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SGV – Proposal by the Ecotox Centre for *Pirimicarb*

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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

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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 pirimicarb 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 pirimicarb of **270 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 Pirimicarb 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 Pirimicarb von **270 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 pirimicarbe 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 pirimicarbe de **270 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 pirimicarb 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 pirimicarb di **270 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 pirimicarb in relation to the soil environment is presented in this chapter. Registration information and risk assessments referred to are as follows:

- *EC (2004): Draft Assessment Report (DAR) – public version. Initial risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance pirimicarb of the second stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC*
- *EFSA (2005): Conclusion regarding the peer review of the pesticide risk assessment of the active substance Pirimicarb. EFSA Journal 43, 1-76.*
- *EC (2017): Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009. Pirimicarb. Rapporteur Member State: United Kingdom; Co-Rapporteur Member State: Sweden*
- *EC (2022): Updated draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009. Pirimicarb. Rapporteur Member State: Sweden*
- *EFSA (2024b): Answer to "Application for public access to documents (PAD) of 24 July 2024", Ref. No.: PAD 2024/116 (00012729). Legal Affairs Services, Parma, 19 September 2024. Ref. LV/BL/mm (2024) - out-31224398 (Pirimicarb)*
- *EFSA (2024a): Peer review of the pesticide risk assessment of the active substance pirimicarb. Conclusion on pesticide peer-review. EFSA Journal, 22:e9046, 1-31.*

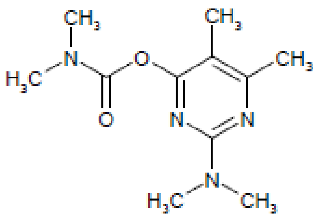
Additional information, i.e. partial access to full study reports, was provided by EFSA under the EU regulation about public access to documents (PAD regulation, EC (2001)). In line with the PAD regulation, additional information accessed via EFSA that are not included in publicly available documents get redacted from the externally published version of the dossier if needed and replaced by the abbreviation of [CPIR] (confidentially provided information, redacted). In this case no confidential information was added but the details of the critical earthworm study and its statistical evaluation were checked and confirmed (Friedrich (2010) and Taylor & Joyce (2015) cited in EC (2022)).

1.1 Identity and physico-chemical properties

Pirimicarb (CAS 23103-98-2; development code number: R32062) is a phenolic type carbamate insecticide. Its provisional minimum purity as manufactured is ≥ 97 % (≥ 970 g/kg), with no relevant impurities in the technical grade material. The compound exists as a white, powdery solid with high water solubility (see further details on physical-chemical properties in Table 1 below). A representative formulation containing pirimicarb as the active ingredient is Pirimor (company code number: A10788A; 500 g/kg of pure pirimicarb (50% w/w)), which is a water dispersible granule (WG) for use of foliar spraying (EC 2017).

Table 1: Identification and physico-chemical properties of pirimicarb. Abbreviations: LoEP – List of Endpoints, DAR – Draft Assessment Report (EC 2004)

Characteristics	Values	References
Common name	Pirimicarb	(EC 2022), LoEP
IUPAC name	2-dimethylamino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate	(EC 2022), LoEP
Chemical group	Carbamate insecticide	(EC 2022), LoEP

