's remit). The ADI of 0.01 mg/kg bw per day established for M3 during the peer review in 2013 (EFSA, 2013) was confirmed.[16]

It is plausible that M3 is the precursor metabolite in soil/environment of **M11, M54, M55 and M56**[17] According to the applicant, the non-relevance of M3 should be considered to address the non-relevance of these metabolites. According to the former RMS, UK,[18] the rabbit developmental toxicity study (OECD 414) conducted with M3 (as precursor in the environment of the other metabolites) may be used to address the relevance of groundwater metabolites M11, M54, M55 and M56.[19] According to the EC Guidance '*the toxicity classification of the **parent active substance** as determined according to Regulation (EC) No 1272/2008 is used for pragmatic reasons as a starting point to focus the screening activity*' (stage 3 of Step 3). The approach to consider the toxicity of the environmental precursor metabolite M3, instead of the parent active substance, was discussed during the Pesticides Peer Review Experts' TC 148 and the experts agreed by consensus that it is not appropriate to consider the toxicological data from the environmental precursor M3 to assess the relevance of the down-stream metabolites without a robust justification for grouping and read-across to M3 (e.g. by considering toxicological arguments such us major mammalian metabolite, toxicophore analysis, structure similarities; see also Appendix D). The sole argument that M3 is the plausible precursor metabolite in soil/environment put forward by the applicant, without further corroborating it with proper argumentations and/or other evidence (see above), does not justify the assumptions concerning the potential mammalian toxicity profile of down-stream metabolites. Therefore, the experts agreed that, based on available information, it cannot be concluded whether these metabolites do not share the toxicological properties of the parent compound pinoxaden (Repr. 2, H361d). The proposed read-across justification to M3 was rejected during the experts' meeting.[20] EFSA also noted that is not known whether M11, M54, M55 and M56 are mammalian (e.g. rabbit) metabolites of M3, and that M55 showed a different genotoxicity profile than M3. Overall, metabolites M11, M54 and M56 are considered **relevant** at **step 3c** of the EC guidance.

Step 4 (consumer exposure assessment triggered) of the EC guidance is only applicable to M3 since the other metabolites are considered relevant (see overview of groundwater metabolites in Table 13).

[13]See experts' consultation point 2.7 at the Pesticides Peer Review Experts' TC 148 (EFSA, 2025). The RMS informed that a new transgenic rodent assay has been provided by the applicant for zonal/national authorisations, but the study was not available for this confirmatory data evaluation procedure.

[14]M3 is not the environmental precursor of M2 or M52.

[15]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

[16]See experts' consultation point 2.6 at the Pesticides Peer Review Experts' TC 148 (EFSA, 2025).

[17]It's plausible that M3 is the precursor of M11, M54, M55 and M56 based on structure but the exact order and pathway of metabolite formation in soil is uncertain.

[18]Following the departure of the United Kingdom from the EU, Austria was designated as the new RMS.

[19]It is acknowledged that during the RMS (former one, UK) evaluation of the confirmatory information, upon RMS request of EFSA consultation as regard the proposed strategy by the applicant, EFSA indicated that the grouping approach would reasonably be applicable to metabolites proven to be its degradation products in the environment. However, such consultation did not represent the final EFSA view since, as explained to the former RMS, it could not be excluded that the 'agreed' grouping approach may be challenged and/or rejected by MS experts, when the confirmatory data on the active substance are peer reviewed. The final EFSA view is expressed in the EFSA conclusion only, issued at the termination of the peer review process and taking into account the latest status of scientific and technical knowledge.

[20]See experts' consultation point 2.7 at the Pesticides Peer Review Experts' TC 148 (EFSA, 2025).

3 | RESIDUES

In the context of the relevance assessment of groundwater metabolite M3, according to steps 4 and 5 of the EC guidance document (European Commission, 2003), an exposure assessment and a refined assessment of the potential toxicological significance of M3 for consumers is triggered, respectively, in view of M3 exceeding 0.75 µg/L in all except two of the modelled scenarios (see Section 1 and Table 13). This assessment should also address whether there are other sources of exposure for consumers but groundwater.

The RMS argued that, since the metabolite M3 was not included in the residue definition for food (plant and animal origin), a corresponding risk assessment was not necessary and therefore the RMS did not provide a reliable and transparent assessment. If a metabolite is not included in the residue definition for risk assessment of pesticide residues in food, this typically reflects a scientific judgement that it is of lower toxicological or quantitative significance in comparison to other residues present in food and feed items. However, this does not equate to an absence of exposure to the metabolite.

