2025

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Schweizerisches Zentrum für angewandte Ökotoxikologie
Centre Suisse d'écotoxicologie appliquée

SGV – Proposal by the Ecotox Centre for

Fenpyroximate

First proposal: 2025 (last bibliographic research)
13.10.2025 (implementation of the expertise)

Imprint

Publisher
Swiss Centre for Applied Ecotoxicology, 8600 Duebendorf/1015 Lausanne

Commissioned by
FOEN, Federal Office for the Environment, Soil and Biotechnology Division, 3003 Bern

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External reviewers are not responsible for the final published SGV or the contents of this dossier. This is the sole responsibility of the authors.

Acknowledgement
This project was funded by the Swiss Federal Office for the Environment. The authors would like to thank Sophie Campiche (EnviBioSoil) and the people listed under scientific support for the exchange we had and the advice they provided.

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Citation Proposal
Balk F, Lauber E, Renaud M, Junghans M. 2025. SGV – Proposal by the Ecotox Centre for Fenpyroximate. Swiss Centre for Applied Ecotoxicology, Dübendorf, Switzerland; 54 pp.

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Policy disclaimer

According to the Action Plan for PPP (AP-PPP) (measure 6.3.3.7), pesticides in soil should be monitored in order to verify the evaluation carried out within the framework of the registration regarding the persistence of pesticides in the environment and their effect on soil organisms and soil functions. Therefore, a suitable method (indicator) for effects of PPP on soil fertility has to be developed and applied in field studies. Risk-based reference values for PPP residues should be available by 2025, and bioindicators for the effects of PPP residues on soil fertility should be developed by 2027.

In response to the AP-PPP and tasked by FOEN and FOAG, experts from the Ecotox Centre and EnviBioSoil have been working since 2018 on an integrative concept to assess the effects of PPP residues in soil. The following dossier represents the full evaluation, derivation and proposal of a Soil Guideline Value (a risk-based reference value), according to the recommended methodology developed within the AP-PPP project (Marti-Roura *et al.* 2023), and does not have a regulatory nature that goes beyond their intended use within the ongoing AP-PPP project. Further information on the ConSoil project and its framework can be found at: https://www.ecotoxcentre.ch/projects/soil-ecotoxicology/monitoring-concept-for-plant-protection-products-in-soils?_ga=2.170121120.1893072167.1726132886-1891293576.1686657912.

The data on the metabolites (Section 5 and Appendix 3) are included only as supporting information and have not been peer reviewed externally.

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Executive summary

As part of the Federal Action Plan on Plant Protection Products (Bundesrat, 2017), the Ecotox Centre develops proposals for Soil Guideline Values (SGV). These values are intended to provide an initial screening tool for assessing the potential risk for the long-term fertility of agricultural soils and for the soil ecosystem in general. Based on existing effect data for fenpyroximate and applying the methodology described in the EU Technical Guidance Document on risk assessment (EC TGD 2003), with adaptations described in Marti-Roura *et al.* (2023), **a generic SGV** for fenpyroximate of **190 µg a.s./kg soil d.w.** is proposed **for a standard soil with 3.4 % organic matter.**

Zusammenfassung

Im Rahmen des Aktionsplans Pflanzenschutzmittel (Bundesrat 2017) erarbeitet das Oekotoxzentrum Vorschläge für Bodenrichtwerte (SGV). Diese Werte sollen ein erstes Screening-Instrument zur Bewertung der potenziellen Risiken für die langfristige Fruchtbarkeit landwirtschaftlicher Böden und für das Ökosystem Boden im Allgemeinen darstellen. Auf der Grundlage vorhandener Wirkungsdaten für Fenpyroximate und unter Anwendung der im Technischen Leitfaden der EU zur Risikobewertung beschriebenen Methodik (EC TGD 2003) und den in Marti-Roura *et al.* (2023) beschriebenen Anpassungen wird **ein generischer SGV** für Fenpyroximate von **190 µg a.s. pro kg Bodentrockengewicht für einen Standardboden mit 3,4 % organischer Substanz** vorgeschlagen.

Résumé

Dans le cadre du plan d'action Produits phytosanitaires (Conseil fédéral, 2017), le Centre Ecotox élabore des propositions de valeurs guides pour les sols (SGV). Ces valeurs sont destinées à fournir un outil de dépistage initial pour évaluer le risque potentiel pour la fertilité à long terme des sols agricoles et pour l'écosystème du sol en général. Sur la base des données existantes relatives aux effets du fenpyroximate et en appliquant la méthodologie décrite dans le document d'orientation technique de l'UE sur l'évaluation des risques (EC TGD 2003), avec les adaptations décrites dans Marti-Roura *et al.* (2023), **une SGV générique** pour le fenpyroximate de **190 µg a.s./kg de sol p.s. est proposée pour un sol standard contenant 3,4 % de matière organique**.

Sommario

Nell'ambito del Piano d'azione dei prodotti fitosanitari (Consiglio federale svizzero, 2017), il Centro Ecotox sviluppa proposte di valori guida per il suolo (SGV). Questi valori sono destinati a fornire uno strumento di screening iniziale per valutare il rischio potenziale per la fertilità a lungo termine dei suoli agricoli e per l'ecosistema del suolo in generale. Sulla base dei dati esistenti sugli effetti del fenpiroximate e applicando la metodologia descritta nel documento tecnico di orientamento dell'UE sulla valutazione del rischio (EC TGD 2003), con gli adattamenti descritti in Marti-Roura *et al.* (2023), viene proposto **un SGV generico per** il fenpiroximate di **190 µg a.s./kg di suolo (peso secco) per un suolo standard con il 3,4% di materia organica.**

Table of content

1 General information

Information on the pesticide active substance fenpyroximate in relation to the soil environment is presented in this chapter. Registration information and risk assessments referred to are as follows:

- *EC (2006): Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur Member State Germany for the existing active substance fenpyroximate of the third stage (part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC.*
- *EC (2008a): Final addendum to the Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur member State Germany for the existing active substance fenpyroximate of the third stage Part A of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC.*
- *EFSA (2008): Conclusion regarding the peer review of the pesticide risk assessment of the active substance fenpyroximate. European Food Safety Authority. EFSA Journal, 197, 1-104.*
- *EC (2013): Final addendum to the addendum to Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur Member State Germany in the context of application for amendment to the conditions of approval and the assessment of confirmatory data for the active substance fenpyroximate.*
- *EFSA (2013): Conclusion on the peer review of the pesticide risk assessment of the active substance fenpyroximate. European Food Safety Auhtority. EFSA Journal, 11 (12), 3493.*
- *EC (2019): Initial Draft Assessment Report prepared according to the Commission Regulation (EU) No. 1107/2009 by the rapporteur Member State Austria for the existing active substance fenpyroximate.*
- *EC (2024b): Renewal Assessment Report prepared according to the Commission Regulation (EU) No. 1107/2009 by the rapporteur Member State Austria for the existing active substance fenpyroximate.*
- *EFSA (2025a): Answer to "Application for public access to documents 15 May 2025 Ref. No.: PAD 2025/100 (00015743)" Legal Affairs Services, Parma, 11 July 2025. Ref. LV/BL/mm (2023) - out-35751238.*
- *EFSA (2025b): Answer to "Application for public access to documents 14 July 2025 Ref.No.: PAD 2025/142 (00020512) "Legal Affairs Services, Parma, 18 September 2025. Ref. LV/BL/AND/mm (2025) – out-36160555*

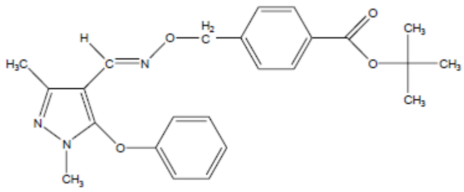
A previous draft assessment report (DAR; EC 2006) with several amendments (EC 2008a) and conclusion from the peer review (EFSA 2008) are available for the active substance fenpyroximate and a representative product. The usage of fenpyroximate was authorised according to the Council Directive 91/414/EEC (EC 1991) and currently it is deemed to have been approved under the regulation in force, (EC) No 1107/2009 (EC 2009). Later more amendments to the DAR were published (EC 2013). Fenpyroximate was included in the framework of the 4th European program for the renewal of approvals of pesticide active substances (EC 2024a AIR IV, Group 1 – *Substances with expiry date before 30 April 2019*) under Regulation (EC) No 1107/2009, for which a new dossier was submitted in the EU. The initial public version of the draft Renewal Assessment Report (dRAR) was subjected to public consultation in 2019 and in 2024, the latter with revision on endocrine disruption (EC 2024b). The previous conclusions were reached on the basis of the evaluation of the representative uses as an acaricide (EFSA 2008). The representative formulated product for the evaluation in the EU was a 51.2 g/L suspension concentrate (SC) registered under different names in Europe (e.g. Danitron 5 SC, Dinamite, Flash, Kendo, Kiron, Ortus, Sequel, Samba, Samba K, Fenpyroximate 5SC) (EC 2024b).

Additional information, i.e. partial access to full study reports, was provided by EFSA under the EU regulation about public access to documents (PAD regulation, EC (2001)). In line with the PAD regulation, additional information accessed via EFSA (2025a) that are not included in publicly available documents got redacted from the externally published version of the dossier and replaced by the abbreviation of *[CPIR]* (confidentially provided information, redacted).

1.1 Identity and physico-chemical properties

Fenpyroximate (CAS 134098-61-6; development code number NNI-850, HOE 094552) is a pyrazolium acaricide. Its minimum purity as manufactured is 960 g/kg and the relevant impurities are NN-4 with maximum 1 g/kg, NN-9 with maximum 1.4 g/kg, methanol with maximum 1g/kg and toluene with < 2.0 g/kg (EC 2024b, LoEP). The pure material (99.6 % purity) is a white chrystalline powder with low water solubility and high hydrophobicity (see further details on physical-chemical properties in Table 1 below). Fenpyroximate is produced and used in its E-isomer, which was deemed to be stable under normal storage conditions (EC 2024b, Vol. 1).

Table 1: Identification and physico-chemical properties of fenpyroximate. Abbreviations: LoEP – List of Endpoints

Characteristics	Values	References
Common name	Fenpyroximate	(EC 2024b) Vol. 1 and LoEP
Producer's development code number	NNI-850, HOE 094552	(EC 2024b) Vol. 1
IUPAC name	tert-butyl (E)-alpha-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-ylmethyleneaminooxy)-p-toluate	(EC 2024b) Vol. 1 and LoEP
Chemical group	Pyrazolium acaricide	(EC 2024b) Vol. 1 and LoEP, (Lewis 2016)
Structural formula		(EC 2024b) LoEP
Molecular formula	$C_{24}H_{27}N_3O_4$	(EC 2024b) Vol. 1 and LoEP
CAS	134098-61-6	(EC 2024b)Vol. 1 and LoEP
EC Number	603-792-1	(EC 2024b)Vol. 1 and LoEP
SMILES code (canonical SMILES)	CC1=NN(C(=C1C=NOCC2=CC=C(C=C2)C(=O)OC(C)(C)C)OC3=CC=CC=C3)C	(Lewis 2016)
International Chemical Identifier key (InChIKey)	YYJNOYZRYGDPNH-MFKUBSTISA-N	(Lewis 2016)
Molecular weight [g/mol]	421.5	(EC 2024b) Vol. 1 and LoEP
Melting point [°C]	102.0 to 102.8 (98.6 %)	(EC 2024b) Vol. 1 and LoEP
Boiling point [°C]	At 222 not determinable (changed colour from clear to light yellow; 99.6 %)	(EC 2024b) LoEP
Solubility		
Water solubility [mg/L]	0.0214 ± 0.0016 (25°C, pH 5, 99.8 %)	(EC 2024b) Vol. 1 and LoEP
Solubility in organic solvents [g/L]	At 20°C (99.6 %): Toluene: 199 Methanol: 13.4	(EC 2024b) LoEP

	Acetone: 116 Ethyl acetate: 148 Heptane: 3.71 halogenated solvents > 250	
Dissociation constant (pKa)	No pKa expected	(EC 2024b) LoEP
Stability		
Aqueous hydrolysis [d]	DT50 (25°C) pH 5: 180, pH 7: 226, pH 9: 221	(EC 2024b) LoEP
Aqueous photolysis [h]	DT50: 1.5	(EC 2024b) LoEP
Photochemical degradation in air [d]	DT50: 0.359 at 24.9°C (arithmetic mean, Atkinson model)	(EC 2024b) LoEP, p. 57
Volatilisation		
Vapour pressure [Pa]	≤ 9.21×10^{-6} (25°C, 99.6 %)	(EC 2024b) Vol. 1 and LoEP
Henry's law constant [$Pa \cdot m^3 \cdot mol^{-1}$]	< 0.0168 (25°C)	(EC 2024b) Vol. 1 and LoEP
Partition/Adsorption		
Octanol-water partition coefficient (log Pow)	5.70 (25°C, pH 6.4-6.5, 99.6 %)	(EC 2024b) LoEP
Organic carbon normalised Freundlich partitioning coefficient (Kfoc)	See section 1.5.3, ***Table 3***	

1.2 Mode of action

In acute exposures of the two-spotted spider mite (*Tetranychus urticae* Koch), fenyproximate showed to function as a contact inhibitor of the mitochondrial Complex I electron transport (EC 2024b, Vol. 1) and inhibited the NADH-coenzyme Q reductase (Motoba *et al.* 1992). These inhibtions lead to a decrease in ATP (adenosine triphosphate) contents and morphological changes in mitochondria and thereby affect cell respiration (Motoba *et al.* 1992). Besides these acute effects, fenpyroximate also inhibits moulting of immature stages at lower doses (Konno *et al*. 1990 cited in EC 2006).

The Z-isomer of fenpyroximate, termed M-1 in the risk assessment (RA) of the EU regulatory process, is principally formed by photolysis, which would only occur on the soil surface. Therefore, it plays a less important role in the exposure to in-soil organisms. Fenpyroximate was not assessed for its endocrine disruptive potential in the initial DAR (EFSA 2008) and the final addendum to the addendum to the DAR in 2013 delivered limited evidence (EC 2013). However, the dRAR (EC 2024b) specifically assessed the endocrine disruptive properties of fenpyroxymate and indicated it not to be endocrine disruptive for humans, mammals and non-target vertebrate organisms other than mammals. Yet, an expert discussion and an EFSA conclusion on the pesticide peer review are still pending.

Apart from the missing conclusion, the current evaluation of ED properties focuses on vertebrates, however, the endocrine system of soil invertebrates displays substantial differences. With this in mind, extrapolation of the endocrine mode of action from vertebrates to soil invertebrates is not possible. At present, no validated tools are available for the determination of any invertebrate endocrine mode of action (Crane *et al.* 2022, OECD 2018). Additionally, a specific literature search on fenpyroximate yielded no data on endocrine-relevant endpoints for in-soil organisms (status 12.2024).

With regard to human toxicology, the potential of genotoxic, carcinogenic and reproductive effects of fenpyroximate were investigated (EC 2013, 2024b). In a battery of *in vitro* and *in vivo* genotoxicity assays, no evidence for genotoxicity could be identified (EC 2024b). Fenpyroximate showed no evidence of carcinogenicity in rats or mice (EC 2024b). Developmental effects in rabbits and rats were only observed in the highest doses with concurrent maternal toxicity. No teratogenicity was observed and fenpyroximate was concluded unlikely to be damaging to fertility. Overall, no classification of genotoxicity, carcinogenicity and reproductive toxicity was specified (EC 2013, 2024b).

1.3 Use and emissions

Fenpyroximate is an acaricide, which was initially authorised at EU level specifically against mites (EC 2008a). Later on, fenpyroximate was additionally evaluated for representative uses as insecticide against leafhoppers (Cicadae) on grapes, pome fruits (max. 1 x 115.2 g a.s./ha) and beans (max. 1 x 102.4 g a.s./ha) for field use (EFSA 2013) – also see the GAP table (good agricultural practices) for the representative uses in the latest EFSA conclusion (EFSA 2013). In the newly submitted EU dossier, the representative uses against mites were extended by the applicant to strawberries and ornamental plants (max. 1 x 102.4 g a.s./ha) for use in greenhouse and on the field (EC 2024b).

In Switzerland, ten products are available with five products only for professional use (BLV 2024). All products are authorised only for uses against mites in different berries, pome and stone fruits, grapewine, hops, fruiting vegetables and ornamental plants in max. 1 x 102.4 g/kg a.s./ha; for details, please refer to the Swiss plant protection registry (BLV 2024).