Structural formula		(EC 2022), LoEP
Molecular formula	$C_{11}H_{18}N_4O_2$	(EC 2022), LoEP
CAS	23103-98-2	(EC 2022), LoEP
EC Number	245-430-1	(EC 2022), LoEP
Molecular weight [g/mol]	238.29	(EC 2022), LoEP
Melting point [°C]	91.6 (Purity 98.8 %, data originally accepted in the DAR)	
Boiling point [°C]	325 (Purity 99.9 %, new data)	(EC 2022), LoEP
Solubility		
Water solubility [mg/L]	Purified water: 3000 pH 5.2: 3600 pH 7.4: 3100 pH 9.3: 3100 at 20°C (Purity 98.8%, data originally accepted in the DAR)	(EC 2022), LoEP
Solubility in organic solvents [g/L]	Acetone: 370 Methanol: 350 Dichloromethane > 500 Octanol: 99 Ethyl Acetate: 280 Toluene: 350 Hexane: 13 at 25°C (Purity 99.5 %, new data)	(EC 2022), LoEP and (EC 2017), Vol. 3CA B.2.6
Dissociation constant (pKa)	4.44 at 20°C and pH 6.4 (Purity 98.8 %, data originally accepted in the DAR)	(EC 2022), LoEP
Stability		
Aqueous hydrolysis [d]	Stable (pH 4, 5, 6 at 90-120°C)	(EC 2022), LoEP
Aqueous photolysis [h]	24-hour aqueous photolysis (pH 5 and pH 7) using simulated sunlight (30ºN), 5 cm path length, half-life = 2.6 h at pH 5, 1.9 h at pH 7 (r^2 = 0.99 and 0.98)	(EC 2022), LoEP
Photochemical degradation in air [h]	DT50 of < 1 h derived by the Atkinson model (AOP v1.8).	(EC 2022), LoEP
Volatilisation		
Vapour pressure [kPa]	4.3 x 10^{-7} kPa at 20°C (by interpolation) (Purity 98.8 %, data originally accepted in the DAR)	(EC 2022), LoEP
Henry's law constant [Pa·m^3·mol^{-1}]	at 20 °C (Purity 98.8 %, data originally accepted in the DAR) ***Value*** ***Type of water*** 3.6 x 10^{-5} Purified water 2.9 x 10^{-5} pH 5.2 3.3 x 10^{-5} pH 7.4 3.3 x 10^{-5} pH 9.3	(EC 2022), LoEP

Partition/Adsorption		
Octanol-water partition coefficient (log Kow)	at 20 °C (Purity 98.2 %, data originally accepted in the DAR) ***Type of water*** ***Log Kow*** Purified 1.7 pH 3.9 buffer 1.1 pH 7.1 buffer 1.7 pH 10.0 buffer 1.7	(EC 2022), LoEP
Organic carbon normalised Freundlich partitioning coefficient (Kfoc)	See section 1.5.3, Table 3	

1.2 Mode of action

Pirimicarb belongs to the carbamate insecticides (IRAC Group 1, Sub-group A) used against sucking insects like aphids (EC 2022; Vol. 1). Pirimicarb acts as an inhibitor of the acetylcholinesterase (AChE) enzyme disrupting normal nerve function. It acts in aphids via direct contact, through feeding on contaminated plant and/or by pirimicarb vapour in the plant canopy after spraying. As a result, pirimicarb provides a quick-acting control, even in crops with dense canopies like potatoes where aphids shelter beneath the leaves. Pirimicarb has a short persistence on plants, as a result of volatilisation from and maybe of photolysis on the plant surfaces after spraying (EC 2022).

Studies performed in mammalian species provided no evidence that pirimicarb would have the potential to affect fertility or reproductive performance in an adverse way, and also no adverse developmental effects could be detected (EC 2022, EFSA 2024a).

The recently submitted and evaluated information does not indicate endocrine disrupting (ED) properties of pirimicarb in relation to the estrogen-, androgen- and thyroid-related organs and functions nor on steroidogenesis (EC 2022, EFSA 2024a). Nevertheless, the current EU assessment scheme and thus the conclusion on ED properties of pesticide active substances focusses on vertebrates (ECHA-EFSA-JRC 2018); 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 (OECD 2018, Crane *et al.* 2022). Additionally, a specific literature search on pirimicarb yielded no data on endocrine-relevant endpoints on soil organisms (status September 2024).

The potential genotoxicity, carcinogenicity and reproductive toxicity of pirimicarb have been investigated at EU level (EC 2022, ECHA 2024). No adverse effects on reproduction could be identified. While regulatory and published literature studies indicated some *in vitro* genotoxic effects, harmlessness could be proven and was concluded based on *in vivo* test results. Pirimicarb showed carcinogenic effects in rat and mouse studies, however, these were considered as limited evidence of carcinogenicity with regard to humans, and as a result pirimicarb was classified as Category 2 (suspected human carcinogen) (EC 2022, ECHA 2024).

1.3 Use and emissions

At EU level the representative uses of pirimicarb includes protection against aphids in wheat and sugar beet for field application (1 x 120 to 2 x 125 g a.s./ha; maximum 250 g a.s./ha/year) as well as in ornamental pot plants in glasshouse (1-3 x 300 g a.s./ha; maximum 900 g a.s./ha/year) (EC 2022; Vol. 1).