EFSA reviewed the available data on M3 in the section of the original assessment report on residues in food and feed prepared by the former RMS UK (United Kingdom, 2005[21], 2013[22]).

Occurrence of metabolite M3 was reported in primary crop metabolism studies in wheat using radiolabeled ([14C]-pyrazol, [14C]-phenyl and [14C]-oxadiazepine) pinoxaden at critical GAP compliant application rates (0.06 kg a.s./ha).

Highest M3 levels were found in fresh forage (0.128 mg/kg), with concentrations declining over time. Distribution varied by plant part: no detectable residues in grain, moderate levels in husks (0.01–0.05 mg/kg) and straw (up to 0.08 mg/kg). Estimates of M3 residues based on metabolite ratios (M3:M4 and M6) derived from wheat metabolism studies and applied to field trial data (which determined M4 and M6) confirmed the order of magnitude of M3 residues observed in the metabolism studies (estimated HR of 0.09 mg/kg in wheat straw and of 0.04 mg/kg in barley straw).

Rotational crop studies at the maximum seasonal rate revealed a consistent pattern of uptake across both [14C]-phenyl and [14C]-oxadiazepine labels studied. EFSA had already previously recommended that at higher application rates, consideration might be given to metabolite M3 that was a major metabolite in the confined rotational crop studies (EFSA, 2013). Wheat forage showed highest residues (0.024 mg/kg), while lettuce contained minimal residues (0.0005–0.0006 mg/kg). Radish tops showed slightly higher levels (0.001–0.002 mg/kg). Wheat husks and straw had moderate residues at ~30 days plant back interval (0.003–0.008 mg/kg) with insignificant decline by the 120 days plant back interval (0.001–0.007 mg/kg).

In ruminant studies conducted with pinoxaden, M3 was also shown to be an animal metabolite that is further metabolised by hydroxylation and conjugation. Goat kidney contained the highest residue of M3 (0.067 mg/kg) with trace amounts in milk (0.0001 mg/kg) and no detectable residues in muscle, fat or liver. Poultry studies with pinoxaden showed no detectable residues of M3 in any tissue or eggs.

Since M3 formation represents only a minor metabolic pathway in the ruminant study conducted with pinoxaden and was not formed in poultry from pinoxaden, a quantitative conclusion regarding potential M3 levels in animal tissues following direct dietary exposure to M3 cannot be drawn based on these studies. Additional evaluation is necessary to determine the potential for significant M3 residue levels in edible animal tissues and products through exposure to M3 from feed (cereal forage and straw, rotational crops), and possibly through in vivo formation from upstream metabolites of M3 also present in the feed items.

With the estimated residue levels of M3 in forage, straw and rotational crops, the trigger value of 0.004 mg/kg bw indicating relevant livestock dietary intake is exceeded for sheep, while it is not exceeded for cattle, swine and poultry. Provisionally, it can therefore be assumed – based on empirical observations – that residues greater than 0.01 mg/kg in most animal commodities are unlikely, although this may differ for lamb.

While this assumption represents a rough estimate that accounts for the existing uncertainties, assuming 0.01 mg/kg residues in all animal commodities as well as in brassica and leafy vegetables – based on observations from rotational crop studies – is considered sufficiently conservative for a provisional dietary intake assessment. Using these input values in EFSA PRIMO rev. 3.1, the highest chronic dietary exposure to M3 is estimated at 0.06 µg/kg bw per day (SE general and NL toddler), corresponding to 0.6% of the ADI, while for infants it is 0.025 µg/kg bw per day (UK infant), corresponding to 0.25% of the ADI (see Section 2 and Table 13).

The consumer exposure estimates for M3 as groundwater metabolite were based on the default assumptions laid down in the WHO Guidelines (WHO, 2011) for drinking water quality for (a) a 60-kg adult drinking 2 L of water per day, (b) a 10-kg child drinking 1 L of water per day and (c) a 5-kg bottle-fed infant drinking 0.75 L of water per day, and the maximum concentration of M3 of 1.545 µg/L. Exposure to M3 as groundwater metabolite accounted for 0.5% of the ADI for adults, 1.6% for children and 2.3% for infants (see Section 2 and Table 13). Although the dietary intake assessment for M3 is provisional due to incomplete data availability and the need for conservative assumptions, combined chronic dietary exposure from both food and water is reasonably expected to remain well below the ADI set for M3 for all population groups (0.01 mg/kg bw per day, see Section 2).