1.4 Classification and environmental limit values

In the latest updated dRAR (EC 2024b), fenpyroximate was classified according to Regulation (EC) No 1272/2008 (EC 2008b) as an acute human toxicity Category 3 (H301 – *Toxic if swallowed*), skin sensitisation Category 1B (H317 – *May cause an allergic skin reaction*), acute human inhalation toxicity Category 2 (H330 – *Fatal if inhaled*), aquatic acute toxicity Category 1 (H400 – *Very toxic to aquatic life*) as well as aquatic chronic toxicity Category 1 (H410 – *Very toxic to aquatic life with long lasting effects*) substance. It is noted that the same classification is listed in Annex VI to the CLP Regulation No 1272/2008 (consolidated version 01/02/2025, (EC 2008b)).
Earlier conclusions proposed classification and labelling as *very toxic*, *harmful if swallowed*, *very toxic by inhalation*, *irritating to eyes* and *may cause skin sensitisation by skin contact* (T+, R22, R26, R36, R43) (EFSA 2008, 2013).

Fenyproximate is not listed as a candidate for substitution in the EU or in Switzerland (BLV 2024, EC 2015). Currently, no soil protection value could be found for fenpyroximate. Please note that the information included here may have changed since the finalisation of this dossier.

1.5 Environmental fate in soil

Isomer-specific behaviour

The manufactured E-isomer of fenpyroximate is the more stable trans isomer but known to transform into the Z-isomer under photolytic conditions (EC 2024b, Vol. 1). The Z-isomer (named M-1) was included in the soil metabolites that were considered in the risk assessment for soil organisms (assuming ten-times higher toxicity of the E-isomer), based on which it was not considered environmentally relevant and was not selected for further environmental monitoring (EC 2008a, EC 2024b, Vol. 1). Additionally, it is noted that M-1 was measured in soil in a confined crop rotation study < 5 % of the applied parent substance, and in a field dissipation study ≤ 0.01 mg/kg (LOQ).

Volatilisation from soil surface

Considering the low vapour pressure of fenpyroximate (see Table 1), volatilisation of fenpyroximate from soil was not considered relevant (FOCUS 2008, EC 2024b, Vol. 1).

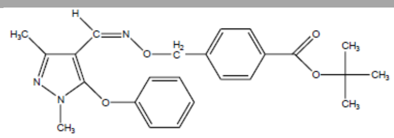
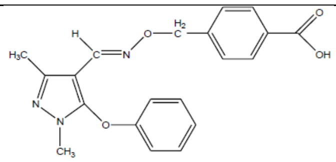
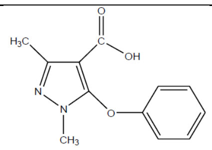
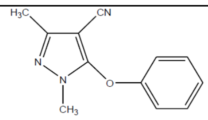
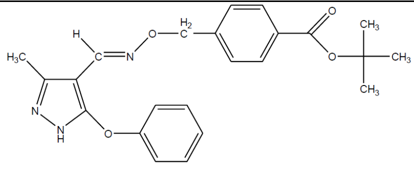
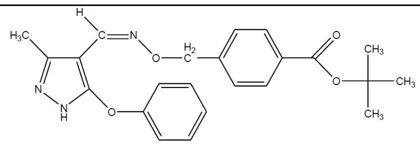
Photodegradation

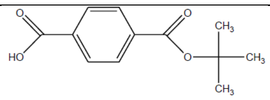
In laboratory soil photodegradation studies, different metabolites were formed than under aerobic and anaerobic conditions (see below).

1.5.1 Route of degradation

Fenpyroximate was observed to degrade under aerobic, anaerobic and photolytic conditions, where aerobic conditions are considered to be the most prevalent route of degradation in agricultural soils (EC 2024b). Major transformation products under aerobic and anaerobic conditions are M-3, M-8 and M-11, while under photolytic conditions M-1, M-12, M-12 isomer and MTBT are formed. For structural details of the major soil metabolites, see Table 2.

Table 2: Major soil metabolites of fenpyroximate. It is important to note that M-1 is the Z isomer of fenpyroximate. Abbreviations: LoEP – List of Endpoints.

Code/Trivial name	Chemical name	Structural formula	Reference
M-1	*Tert*-butyl*(Z)*-α-(1,3-dimethyl-5-phenoxypyrazol-4-ylmethylene amino-oxy)-*p*-toluate (Registry No. 134098-61-6)		(EC 2024b) LoEP (EC 2024b), Vol. 3CA, B.9.11., pp.308
M-3	(E)-4-[(1,3-dimethyl-5-phenocypyrazole-4-yl)-methyleneaminooxy-methyl]benzoic acid (Registry No. 149054-56-8)		(EC 2024b) LoEP (EC 2024b), Vol. 3CA, B.9.11., pp.308
M-8	1,3-dimethyl-5-phenoxypyrzole-4-carboxylic acid (Registry No. 149054-60-4)		(EC 2024b) LoEP (EC 2024b), Vol. 3CA, B.9.11., pp.308
M-11	1,3-dimethyl-5-phenoxypyrzole-4-carbonitrile (Registry No. 149054-59-1)		(EC 2024b) LoEP (EC 2024b), Vol. 3CA, B.9.11., pp.308
M-12	*Tert*-butyl (E)-4-(3-methyl-5-phenoxypyrazole-4-ylmethylene aminooxy)-*p*-toluate (Registry No. 149054-66-0)		(EC 2024b) LoEP (EC 2024b), Vol. 3CA, B.9.11., pp.308
M-12 isomer	*Tert*-butyl (E)-4-(3-methyl-5-phenoxypyrazole-4-ylmethylene aminooxy)-*p*-toluate (Registry No. not available)		(EC 2024b) LoEP (EC 2024b), Vol. 3CA,

			B.9.11., pp.308
MTBT	Mono-(tert-butyl) terephthalate (Registry No. 20576-82-3)		(EC 2024b) LoEP (EC 2024b), Vol. 3CA, B.9.11., pp.308

Aerobic degradation in soil

Three major soil metabolites of fenpyroximate were found and determined in the aerobic degradation studies in soil: M-3 (max. 28.7 % AR after 14 days), M-8 (max. 15.9 % AR after 120 days), M-11 (max. 9.6 % AR after 170 days) (EC 2024b, LoEP).

Anaerobic degradation in soil

Fenpyroximate degraded to the same transformation products under anaerobic conditions as under aerobic conditions: M-3 (max. 59.5 % AR after 121 days), M-8 (7.4 % AR after 121 days) and M-11 (5.2 % AR after 70 days) (EC 2024b, LoEP).

Photolytic degradation on soil

Degradation of fenpyroximate under photolytic conditions was comparably low relative to aerobic conditions. The major transformation products formed were M-1 (max. 17.4 % AR after 20 days), M-12 (max. 5.5 % AR after 30 days), M-12 isomer (max. 5.1 % after 30 days) and MTBT (max. 8.3 % AR after 24 days) (EC 2024b, LoEP).

Mineralisation and non-extractable residues

In aerobic conditions, mineralisation tended to increase, and the amount of non-extractable residues decreased with time reaching a maximum of 57.8 % mineralisation and a minimum of 26.5 % non-extractable residues after 365 days. In anaerobic conditions, they were studied for a shorter period; after 121 days, mineralisation of fenpyroximate was low (1.4 and 7.3 %) with relatively higher values of non-extractable residues (8.1 and 11.1 %). Photolytic degradation was followed for 30 days with max. 1.4 and 1.8 % mineralisation after 20 and 21 days and max. 1.8 and 5.3 % non-extractable residues after 20 and 30 days, respectively (EC 2024b, LoEP).

1.5.2 Rate of degradation

Laboratory degradation studies

Fenpyroximate is moderately to highly persistent in soil under aerobic conditions as indicated by the non-normalised DT50 range from 21.1 to 238 days in five different soils at a pH range from 5.4 to 8.6 (EC 2024b).

A scientific study found a DT50 range of 26.3 to 49.7 days under laboratory conditions in two different Japanese soils at a pH range of 5.5 to 5.8 (Izawa *et al.* 1993). This confirms that fenpyroximate is at least moderately persistent in soil.

Photodegradation of fenpyroximate varied in different soil types with a DT50 range of 53.9 to 94.4 days (EC 2024b, Vol 3CP, B.8 and LoEP), which means that it can significantly contribute to the dissipation of the substance in the field.

The major transformation products M-3, M-8, M-11, M-12 and MTBT showed non-normalised DT50 ranges under aerobic conditions in different soil types of 12.1 to 50.8 days, 29.9 to 83.2 days, 49.6 to 197 days, 17.2 to 23 days and 3 to 4.1 days, respectively, all being independent from pH (EC 2024b). These ranges indicate different persistences for the different transformation products (MTBT: low persistence, M-3 and M-12: moderate persistence, M-8: moderate to medium persistence and M-11: moderate to high persistence). It is noted that only the DT50 values for MTBT came from a metabolite dosed experiment, while the DT50 values for all other transformation products were derived from parent-dosed experiments.

Field dissipation studies

In the DAR (EC 2006), a field dissipation study in four different German soils found DisT50 values of 9.7 to 16.7 days (EC 2006, EFSA 2008). In addition, an old American study (2001) was submitted for the EU renewal assessment investigating fenpyroximate dissipation in North Carolina, Arkansas and California (EC 2019). While both studies were deemed valid by the RMS in the initial version of the dRAR, the kinetic re-evaluation resulted in a disagreement between the RMS and co-RMS about the acceptable sites and data points (EC (2019), Vol. 3CA, B.8.1.2.2.1, p.147). In the Pesticide Peer Review expert meeting (TC 61, 15-16 September 2021, https://www.efsa.europa.eu/sites/default/files/2021-10/pesticides-fate-behaviour-minutes.pdf) it was concluded that only the Porterville soil was representative of European soils (Southern Europe), however, due to the few data points only one persistence endpoint could be derived. It was noted that some key information was missing from the German field dissipation studies and there were not enough data for a proper derivation of modelling and persistence endpoints. In the updated dRAR (EC 2024b), it was concluded that no reliable endpoints could be derived from the field dissipation studies and the risk assessment was solely based on laboratory data (EC 2024b). Studies on accumulation of fenypyroximate in soils were not required (EC 2024b, EFSA 2013).

A field study from the scientific literature found a DisT50 range of 8.8 to 9.6 days in soil (Li *et al.* 2009) that is comparable to the previously agreed regulatory results (EC 2006, EFSA 2008). However, no further information on the method, the tested soil type or its properties were available, which limits their reliability.

1.5.3 **Adsorption/desorption properties and bioavailability**

Adsorption

Based on the laboratory adsorption studies, fenpyroximate can be classified as immobile in soil, while the metabolites vary considerably from being mobile to slightly mobile according to the FAO soil mobility classification (FAO 2000). The adsorption properties of fenpyroximate and its major metabolites are summarised in Table 3.

Table 3: Summary of soil adsorption of the active substance fenpyroximate and the major soil metabolites. The metabolite M-12 was also assessed for soil mobility but was not deemed to be a major metabolite in the present report. Abbreviations: Kfoc – organic carbon-normalised Freundlich distribution coefficients; 1/n – Freundlich exponent. Classified according to US EPA recommendation to use AO Soil Mobility Classification McCall et al. (1980). Data source: EC (2024b).

Substance	**Range of Kfoc [mL/g]**	**Geometric mean of Kfoc [mL/g]***	**Arithmetic mean of 1/n**	**pH dependence**	**Mobility category according to McCall *et al.* (1980)**
Fenpyroximate	11 091 - 72 677	39 065	0.926	no	Immobile**
M-3	351 - 774	503	0.775	no	Medium to low mobility**
M-8	10 - 169	58	0.69	no	Very high to medium mobility***
M-11	323 - 1089	557	0.773	no	Medium to low mobility***
M-12	15 019 - 56 280	29 450	0.935	no	Immobile****
MTBT	3 - 18	10	0.786	no	Very high mobility ****

Note: *Geometric mean of Kfoc given due to large range of Kfoc in different soils (EC 2024b). **tested in silt loam, loamy sand, clay loam and sand with pH of 6.4, 8.8, 7.5, 7 and 8.2, respectively, ***tested in sand, sand clay loam, clay loam and sandy loam with pH of 5.0, 7.7, 4.9 and 4.9, respectively, ****tested in silt loam, clay loam, sandy clay loam, clay with pH of 1.7, 4.1, 1.0 and 2.1, respectively.

Leaching

There is no information provided in the most current draft assessment report (EC 2019) regarding the leaching potential of fenpyroximate and its metabolites in soil column leaching tests or lysimeter/field leaching studies, since sufficient data is available from the adsorption/desorption studies, as summarised in Table 3. An older assessment (EC 2008b) reports three soil column leaching studies, which were not re-evaluated in the subsequent renewal (EC 2019). Briefly, those three studies found that the majority of fenpyroximate and the studied metabolites M-1, M-3 and M-8 (formed at max. 3 % of the applied amount) adsorbed to the topsoil layer with negligible leaching to deeper soil layers. Based on the information in Table 3, fenpyroximate is unlikely to leach from soil.

Bioavailability

The bioavailability of a chemical compound and in turn the actual toxicity of a substance to in-soil organisms is dependent on various factors including the soil physical and chemical properties (e.g. organic matter content, texture/clay content, pH and/or cation exchange capacity) as well as the physiology and behaviour of the organism considered (e.g. surface-volume ratio, anatomy, feeding strategy and/or preferences in habitat) (Marti-Roura *et al.* 2023, Peijnenburg 2020). Proper consideration of bioavailability can help with reducing the overestimation of the actual risk. In order to account only for the bioavailable portion of the tested substance, the test results need to be normalised to the above mentioned soil properties. However, in the absence of appropriate equations that can mirror the whole complex system, normalisation takes place only to the organic matter content in regulatory context. It is considered the main factor influencing bioavailability for organic compounds (Marti-Roura *et al.* 2023).

In the case of fenpyroximate, soil pH and texture do not affect the adsorption of the compound to soil particles. For non-ionised organic compounds like fenpyroximate (Table 1), it is assumed that bioavailability is mainly driven by the organic matter content of the soil (EC TGD 2003); therefore the test results are normalised to a standard organic matter content (see Section 3).

1.6 Bioaccumulation and biomagnification

Substances, such as lipophilic organic compounds, can potentially accumulate along the food chain resulting in a risk for higher vertebrates, such as worm-eating birds and mammals. Especially compounds with a log Kow greater than three can pose a risk of secondary poisoning to animals at higher trophic levels. Fenpyroximate has a log Kow of 5.7 (Table 1), and thus there is a potential for bioaccumulation and biomagnification. The bioconcentration factors of fenpyroximate in fish range from 1601 to 2238 (lowest steady state to highest kinetic BCF, EC (2024b) LoEP p.136), which is well above the trigger value of 100. Thus, it is warranted to assess fenpyroximate for bioaccumulation and biomagnification in a separate assessment (as it is out of the scope of the current SGV derivation).

2 Chemical analysis and environmental concentrations

Comprehensive techniques are necessary for the extraction of plant protection product residues from soil and for their analysis. A new multi-residue method has been developed and will be used for soil monitoring in Switzerland (Acosta-Dacal *et al.* 2021, Rösch *et al.* 2023). Pesticides are extracted using an optimised QuEChERS (quick, easy, cheap, effective, rugged and safe) approach followed by chemical analysis *via* liquid chromatography coupled to tandem mass spectrometry with electrospray ionisation (LC-ESI-MS/MS, triple quadrupole). In the case of fenpyroximate, the limit of quantification of this method (MLOQ) was determined as 0.1 ng a.s./g (corresponding to 0.0001 mg a.s./kg soil; Table S6, Rösch *et al*., 2023).[1]

The soil guideline value that is derived in this dossier for fenpyroximate will be used in conjunction with the actual soil concentrations monitored in Swiss soils by using the above-described measurement method. Initial measurements on some selected, partly agricultural, Swiss soils resulted in fenpyroximate concentrations of mostly < 0.0001 mg a.s./kg soil (< MLOQ) and one detection of 0.0008 mg a.s./kg soil in orchard (Table S12 in Rösch *et al*. 2023).