In Switzerland pirimicarb can be used against aphids in various leafy and root vegetables, trees and bushes as well as in ornamental plants (including flowering cultures) in home garden and for professional application (BLV 2024). For professional field uses, applications in arable crops (e.g. sugar/fodder beet, cereals, oilseed rape and potato) as well as in orchards and various berries are also authorised up to 400 g a.s./ha, maximum twice a year (maximum 800 g a.s./ha/year).

1.4 Classification and terrestrial limit values

Pirimicarb is classified as carcinogenic Category 2 (H351 – *Suspected of causing cancer*), acute human toxicity Category 3 (H331 – *Toxic if inhaled*, H301 – *Toxic if swallowed*), skin sensitiser Category 1 (H317 – *May cause an allergic skin reaction*), aquatic acute toxicity Category 1 (H400 – *Very toxic to aquatic life*) and aquatic chronic toxicity Category 1 (H410 – *Very toxic to aquatic life with long lasting effects*) substance (EC 2022, ECHA 2024).

Pirimicarb is not considered to be a POP, PBT or vPvB substance as further explained in section 1.5.2.

Pirimicarb is listed as a candidate for substitution in the EU (EC 2015) and in Switzerland (PSMV 2010, consolidated version: 01.01.2024).

Please note that the information included here may have changed since the finalisation of this dossier.

For the Netherlands, a soil quality standard of 0.02 µg pirimicarb/kg soil dry weight (Protection Level: Precaution) is listed in the ETOX database (UBA 2024).

1.5 Environmental fate in soil

Volatilisation from soil surface

Based on the vapour pressure (4.3 x 10^{-7} kPa at 20°C), pirimicarb can be considered as non-volatile (EC 2008) and as such it is not expected to volatilise from the soil surface in significant amount.

Based on the conducted studies, the following was considered at EU level (EC 2022; Vol. 1): "*Volatilisation from soil and plant surfaces was studied in a laboratory study for 24 hours. Pirimicarb does not volatilise appreciably from soil surfaces, with 89.5% recovery of applied radioactivity at 24 hours. Dissipation of applied radioactivity from leaf surfaces was greater (47.4% recovery after 24 hours). Some of this loss may be due to volatilisation, however photolysis may also have contributed to the loss of radioactivity*." Altogether the likelihood that pirimicarb would reach significant atmospheric concentration was considered low, as the amount that could volatilise from plant surfaces would degrade quickly by photodegradation.

Photodegradation

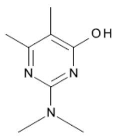
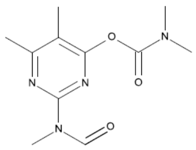
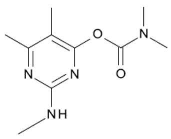
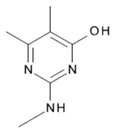
Photodegradation on soil surface was not considered to change the route and rate of degradation of pirimicarb. As a result it was not included in the environmental exposure assessment during the EU renewal of the active substance (EC 2022; Vol. 1).

1.5.1 **Route of degradation**

Aerobic degradation in soil

During the EU regulatory/renewal assessment, four major soil metabolites of pirimicarb were found, these are summarised in Table 2 (EC 2022). All four were found in aerobic degradation and one also in anaerobic degradation (see below).

Table 2: Major soil metabolites of pirimicarb. Note: AR – applied radioactivity

Code number / Trivial name	Chemical name	Structural formula	Maximum formation [% of AR]	Reference
R31805[#]	2-(dimethylamino)-5,6-dimethyl-pyrimidin-4-ol		26.5 (aerobic) 11.1 (anaerobic)	Volume 1 and LoEP in (EC 2022)
R34885* Desmethylformamido pirimicarb	[2-[formyl(methyl)amino]-5,6- dimethyl-pyrimidin-4-yl] N,N-dimethylcarbamate		12.4	Volume 1 and LoEP in (EC 2022)
R34836* Desmethyl pirimicarb	[5,6-dimethyl-2-(methylamino) pyrimidin-4-yl] N,N-dimethylcarbamate		18.9	Volume 1 and LoEP in (EC 2022)
R34865	5,6-dimethyl-2-(methylamino)pyrimidin-4-ol		31.2	Volume 1 and LoEP in (EC 2022)

Note: * - metabolite containing the carbamate moiety; [#] metabolite found both in aerobic and anaerobic route of degradation

Anaerobic degradation in soil

In addition to the aerobic degradation route, metabolite R31805 occurs significantly in anaerobic degradation of pirimicarb in soil with a maximum formation of 11.1 % AR (applied radioactivity) (EC 2022; LoEP).