[21]Available at: https://www.efsa.europa.eu/it/consultations/call/public-consultation-active-substance-pinoxaden.

[22]Available in OpenEFSA (under supporting documents) at the following link: https://open.efsa.europa.eu/questions/EFSA-Q-2009-00329.

4 | OVERVIEW OF THE COMPOUNDS LISTED IN THE RESIDUE DEFINITION FOR GROUNDWATER TRIGGERING THE ASSESSMENT OF EFFECTS DATA

TABLE 13 Groundwater.[a]

Compound (name and/or code)	>0.1 µg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
pinoxaden	No	Yes	–	–	Yes
M2	No in FOCUS modelling and lysimeters. Application rate normalised all time high concentrations from 33 monitoring sites representing FOCUS Hamburg climate zone 99th percentile < 0.1 µg/L. Application rate normalised all time high concentrations from 21 monitoring sites representing FOCUS Thiva climate zone 99th percentile 0.104 µg/L 97th percentile < 0.1 µg/L.	Yes Biological activity was tested using an in vitro assay (ACCase activity). Activity comparable to parent pinoxaden (both having an inhibitory activity of 1 µmolar/L, expressed as I50 concentration)	Yes No data are available to show that M2 does not share the toxicological properties of pinoxaden (Repr. 2 H361d); Genotoxic potential open.	No	Yes (already relevant at step 3a)
M3	Winter cereals 8/9 FOCUS scenarios all except Sevilla 0.335 to 1.545 µg/L. Thiva < 0.75 µg/L. Spring cereals All 6 FOCUS scenarios 0.42 to 1.402 µg/L. Chateaudun and Porto < 0.75 µg/L. Up to 0.15 and 0.206 µg/L as annual averages in lysimeter studies in Switzerland & Germany respectively. Application rate normalised all time high concentrations from 33 monitoring sites representing FOCUS Hamburg climate zone 99th percentile 0.16 µg/L 97th percentile 0.117 µg/L 95th percentile 0.112 µg/L. Application rate normalised all time high concentrations from 21 monitoring sites representing FOCUS Thiva climate zone 99th percentile 0.281 µg/L 97th percentile 0.154 µg/L 95th percentile < 0.1 µg/L.	No	No Unlikely to be genotoxic; Low acute oral toxicity (rat). Developmental effects (delayed development) observed with the metabolite M3 are not of sufficient severity for classification purposes. ADI 0.01 mg/kg bw per day.	Yes Consumer intake (food + water) 1.1% of the ADI for adults, 2.2% of the ADI for children, 2.6% of the ADI for infants	No for the representative uses assessed
M52	Winter cereals Only Hamburg 0.113 µg/L & Okehampton 0.14 µg/L. Spring cereals Only Hamburg 0.105 µg/L. Up to 0.13 µg/L as annual average in lysimeter in Germany. Application rate normalised all time high concentrations from 33 monitoring sites representing FOCUS Hamburg climate zone 99th percentile < 0.1 µg/L. Application rate normalised all time high concentrations from 21 monitoring sites representing FOCUS Thiva climate zone 99th percentile 0.15 µg/L 97th percentile 0.145 µg/L 95th percentile 0.14 µg/L.	No Biological activity assessed based on in vitro assay (ACCase activity) for related molecules and structure/ activity consideration No significant activity expected	Yes, unlikely to be genotoxic; Data are not available to show that the metabolite does not share the toxicological properties of pinoxaden (Repr. 2, H361d)	No	Yes

(Continues)

TABLE 13 (Continued)