For the representative uses of fenpyroximate in the EU, the maximum initial predicted environmental concentrations in soil (PECsoil) were 0.096 and 0.137 mg a.s./kg soil; while the predicted plateau values, resulting from accumulation after long-term use, were predicted to be 0.050 and 0.072 mg a.s./kg soil for single application, following the worst case EU GAPs (Good Agricultural Practices, i.e. the proposed and evaluated representative uses of fenpyroximate in the EU; max. 1 x 102.4 g a.s./ha/season in strawberry and ornamental plants with 30 and 0 % plant interception, respectively; EC (2024). So the estimated overall PECsoil,accumulation values (= PECsoil,initial + PECsoil,plateau) are 0.146 (strawberries) and 0.209 (ornamental plants) mg a.s./kg soil. [It is noted that in the updated LoEP (EC 2024b), in the risk assessment for soil macro organisms, PECsoil of 0.346 mg a.s./kg was used as the highest critical value, which seems to be erroneously calculated as a sum of the PECsoil,accumulation and the PECsoil,initial values for ornamental plants, i.e. the PECsoil,initial value was twice added to the PECsoil,plateau value.]

[1] Unless it is specified otherwise, active substance concentrations in soil are meant per kg soil dry weight.

3 Effect data on fenpyroximate

Effect data for soil organisms were collected from studies retrieved from the European registration information. Additionally, a bibliographic search was performed for fenpyroximate and its CAS number (CAS 134098-61-6) in the ECOTOX Knowledgebase (286 hits for combination "fenpyroximate" and "134098-61-6" (US EPA 2024) and in the database of the German Federal Environment Agency (no hits for combinations "Fenpyroximate", "134098-61-6", or the corresponding IUPAC name (UBA 2024). However, those searches did not give usable results. Furthermore, a literature search was performed on Scopus by using a combination of key words (Soil, EC50, LC50, NOEC, LOEC, LCx, ECx, toxicity and the English and Latin names of various soil organisms such as earthworm, Collembola or mite) and the compound's name or CAS number. No usable result for soil toxicity endpoints were found via Scopus. Studies performed with formulated products were included in the dataset unless the amount of active substance within the formulation was unknown or the formulation contained other active substances in addition to fenpyroximate. Since only the E-isomer of fenpyroximate is manufactured and is deemed to be stable, any potential difference in toxicity was not asssessed.

In general, only reliable and relevant data should be used for SGV derivation. Different approaches to assessment and classification of (eco)toxicological data have been published. An established method introduced by Klimisch *et al.* (1997) uses four levels of quality: (1) reliable, (2) reliable with restrictions, (3) not reliable, (4) not assignable. The CRED approach (criteria for reporting and evaluating ecotoxicity data; Moermond *et al.* 2016) is based on a similar classification scheme but takes into account the relevance of test results in a more detailed way. This assessment method was originally developed for the aquatic environment and therefore in order to assess and classify (eco)toxicological studies performed in the soil compartment, the CRED approach needed to be adapted by incorporating soil specific aspects (Casado-Martinez *et al.* 2024). This modified approach is applied for the assessment of the studies in this dossier and used for evaluating the reliability and relevance of the studies (see scores for "R" and "C", respectively, in Table 4, Table A1 and Table A2).

A short summary of the main points of considerations are given below. For further details on the consideration with regard to the study evaluation and the SGV derivation, please refer to Appendix 1 as well as to the above mentioned soil CRED article (Casado-Martinez *et al.* 2024) and the methodological proposal for deriving soil guideline values (Marti-Roura *et al.* 2023).

Since the bioavailability of non-ionised organic compounds, like fenpyroximate, to soil organisms is assumed to be mainly driven by the organic matter (OM) content of soil (EC TGD 2003), effect data should be normalised to a standard organic matter content in order to make the results comparable among different soil types. The EC TGD (2003, p.116) recommends for non-ionic organic compounds, a normalisation to a standard organic matter content of 3.4 % (corresponding to 2 % organic carbon (OC)). This is in line with the findings in Swiss agricultural soils (Meuli *et al.* (2014); personal communication from NABO). The normalisation has been performed according to the following equation:

$$Effect\ concentration\ [standard] = Effect\ concentration\ [exp] \times \frac{Fom\ soil\ (standard)}{Fom\ soil\ (exp)}$$

Where:
Effect concentration [standard] – effect concentration in standard soil [mg/kg]
Effect concentration [exp] – effect concentration in experiment [mg/kg]
Fom soil (standard) – fraction of organic matter in standard soil (0.034) [kg/kg]
Fom soil (exp) – fraction of organic matter in experimental soil [kg/kg]

Studies, where the information about the organic matter (or carbon) content is missing are classified as "*not assignable*" (R4) in accordance with the CRED criteria. Besides the organic matter content, other soil properties such as pH and texture (clay content) need to be also considered. The pH ($CaCl_2$ method) for Swiss agricultural soils ranges between 4.5 and 7.5 (median 6.0) whereas clay content ranges between 5 % and 50 % (median 20 %; Marti-Roura *et al.* 2023). As there is no evidence that bioavailability of fenpyroximate is affected by soil pH (EC 2019), studies outside the recommended range (or without knowing the pH) were not excluded from the data set. However, due to the high Kow of fenpyroximate it was essential to know the organic matter content in the tested soils.

In the course of the evaluation, reproduction endpoints are considered the most relevant endpoints as they are good indicators of the long-term sustainability of the population. Other chronic endpoints affecting survival and growth (biomass) of individuals are also accepted, since they are traditionally measured endpoints frequently extrapolated to represent the impact at population level (Marti-Roura *et al.* 2023). If multiple comparable toxicity values for the same species and the same measured effect are available, the geometric mean of the effect values is calculated.

Regulatory studies and their endpoints are either accepted without additional assessment (at face value, although without applying the additional divison of the endpoint by two in case of log Pow $\geq$ 2) or partially/fully re-considered if needed to set the endpoints in line with our criteria as summarised in Appendix 1. This is the case, for example, when organisms were not exposed through soil (e.g. plant vegetative vigour tests *via* foliar application); normalisation to a standard organic matter content was not possible due to lack of data or not the statistically most robust effect concentration was proposed/agreed upon as a final endpoint.

If more than one endpoint is available from the same study for the same effect, the statistically more robust one is preferred. This means that the statistically more robust endpoint is chosen even if it is higher than another one or it includes more than 10 % effect (choosing non-significant endpoints with < 10 % effects is a precautionary approach that is often used at European level). If the latter is the case, it will be highlighted and discussed further in the uncertainty analysis (see below). If both NOEC and EC10 are available from the same study and statistically both are equally robust, due to the inherent uncertainties of the NOEC, the EC10 is preferred over the NOEC (for further explanation, please refer to Appendix 1).

Complete lists of relevant laboratory and field studies reporting soil effect values for fenpyroximate and its transformation products are shown in Appendix 2 (for fenpyroximate, Table A1 with laboratory studies, no field studies were found) and in Appendix 3 (for the major soil metabolites, Table A2). If necessary, some clarifications and/or justifications of the assessment are provided in form of notes to those tables as well as for Table 4. In Table 4 of the main text, all the reliable and relevant results are summarised and the lowest values per species/group per test setup are shown in bold. If there are only greater-than values available for the same species/group from different setups, the highest one is considered decisive as they mean that up to the highest tested concentration no adverse effects could be observed. This sifting procedure helps to choose the lowest effect concentrations per species/group for the SGV derivation (see Table 5).

3.1 Comparison between data for active substance and formulated products

A statistical analysis of potential differences in the toxicity of the active substance and the formulated products was not possible due to the scarcity of data. Mostly effect data with formulation were available for the parent compound (Table 4).

Table 4: Fenpyroximate – All reliable (R1-R2) and relevant (C1-C2) effect data. The lowest reliable and relevant effect concentrations per species per test setup are shown in bold. Calculated data are rounded to three significant figures. Abbreviations: OM – organic matter, a.s. – active substance, cc. – concentration, [CPIR] – confidentially provided information, redacted. The full set of studies can be found in Appendix 2 (Table A1). Data were evaluated for reliability and relevance according to the modified CRED criteria (see R/C scores) or taken at face value from regulatory dossiers (Assessment score 1-3). The explanation of notes are included after this table (Notes 1).

Species (Taxonomic group)[2]	Test substance	Measured effect[3]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
Zea mays **M (Terrestrial plant)**	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Avena sativa **M (Terrestrial plant)**	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Allium cepa **M (Terrestrial plant)**	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lolium perenne **M (Terrestrial plant)**	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Brassica oleracea **D (Terrestrial plant)**	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Cucumis sativus **D (Terrestrial plant)**	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lactuca sativa **D (Terrestrial plant)**	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence/Growth (shoot**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**

[2] M – monocotyledonous, D – dicotyledonous plant species

[3] FE – functional endpoint

Species (Taxonomic group)[2]	Test substance	Measured effect[3]	Dura tion	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
		length)/Biomass (shoot dry weight)									
Brasscia rapa [D] (Terrestrial plant)	Fenpyroximate 5SC (5.1 % w/w)	Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R2/C1	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269
Lycopersicon esculentum [D] (Terrestrial plant)	Fenpyroximate 5SC (5.1 % w/w)	Seedling emergence/Growth (shoot length)/Biomass (shoot dry weight)	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J K	(3) R2/C1	Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p.269
Microorganisms	Fenpyroximate 5 SC (Hoe 094552 00 SC 05 A104, 5 % w/w a.s.)	Carbon transformation (O_2 cc.) [FE]	28 d	≤25 % effect (< 10 % effect)	≥ 1.5	0.91	≥ 5.60	Field soil I (clay loam): 54.4 % sand, 10.0 % clay, 35.6 % silt, pH 6.2, microbial biomass 17 mg C/100 g soil, MWHC 31.5 %, 45 % of MWHC	B	1 (R2/C2)	Baedelt (1991a) cited in EC (2006) Vol. 3, B.9.8.1, p.705
Microorganisms	Fenpyroximate 5 SC (Hoe 094552 00 SC 05 A104, 5% w/w a.s.)	Carbon transformation (O_2 cc.) [FE]	28 d	≤ 25 % effect (< 10 % effect)	≥ 1.5	1.37	≥ 3.72	Field soil II (sandy loam): 11.2 % sand, 20.3 % clay, 68.5 % silt, pH 7.1, microbial biomass 47.1 mg C/100 g soil, MWHC 51.3 %, 40 % of MWHC	B	1 (R2/C2)	Baedelt (1991a) cited in EC (2006) Vol. 3, B.9.8.1, p.705
Microorganisms	Fenpyroximato 50 SC [CPIR]	Nitrogen transformation (NO_3^- cc.)[FE]	28 d	≤ 25 % effect	≥2.4	[CPIR]	[CPIR]	[CPIR]	C	(1) R2/C1	Anonymous (2019) cited in EC (2024b), LoEP, p.174 accessed via EFSA (2025a) and EFSA (2025b)
Eisenia fetida (Earthworm)	Fenpyroximate 5% SC (NNI-850 5SC, 5.31 % w/w, 54.54 g/L, density 1.0271 g/mL)	Reproduction (number of juveniles)	56 d	NOEC	5.58	10	1.90	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 70 % industrial sand, < 1 % calcium carbonate, pH 5.7-6.2, max WHC 57.9 – 60.7 %	F S	(1) R1/C1	Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1, p.246

Species (Taxonomic group)[2]	Test substance	Measured effect[3]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
Eisenia fetida (Earthworm)	Fenpyroximate 5% SC (NNI-850 5SC, 5.31 % w/w, 54.54 g/L, density 1.0271 g/mL)	Biomass (adult weight change)	28 d	NOEC	≥ 10.0	10	≥ 3.40	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 70 % industrial sand, < 1 % calcium carbonate, pH 5.7-6.2, max WHC 57.9 – 60.7 %	F S	(1) R1/C1	Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1, p.246
Eisenia fetida (Earthworm)	Fenpyroximate 5% SC (NNI-850 5SC, 5.31 % w/w, 54.54 g/L, density 1.0271 g/mL)	Mortality (number of dead adults)	28 d	NOEC	≥ 10.0	10	≥ 3.40	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 70 % industrial sand, < 1 % calcium carbonate, pH 5.7-6.2, max WHC 57.9 – 60.7 %	F S	(1) R1/C1	Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1, p.246
***Folsomia candida* (Springtail)**	**Fenpyroximate 5SC (4.98 % a.s. content)**	**Reproduction (number of juveniles)**	**28 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % industrial quartz sand, pH 5.87-6.16, max WHC 57.2-58.4 %**	**H V S P**	**1 (R2/C1)**	**Friedrich (2015b), cited in EC (2019) Vol. 3CP, B.9.7.2, p.252**
***Folsomia candida* (Springtail)**	**Fenpyroximate 5SC (4.98 % a.s. content)**	**Mortality (number of dead adults)**	**28 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % industrial quartz sand, pH 5.87-6.16, max WHC 57.2-58.4 %**	**H V S P**	**1 (R2/C1)**	**Friedrich (2015b), cited in EC (2019) Vol. 3CP, B.9.7.2, p.252**
***Hypoaspis aculeifer* (Mite)**	**Fenpyroximate 5SC (4.98 % a.s. content)**	**Reproduction (number of juveniles)**	**14 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 0.2 % calcium carbonate, 74.8 % industrial quartz sand, pH 5.7-6.2, max WHC 47.85-48.92 %**	**I V S P**	**1 (R2/C1)**	**Schulz (2015), cited in EC (2019), Vol. 3CP, B.9.7.2, p.255**
***Hypoaspis aculeifer* (Mite)**	**Fenpyroximate 5SC (4.98 % a.s. content)**	**Mortality (number of dead adults)**	**14 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 0.2 % calcium carbonate, 74.8 % industrial quartz sand, pH 5.7-6.2, max WHC 47.85-48.92 %**	**I V S P**	**1 (R2/C1)**	**Schulz (2015), cited in EC (2019), Vol. 3CP, B.9.7.2, p.255**

Notes 1: Notes on soil studies for fenpyroximate (reliable and relevant data).

B	The study was conducted in line with an old test guideline (BBA 1990) that defined no validity criteria. The following deviation to the BBA (1990) test guideline occurred: • The results of a toxic reference substance were not documented in the study summary. It is noted that this is not a requirement in the newer OECD 217 guideline (see below). The RMS did not re-evaluate this study during the renewal assessment of fenpyroximate (EC 2019) as soil respiration/carbon transformation is no longer a data requirement for the prospective assessment of pesticides. Therefore, the test has been evaluated by OZ according to the latest relevant OECD 217 test guideline (OECD 2000b) as follows: • The environmental conditions in the tests were in line with the test guideline. • The soil characteristics of Field soil I were in line with the soil parameter recommendations of the guideline. Field soil II contained only 11.25 % sand that is much lower than recommended (50-75 %). High soil sand content is recommended in the guideline as it contributes to providing a worst-case situation for this type of test. However, the use of other soils may be accepted if their relevance is justified. The sand content of Swiss soils range between 7 and 86 % with a median of 48 % (Reusser *et al.* 2023). The majority of Swiss soils (25-75 percentiles) contains 36-59 % sand. In general, the representativeness of Field soil II to Swiss soils does not seem to be justified. On the other hand, the test item concentrations were the same for both soils and both showed < 10 % effects at both test concentrations. The difference in the normalised effect concentrations is a result of the difference in the OM content of the soils. The OM content of 0.91 and 1.37 % correspond to 0.53 and 0.80 % OC content for Field soil I and II, respectively, which is rather low (lower than the 5-95 %ile of Swiss soils; Reusser *et al*. 2023) and could help with providing the worst-case situation for testing. Consequently, the results for both soils are retained as they could provide worst-case scenarios for soil respiration/carbon transformation testing. • The amount of glucose added (4000 ppm) and the measurement days (0, 7, 14, 28 d after treatment) were in line with the test guideline. However, according to the study summary, the measurements of oxygen consumption lasted 24 instead of 12 hours. It is noted that the BBA guideline requires 24-h measurements but for the evaluation to use only the first 12 hours before the measured values reach their peak. It is not specified in the study summary if the results were based on the initial 12-h or on the full 24-h measurements and in case of the latter, if the peak oxygen consumption was reached. • Based on the mean ± SD values, the validity criterion (i.e. < 15 % variation in the control) was met for both soils. • No positive/toxic control is required according to the OECD 217 guideline. • The results are shown as concentration (in mg O_2/100 g soil) instead of rates (per hour). As the differences to the control are evaluated in percentages (either as all measured oxygen consumption per soil dry weight per 12/24 h or as rate per hour), this is considered not to have an impact on the outcome of the tests. It is noted that the summarised values are similar to rates (in mg O_2/dry weight soil/h) reported in other soil respiration/carbon transformation tests after 12-h measurements, not to the sum of oxygen consumption in 12 or 24 hours. Due to the uncertainty about the duration of measurement used for calculating the results, both tests are considered reliable with restrictions (R2). Soil respiration/carbon transformation is considered a less effective indicator of soil health and biodiversity and as such the soil respiration/carbon transformation test result is not a mandatory data requirement for the EU pesticide risk assessment anymore. However, it is still considered relevant for the SGV derivation but with restrictions due to its limitations (C2). The concentration of the test substance in the soil was calculated following both above-mentioned guidelines assuming 5 cm soil depth and 1.5 kg/L soil bulk density.