Mineralisation and non-extractable residues

Mineralisation occurs between 0.3 and 61.6 % after 90-112 days under aerobic and at 0.1 % after 112 days under anaerobic conditions. Non-extractable residues range from 6.6 to 36.2 % after 90-112 days under aerobic and at 9.4 % after 112 days under anaerobic conditions (EC 2022; Vol. 1 and LoEP).

1.5.2 **Rate of degradation**

Laboratory degradation studies

Depending on the soil, the laboratory degradation of **pirimicarb** in soil can follow either simple first-order (SFO) kinetics or bi-exponential kinetics (DFOP, double first-order in parallel). The actual DT50 values (taken from a mixture of SFO and DFOP fits) calculated as persistence endpoints ranged between 5.5 and 275 days (EC 2022; Vol. 1).

Degradation of metabolite **R31805, R34885, R34836** and **R34865** resulted in actual DT50 values of 12.0-428 d, 10.3-196 d, 2.14-354 and 22.4-55.9 d, respectively (EC 2022; Vol. 1).

Based on these persistence endpoints, pirimicarb in general can be considered as persistent in soil (DT50 ≥ 60 d). However, it was considered that it did not fulfil the persistence criteria of POP (persistent organic pollutant), PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent, very bioaccumulative) substances as soil half-life was less than 6 months (with 1 soil above and 7 soils below the trigger) based on actual DT50 values from best fit kinetics (EC 2022; Vol. 1). Metabolite R31805, R34885 and R34836 can also be considered persistent in soil, while R34865 is moderately persistent.

Field dissipation studies

The field dissipation studies were not found reliable, but no data gap was indicated during the EU assessment procedure and no new studies were submitted (EC 2022; Vol. 1).

1.5.3 Adsorption/desorption properties and bioavailability

Adsorption

The adsorption properties of the parent and the major soil metabolites are summarised in Table 3 below. The mobility of pirimicarb and its metabolites vary widely depending on the soil properties, however, no clear trend was found with the exception of metabolite R31805 that showed pH-dependence (EC 2022; Vol. 1 and LoEP).

During the original review of pirimicarb, it was noted that for the metabolites, the highest one or two Kfoc values were associated with soils containing the highest clay content, but no consistent trend was observed (EC 2017). Similarly to the metabolites, no clear trend could be observed for the parent compound: the highest Kfoc value was determined in the soil with the highest clay content (47 %), but results from the other three soils with lower clay content (5-17 %) did not show a correlation of the clay content with the Kfoc values.

Table 3: Summary of soil adsorption of the active substance pirimicarb and the major soil metabolites. Abbreviations: Kfoc – organic carbon-normalised Freundlich distribution coefficients; 1/n – Freundlich exponent. Source: Volume 1 and List of Endpoint in EC (2022).

Substance	Range of Kfoc [mL/g]	Geometric mean of Kfoc [mL/g]	Arithmetic mean of 1/n	pH dependence	Mobility category
Pirimicarb	45 – 730	166.8	0.85	no	slightly mobile - mobile
R31805	130 – 80 000	25 768* 163.8**	0.78* 0.753**	yes, stronger adsorption on acidic soils	moderately mobile - immobile
R34885	57.2 – 867	182	0.922	no	mobile – slightly mobile
R34836	33.6 – 4320	289.6	0.902	no	mobile – immobile
R34865	179 – 9650	1654	0.760	no	moderately mobile – immobile

Note: * acidic soils, pH 4.4-4.9; ** alkaline soils, pH 7.8-7.9

Leaching

No column or field leaching study is available at EU level (EC 2022; Vol. 1).

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) (Peijnenburg 2020, Marti-Roura *et al.* 2023). 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, in regulatory context normalisation takes place only to the organic matter content that is considered the main factor influencing bioavailability for organic compounds (Marti-Roura *et al.* 2023).