Compound (name and/or code)	> 0.1 μg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
M11 (SYN 504574)	Winter cereals All 9 FOCUS scenarios 0.188 to 1.209 μg/L. Only Jokioinen > 0.75 μg/L. Spring cereals All 6 FOCUS scenarios 0.274 to 1.01 μg/L. Hamburg & Jokioinen > 0.75 μg/L. Up to 0.229 μg/L as annual average in lysimeter in Germany. Application rate normalised all time high concentrations from 33 monitoring sites representing FOCUS Hamburg climate zone 99th percentile < 0.1 μg/L. Application rate normalised all time high concentrations from 21 monitoring sites representing FOCUS Thiva climate zone 99th percentile 0.129 μg/L 97th percentile 0.103 μg/L 95th percentile < 0.1 μg/L.	No	Yes Unlikely to be genotoxic; data are not available to show that the metabolite does not share the toxicological properties of pinoxaden (Repr. 2, H361d)	No	Yes
M54	Winter cereals 8/9 FOCUS scenarios all except Sevilla 0.143 to 0.299 μg/L. Spring cereals All 6 FOCUS scenarios 0.122 to 0.292 μg/L. Up to 0.15 μg/L as annual average in lysimeter in Germany. Application rate normalised all time high concentrations from 33 monitoring sites representing FOCUS Hamburg climate zone 99th percentile 0.128 μg/L 95th %tile < 0.1 μg/L. Application rate normalised all time high concentrations from 21 monitoring sites representing FOCUS Thiva climate zone 99th percentile < 0.1 μg/L.	No. Evidence as for M52	Yes Unlikely to be genotoxic; data are not available to show that the metabolite does not share the toxicological properties of pinoxaden (Repr. 2, H361d)	No	Yes
M55	Winter cereals All 9 FOCUS scenarios 0.699 to 3.86 μg/L. Only Okehampton < 0.75 μg/L. Spring cereals All 6 FOCUS scenarios 0.853 to 3.056 μg/L. Up to 0.134 μg/L as annual average in lysimeter in Germany. Application rate normalised all time high concentrations from 33 monitoring sites representing FOCUS Hamburg climate zone 99th %tile 0.1 μg/L 95th percentile < 0.1 μg/L. Application rate normalised all time high concentrations from 21 monitoring sites representing FOCUS Thiva climate zone 99th percentile <0.1 μg/L.	No. Evidence as M52	Yes M55 showed equivocal/positive results in the in vivo Comet assay; data are not available to show that the metabolite does not share the toxicological properties of pinoxaden (Repr. 2, H361d)	No	Yes

TABLE 13 (Continued)

Compound (name and/or code)	>0.1 μg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
M56	Winter cereals All 9 FOCUS scenarios 0.721 to 3.96 μg/L. Only Okehampton < 0.75 μg/L. Spring cereals All six FOCUS scenarios 0.862 to 2.869 μg/L. Up to 0.266 μg/L as annual average in lysimeter in Germany. Application rate normalised all time high concentrations from 33 monitoring sites representing FOCUS Hamburg climate zone 99th percentile < 0.1 μg/L. Application rate normalised all time high concentrations from 21 monitoring sites representing FOCUS Thiva climate zone 99th percentile < 0.1 μg/L.	No. Evidence as M52	Yes Unlikely to be genotoxic; data are not available to show that the metabolite does not share the toxicological properties of pinoxaden (Repr. 2, H361d)	No	Yes

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).

[b]FOCUS scenarios, relevant lysimeter and targeted groundwater monitoring. Ranges indicated for FOCUS scenarios include the result from the model giving the highest concentration at each scenario, as needed to comply with European Commission (2014) guidance.

5 | CONCERNS AND RELATED DATA GAPS FOR THE REPRESENTATIVE USES EVALUATED

5.1 | Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[23] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

Issues that could not be finalised were not identified in the scope of this evaluation.

5.2 | Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

[23]Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

Critical areas of concern were not identified in the scope of this evaluation considering the highest tier level of assessment available (groundwater monitoring data) and the 70 vulnerable sites monitored, when all groundwater metabolites except M3 have been concluded as relevant (see Section 1).

6 | OVERVIEW OF THE CONCERNS IDENTIFIED FOR EACH REPRESENTATIVE USE CONSIDERED (TABLE 14)

TABLE 14 Overview of groundwater concerns reflecting the risk to groundwater quality identified, that was applicable for all uses and some assessment scenarios.