C	The microorganism study on nitrogen transformation of a fenpyroximate product (Fenpyroximato 50SC) was listed in the LoEP (EC 2024), and the company study summary as well as the RAR summary were made available under two PAD applications (EFSA 2025a, 2025b). The study was in line with OECD TG 216 validity criteria, however, the results were not properly calculated (nitrate-N concentrations instead of rates) and no product density was reported. However, the Nitrate-N transformation rates could be calculated from the available information. The study was considered relevant (C1) and due to the missing product density as reliable with reservations (R2).
F	The study from Wagenhoff (2019) on earthworm reproduction was conducted in line with the OECD TG 222 (OECD 2016c). Statistically significant effects were found only on reproduction (number of juveniles). The estimation of the effect cc (cc = concentration) on reproduction was cross checked using a cumulative normal distribution function for model fitting, which resulted in comparable effect estimates to the study summary: *estimated: EC10 = 100, EC20 = 118.1, EC50 = 161 mg test item/kg soil dw* *from the summary: EC10 = 102, EC20 = 119, EC50 = 162 mg test item/kg soil dw* The lower ends of the confidence intervals summarised in the dRAR (EC 2019) for EC20 and EC50 (75.9 and 92.1 mg product/kg soil, respectively) were lower than the median EC10 (102 mg product/kg soil), thus the EC10 is not considered reliable. Consequently, only the NOEC values are considered regarding reproduction in the SGV derivation not the EC10 value. The study summary indicates that the test is of high quality and relevant for SGV derivation. Therefore, the NOEC for reproduction, biomass and mortality was rated as relevant (C1) and reliable (R1). Due to the flat dose-response curve indicated by the wide CI, the ECx values were considered unreliable (R3).
H	The test was conducted following an older version of the OECD 232 test guideline from 2009 but fulfilled the validity criteria of the updated guideline from 2016 as well (OECD 2016a). A NOEC of ≥1000 mg test item/kg soil for both adult mortality and reproduction was determined resulting in approx. 48.5 mg a.s./kg soil here. However, due to the missing accurate qualifier of the a.s. content of the product (if it was expressed in % w/v or w/w), the a.s. conversion is only an approximation assuming % w/v (see note P). It is noted that at EU level, a NOEC of 50 mg a.s./kg soil was agreed upon (EC 2024b). The reliability of the study is rated as *reliable with restrictions* (R2) because of the uncertainty of the a.s. conversion. However, the study is considered relevant (C1) for SGV derivation due to the study design and method.
I	The study was conducted to an earlier version of the OECD 226 test guideline (2008) but fulfilled the validity criteria of the updated test guideline (OECD 2016b). A NOEC of ≥1000 mg test item/kg soil for both adult mortality and reproduction was determined resulting in approx. 48.5 mg a.s./kg soil here. However, due to the missing accurate qualifier of the a.s. content of the product (if it was expressed in % w/v or w/w), the a.s. conversion is only an approximation assuming % w/v (see note P). It is noted that at EU level, a NOEC of 50 mg a.s./kg soil was agreed upon (EC 2024b). The reliability of the study is rated as *reliable with restrictions* (R2) because of the uncertainty around the a.s. conversion. However, the study is considered relevant (C1) for the SGV derivation due to the study design and method.
J	The summarised study (Teixeira 2001a) on seedling emergence upon spray application onto soil in 10 plant species was conducted in line with the outdated test guidelines of OPPTS 850.4100 and OPPTS 850.4225 (US EPA 1996a, 1996b). It is noted that in these outdated versions of the guidelines, no validity criteria were included. Since then, the guidelines have been updated and validity criteria have been added (OCSPP 850.4100; US EPA 2012). These criteria are almost identical with the updated, currently valid OECD 208 test guideline for plant seedling emergence (OECD 2006).

The summarised study results were confirmed via the study report to which we got access through a PAD application (EC (2019), Vol. 3CP, B.9.11.2, p.269; (EFSA 2025a), see Section 1).
To properly assess the robustness of a study in line with modern evaluation standards, the tests should meet the validity criteria of the updated guidelines. The comparison of the guideline validity criteria and their fulfilment in the tests are summarised by OZ below:

Test validity criteria	OCSPP 850.4100 (2012)	OECD 208 (2006)	In Teixeira (2001a)
Seedling germination	Not specified as a validity criterion. Test is not acceptable if control seed germination < 70 %.	≥ 70 % in the control	Met in control for all species
Phytotoxicity effects	None visible in control	None visible in control	Minor effects in control in cucumber, none in other species
Mean survival of seedlings	≥ 90 % in control	≥ 90 % in control	Not met in the **soybean** control, met in all other species (not clear if it was met for tomato tier I test)
Environmental criteria per species	Identical	Identical	Met in control for all species
Source and lot No. per species	Identical	Not validity criterion. Seed should be from the same source.	Identification of seed source required in the old guideline. Met for all species
Control group	To be included	Not a validity criterion. Appropriate control groups need to be included.	Included
Test concentration	For dose-response test, the lowest test cc. < EC25 and NOEC/EC05. For limit test, the test cc. statistically less than EC25 and NOEC. For pesticides, the limit cc. is based on the max. label rate.	Not a validity criterion. For limit test, the max. application rate of the pesticide is used; for dose-response test, the lowest test cc. shold be lower than the aimed ERx to be determined.	Met
Additional pesticide use	No effect and interaction between the test substance and the additional pesticide	Not a validity criterion; not specified	Not used
Water amount used in the application solution [L/ha]	Not exceeding label prescription	Not a validity criterion. Spray volumes should be in the range of normal agricultural practice.	The old guideline required the maximum recommended amount of pesticide in the recommended minimum quantity of carrier such as water to be used. Met

Deviations to the guidelines:

- ***Test duration.*** According to the guidelines, the test duration is usually 14 to 21 days after 50 % emergence of the seedlings in the control (OECD 208) or at least 2 weeks after germination (US EPA). These were 14-day tests for all species that is somewhat shorter. It is not clear, why the RMS noted that the "tier 2 test in tomato should have been extended to 21 days duration". According to the updated OCSPP guideline, if phytotoxicity symptoms occur on day 7-14 post-emergence, the test should be extended to 21 days after 50 % emergence in the control. No phytotoxic effects were observed for the tier II tomato test.

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Deviations to the OECD 208 (2006) guideline:

Seed density. Seeding density is higher than recommended for some species in the updated guideline so that overcrowding of the seedlings could not be excluded. In the guideline for example, 1-2 seeds per 15-cm pot is recommended for corn, soybean, tomato, cucumber and sugar beet, 3 seeds for rape and pea, 5-10 seeds for onion, wheat or other smaller seeds. In general, the maximum plant density is recommended as 3-10 seeds per 100 cm^2 depending on the size of the seeds. It should be noted that the general recommendation allows for higher seeding density than the examples for the 15-cm pots (i.e. 177 cm^2 area). In the study, 13-cm pots were used with 10 seeds/pot for onion and ryegrass (10 very small seeds per 133 cm^2), 5 seeds/pot for oat, cabbage, cucumber, lettuce, tomato and turnip (5 small to medium seeds per 133 cm^2) and 5 seeds/pot for corn and soybean (5 medium to large seeds per 133 cm^2). This means 3.8 seeds/100 cm^2 for medium to large seeds that is higher than recommended in the OECD guideline. In addition, it seems that the results were not affected by possible overcrowding. For instance, there were 7-8 non-emerged/dead plants in the control and < 10 % effects on growth and biomass in the treatment in onion and ryegrass (overcrowding excluded). 6 plants did not emerge/died in the soybean control and 8 in the treatment with 2-9 % increase in growth and biomass in the treatment (possible overcrowding). In the meantime, no mortality/non-germination occurred in the corn control with 5-8 % increase in growth and biomass in the treatment (also proned to possible overcrowding). The RMS also noted that despite the possible overcrowding "plants seemed to develop sufficiently". It should also be noted that the requirements of the OPPTS guideline, in force at time of the study, with regard to number and density of seeds were met (3 replicates using at least 10 seeds per pot; pot size was not specified). In the updated OCSPP guideline, a minimum of four replicates, each with minimum of 10 seeds are required to be used. "The number of plants per pot is left to the discretion of the laboratory conducting the test, avoid overcrowding." The given example numbers of seeds per pot are similar to the examples in the OECD 208 guideline mentioned above.
Test conditions. During the test temperature varied between 15 and 35°C and the relative humidity between 11 and 96 %. The OPPTS guideline did not specify the environmental conditions for testing, it only requires "optimal conditions" for the species/variety. The updated OCSPP guideline requires 25/20°C (daytime/nighttime) ± 6°C temperature (= 14-31°C) and 70 % (daytime) ± 15 % relative humidity (= 55-85 % daytime rel.humidity). The study temperatures were more or less within the required range. It is noted that in the updated OECD guideline narrower ranges are given as examples for certain commonly used crop species (17-28°C temperature and 65-95 % relative humidity range including light and dark periods). While the relative humidity at night is not specified in the OCSPP guideline, it is expected to be higher than the specified daytime humidity due to the lower temperature. The lowest relative humidity was lower than specified for daytime in the updated OCSPP guideline. The RMS noted that "humidity fell below the required level on occasion". In general, it is usually assumed that if the control performed well, the deviations to the guideline specified environmental conditions did not affect substantially the outcome of the test. The control groups performed clearly well in corn and oat, likely well in tomato and possibly well in onion, ryegrass, lettuce, soybean and turnip.

For tomato, the detailed tier I test results were not included in the study report, thus these are not considered reliable here. The tier II test was conducted following the test guideline OPPTS 850.4225 (1996b) due to adverse effects (> 25 %) on shoot lenght relative to the control in the tier I test.

Due the above noted uncertainties, the validity and reliability of the study was questioned by the RMS. However, as the detailed re-evaluation above shows the validity criteria were met (except for soybean) and the test conditions were acceptable. The largest shortfall was the shorter duration of the study. Considering that there were no statistically significant effects (and all effects were < 25 %), the study results are scored as *reliable with reservations* (R2) and *relevant* (C1) concerning the SGV derivation.

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The a.s. content of the product was given in percentage. It was not indicated if this percentage was weight based (w/w) or volume based (w/v). This can lead to uncertainties in calculating the effect concentrations in terms of a.s. when necessary, if the product density deviates from 1 g/cm^3.

The study summary by Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246, reported a density of 1.0271 g/cm^3 for the product Fenpyroximate 5% SC with

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	5.31 % w/w a.s. content, which means that 1000 mL of this product would contain 54.5 g a.s. If the a.s. content would have been expressed as % w/v, the a.s. content would be 53.1 g a.s./L product, so a difference of 1.4 g/L. In order to account for this uncertainty, it is prudent to calculate effect concentrations with the given product density from Wagenhoff (2019) in applicable cases, where a similar SC product was used and information on a.s. content is ambiguous. As for SC (suspension concentrate) pesticide formulations the product density is expected to be > 1.00 kg/L, the use of the volume-based (w/v) calculation provides slightly lower a.s. content, which was then taken to calculate the effect cc. as a.s. and the OC-normalised effect cc. This approach is justified as the missing w/w or w/v indication calls for choosing the lower effect cc. as a protective measure.
S	Statistical evaluation to recalculate the NOEC was not possible since the raw data (replicates) were not documented in the study summary.
V	The results from the dRAR (EC 2019) were accepted without additional assessment (i.e. at face value).

3.2 Graphic representation of effect data

The lowest relevant and reliable data (R1-2/C1-2) per test – normalised to a standard organic matter content of 3.4 % – are plotted in Figure 1. If values for more measured effects for the same species from the same test are available (e.g. reproduction, biomass, mortality etc.), the lowest one is included in the figure.

This figure aims to provide an overview of the distribution of the chronic effect concentrations, i.e. to indicate the most sensitive species/group. The effect concentrations for earthworms and microorganisms are comparable whereas the chronic effect concentrations for springtails and mites are considerably higher at the same effect concentration (Figure 1 and Table 4). The highest sensitivity is shown for earthworms.

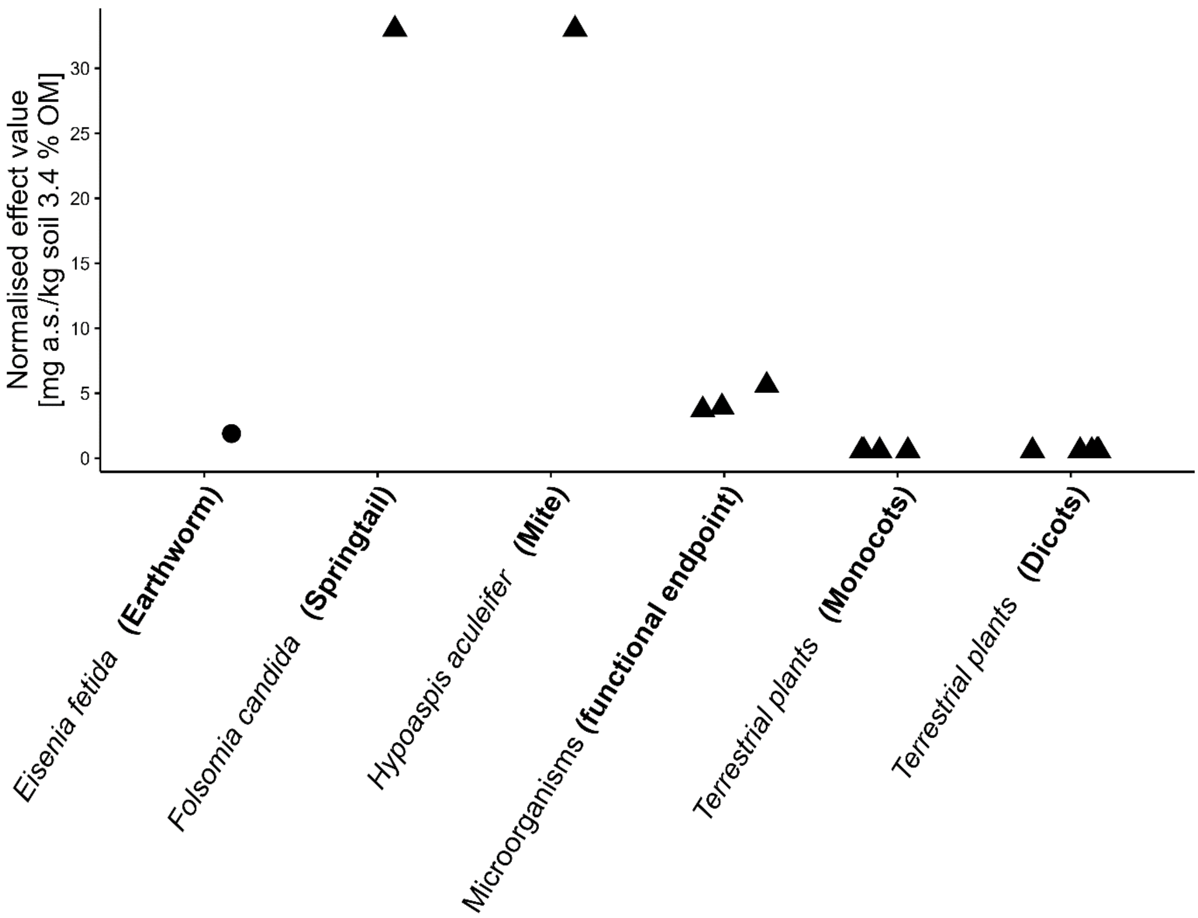

Figure 1: Effect data for fenpyroximate after normalisation to a standard organic matter content of 3.4 % - the statistically most robust lowest effect values of the relevant and reliable endpoints per species per test setup are shown. Triangles represent unbound data with the triangle facing up symbolising ≥ or > values. For all groups chronic data (NOEC/EC10) or equivalent to that (≤ 25 % effect) are presented.

4 Derivation of SGV

For the SGV derivation of fenpyroximate, the relevant and reliable effect concentrations of the active substance were normalised to a standard organic matter content of 3.4 %. Data on formulations were re-calculated to active substance content (Table 4). Then the lowest toxicity endpoints were summarised (Table 5).

Table 5: The lowest relevant and reliable, statistically robust chronic data for fenpyroximate per species/group, rounded to three significant figures, summarised from Table 4. Effect concentrations are expressed as concentrations normalised to 3.4 % of soil organic matter content.