In the case of pirimicarb itself, soil pH does not seem to affect the adsorption of the compound to soil particles. However, soil texture (namely clay content) might slightly influence the adsorption for soils with high clay content. This may need further consideration if toxicity studies are conducted with natural soils with high clay content, or for the actual risk assessment for areas with clay-type soils. The clay content in Swiss agricultural soils range between 5 and 50 % with a median value of 20 % (Meuli *et al.* 2014, Marti-Roura *et al.* 2023). The higher adsorption was observed for a soil with 47 % clay content, which means that some increase in adsorption/decrease in mobility of pirimicarb – and in turn some possible decrease in bioavailability – may occur in certain Swiss soils. On the other hand, for non-ionized organic compounds like pirimicarb (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 the 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. Pirimicarb has a log Kow of 1.1-1.7 (see Table 1), and thus there is no potential for bioaccumulation and biomagnification and no need for further consideration of secondary poisoning.

2 Chemical analysis and environmental concentrations

Comprehensive techniques are necessary for the extraction of plant protection product residues from soil and for their analysis. Through a recent development, 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 pirimicarb, the limit of quantification for the method (MLOQ) was determined as 0.1 ng a.s./g soil (corresponding to 0.0001 mg a.s./kg soil; Rösch *et al.* 2023).[1]

The soil guideline value that is derived in this dossier for pirimicarb will be used in conjunction with the actual soil concentrations monitored in Swiss soils by using the above-described analytical method.

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

The initial measurements on some selected, partly agricultural, Swiss soils resulted in pirimicarb concentrations between < 0.0001 mg a.s./kg soil (i.e. < MLOQ) and 0.0003 mg a.s./kg soil (Rösch *et al.* 2023, Table S12).

For pirimicarb, the initial predicted environmental concentrations in soil (PECsoil) range from 0.032 to 0.160 mg a.s./kg soil, following the EU GAPs (1 x 120-150 to 2 x 125 g a.s./ha/season; EC (2022) and (EFSA 2024a)). The estimated PECsoil,accumulation values (PECsoil,initial + PECsoil,plateau) are 0.0571 (winter cereals, 5 cm tillage depth, after 7 years), 0.1156 (spring cereals, 5 cm tillage depth, after 7 years) and 0.1914 (sugar beets, 20 cm tillage depth, after 10 years) mg a.s./kg soil. It is noted that in Switzerland uses in higher doses than the EU GAPs are also authorised (1-2 x 400 g a.s./ha, see Section 1.3 above).

3 Effect data on pirimicarb

Effect data for soil organisms were collected from studies retrieved from the European registration information (EFSA 2005, EC 2017, 2022). Additionally, a bibliographic search was performed for pirimicarb and its CAS number (CAS 23103-98-2) in the ECOTOX Knowledgebase (US EPA 2024) and in the database of the German Federal Environment Agency (UBA 2024). Furthermore, a search was performed on Scopus by using a combination of key words (soil, EC50, LC50, NOEC, LOEC, LCx, ECx, toxicity and various soil organisms such as earthworm, Collembola or mite) and the compound's name or CAS number. 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 pirimicarb.

In general, only relevant and reliable 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 and Table A1-Table A4).

Since the bioavailability of non-ionized organic compounds, like pirimicarb, to soil organisms is assumed to be mainly driven by the organic matter (OM) content of soil (EC TGD 2003), effect data are 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) and 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 (e.g. clay content) may also need to be 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). While neither adsorption nor degradation of pirimicarb are affected by pH, there are some indications that higher adsorption may occur in soils with high clay content that can in turn affect (potentially lower) the bioavailability of pirimicarb (see results and discussion in Section 1.5.3 and 1.6). As a result, studies outside the clay range in Swiss soils are excluded from the relevant data set. Studies conducted with (natural) soils without specifying the clay content will be dealt with caution (they will be considered as relevant with restrictions if the results are within the range of other similar studies, or not assignable if the results indicate much lower toxicity).

In the course of the evaluation, reproduction endpoints are considered the most relevant ones 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 impacts at the population level (Marti-Roura *et al.* 2023). If multiple comparable toxicity values from more tests for the same species and the same measured effect are available, the geometric mean of the effect values is calculated.

In most cases regulatory studies and their endpoints are accepted without additional assessment (at face value) or re-considered if needed to set the endpoints in line with our criteria as summarised in detail 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 final endpoint. Where the results are inconsistent or not well summarised, full re-assessments may be performed using the original study reports (depending on their availability and the importance of their results).