		Winter cereals	Spring cereals	Durum wheat
Representative use		**Spring foliar spray**	**Spring foliar spray**	**Spring foliar spray**
Consumer risk	Risk identified			
	Assessment not finalised			
Groundwater exposure to active substance	Legal parametric value breached			
	Assessment not finalised			
Groundwater exposure to metabolites	Legal parametric value breached[a]	5 of 70 sites monitored 4 of 21 sites representing the Thiva FOCUS climate zone 1 of 33 sites representing the Hamburg FOCUS climate zone	5 of 70 sites monitored 4 of 21 sites representing the Thiva FOCUS climate zone 1 of 33 sites representing the Hamburg FOCUS climate zone	5 of 33 sites monitored[c] 4 of 21 sites representing the Thiva FOCUS climate zone
	Parametric value of 10 µg/L[b] breached			
	Assessment not finalised			

[a]When the harmonised classification confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 is considered.
[b]Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 11 final, European Commission (2003).
[c]Information is that for the monitoring sites with climates considered representative of the southern EU regulatory zone, as indicated in Appendix B. This was chosen as durum wheat cultivation outside N. America and Asia, is primarily located in the Mediterranean basin.

7 | LIST OF OTHER OUTSTANDING ISSUES

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements in relation to the topic of the mandate for confirmatory data, and which are relevant for some, or all, of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

None identified in the scope of this evaluation.

8 | DOCUMENTATION PROVIDED TO EFSA

1. Austria, 2018. Addendum to the assessment report on Pinoxaden, confirmatory data (point 1), November 2018. https://open.efsa.europa.eu/questions/EFSA-Q-2023-00458?search=pinoxaden
2. Austria, 2019. Revised addendum to the assessment report on Pinoxaden, confirmatory data (point 1), January 2019. https://open.efsa.europa.eu/questions/EFSA-Q-2023-00458?search=pinoxaden
3. Austria, 2022. Addendum to the assessment report on Pinoxaden, confirmatory data (point 2), May 2022. https://open.efsa.europa.eu/questions/EFSA-Q-2023-00458?search=pinoxaden
4. Austria, 2023. Revised addendum to the assessment report on Pinoxaden, confirmatory data (point 2), June 2023. https://open.efsa.europa.eu/questions/EFSA-Q-2023-00458?search=pinoxaden
5. Austria, 2024. Revised addendum to the assessment report on Pinoxaden, confirmatory data (point 2) following the Pesticides Peer Review Experts' Meeting TC 148 and 149, December 2024. https://open.efsa.europa.eu/questions/EFSA-Q-2024-00327?search=pinoxaden

ABBREVIATIONS

a.s. active substance
ACCase Acetyl-CoA carboxylase enzyme that catalyses the carboxylation of acetyl-CoA to malonyl-CoA

ADI	acceptable daily intake
bw	body weight
CAS	Chemical Abstracts Service
DAR	draft assessment report
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	Emulsifiable Concentrate
ECHA	European Chemicals Agency
EU	European Union
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LOD	limit of detection
LOQ	limit of quantification (determination)
M/L	mixing and loading
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PEC	predicted environmental concentration
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	pre-harvest interval
P_{ow}	partition coefficient between *n*-octanol and water
SFO	single first-order
SMILES	simplified molecular-input line-entry system
TRR	total radioactive residue
WHO	World Health Organization

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REQUESTOR

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

Consideration of cut-off criteria for pinoxaden according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion
CMR	Carcinogenicity (C)	Pinoxaden is not considered to be a carcinogen (category 1A or 1B) according to point 3.6.3 of Annex II of Regulation (EC) No 1107/2009, based on: Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]: ATP 13,[24] no classification for carcinogenicity
	(Germ cell) Mutagenicity (M)	Pinoxaden is not considered to be a Germ Cell mutagen (category 1A or 1B) according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009, based on: Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]: ATP 13, no classification for Germ cell mutagenicity
	Toxic for Reproduction (R)	Pinoxaden is not considered to be toxic for reproduction (category 1A or 1B) according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009, based on: Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]: ATP 13, Repr. 2 H361d
Endocrine disrupting properties		Not assessed in this confirmatory data evaluation.
POP	Persistence Bioaccumulation Long-range transport	Pinoxaden is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
PBT	Persistence Bioaccumulation Toxicity	Pinoxaden is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
vPvB	Persistence Bioaccumulation	Pinoxaden is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.

[24] Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776.