Trophic level	Species	Type of effect concentration	Normalised effect concentration [mg a.s./kg soil]	Reference
Primary producers (terrestrial plants)	*Allium cepa, Amaryllidaceae* (Monocot)	NOEC	≥ 0.586	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I tests), p.269
	Avena sativa, Poaceae (Monocot)	NOEC	≥ 0.586	
	Lolium perenne, Poaceae (Monocot)	NOEC	≥ 0.586	
	Zea mays, Poaceae (Monocot)	NOEC	≥ 0.586	
	Brassica oleracea, Brassicaceae (Dicot)	NOEC	≥ 0.586	
	Brassica rapa, Brassicaceae (Dicot)	NOEC	≥ 0.586	
	Cucumis sativus, Cucurbitaceae (Dicot)	NOEC	≥ 0.586	
	Lactuca sativa, Asteraceae (Dicot)	NOEC	≥ 0.586	
	Lycopersicon esculentum, Solanaceae (Dicot)	NOEC	≥ 0.586	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier II test), p.269
Decomposers (nutrient transformers)	Microorganisms (Functional endpoint)	< 10 % effect	≥ 5.60	Baedelt (1991a) cited in EC (2006) Vol. 3, B.9.8.1, p.705
Decomposers (litter transformers/ primary consumers)	*Eisenia fetida* (Earthworm)	NOEC	1.90	Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246
	Folsomia candida (Springtail)	NOEC	≥ 33.0	Friedrich (2015b), cited in EC (2019) Vol. 3CP, B.9.7.2., p.252
Secondary consumers	*Hypoaspis aculeifer* (Mite)	NOEC	≥ 33.0	Schulz (2015), cited in EC (2019), Vol. 3CP, B.9.7.2., p.255

4.1 Derivation of SGV using the assessment factor (AF) method

The SGV_{AF} is determined using assessment factors applied to the lowest valid toxicity endpoint (e.g. NOEC, EC10) from long-term toxicity tests. The magnitude of the AF is selected according to the adapted methods of the European guidance document on environmental risk assessment (EC TGD 2003, Marti-Roura *et al.* 2023).

The lowest equal-to toxicity endpoint available for fenpyroximate (Table 5) is the NOEC of 1.90 mg a.s./kg soil for reproduction of earthworms. The overall lowest toxicity endpoints are available for plants with unbound values of ≥ 0.586 mg a.s./kg soil (Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2., p.269). Fenpyroximate is an acaricide, which acts in a non-systemic way but via a specific mode of action (cell respiration, inhibition of moulting). Therefore, it is expected that mites are the most sensitive group of organisms. However, only one data point for the most relevant group, terrestrial (i.e. soil-dwelling) mites (*Hypaspis aculeifer*) is available (Schulz (2015), cited in EC (2019), Vol. 3CP, B.9.7.2, p.255) and the NOEC for this species (≥ 33.0 mg a.s./kg soil) is considerably higher than the NOEC for earthworm (1.90 mg a.s./kg soil, Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1, p.246). This lower toxicity to mites – otherwise the main target group of organisms – may be explained by the target application method of fenpyroximate, which is spraying onto the foliage, to protect the crop from sucking mites. These pest mites do not dwell in soil but live in the plant canopy. Accordingly, regulatory and scientific literature studies focussing on spray applications of fenpyroximate and non-target effect assessment on (beneficial) canopy-dwelling predatory mites are not relevant for SGV derivation.

The lowest toxicity endpoints are available for **primary producers (terrestrial plants)**. However, these are unbound values from limit tests (Tier I tests for all species except tomato) or without significant effects at the highest test concentration (Tier II test for tomato). No statistically significant effects on germination, growth and biomass were found in the study for any of the tested monocotyledonous or dicotyledonous plant species (Table 5; Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2., p.269). As unbound values are not suitable for SGV derivation, a data gap for terrestrial plants needs to be considered.

The regulatory data on soil microorganisms – **decomposers (nutrient transformers)** – cover < 25 % effects per guideline definition. There are two relevant and reliable studies on soil microorganisms, one on soil respiration/carbon transformation (Baedelt (1991a) cited in EC (2006) Vol. 3, B.9.8.1, p.705) and one on nitrogen transformation (Anonymous (2019) cited in EC (2024b), LoEP, p.174 and EFSA (2025b)). The study by Baedelt (1991a) resulted in < 10 % effect in two soils at ≥ 3.72 and ≥ 5.60 mg a.s./kg soil normalised concentrations (see Table 4), out of which the higher is considered for the SGV derivation as the data show that up to that concentration there were no significant effects on soil microorganisms (two concentrations in two soils, all being greater-than/equal-to values with < 10 % effect). The anonymous study (Anonymous (2019) cited in EC (2024b), LoEP, p.174 and EFSA (2025b)) showed < 25 % effects on nitrogen transformation after 28 days at [CPIR] and [CPIR] mg a.s./kg soil normalised concentrations in one soil type. Since, the study by Baedelt (1991a) shows a higher exposure concentration at which no significant effect was observed on soil respiration/carbon transformation than the anonymous study on nitrogen transormation, the highest concentration of ≥ 5.60 mg a.s./kg soil normalised concentration by Beadelt (1991a) was used as the lowest relevant and reliable endpoint. Altogether, the microorganism data are considered to indicate that no effects on soil respiration/carbon transformation and on nitrogen transformation is expected.

The lowest equal-to data for fenpyroximate are on **decomposers (litter transformers/primary consumers)** with a 56-d reproduction NOEC of 1.90 mg a.s./kg soil from a chronic earthworm study (Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1, p.246). In addition, a 28-d mortality/reproduction NOEC of ≥ 33.0 mg a.s./kg soil is available for Collembola (Friedrich (2015b), cited in EC (2019) Vol. 3CP, B.9.7.2, p.252); however, this NOEC is an unbounded, greater-than/equal-to effect concentration.

Secondary consumers, namely *Hypoaspis aculeifer* (predatory mite), also did not show an exceptional sensitivity with a 14-d mortality/reproduction NOEC of ≥ 33.0 mg a.s./kg soil (Schulz (2015), cited in EC (2019), Vol. 3CP, B.9.7.2, p.255).

When long-term test results (NOEC or EC10 values) are available for at least three species/group representing three trophic levels with different living and feeding conditions, the EC TGD (2003) recommends the application of an assessment factor of 10 to the lowest valid effect datum (Table 20 in EC TGD (2003)). In the case of fenpyroximate, toxicity data are available for four species/group at three trophic levels with the lowest equal-to endpoint for earthworms as decomposers. To account for the uncertainties in the available data, an AF of 10 is applied to the lowest equal-to effect value:

$$SGV_{AF} = \frac{lowest\ EC10\ or\ NOEC}{AF}$$

$$SGV_{AF} = \frac{1.90\left(\frac{mg\ a.s.}{kg\ soil}\right)}{10} = 0.19\left(\frac{mg\ a.s.}{kg\ soil}\right)$$

The application of an AF of 10 to the lowest equal-to chronic datum results in a SGV_{AF} = **0.19 mg a.s./kg soil** for a standard soil with 3.4 % OM content (shown to two significant figures).

4.2 Derivation of SGV using the species sensitivity distribution (SSD) method

There is not enough data for applying the SSD method. The minimum data requirements recommended for the application of the SSD approach for SGV_{SSD} is at least ten exact data points (NOEC/EC_{10}) from three taxonomic groups whereas data from microbial functional processes should not be used in the distribution (Marti-Roura *et al.* 2023). In the case of fenpyroximate, one exact datum is available for Annelida (*Eisenia fetida*). Thus, the minimum data requirements for an SSD are not met.

4.3 Derivation of SGV using the equilibrium partitioning (EqP) approach

If no reliable data on terrestrial organisms is available, the equilibrium partitioning (EqP) utilising aquatic toxicity data can be used to estimate the SGV_{EqP} (EC TGD 2003). In the case of fenpyroximate, a sufficient amount of data is available for soil organisms to cover a wide range of different types of physiology and behaviour of species at various trophic levels. Therefore, the derivation of an SGV_{EqP} using the equilibrium partitioning approach is not required.

4.4 Determination of SGV using mesocosm/field data

No field studies on soil-dwelling organisms exposed to fenpyroximate products or the active substance were available. Numerous field studies were conducted for canopy-dwelling non-target arthropods exposed via spray applications (EC 2019). However, none of the studied species was relevant for soil risk assessment as they do not inhabit the soil and plant spraying applications were used as exposure strategy. Therefore, none of the field studies could be considered relevant for SGV derivation.

5 Toxicity of major transformation products

Since fenypyroximate had a DisT50 range of 8.8-9.6 days in a field dissipation study and DT50 of 21.1 - 238 days under laboratory conditions, fenpyroximate metabolites can play a role in chronic toxicity studies, which usually last 14-56 (up to 100) days in laboratory and up to a year in field conditions. Effect data are available only for one major soil metabolite of fenpyroximate, namely M-3 (Reg. No. 149054-56-8). M-3 formed under aerobic (28.7 % AR) and anaerobic (59.5 % AR) conditions in laboratory soil degradation studies (see Section 1.5.1). The full effect data table is presented in Appendix 3 (Table A2), whereas Table 6 below summarises the lowest effect concentrations for M-3 metabolite with regard to relevant and reliable data available per organism/group of organisms. It is noted that for the other aerobic, anaerobic and soil photolysis metabolites (see Table 2 in Section 1.5.1) as well as for M-3 in case of other soil organisms (*F. candida* and *H. aculeifer*), a ten-times toxicity of the parent compound was assumed and used in the prospective risk assessment at EU level.

For M-3, the earthworm and the microorganism results are very similar to each other (Table 6). No further relevant and reliable data on other soil organisms are available from EU pesticide authorisation or scientific literature (Appendix 3, Table A2). The existing data on earthworm indicate somewhat lower toxicity of M-3 than the active substance itself in case of earthworms, which is the most sensitive organism group to the parent substance (earthworm NOEC of M-3: 5.76 and 18.7 mg a.s./kg soil, of parent: 1.90 and ≥ 3.40 mg a.s./kg soil for reproduction and biomass, respectively). In case of microorganisms, the toxicity of M-3 and the parent is very similar with < 10 % effects of M-3 at ≥ 4.03 mg/kg soil on nitrogen transformation and < 10 % effect of fenpyroximate on soil respiration at ≥ 5.60 mg/kg soil (both normalised effect concentrations) and potentially < 10 % effect of fenpyroximate on nitrogen transformation at ≥ 2.40 mg a.s./kg soil (non-normalised value; new study accepted at EU level, reliability for SGV not proven, see details in Section 4.1 and 7). Thus, the SGV of 0.19 mg a.s./kg soil derived for fenpyroximate with the AF method seems to be protective of the toxicity of M-3 to both microorganisms and earthworms.

The other soil macro-organisms (springtail and mite) showed much lower sensitivity to fenpyroximate than earthworms and microorganisms (Table 5). Therefore, it is likely that the proposed SGV for fenpyroximate is also protective of the toxicity of the soil metabolites to these groups especially that the metabolites form and degrade at different rates resulting in a lower concentration than the applied parent compound (see Section 1.5.1).

Table 6: Lowest reliable and relevant soil effect data for the fenpyroximate transformation product M-3 (Reg. No. 149054-56-8). Endpoints are shown as effect concentrations normalised to 3.4 % soil organic matter.

Species (Taxonomic group)	Duration	Type of effect concentration	Effect value [mg/kg soil]	Reference
Microorganisms	28 d	< 10 % effect	≥ 4.03	Schulz (2016) cited in EC (2019), Vol. 3CA, B.9.5., p.231
Eisenia fetida (Earthworm)	56 d	NOEC	5.76	Friedrich (2015a) cited in EC (2019), Vol. 3CA, B.9.4.1., p.228

6 Proposed SGV to protect soil organisms

Depending on the degree of uncertainty or the representativeness of the derivation method and/or the assessment factor used for the derivation of the SGV, the final SGV can be classified as preliminary or definitive. With the available data for fenpyroximate, only the assessment factor method could be applied for deriving an SGV. Since the dataset included enough relevant and reliable data, the AF is not exceeding 10 and, consequently, the SGV is considered definitive.

A definitive **SGV of 0.19 mg a.s./kg soil for fenpyroximate** is suggested.

7 Protection of soil organisms and uncertainty analysis

The SGV of 0.19 mg a.s./kg soil for fenpyroximate was derived based on a relatively small dataset that comprised relevant and reliable data for microorganisms, earthworms (*Eisenia fetida*), springtails (*Folsomia candida*) and mites (*Hypoaspis aculeifer*). Fenpyroximate is an acaricide, and therefore mites and potentially insects are expected to show the highest sensitivity. However, reproduction in earthworms showed a lower NOEC than the NOEC for reproduction or mortality in mites (Table 4) and no toxicity data was available for soil-dwelling insects (only for Collembola that are not regarded insects anymore). In addition, with the exception of one datum (reproduction NOEC for earthworms, Table 4 and 5), all the other relevant and reliable toxicity data were unbound, greater-than values, which indicate

that other soil organism species than earthworms are less sensitive to fenpyroximate.
Overall, toxicity data were available for four species/group at three trophic levels (Table 5). This allowed for the selection of an AF of 10 for the SGV derivation.

A seedling emergence study (Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2, p.269) was evaluated but not accepted in the dRAR (EC 2024b). Based on the original study report (EFSA 2025a) we have re-evaluated the study (see note J in Notes 1 to Table 4) that showed acceptable validity criteria for nine out of the ten tested plant species. It is noted though that the shorter test duration (14 days altogether instead of 14 days after germination/after 50 % germination in control) have raised some uncertainties about the reliability of the results (R2). Eight of the nine valid tests were Tier I limit tests, for tomato a Tier II dose-response test was conducted. There were no statistically significant effects at the (highest) tested concentration resulting in a normalised NOEC of ≥ 0.586 mg a.s./kg soil for nine plant species. The validity criteria were not met for soybean (*Glycine* max), the tenth tested species. While the limit NOEC value is lower than the lowest equal-to value for earthworms, the results do not indicate any sensitivity of plants to fenpyroximate. In the absence of statistically robust equal-to NOEC values, ***a data gap is determined for*** **primary producers (terrestrial plants)**.

For microorganisms, a soil respiration/carbon transformation study with two soils has been found relevant and reliable (Baedelt (1991a) cited in EC (2006) Vol. 3, B.9.8.1, p.705). While it was not clear from the study summary if the oxygen consumption was summarised as an overall value per measurement or as a rate per hour, this uncertainty was considered not critical in light of the results expressed and compared to the control in percentages (for further details, please refer to note B in Notes 1 to Table 4). In addition, a new relevant study on nitrogen transformation was accepted and used in the risk assessment in the EU renewal process (Anonymous (2019) cited in EC (2024b), LoEP, p.174), for which a study summary and a company study summary was made available to us upon request to EFSA (EFSA 2025a, 2025b). The validity criteria defined by the OECD TG 216 (OECD 2000a) were met and the study showed similar results to the soil respiration/carbon transformation study but with higher non-normalised unbound effect cc (cc = concentration). Therefore, the study by Baedelt (1991a) still represented the highest unbound NOEC for microorganisms. Two other studies on nitrogen transformation could not be validated for this dossier: one using a formulation with two a.s. instead of fenpyroximate alone (Haeuser (2016) cited in EC (2019), Vol. 3CP, B.9.9, p.264) and another one with a study summary that is not detailed enough (Baedelt (1991b) cited in EC (2019) Vol. 3CP, B.9.9, p.260). Overall, the acceptable data indicate ***lower sensitivity of*** **microorganisms (decomposers; nutrient transformers)** ***compared to earthworms***.

Springtail – the other major group in decomposers (litter transformers/primary consumers) – **and mite** (secondary consumers) showed much lower sensitivity to fenpyroxymate and as such, they ***are not considered organism groups critical to the SGV derivation***.

Based on the laboratory degradation results, metabolite formation during the chronic laboratory toxicity tests on soil organisms may or may not occur. Therefore, metabolite toxicity also needs to be considered for the risk assessment of fenpyroximate. The derived SGV is likely to be sufficient to protect soil organisms from the effects of fenpyroximate metabolites due to their different formation, sorption and degradation properties in soil, as a result of which they are expected to be present in lower concentrations than the parent compound. M-3 was the only tested metabolite and it showed lower toxicity to earthworms than the parent substance and similar toxicity to microorganisms as fenpyroximate (Table 6). Also, M-3, M-8 and M-11 lack the *tert*-butyl ester functionality that appears to be responsible for the effects on target organisms (EFSA 2008). Photolytic degradation of fenpyroximate seems to be considerable but less pronounced. While the photolytic metabolites (M-1, M-12, M-12 isomer and

MTBT) contain the toxic moiety, their formation is relatively low along with rapid degradation. Altogether, ***the SGV for fenpyroximate is likely to be protective of* the soil metabolites**.