If more endpoints are available from the same study for the same type of effect, the statistically more robust one is preferred. This means that the statistically more robust effect concentration (EC10 or NOEC) is chosen even if it is higher than another effect concentration or is based on more than 10 % effect (it is acknowledged that in the EU regulatory assessment, 10 % effect is often used as a threshold for biologically significant effects as a precautionary approach). If the latter is the case, it will be highlighted and discussed further in the uncertainty analysis (see Section 7 below). If both NOEC and EC10 are available from the same study and statistically both are robust, due to the inherent uncertainties of the NOEC, the EC10 is preferred over the NOEC. Further details of the main criteria used for the study evaluations are included in Appendix 1.

Complete lists of laboratory and field studies reporting soil effect values for pirimicarb and its transformation products are shown in Appendix 2 (for pirimicarb, Table A1 with laboratory and Table A2 with field studies) and Appendix 3 (for two major soil metabolites, Table A3 to Table A4). If necessary, some clarifications and/or justifications of the assessment are provided in form of Notes to those tables (see Notes A1 and Notes A2 in Appendix 2 and 3, respectively). In Table 4 of the main text, all the relevant and reliable study results are summarised and the lowest data per species per test setup are shown in bold as well as depicted in Figure 1 (Section 3.2).

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 product was not possible due to data scarcity. Therefore, toxicity data obtained with the active ingredient and the formulation were merged (see data for the parent in Table 4 and Table A1). When multiple comparable toxicity values for the same species and the same endpoint were available, the geometric mean of the effect values was calculated, irrespective of whether the data was obtained with the active ingredient or the formulation.

Table 4: Pirimicarb – All reliable (R1-R2) and relevant (C1-C2) effect data. The lowest reliable and relevant effect data per species per test setup are shown in bold. The secondary endpoints for the same effects[2] are greyed out. Calculated data are rounded to three significant figures. Abbreviations: n.r. – not reported; n.a. – not applicable; cc. – concentration; WHC – water holding capacity; OC – organic carbon; OM – organic matter; CFU – colony forming units. The full set of studies can be found in Appendix 1 (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)[3]	Test substance	Measured effect[4]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida andrei (Earthworm)	Pirimicarb (a.s.)	adult mortality	14 d	NOEC	125	10	42.5	Artificial soil: 10% sphagnum peat, 20% kaolinite clay, 69.5% industrial quartz sand, 0.5 % calcium carbonate, pH 5.99-6.24, 56.3-56.4 % MWHC		R1/C2	Friedrich (2011) cited in (EC 2022), Vol. 3CA B.9.4, p.236
***Eisenia fetida andrei* (Earthworm)**	**Pirimicarb (a.s.)**	**biomass (adult weight change)**	**14 d**	**NOEC**	**62.5**	**10**	**21.3**	**Artificial soil: 10% sphagnum peat, 20% kaolinite clay, 69.5% industrial quartz sand, 0.5 % calcium carbonate, pH 5.99-6.24, 56.3-56.4 % MWHC**	**F**	**1 (R1/C2)**	**Friedrich (2011) cited in (EC 2022), Vol. 3CA B.9.4, p.236**
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	adult mortality	28 d	NOEC	≥ 10.92	5	≥ 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23	C	R1/C2	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	biomass (adult weight change)	28 d	NOEC	≥ 10.92	5	≥ 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23	C, F	1 (R1/C2)	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238

[2] The less reliable / statistically less robust / less preferred endpoint (see e.g. EC_{10} vs NOEC) per test / measured effect / duration
[3] [M] – monocotyledonous, [D] – dicotyledonous plant species
[4] [DE] – diversity endpoint, [EE] – enzymatic endpoint, [FE] – functional endpoint

Species (Taxonomic group)[3]	Test substance	Measured effect[4]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
***Eisenia fetida* (Earthworm)**	**Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)**	**biomass (adult weight change)**	**28 d**	**EC10**	**4.00**	**5**	**2.72**	**Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23**	**C**	**1 (R1/C2)**	**Taylor & Joyce (2015) re-evaluating Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.242; confirmed via (EFSA 2024b)**
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	reproduction	56 d	EC50	> 10.92	5	> 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23	C, F	1 (R1/C2)	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	reproduction	56 d	NOEC	≥ 10.92	5	≥ 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23	C	R1/C1	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	reproduction	56 d	EC10	5.71	5	3.88	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23	C, F	1 (R1/C1)	Taylor & Joyce (2015) re-evaluating Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.242; confirmed via (EFSA 2024b)
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	adult mortality	28 d	NOEC	29.5	5	20.1	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium, carbonate, pH 6.4-6.9	E	R1/C2	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	reproduction (number of juveniles)	28 d	NOEC	16.2	5	11.0	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay,	E, F	1 (R1/C2)	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273