APPENDIX B

List of end points for the active substance and the formulation for representative uses relevant for the confirmatory data assessed

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2025.9622

APPENDIX C

Wording EFSA used in Section 1 of this conclusion, in relation to Environmental fate and behaviour: DT and Koc 'classes' exhibited by each compound assessed

Wording	DT_{50} normalised to 20°C for laboratory incubations[25] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT50 when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1 to < 10 days
Moderate persistence	10 to < 60 days
Medium persistence	60 to < 100 days
High persistence	100 days to < 1 year
Very high persistence	A year or more

Note: These classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

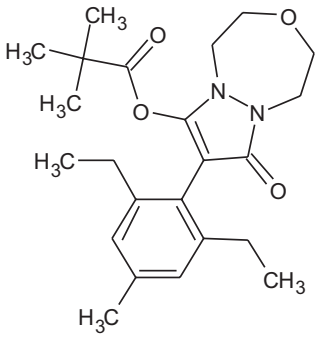
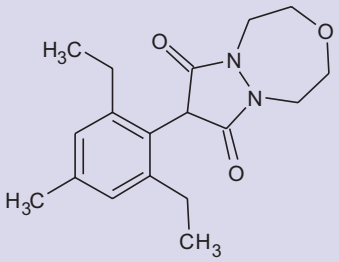
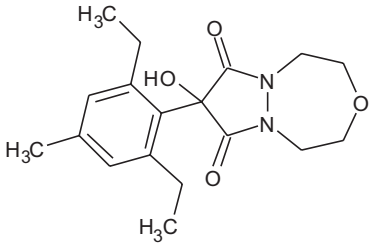
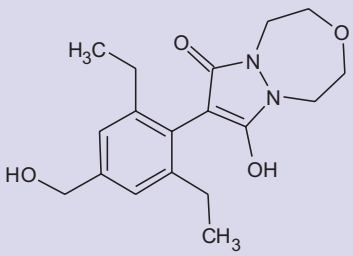
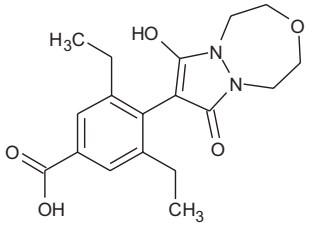
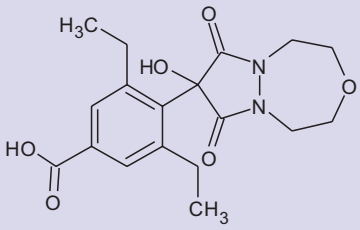
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2000
Slight mobility	2001–5000
Immobile	> 5000

Note: Based on McCall et al. (1980).

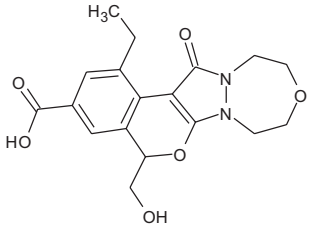
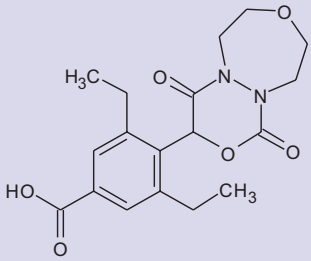
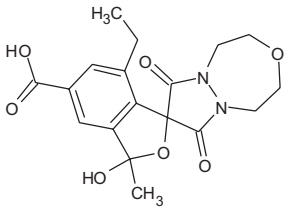
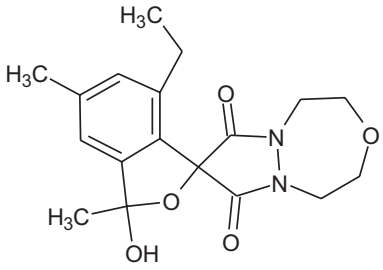
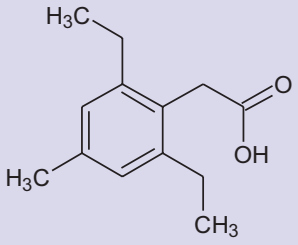
[25] For laboratory soil incubations normalisation was also to field capacity soil moisture (pF2/10 kPa).