A few study summaries (see Table A1, and note P in Notes A1) did not provide details on whether the a.s. content of the formulation was expressed in percentage of **weight/volume or weight/weight**, which implies that effect concentrations calculated as a.s. could vary slighty. For example, while an a.s. content of **5.31 % w/v corresponds to 53.1 g a.s./L product** (density = 1027.1 g/L), an a.s. content of **5.31 % w/w corresponds to 54.5 g a.s./L product**. This results in a difference 1439 mg a.s. content per liter of product. Translated to an effect size of 189 mg product/kg soil, the effect concentration in a.s. would be **10.0 mg a.s./kg soil** in the **w/w scenario**, while it would be **9.77 mg a.s./kg soil** in the **w/v scenario**. In all cases, where both the w/w- and w/v-based effect cc. was quantifiable, the w/v showed slightly lower effect cc. Where the w/w or w/v indication was not reported in the study summaries, the lower w/v-based effect concentrations were preferred over the w/w-based calculations. Effectively it makes only a small difference, considering that the observed effect concentrations ranged in the mg/kg rather than in the µg/kg range. Therefore, this issue is considered negligible for the overall SGV derivation.

According to the current analytical methods described in Section 2, the concentration range around the proposed SGV is possible to be detected and quantified during the national soil monitoring (SGV of 0.19 mg a.s./kg soil vs MLOQ of 0.0001 mg a.s./kg soil). Therefore, no analytical issues are foreseen for the use of the derived SGV.

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Appendix 1 Considerations for the evaluation of the studies

General considerations

- ***Effects on target species*** (pests) against which the active substance can be used are not considered (they are not included in any of the data tables in the SGV dossier).
- ***Efficacy studies on terrestrial plants*** with the aim to evaluate the effectiveness of the chemical compound on target species (pests) are not considered for the evaluation (they are not included in any of the data tables). The potential increase of the plant health due to a reduction of the pest is unrelated to the ecotoxicological effects of the substance.
- Only the effects of the substance *via* ***soil exposure*** is considered relevant. Effects resulting from using sand or other material instead of soil, or from direct over spraying of the test organism instead of exposure through soil, are *not* considered *relevant* (**C3**).
- For ***seedling emergence tests*** following the standard OECD 208 guideline, the use of 15-cm containers is recommended and followed by many of the contract laboratory. A 15-cm pot usually has a depth of approx. 13-14 cm and – based on photos of the test in contract laboratory (e.g. Ibacon, Eurofins etc.) – the planted pots are usually filled up to the lower end of the brim, i.e. approx. to 10-11-12 cm. In other studies for instance it was specified that they used pots with 11-cm diameter and 10-cm depth (see Anonymous (2016) cited in (BASF 2021) or 7-cm depth trays (Fleming *et al*. (1996a) cited in (EC 2022)). The specific container size/soil depth is used if it is reported/summarised. Otherwise the use of an average soil depth of 10 cm along with 1.5 g/cm^3 soil bulk density for converting the applied rate of the test item to a concentration in the soil is considered reasonable and pragmatic (also see the recommendation in Info-box 13 in (ECHA 2017), p.149). This is based on the above detailed information, i.e. the test guideline recommendation in conjunction with available information in standard regulatory study reports, information available publicly on the methods used by contract laboratories as well as personal communication with experts conducting such studies. While the soil depth can slightly vary depending on the plant species/test facility, ten centimetres soil depth is considered as a reasonable average for studies where the container size is not reported, which also allows comparability of the non-target terrestrial plant results with other studies, where either the test item is mixed into the soil, i.e. the test item concentration in the soil is known (most laboratory studies) or the upper 10-cm layer is sampled for analytical measurements (see e.g. field earthworm studies). If specific information is available for a certain study, the concentrations are calculated accordingly.
  It is noted that the behaviour of the test substances can vary and can result in different distributions in the soil in case of over-spraying. However, choosing and considering a certain soil depth is a pragmatic approach and a pragmatic solution that is already applied for the authorisation/registration of pesticides (but with different depths, i.e. 5 cm for permanent crops and 20 cm for crops where ploughing in the season takes place, even if the substance is actually not mixed into the soil after application, see e.g. (FOCUS 1997) and (EC 2002)) as well as of biocides (ECHA 2017).
- Reproductive endpoints are considered the most relevant endpoints as they are good indicators of the sustainability of the population in the long-term. Other endpoints affecting survival and growth (biomass) of individuals are also accepted, since they were traditionally measured endpoints frequently extrapolated to represent the impact at population level. If multiple comparable toxicity values for the same species and the same measured effect are available, the ***geometric mean*** of the effect values is calculated.
- Following a critical consideration (Azimonti *et al.* 2015, EFSA 2019), the statistically more robust endpoint of ***EC10 vs NOEC*** is chosen. If both endpoints seem to be equally robust (e.g. details of statistical methods and results are reported; clear dose-response; descriptive

statistics; NOEC: also statistically significant LOEC is reported; EC10: width/lower/higher limits of confidence intervals for EC10/20/50; steepness of curve etc. are available), then EC10 is preferred due to the general inherent uncertainties a NOEC is surrounded by (Azimonti *et al.* 2015). When no or not statistically robust EC10median is available, the statistically robust NOEC is preferred. It is noted that statistically non-robust (but "biologically significant") NOEC values are often preferred during the EU pesticide authorisation/renewal processes, to provide long-term endpoints with not higher than 10 % effects. However, such endpoint could not account for the variability of data in soil studies (where coefficient of variation in the control is accepted up to 15, 30 or 50 %). The uncertainty in a NOEC value with higher level of effects may need to be highlighted and discussed. In the absence of a statistically robust endpoint, the study results are considered *not reliable* (**R3**) or *not assignable* (**R4**) depending on the actual flaws.

- ***Regulatory studies and their endpoints*** (e.g. EFSA, US EPA) are generally accepted without additional assessment (at face value) or partially re-considered if needed to set the endpoints in line with our criteria as summarised here and detailed above (Marti-Roura *et al.* 2023, Moermond *et al.* 2016). This is the case, for example, when organisms are not exposed through soil (e.g. plant vegetative vigour tests *via* foliar application); normalisation to a standard organic matter content is not possible due to lack of data; not the statistically most robust effect concentration is proposed/agreed upon as an endpoint etc. A full re-assessment may also be carried out for regulatory studies, where the study summary is not sufficiently detailed and we can get access to the original study report.
- Study ***endpoints from authorisation reports*** (e.g. EFSA, US EPA) are subjected to the same scrutiny as open literature data. These include but are not limited to careful consideration of the study design (e.g. number of replicates and test concentrations), the way the tests were conducted (e.g. environmental conditions, observations), their results (e.g. performance of control, validity criteria, dose-response, deviation) as well as the statistical analysis (e.g. methods and reported details). Authorisation reports are accepted at face value and used in the risk assessment if they meet the criteria of reliability and relevance as detailed above (Marti-Roura *et al.* 2023, Moermond *et al.* 2016). If they have flaws in terms of reliability and relevance or other requirements as detailed here and in the above cited documents (e.g. validity criteria of the study were not met; no statistically robust EC10median could be derived; endpoint could not be standardised due to lacking information on OM/OC content of the test soil etc.), the regulatory endpoints are listed at face value but not used in deriving an SGV.
- In general, ***biomarker studies*** are not included in the tables since they are based on endpoints, whose relationship to effects at population level is uncertain. However, some exo-enzymes produced by soil microorganisms can be used as biomarkers of soil fertility and are important in the ecological functioning of the soil (e.g. Filimon *et al.* 2015, NEPC 2011, RIVM 2007). For this reason, microbial-mediated enzymatic activities are included in the assessment as "*relevant with restrictions*" (**C2**).
- The relationship between ***microbial biodiversity and function*** is quite complex. Although it cannot be denied that loss of microbial diversity can have an impact on function, the role of biodiversity in supporting microbial functions needs a better understanding (EFSA 2019). For this reason, in this report, microbial endpoints directly involved in soil functions are preferred over microbial diversity endpoints.
- ***Recovery of effects*** – that can be seen e.g. in earthworm field studies – is not considered acceptable within the scope of SGV that is used in relation to long-term pesticide residues, not immediate effects after application of pesticides.
- Long-term endpoints from ***field studies*** are considered as supportive information unless there is analytical verification. A robust effect concentration can only be derived when it is

confirmed by analytical verification and it should be within approximately a month of the assessment of the effect endpoint to ensure its reliability with regards to any potential loss of the test substance through degradation/dissipation and as a result to underestimate the risk. In order to derive effect concentration(s) for the whole duration of a field study, the test substance concentration should be monitored regularly until the end of the study. When the test substance concentrations are measured only at the beginning of the study, the derivation of an approx. one-month endpoint is considered reliable enough for a quantitative use (see e.g. field earthworm studies). As the actual degradation/dissipation of a pesticide can be affected by a mixture of various biotic and abiotic factors, without measured residues in the test site it is not possible to calculate a meaningful (time-weighted average) concentration in the soil and derive a robust endpoint (see e.g. concentration-dependent dissipation of pesticides in Muñoz-Leoz *et al.* (2013). It is noted that, for instance, according to the often used field earthworm study guideline (ISO 2014) 50 % deviation from the nominal concentration is acceptable. However, as we compare the derived effect concentrations – and in turn the derived SGV – directly to the measured environmental concentrations, it is more reasonable to base the effect values on the measured amount of test substance present in the soil during the study. Altogether it is considered a pragmatic approach to use the analytical verification results for the upper 10-cm soil layer. It is noted that the sampled upper 10-cm soil layer does not cover the whole depth where earthworms can occur. However, a) while it is not ideal, it is usually the only analytical information available (see e.g. the respective requirement in ISO (2014)); b) depending on the ecological group (i.e. epigeic, endogeic or anecic species) the exposure of earthworms to pesticides can highly vary anyway. In a pilot study it was shown that even anecic species living usually in deep burrows can be affected by pesticide treatments due to their feeding and mating habits, i.e. gathering food and mating on the contaminated soil surface (Toschki *et al.* 2020). The abundance, diversity and activity of soil biota are in general the highest in the top soil layer (Anderson *et al.* 2010, Toschki *et al.* 2020).

Soil organic matter content

- When only ***total organic carbon*** is reported in a study, the total organic carbon value is transformed to organic matter by using a factor of 1:1.7.
- If only a ***percentage of sphagnum peat*** is reported in laboratory studies with artificial soil, the soil organic matter content is estimated assuming that the only source of organic matter in the soil comes from the sphagnum peat and that the organic matter content of the sphagnum peat is approximately 100 %.
- If ***no organic carbon/matter content*** is reported, the study endpoint cannot be normalised and thus is not suitable for further use. As a result the study is scored as *not assignable: Information needed to make an assessment of the study is missing* (R4; Casado-Martinez *et al.* 2024, Moermond *et al.* 2016).

For the adapted criteria – that were mainly based on the European technical guidance document (EC TGD 2003) – and further details on the parameters and methods that are used for the SGV derivation, please refer to Marti-Roura *et al.* (2023). The criteria beyond these resources will be included in an updated methodological report.

Appendix 2 Data on the active substance

Table A1: Soil effect data for fenpyroximate from laboratory experiments. The lowest, statistically most robust, reliable and relevant effect data per species per test setup are shown in bold. Unreliable, not relevant and not assignable data are greyed out. Calculated data are rounded to three significant figures. Abbreviations: n.r. – not reported; n.a. – not applicable; cc. – concentration; MWHC – maximum water holding capacity; OC – organic carbon; OM – organic matter; TG – test guideline; M – monocotyledonous; D – Dicotyledonous, [CPIR] – confidentially provided information, redacted. Data were evaluated for reliability and relevance according to the modified CRED criteria (see R/C scores) or taken at face value from regulatory dossiers (Assessment score 1-3). For notes, please refer to the end of Appendix 2 (Notes 1A).

Species (Taxonomic group)	Test substance	Measured effect[4]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
Zea mays (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Avena sativa (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Allium cepa (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lolium perenne (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Brassica oleracea (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Cucumis sativus (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lactuca sativa (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**

[4] FE – functional endpoint

Species (Taxonomic group)	Test substance	Measured effect[4]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
Glycine max (D)	Fenpyroximate 5SC (5.1 % w/w)	Seedling emergence	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R3/C1	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Seedling emergence	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R4/C1	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269
Brasscia rapa (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Zea mays (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Avena sativa (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Allium cepa (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lolium perenne (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Brassica oleracea (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Cucumis sativus (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p. 269**
Lactuca sativa (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Glycine max (D)	Fenpyroximate 5SC (5.1 % w/w)	Growth (shoot length)	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R3/C1	Teixeira (2001a) cited in EC (2019), Vol. 3CP,

Species (Taxonomic group)	Test substance	Measured effect[4]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
											B.9.11.2. (Tier I test), p.269
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Growth (shoot length)	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R4/C1	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269
Brassica rapa (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Zea mays (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Avena sativa (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Allium cepa (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lolium perenne (M)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Brassica oleracea (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Cucumis sativus (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lactuca sativa (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Glycine max (D)	Fenpyroximate 5SC (5.1 % w/w)	Biomass (shoot dry weight)	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R3/C1	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269

Species (Taxonomic group)	Test substance	Measured effect[4]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Biomass (shoot dry weight)	14 d	NOEC	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R4/C1	Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269
Brasscia rapa (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019), Vol. 3CP, B.9.11.2. (Tier I test), p.269**
Lycopersicon esculentum (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Seedling emergence**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p. 269**
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Seedling emergence	14 d	EC25	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R2/C2	Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p.269
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Seedling emergence	14 d	EC50	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R2/C2	Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p.269
Lycopersicon esculentum (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Growth (shoot length)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p.269**
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Growth (shoot length)	14 d	EC25	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R2/C2	Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p.269
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Growth (shoot length)	14 d	EC50	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R2/C2	Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p.269
Lycopersicon esculentum (D)	**Fenpyroximate 5SC (5.1 % w/w)**	**Biomass (shoot dry weight)**	**14 d**	**NOEC**	**≥ 0.224**	**1.3**	**≥ 0.586**	**1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand**	**J**	**(3) R2/C1**	**Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study), p. 269**
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Biomass (shoot dry weight)	14 d	EC25	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R2/C2	Teixeira (2001a) cited in EC (2019) Vol. 3CP, B.9.11.2. (Tier II study) ,p.269
Lycopersicon esculentum (D)	Fenpyroximate 5SC (5.1 % w/w)	Biomass (shoot dry weight)	14 d	EC50	≥ 0.224	1.3	≥ 0.586	1:1 mixture of sandy-loam (Fairhaven, Massachusetts) with 20- to 40-mesh silica sand	J	(3) R2/C2	Teixeira (2001a) cited in EC (2019) Vol. 3CP,