Species (Taxonomic group)[3]	**Test substance**	**Measured effect[4]**	**Duration**	**Type of effect concentration**	**Effect concentration [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
								74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9			
***Folsomia candida* (Collembola)**	**Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)**	**reproduction (number of juveniles)**	**28 d**	**EC10**	**16.7**	**5**	**11.4**	**Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9**	**E, F**	**1 (R1/C1)**	**Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273**
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	reproduction (number of juveniles)	28 d	EC50	27.6	5	18.8	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9	E, F	1 (R1/C2)	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
Hypoaspis aculeifer (Mite)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	adult mortality	14 d	NOEC	≥ 1000	10	≥ 340	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 70 % fine quartz-sand, < 1 % calcium carbonate, pH 6.0-6.9	F	1 (R1/C2)	Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277
Hypoaspis aculeifer (Mite)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	reproduction	14 d	NOEC	309	10	105	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 70 % fine quartz-sand, < 1 % calcium carbonate, pH 6.0-6.9	G	R1/C1	Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277
***Hypoaspis aculeifer* (Mite)**	**Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)**	**reproduction**	**14 d**	**EC10**	**222**	**10**	**75.5**	**Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 70 % fine quartz-sand, < 1 % calcium carbonate, pH 6.0-6.9**	**F, G**	**1 (R1/C1)**	**Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277**
Microorganisms	**Pirimicarb WG (YF7321A, actual 47.5 % a.s. w/w)**	**Nitrogen transformation[FE]**	**28 d**	**< 10 % effect**	**≥ 5.00**	**2**	**≥ 8.50**	**Frensham soil: sandy loam, 11 % clay, 14 % silt, 75 % sand, pH 6.7**	**F**	**1 (R1/C1)**	**Mason *et al*. (1991) cited in (EC 2022), Vol. 3CA B.9.5, p.288**

Species (Taxonomic group)[3]	Test substance	Measured effect[4]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Beta vulgaris[D] *Brassica napus*[D] *Cucumis sativus*[D] *Lactuca sativa*[D] *Raphanus sativus*[D] *Avena sativa*[M] *Cyperus rotundus*[M] *Triticum aestivum*[M] *Zea mays*[M] (Terrestrial plants)	Pirimicarb DF (dry flowables, YF7904B, actual 52.37 % a.s. w/w)	seedling emergence	21 d	NOEC	≥ 0.676 (710 g a.s./ha) ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676	1	≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30	SC compost: loamy sand soil, 88 % sand, 6 % silt, 6 % clay, pH 6.1-6.4	L	R2/C1	Fleming *et al*. (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295
***Beta vulgaris*[D]** ***Brassica napus*[D]** ***Cucumis sativus*[D]** ***Lactuca sativa*[D]** ***Raphanus sativus*[D]** ***Avena sativa*[M]** ***Cyperus rotundus*[M]** ***Triticum aestivum*[M]** ***Zea mays*[M]** **(Terrestrial plants)**	**Pirimicarb DF (dry flowables, YF7904B, actual 52.37 % a.s. w/w)**	**biomass (plant dry weight)**	**21 d**	**NOEC**	**≥ 0.676 (710 g a.s./ha)** **≥ 0.676** **< 0.676** **≥ 0.676** **< 0.676** **≥ 0.676** **≥ 0.676** **≥ 0.676** **≥ 0.676**	**1**	**≥ 2.30** **≥ 2.30** **< 2.30** **≥ 2.30** **< 2.30** **≥ 2.30** **≥ 2.30** **≥ 2.30** **≥ 2.30**	**SC compost: loamy sand soil, 88 % sand, 6 % silt, 6 % clay, pH 6.1-6.4**	**L**	**R2/C1**	**Fleming *et al*. (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295**