APPENDIX D

Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation/InChIKey[b]	Structural formula[c]
Pinoxaden	8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate CC(C)(C)C(=O)OC1=C(C(=O)N2CCOCCN21)c1c(CC)cc(C)cc1CC MGOHCFMYLBAPRN-UHFFFAOYSA-N	
M2	8-(2,6-diethyl-4-methylphenyl)tetrahydro-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepine-7,9(8*H*)-dione CCc1cc(C)cc(CC)c1C1C(=O)N2CCOCCN2C1=O QHUWVQWAKAJLTJ-UHFFFAOYSA-N	
M3	8-(2,6-diethyl-4-methylphenyl)-8-hydroxytetrahydro-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepine-7,9(8*H*)-dione CCc1cc(C)cc(CC)c1C1(O)C(=O)N2CCOCCN2C1=O XTDSHACLOHQSIG-UHFFFAOYSA-N	
M4	8-[2,6-diethyl-4-(hydroxymethyl)phenyl]-9-hydroxy-1,2,4,5-tetrahydro-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-7-one CCc1cc(CO)cc(CC)c1C=1C(=O)N2CCOCCN2C=1O WGVDNRLFXQNIMF-UHFFFAOYSA-N	
M6	3,5-diethyl-4-(9-hydroxy-7-oxo-1,2,4,5-tetrahydro-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-8-yl)benzoic acid O=C(O)c1cc(CC)c(C=2C(=O)N3CCOCCN3C=2O)c(CC)c1 IGUXRAORVWEOEM-UHFFFAOYSA-N	
M11 (SYN 504574)	3,5-diethyl-4-(8-hydroxy-7,9-dioxohexahydro-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-8-yl)benzoic acid O=C(O)c1cc(CC)c(c(CC)c1)C1(O)C(=O)N2CCOCCN2C1=O TYFDZZRIQWKTIX-UHFFFAOYSA-N	

(Continued)

Code/trivial name[a]	Chemical name/SMILES notation/InChIKey[b]	Structural formula[c]
M52	1-ethyl-5-(hydroxymethyl)-14-oxo-8,9,11,12-tetrahydro-5*H*,14*H*-[2] benzopyrano[3′,4′:3,4]pyrazolo[1,2-*d*][1,4,5]oxadiazepine-3-carboxylic acid O=C(O)c1cc2c(C=3C(=O)N4CCOCCN4C=3OC2CO)c(CC)c1 LOMMJLDVYWDSCR-UHFFFAOYSA-N	
M54	4-(1,4-dioxohexahydro-1*H*-[1,3,4]oxadiazino[3,4-*d*][1,4,5]oxadiazepin-3-yl)-3,5-diethylbenzoic acid O=C(O)c1cc(CC)c(c(CC)c1)C1OC(=O)N2CCOCCN2C1=O DMAYIZFOQDBUEV-UHFFFAOYSA-N	
M55	7-ethyl-3-hydroxy-3-methyl-7′,9′-dioxo-1′,2′,4′,5′-tetrahydro-3*H*,7′*H*,9′*H*-spiro[[2] benzofuran-1,8′-pyrazolo[1,2-*d*][1,4,5]oxadiazepine]-5-carboxylic acid O=C(O)c1cc(CC)c2c(c1)C(C)(O)OC21C(=O)N2CCOCCN2C1=O YMOZJKIMMVZGEL-UHFFFAOYSA-N	
M56	7-acetyl-3-hydroxy-3,5-dimethyl-1′,2′,4′,5′-tetrahydro-3*H*,7′*H*,9′*H*-spiro[[2] benzofuran-1,8′-pyrazolo[1,2-*d*][1,4,5]oxadiazepine]-7′,9′-dione CC(=O)c1cc(C)cc2c1C1(OC2(C)O)C(=O)N2CCOCCN2C1=O NTVGVBNYCCFRPZ-UHFFFAOYSA-N	
SYN 515622[d,e]	7-ethyl-3-hydroxy-3,5-dimethyl-1′,2′,4′,5′-tetrahydro-3H-spiro[[2]benzofuran-1,8′-pyrazolo[1,2-d][1,4,5]oxadiazepine]-7′,9′-dione CC1(O)OC2(C(=O)N3CCOCCN3C2=O)c2c1cc(C)cc2CC XVUFBIOTDSAKJU-UHFFFAOYSA-N	
NOA 437397[d,e]	(2,6-diethyl-4-methylphenyl)acetic acid Cc1cc(CC)c(CC(O)=O)c(c1)CC SCEARLNFHOOSLL-UHFFFAOYSA-N	

[a]The compound name in bold is the name used in the conclusion.

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).

[d]InChIKey: ACD/Name 2024.2.3 ACD/Labs 2024.2.3 (File Version N25E41, Build 142837, 21 January 2025).

[e]Structural formula: ACD/ChemSketch 2024.2.3, ACD/Labs 2024.2.3 (File Version C45H41, Build 142855, 23 January 2025).