Species (Taxonomic group)	Test substance	Measured effect[4]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
											B.9.11.2. (Tier II study), p.269
Microorganisms	NSN-001 SC (formulation with two a.s.: 5.18 % w/w fenpyroximate (53.3 g/L) and 2.52 % w/w hexythiazox (25.9 g/L))	Nitrogen transformation (nitrate-N rate)[FE]	28 d	≤25 % effect	n.a.	1.22 (0.72 % OC)	n.a.	Natural soil (medium silty sand; according to German DIN classification): 6.8 % clay, 36.3 % silt, 49.9 % sand, 42 % of MWHC, pH 6.8-7.0	A	(1) R1/C3	Haeuser (2016) cited in EC (2019), Vol. 3CP, B.9.9., p.264
Microorganisms	**Fenpyoximato 50 SC [CPIR]**	**Nitrogen transformation (NO_3^- cc.)[FE]**	**28 d**	**≤ 25 % effect**	**≥ 2.4**	**[CPIR]**	**[CPIR]**	**[CPIR]**	**CC**	**(1) R2/C1**	**Anonymous (2019) cited in EC (2024b), LoEP, p.174 accessed via EFSA (2025a) and EFSA (2025b)**
Microorganisms	**Fenpyroximate 5 SC (Hoe 094552 00 SC 05 A104, 5% w/w a.s.)**	**Carbon transformation** (O2 cc.) [FE]	**28 d**	**≤ 25 % effect (< 10 % effect)**	**≥ 1.5**	**0.91**	**≥ 5.60**	**Field soil I (clay loam): 54.4 % sand, 10.0 % clay, 35.6 % silt, pH 6.2, microbial biomass 17 mg C/100 g soil, MWHC 31.5 %, 45 % of MWHC**	**B**	**1 (R2/C2)**	**Baedelt (1991a) cited in EC (2006) Vol. 3, B.9.8.1, p.705**
Microorganisms	**Fenpyroximate 5 SC (Hoe 094552 00 SC 05 A104, 5% w/w a.s.)**	**Carbon transformation** (O2 cc.) [FE]	**28 d**	**≤ 25 % effect (< 10 % effect)**	**≥ 1.5**	**1.37**	**≥ 3.72**	**Field soil II (sandy loam): 11.2 % sand, 20.3 % clay, 68.5 % silt, pH 7.1, microbial biomass 47.1 mg C/100 g soil, MWHC 51.3 %, 40 % of MWHC**	**B**	**1 (R2/C2)**	**Baedelt (1991a) cited in EC (2006) Vol. 3, B.9.8.1, p.705**
Microorganisms	Fenpyroximate 5SC (Hoe 094552 00 SC05 A104, 5 % w/w a.s.)	Nitrogen transformation (NH_4+ cc. and NO_3-cc.) [FE]	28 d	≤ 25 % effect (< 10 % effect)	≥ 1.5	0.91	≥ 5.6	Field soil I (clay loam): 54.4 % sand, 10.0 % clay, 35.6 % silt, pH 6.2, microbial biomass 17 mg C/100 g soil, MWHC 31.5 %	C	3 (R4/C2)	Baedelt (1991b) cited in EC (2019) Vol. 3CP, B.9.9., p.260
Microorganisms	Fenpyroximate 5SC (Hoe 094552 00 SC05 A104, 5 % w/w a.s.)	Nitrogen transformation (NH_4+ cc. and NO_3-cc.) [FE]	28 d	≤ 25 % effect (< 10 % effect)	≥ 1.5	1.37	≥ 3.72	Field soil II (sandy loam): 11.2 % sand, 20.3 % clay, 68.5 % silt, pH 7.1, microbial biomass 47.1 mg C/100 g soil, MWHC 51.3 %	C	3 (R4/C2)	Baedelt (1991b) cited in EC (2019) Vol. 3CP, B.9.9., p.260
Eisenia (fetida) andrei (Earthworm)	Fenpyroximate 5SC (Hoe 094552 00 SC05 A104, 5.2 % a.s.)	Mortality (number of dead adults)	14 d	NOEC	5.2	10	1.72	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 69.7 % industrial quartz sand, pH 6.4, Moisture content 27.7-27.9 % of soil dry weight	E P	R4/C2	Fischer (1990b) cited in EC (2019), Vol. 3CP, B.9.7.1., p.241

Species (Taxonomic group)	Test substance	Measured effect[4]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
Eisenia (fetida) andrei (Earthworm)	Fenpyroximate 5SC (Hoe 094552 00 SC05 A104, 5.2 % a.s.)	Mortality (number of dead adults)	14 d	LC50	9.4	10	3.1	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 69.7 % industrial quartz sand, pH 6.4, Moisture content 27.7-27.9 % of soil dry weight	E P	R4/C2	Fischer (1990b) cited in EC (2019), Vol. 3CP, B.9.7.1., p.241
Eisenia fetida (Earthworm)	Fenpyroximate (97 % purity)	Mortality (number of dead adults)	14 d	LC50	73.3	10	24.9	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 70 % industrial sand, calcium carbonate, pH 6.0 ± 0.5, mx Water content 35 % of soil dry weight	M	R4/C2	Wang *et al.* (2012)
Eisenia fetida **(Earthworm)**	**Fenpyroximate 5% SC (NNI-850 5SC, 5.31% w/w a.s., 54.54 g a.s./L, density 1.0271 g/cm3)**	**Biomass (adult weight change)**	**28 d**	**NOEC**	**≥ 10.0**	**10**	**≥ 3.40**	**Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 70 % industrial sand, < 1 % calcium carbonate, pH 5.7-6.2, 57.9 – 60.7 % of MWHC**	**F S**	**(1) R1/C1**	**Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246**
Eisenia fetida **(Earthworm)**	**Fenpyroximate 5% SC (NNI-850 5SC, 5.31% w/w a.s., 54.54 g a.s./L, density 1.0271 g/cm3)**	**Mortality (number of dead adults)**	**28 d**	**NOEC**	**≥ 10.0**	**10**	**≥ 3.40**	**Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 70 % industrial sand, < 1 % calcium carbonate, pH 5.7-6.2, 57.9 – 60.7 % of MWHC**	**F S**	**(1) R1/C1**	**Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246**
Eisenia fetida (Earthworm)	Fenpyroximate 5% SC (Hoe 094552 00 SC05 A106, 5.15 % a.s.)	Mortality (number of dead adults)	42 d	NOEC	≥ 2.56	10	0.87	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, approx. 69.6 % industrial quartz sand, pH 5.7-5.9, Moisture content 28.6 – 28.8 % of soil dry weight	G P	3 (R3/C3)	Heusel (1994) cited in EC (2019), Vol. 3CP, B.9.7.1., p.243
Eisenia fetida **(Earthworm)**	**Fenpyroximate 5% SC (NNI-850 5SC, 5.31% w/w, 54.54 g/L, density 1.0271 g/cm3)**	**Reproduction (number of juveniles)**	**56 d**	**NOEC**	**5.58**	**10**	**1.90**	**Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 44pprox.. 70 % industrial sand, < 1 % calcium carbonate, pH 5.7-6.2, 57.9 – 60.7 % of MWHC**	**F S**	**(1) R1/C1**	**Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246**
Eisenia fetida (Earthworm)	Fenpyroximate 5% SC (NNI-850 5SC, 5.31% w/w,	Reproduction (number of juveniles)	56 d	EC10	5.42	10	1.84	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 44pprox.. 70 % industrial sand, < 1 %	F	(1) R3/C1	Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246

Species (Taxonomic group)	Test substance	Measured effect[4]	Duration	Type of effect cc.	Effect cc. [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Reference
	54.54 g/L, density 1.0271 g/cm3)							calcium carbonate, pH 5.7-6.2, 57.9 – 60.7 % of MWHC			
Eisenia fetida (Earthworm)	Fenpyroximate 5% SC (NNI-850 5SC, 5.31% w/w, 54.54 g/L, density 1.0271 g/cm3)	Reproduction (number of juveniles)	56 d	EC50	8.60	10	2.92	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 45pprox.. 70 % industrial sand, < 1 % calcium carbonate, pH 5.7-6.2, 57.9 – 60.7 % of MWHC	F	(1) R3/C1	Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246
Eisenia fetida (Earthworm)	Fenpyroximate 5% SC (Hoe 094552 00 SC05 A106, 5.15 % a.s.)	Reproduction (number of juveniles)	70 d	NOEC	≥ 0.901	10	0.306	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 45pprox.. 69.6 % industrial quartz sand, pH 5.7-5.9	G P	3 (R3/C3)	Heusel (1994) cited in EC (2019), Vol. 3CP, B.9.7.1. p. 243
***Folsomia candida* (Springtail)**	**Fenpyroximate 5SC (4.98 % a.s.)**	**Reproduction (number of juveniles)**	**28 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % industrial quartz sand, pH 5.87-6.16, 57.2-58.4 % of MWHC**	**H V S P**	**1 (R2/C1)**	**Friedrich (2015b), cited in EC (2019) Vol. 3CP, B.9.7.2., p.252**
***Folsomia candida* (Springtail)**	**Fenpyroximate 5SC (4.98 % a.s.)**	**Mortality (number of dead adults)**	**28 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % industrial quartz sand, pH 5.87-6.16, 57.2-58.4 % of MWHC**	**H V S P**	**1 (R2/C1)**	**Friedrich (2015b), cited in EC (2019) Vol. 3CP, B.9.7.2., p.252**
***Hypoaspis aculeifer* (Mite)**	**Fenpyroximate 5SC (4.98 % a.s.)**	**Reproduction (number of juveniles)**	**14 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 0.2 % calcium carbonate, 74.8 % industrial quartz sand, pH 5.7-6.2, 47.85-48.92 % of MWCH**	**I V S P**	**1 (R2/C1)**	**Schulz (2015), cited in EC (2019), Vol. 3CP, B.9.7.2., p.255**
***Hypoaspis aculeifer* (Mite)**	**Fenpyroximate 5SC (4.98 % a.s.)**	**Mortality (number of dead adults)**	**14 d**	**NOEC**	**≥ 48.5**	**5**	**≥ 33.0**	**Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 0.2 % calcium carbonate, 74.8 % industrial quartz sand, pH 5.7-6.2, 47.85-48.92 % of MWCH**	**I V S P**	**1 (R2/C1)**	**Schulz (2015), cited in EC (2019), Vol. 3CP, B.9.7.2., p.255**

Notes A1: Notes on soil studies for fenpyroximate.

A	The test was conducted according to OECD TG 216 with analysed a.s. contents of 2.52 % w/w (25.9 g/L) and 5.18 % w/w (53.3 g/L) for hexythiazox and fenpyroximate in the tested SC formulation, respectively. Analysed product density was 1.0295 g/cm³.

	Despite the acceptance of this study by the RMS, the study was found not relevant (C3) for the purpose of SGV derivation, due to the use of two a.s. in the tested formulation.
B	The study was conducted in line with an old test guideline (BBA 1990) that defined no validity criteria. The following deviation to the BBA (1990) test guideline occurred: • The results of a toxic reference substance were not documented in the study summary. It is noted that this is not a requirement in the newer OECD 217 guideline (see below). The RMS did not re-evaluate this study during the renewal assessment of fenpyroximate (EC 2019) as soil respiration/carbon transformation is no longer a data requirement for the prospective assessment of pesticides. Therefore, the test has been evaluated by OZ according to the latest relevant OECD 217 test guideline (OECD 2000a) as follows: • The environmental conditions in the tests were in line with the test guideline. • The soil characteristics of Field soil I were in line with the soil parameter recommendations of the guideline. Field soil II contained only 11.25 % sand that is much lower than recommended (50-75 %). High soil sand content is recommended in the guideline as it contributes to providing a worst-case situation for this type of test. However, the use of other soils may be accepted if their relevance is justified. The sand content of Swiss soils range between 7 and 86 % with a median of 48 % (Reusser *et al.* 2023). The majority of Swiss soils (25-75 %iles) contains 36-59 % sand. In general, the representativeness of Field soil II to Swiss soils does not seem to be justified. On the other hand, the test item concentrations were the same for both soils and both showed < 10 % effects at both test concentrations. The difference in the normalised effect concentrations is a result of the difference in the OM content of the soils. The OM content of 0.91 and 1.37 % correspond to 0.53 and 0.80 % OC content for Field soil I and II, respectively, which is rather low (lower than the 5-95 %ile of Swiss soils; Reusser *et al*. 2023) and could help with providing the worst-case situation for testing. Consequently, the results for both soils are retained as they could provide worst-case scenarios for soil respiration/carbon transformation testing. • The amount of glucose added (4000 ppm) and the measurement days (0, 7, 14, 28 d after treatment) were in line with the test guideline. However, according to the study summary, the measurements of oxygen consumption lasted 24 instead of 12 hours. It is noted that the BBA guideline requires 24-h measurements but for the evaluation to use only the first 12 hours before the measured values reach their peak. It is not specified in the study summary if the results were based on the initial 12-h or on the full 24-h measurements and in case of the latter, if the peak oxygen consumption was reached. • Based on the mean ± SD values, the validity criterion (i.e. < 15 % variation in the control) was met for both soils. • No positive/toxic control is required according to the OECD 217 guideline. • The results are shown as concentration (in mg O_2/100 g soil) instead of rates (per hour). As the differences to the control are evaluated in percentages (either as all measured oxygen consumption per soil dry weight per 12/24 h or as rate per hour), this is considered not to have an impact on the outcome of the tests. It is noted that the summarised values are similar to rates (in mg O_2/dry weight soil/h) reported in other soil respiration/carbon transformation tests after 12-h measurements, not to the sum of oxygen consumption in 12 or 24 hours. Due to the uncertainty about the duration of measurement used for calculating the results, both tests are considered reliable with restrictions (R2). Soil respiration/carbon transformation is considered a less effective indicator of soil health and biodiversity and as such the soil respiration/carbon transformation test result is not a mandatory data requirement for the EU pesticide risk assessment anymore. However, it is still considered relevant for the SGV derivation but with restrictions due to its limitations (C2).

	The concentration of the test substance in the soil was calculated following both of the above-mentioned guidelines assuming 5 cm soil depth and 1.5 kg/L soil bulk density.
CC	The microorganism study on nitrogen transformation of a fenpyroximate product (Fenpyroximato 50SC) was listed in the LoEP (EC 2024), and the company study summary as well as the RAR summary were made available under two PAD applications (EFSA 2025a, 2025b). The study was in line with OECD TG 216 validity criteria, however, the results were not properly calculated (nitrate-N concentrations instead of rates) and no product density was reported. However, the Nitrate-N transformation rates could be calculated from the available information. The study was considered relevant (C1) and due to the missing product density as reliable with reservations (R2).
C	The test for nitrogen-transformation in soil was conductced according to an old guideline (BBA 1990, Part VI), where no validity criteria were defined. The study has been re-considered in line with the currently valid OECD TG 2016. The nitrate-formation rates and their differences in the treatments as compared to the control were not calculated as otherwise required by the OECD TG 216. It is noted that the BBA guideline requires the calculation and comparison of only the mean values and their differences to the control. Contrary to the guideline requirements, horn rather than lucerne meal was added to the soil as organic substrate. These differences do not invalidate the study *per* se. However, along with the other deviations noted by the RMS (e.g. maintained soil water content was not reported, no results per replicate was provided), the validity and the reliability of the study cannot be evaluated to the current standards. The study results are considered *relevant with restrictions* (C2; due to the differences to the method of the current valid TG) with *not assignable* reliability (R4; due to the missing details on the results). In line with the RMS argumentation, this study is considered not acceptable for SGV derivation. For the rate to concentration conversion, even distribution of the test item in 5 cm soil layer with a soil bulk density of 1.5 kg/L is assumed in line with both of the relevant guidelines (BBA 1990, OECD 2000a). The reported active substance content of 5 % w/w was used for effect cc derivation. Since the measured effects on nitrogen formation rates were well below 25 % at the end of the test, in fact even below 5 % effect, the reported effect was also documented as < 10 % effect.
E	The study by Fischer (1990b) followed the OECD TG 207 (OECD 1984) for acute toxicity exposures on earthworms. Only validity criteria is a ≤ 10 % mortality in the controls, which was met according to the test summary. Also, most of the guideline recommendations were followed. Statistical evaluation to recalculate the NOEC was not possible since the raw data (replicates) were not documented in the study summary. As opposed to the statement in the results of the study summary, there was dose-response in the effects on mortality and qualitatively measured biomass. The given NOEC of 32 mg product/kg soil dw for sublethal effects is based on qualitatively measured symptoms and as such statistically not significant and not suitable for SGV derivation. The statistically significant 14-d mortality NOEC is 100 mg product/kg soil dw. The mean mortality was 50 % at 180 mg product/kg soil concentration. The 14-d LC50 estimation could not be recalculated and confirmed. Due to the missing qualifier of the a.s. content percentages (if it was given as w/v or w/w), the study is considered not assignable with regard to reliability (R4; also see note P for a.s. approximation). Due to the missing information and being an acute test, this earthworm study is considered *relevant with restrictions* (C2) and *not assignable* with regard to reliability (R4).

F	The study from Wagenhoff (2019) on earthworm reproduction was conducted in line with the OECD TG 222 (OECD 2016c). Statistically significant effects were found only on reproduction (number of juveniles). The estimation of the effect cc. on reproduction was cross checked using a cumulative normal distribution function for model fitting, which resulted in comparable effect estimates to the study summary: *estimated: EC10 = 100, EC20 = 118.1, EC50 = 161 mg test item/kg soil dw* *from the summary: EC10 = 102, EC20 = 119, EC50 = 162 mg test item/kg soil dw* The lower ends of the confidence intervals summarised in the dRAR (EC 2019) for EC20 and EC50 (75.9 and 92.1 mg product/kg soil, respectively) were lower than the median EC10 (102 mg product/kg soil), thus the EC10 is not considered reliable. Consequently, the NOEC values are considered further with regard to reproduction in the SGV derivation not the EC10 value. The study summary indicates that the test is of high quality and relevant for SGV derivation. Therefore, the NOEC for reproduction, biomass and mortality was rated as relevant (C1) and reliable (R1). Due to the flatdose-response curve indicated by the wide CI, the ECx values were considered rather unreliable (R3).
G	The study of Heusel (1994) was conducted according to old guidelines and did not meet the criteria in the OECD TG 222 (OECD 2016c): The test substance was applied via grapho-sprayer onto the soil after earthworms buried into the soil (not incorporated in soil before exposure) and no results of a reference toxic standard (that is advised to run at least once a year) was included in the study report according to the RMS comments. Due to the exposure method and the missing information on the precise a.s. content of the tested formulation, there is only a concentration approximation possible: The highest product application was 26.25 L/ha corresponding to 2.56 mg a.s./kg soil (not normalised; assuming that the summarised 5.15 % a.s. content of the product was expressed as w/v and the application rate involved 3.52 cm soil layer with 1.5 kg/L soil bulk density and 1 L of soil used) at which no effect has been observed (taken as NOEC in study summary). Due to the exposure method, the study is considered unreliable (R3) and not relevant (C3) and as such, not usable for SGV derivation.
H	The test was conducted following an older version of the OECD 232 test guideline from 2009 but fulfilled the validity criteria of the updated guideline from 2016 as well (OECD 2016a). A NOEC of ≥1000 mg test item/kg soil for both adult mortality and reproduction was determined resulting in approx. 48.5 mg a.s./kg soil here. However, due to the missing accurate qualifier of the a.s. content of the product (if it was expressed in % w/v or w/w), the a.s. conversion is only an approximation assuming % w/v (see note P). It is noted that at EU level, a NOEC of 50 mg a.s./kg soil was agreed upon (EC 2024b). The reliability of the study is rated as *reliable with restrictions* (R2) because of the uncertainty around the a.s. conversion. However, the study is considered relevant (C1) for SGV derivation due to the study design and method.
I	The study was conducted to an earlier version of the OECD 226 test guideline (2008) but fulfilled the validity criteria of the updated test guideline (OECD 2016b). A NOEC of ≥1000 mg test item/kg soil for both adult mortality and reproduction was determined resulting in approx. 48.5 mg a.s./kg soil here. However, due to the missing accurate qualifier of the a.s. content of the product (if it was expressed in % w/v or w/w), the a.s. conversion is only an approximation assuming % w/v (see note P). It is noted that at EU level, a NOEC of 50 mg a.s./kg soil was agreed upon (EC 2024b).

The reliability of the study is rated as *reliable with restrictions* (R2) because of the uncertainty around the a.s. conversion. However, the study is considered relevant (C1) for the SGV derivation due to the study design and method.

J

The summarised study (Teixeira 2001a) on seedling emergence upon spray application onto soil in 10 plant species was conducted in line with the outdated test guidelines of OPPTS 850.4100 and OPPTS 850.4225 (US EPA 1996a, 1996b). It is noted that in these outdated versions of the guidelines, no validity criteria were included. Since then, the guidelines have been updated and validity criteria have been added (OCSPP 850.4100; US EPA 2012). These criteria are almost identical with the updated, currently valid OECD 208 test guideline for plant seedling emergence (OECD 2006).
The summarised study results were confirmed via the study report to which we got access through a PAD application (EC (2019), Vol. 3CP, B.9.11.2, p.269; EFSA (2025a), see Section 1).
To properly assess the robustness of a study in line with modern evaluation standards, the tests should meet the validity criteria of the updated guidelines. The comparison of the guideline validity criteria and their fulfilment in the tests are summarised by OZ below:

Test validity criteria	**OCSPP 850.4100 (2012)**	**OECD 208 (2006)**	**In Teixeira (2001a)**
Seedling germination	Not specified as a validity criterion. Test is not acceptable if control seed germination < 70 %.	≥ 70 % in the control	Met in control for all species
Phytotoxicity effects	None visible in control	None visible in control	Minor effects in control in cucumber, none in other species
Mean survival of seedlings	≥ 90 % in control	≥ 90 % in control	Not met in the **soybean** control, met in all other species (not clear if it was met for tomato tier I test)
Environmental criteria per species	Identical	Identical	Met in control for all species
Source and lot No. per species	Identical	Not validity criterion. Seed should be from the same source.	Identification of seed source required in the old guideline. Met for all species
Control group	To be included	Not a validity criterion. Appropriate control groups need to be included.	Included
Test concentration	For dose-response test, the lowest test cc. < EC25 and NOEC/EC05. For limit test, the test cc. statistically less than EC25 and NOEC. For pesticides, the limit cc. is based on the max. label rate.	Not a validity criterion. For limit test, the max. application rate of the pesticide is used; for dose-response test, the lowest test cc. shold be lower than the aimed ERx to be determined.	Met
Additional pesticide use	No effect and interaction between the test substance and the additional pesticide	Not a validity criterion; not specified	Not used

Water amount used in the application solution [L/ha]	Not exceeding label prescription	Not a validity criterion. Spray volumes should be in the range of normal agricultural practice.	The old guideline required the maximum recommended amount of pesticide in the recommended minimum quantity of carrier such as water to be used. Met

Deviations to the guidelines:

- ***Test duration.*** According to the guidelines, the test duration is usually 14 to 21 days after 50 % emergence of the seedlings in the control (OECD 208) or at least 2 weeks after germination (US EPA). These were 14-day tests for all species that is somewhat shorter. It is not clear, why the RMS noted that the "tier 2 test in tomato should have been extended to 21 days duration". According to the updated OCSPP guideline, if phytotoxicity symptoms occur on day 7-14 post-emergence, the test should be extended to 21 days after 50 % emergence in the control. No phytotoxic effects were observed for the tier II tomato test.

Deviations to the OECD 208 (2006) guideline:

- ***Seed density.*** Seeding density is higher than recommended for some species in the updated guideline so that overcrowding of the seedlings could not be excluded. In the guideline for example, 1-2 seeds per 15-cm pot is recommended for corn, soybean, tomato, cucumber and sugar beet, 3 seeds for rape and pea, 5-10 seeds for onion, wheat or other smaller seeds. In general, the maximum plant density is recommended as 3-10 seeds per 100 cm^2 depending on the size of the seeds. It should be noted that the general recommendation allows for higher seeding density than the examples for the 15-cm pots (i.e. 177 cm^2 area). In the study, 13-cm pots were used with 10 seeds/pot for onion and ryegrass (10 very small seeds per 133 cm^2), 5 seeds/pot for oat, cabbage, cucumber, lettuce, tomato and turnip (5 small to medium seeds per 133 cm^2) and 5 seeds/pot for corn and soybean (5 medium to large seeds per 133 cm^2). This means 3.8 seeds/100 cm^2 for medium to large seeds that is higher than recommended in the OECD guideline. In addition, it seems that the results were not affected by possible overcrowding. For instance, there were 7-8 non-emerged/dead plants in the control and < 10 % effects on growth and biomass in the treatment in onion and ryegrass (overcrowding excluded). 6 plants did not emerge/died in the soybean control and 8 in the treatment with 2-9 % increase in growth and biomass in the treatment (possible overcrowding). In the meantime, no mortality/non-germination occurred in the corn control with 5-8 % increase in growth and biomass in the treatment (also proned to possible overcrowding). The RMS also noted that despite the possible overcrowding "*plants seemed to develop sufficiently*". It should also be noted that the requirements of the OPPTS guideline, in force at time of the study, with regard to number and density of seeds were met (3 replicates using at least 10 seeds per pot; pot size was not specified). In the updated OCSPP guideline, a minimum of four replicates, each with minimum of 10 seeds are required to be used. "The number of plants per pot is left to the discretion of the laboratory conducting the test, avoid overcrowding." The given example numbers of seeds per pot are similar to the examples in the OECD 208 guideline mentioned above.
- ***Test conditions.*** During the test temperature varied between 15 and 35°C and the relative humidity between 11 and 96 %. The OPPTS guideline did not specify the environmental conditions for testing, it only requires "*optimal conditions*" for the species/variety. The updated OCSPP guideline requires 25/20°C (daytime/nighttime) ± 6°C temperature (= 14-31°C) and 70 % (daytime) ± 15 % relative humidity (= 55-85 % daytime rel.humidity). The study temperatures were more or less within the required range. It is noted that in the updated OECD guideline narrower ranges are given as examples for certain commonly used crop species (17-28°C temperature and 65-95 % relative humidity range including light and dark periods). While the relative humidity at night is not specified in the OCSPP guideline, it is expected to be higher than the specified daytime humidity due to the lower temperature. The lowest relative humidity was lower than specified for daytime in the updated OCSPP guideline. The RMS noted that "*humidity fell below the required level on occasion*". In general, it is usually assumed that if the control performed well, the deviations to the guideline specified environmental

	conditions did not affect substantially the outcome of the test. The control groups performed clearly well in corn and oat, likely well in tomato and possibly well in onion, ryegrass, lettuce, soybean and turnip. For tomato, the detailed tier I test results were not included in the study report, thus these are not considered reliable here. The tier II test was conducted following the test guideline OPPTS 850.4225 (1996b) due to adverse effects (> 25 %) on shoot lenght relative to the control in the tier I test. Due the above noted uncertainties, the validity and reliability of the study was questioned by the RMS. However, as the detailed re-evaluation above shows the validity criteria were met (except for soybean) and the test conditions were acceptable. The largest shortfall was the shorter duration of the study. Considering that there were no statistically significant effects (and all effects were < 25 %), the study results are scored as *reliable with reservations* (R2) and *relevant* (C1) concerning the SGV derivation.
M	The study examined 14-d mortality of earthworms, according to the OECD 207 (OECD 1984) guideline. It is unclear whether the documented purity was based on volume- or weight-based percentages (% w/v or w/w) and if units for LC50 were per soil dry weight or wet weight. Due to the missing information on a.s. content and soil water content, the a.s. conversion is only an approximation. The CI around the LC50 is narrow, which indicates good quality of the dose-response curve: *73.3 95 mg a.s./kg soil with CI of 66.2-83.9 mg a.s./kg soil dw.* Due to the missing information and being an acute test, this earthworm study is considered *relevant with restrictions* (C2) and not assignable with regard to reliability (R4).
MM	The microorganism study on nitrogen transformation of a fenpyroximate product (Fenpyroximato 50SC) was listed in the LoEP (EC 2024), and the company study summary as well as the RAR summary were made available under two PAD applications (EFSA 2025a, 2025b). The study was in line with OECD TG 216 validity criteria, however, the results were not properly calculated (nitrate-N concentrations instead of rates) and no product density was reported. The study was considered relevant (C1) and, due to the missing product density, reliable with reservations (R2).
P	The a.s. content of the product was given in percentage. It was not indicated if this percentage was weight based (w/w) or volume based (w/v). This can lead to uncertainties in calculating the effect concentrations in terms of a.s. when necessary, if the product density deviates from 1 g/cm^3. The study summary by Wagenhoff (2019) cited in EC (2019), Vol. 3CP, B.9.7.1., p.246, reported a density of 1.0271 g/cm^3 for the product Fenpyroximate 5% SC with 5.31 % w/w a.s. content, which means that 1000 mL of this product would contain 54.5 g a.s. If the a.s. content would have been expressed as % w/v, the a.s. content would be 53.1 g a.s./L product, so a difference of 1.4 g/L. In order to account for this uncertainty, it is prudent to calculate effect concentrations with the given product density from Wagenhoff (2019) in applicable cases, where a similar SC product was used and information on a.s. content is ambiguous. As for SC (suspension concentrate) pesticide formulations the product density is expected to be > 1.00 kg/L, the use of the volume-based (w/v) calculation provides slightly lower a.s. content, which was then taken to calculate the effect cc. as a.s. and the OC-normalised effect cc. This approach is justified as the missing w/w or w/v indication calls for choosing the lower effect cc. as a protective measure.
S	Statistical evaluation to recalculate the NOEC was not possible since the raw data (replicates) were not documented in the study summary.

V	The results from the dRAR (EC 2019) were accepted without additional assessment (i.e. at face value).

It is noted that the following study was considered potentially relevant but did not meet the most important requirement with regard to information on whether the pure a.s. or a formulation with concurrent a.s. content on a w/w or w/v basis was applied (and they may have other deficiencies as well), thus they have not been evaluated and listed in detail (they are considered as not relevant, i.e. C3):

- Ahmadpour, M., Wang, W., Sinkakarimi, M.H., Ahmadpour, M. and Hosseini, S.H. (2023) Joint toxicity of cadmium and fenpyroximate on two earthworms: Interspecific differences, subcellular partitioning and biomarker responses. Chemosphere 337, 139329.

Appendix 3 Data on the metabolites

Table A2: Soil effect data for M-3 ((E)-4-[(1,3-dimethyl-5-phenocypyrazole-4-yl)- ethyleneaminooxy-methyl]benzoic acid), a soil transformation product of fenpyroximate. Values resulting from calculations are shown with three significant figures. The lowest effect datum per organism is shown in bold. Unreliable, not relevant and not assignable data are greyed out. Abbreviations: n.r. – not reported; n.a. – not applicable; WHC – water holding capacity; OC – organic carbon; OM – organic matter. For notes, please refer to the end of Appendix 3 (Notes A2).

Species (Taxonomic group)	Measured effect	Duration	Type of effect concentration	M-3 effect concentration [mg a.s./kg soil]	Total OM (%)	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Assessment score	Note	Source
Microorganisms	**Nitrogen transformation (NO_3- cc.)**	**28 d**	**< 10 % effect**	**≥ 2.96**	**2.5 (1.47 % OC)**	**≥ 4.03**	**Field soil (Saxony, Germany) Loamy sand: 53 % sand, 36.5 % silt, 10.5 % clay, 1.47 % organic carbon, pH 6.6**	**C1/R2**	**Z**	**Schulz (2016) cited in EC (2019), Vol. 3CA, B.9.5., p.231**
Eisenia fetida (Earthworm)	Biomass (adult weight change)	56 d	NOEC	55.0	10	18.70	artificial soil: 10 % sphagnum peat, 20 % kaolin clay and 69.5 % industrial quartz sand	C1/R2	Y	Friedrich (2015a) cited in EC (2019), Vol. 3CA, B.9.4.1., p. 228
***Eisenia fetida* (Earthworm)**	**Reproduction (Number of juveniles)**	**56 d**	**NOEC**	**16.9**	**10**	**5.76**	**artificial soil: 10 % sphagnum peat, 20 % kaolin clay and 69.5 % industrial quartz sand**	**C1/R2**	**Y**	**Friedrich (2015a) cited in EC (2019), Vol. 3CA, B.9.4.1., p. 228**
Eisenia fetida (Earthworm)	Reproduction (Number of juveniles)	56 d	EC10	19.2	10	6.53	artificial soil: 10 % sphagnum peat, 20 % kaolin clay and 69.5 % industrial quartz sand	C1/R3	Y	Friedrich (2015a) cited in EC (2019), Vol. 3CA, B.9.4.1., p. 228
Eisenia fetida (Earthworm)	Reproduction (Number of juveniles)	56 d	EC20	28.8	10	9.80	artificial soil: 10 % sphagnum peat, 20 % kaolin clay and 69.5 % industrial quartz sand	C1/R3	Y	Friedrich (2015a) cited in EC (2019), Vol. 3CA, B.9.4.1., p. 228
Eisenia fetida (Earthworm)	Reproduction (Number of juveniles)	56 d	EC50	62.6	10	21.3	artificial soil: 10 % sphagnum peat, 20 % kaolin clay and 69.5 % industrial quartz sand	C1/R3	Y	Friedrich (2015a) cited in EC (2019), Vol. 3CA, B.9.4.1., p. 228

Notes A2: Notes on soil effect data for M-3.

Y	Since the raw data were not accessible for SGV derivation and the RMS accepted the study, the at face value is taken here. The estimated effect sizes for reproduction were recalculated and gave similar estimations: *estimated - EC10 = 17.8, EC20 = 27.2, EC50 = 60.8 mg test item/kg soil* *reported in summary - EC10 = 19.4, EC20 = 29.1, EC50 = 63.2 mg test item/kg soil* The EC10 confidence interval is fairly broad and the lower end of it (10.6 mg test item/kg soil dw) includes the NOEC (17.1 mg test item/kg soil dw), while the upper end (35.5 mg test item /kg soil dw) includes the EC20 (29.2 mg test item /kg soil dw). Therefore, NOEC is taken here as the more reliable effect value.

	The ECx values are greyed out, because they were considered unreliable due to the above described spread of the EC10. In conclusion, the ECx values were considered unreliable (R3) but relevant (C1) and the NOEC as reliable with reservations (R2, at face value taken) and relevant (C1).
Z	Effect after 28 days was below 10 % effect relative to the control, therefore instead of giving an ≤ 25 % effect a < 10 % effect is given here.