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

C	For the Friedrich (2010) study, the RMS considered the statistically non-significant second highest test concentration as an endpoint for the reproduction NOEC as the highest test concentration included 24.1 % reduction in reproduction, while the second highest concentration only 9.4 %. It should be noted though that the coefficient of variation (CV) for reproduction in the control was 18.1, at the second highest concentration 18.4 and at the highest test concentration 24.4 %. (The OECD 222 guideline requires CV of < 30 % in the control, i.e. the occurred CVs were not exceptionally high.) This means that with this level of variation, no observed effect concentrations with < 10 % difference from the control cannot be statistically

	demonstrated. Following the evaluation requirements for SGV derivation (see Appendix 1), the statistically robust endpoint, i.e. the highest test concentration has been chosen here and listed as reproduction NOEC. Taylor and Joyce (2015) conducted a statistical re-evaluation of Friedrich (2010). As the effects did not exceeded 50 %, only EC10 and EC20 values could be calculated both for reproduction and adult biomass change. The reproduction EC10 had a “fair”, the biomass EC10 a “good” normalised width of the confidence interval (EFSA 2019). In both cases the confidence intervals of the EC10 do not overlap with the confidence intervals of the EC20, i.e. the latter are clearly higher. The detailed experimental results and their statistical re-evaluation could be confirmed via access to the full study reports (EFSA 2024b). Altogether the EC10 values are considered robust and suitable for further use (and preferred over the NOEC values – see explanation in Appendix 1). The results in terms of active substance were re-calculated with the actual active substance concentration of 50.8 % (w/w) of the applied product and shown to three significant figures. Thus, they can slightly differ here from the values listed in the EU dossier (where they stated that the ECx values as mg a.s./kg soil were based on the actual a.s. content of the product, but they were based on the nominal a.s. content).
E	The confidence interval (CI) of the calculated mortality EC10 is too wide (normalised width of CI falls into the “bad” category (EFSA 2019)) and the EC20low falls below the EC10 median. Altogether the calculated mortality EC10 is not considered statistically robust and scored as unreliable. Both the reproduction NOEC and EC10 are considered statistically robust and reliable. Following our evaluation approach (see Appendix 1), the EC10 is preferred over the NOEC. The results in terms of active substance were re-calculated with the actual active substance concentration of 49.2 % (w/w) of the product and given to three significant figures. Thus they can slightly differ here from the values listed in the EU dossier.
F	The assessment from the renewal assessment report was adopted and accepted without additional assessment (i.e. at face value). The results were re-calculated according to the actual measured active substance content of the applied formulation (if it was available) thus slight differences to the EU-listed endpoints may occur (if they used the nominal a.s. content).
G	It is noted that the ECx results in Table B.9.4.2-3 in Vol. 3CA B.9.4.2 (Kimmel (2015b) cited in EC (2022)) were erroneously reported, but in the RMS comments it is clearly stated that the reproduction EC10 is 452 mg test item/kg soil. Also, that the reproduction NOEC was originally reported as 628 mg test item/kg soil, but that was not accepted by the RMS (as it could potentially be the beginning of the dose-response relationship and as such it was not considered reliable). From the size of the effect concentrations it can be understood that the EC10, EC20 and EC50 were 452 (367-524), 547 (464-622) and 789 (699-894) mg test item/kg soil, respectively. – The EC10 is considered as follows: the normalised width of the EC10 falls into the “good” category, the EC20low is higher than the median EC10 and the steepness of the fitted curve (EC10/EC50) seems to be neither too steep nor too shallow (EFSA 2019). Altogether the reproduction EC10 is considered statistically robust and preferred over the reproduction NOEC (see Appendix 1).
J	Although the Mason *et al.* study was dated to 1991, it was evaluated to the relevant OECD 216 guideline from 2000. The original study report did not contain the results per replicate and thus the RMS could not check the fulfilment of the validity criterion. For further request the applicant sent the detailed results that showed that the validity criterion (i.e. < 15 % CV in the control) for both soils was met. However, neither the applicant nor the RMS calculated the nitrate formation rate as it is required in the OECD (2000) guideline. In the Frensham soil, the differences of the nitrate transformation rates to the control were -7 and +1 % at 0.5 and 5.0 mg a.s./kg concentration, respectively. This implies a ≥ 5.0 mg a.s./kg non-normalised effect concentration (with < 10 % effects) for this soil.
L	A limit test was conducted to a US EPA guideline (Subdivision J, Series 122-1(s) (New Series 850.4100) Seedling Emergence Tier I (undated)) rather than the OECD 208 guideline. However, the RMS evaluated the study according to the OECD 208 guideline validity criteria (see below). For this seedling emergence test disposable plastic seed trays (11 cm x 15 cm x 7 cm with base holes) rather than pots were used. For calculating the concentration from the applied rate, the 7 cm depth of the trays was used. The measured concentration in the stock solution corresponded to 710 g a.s./100 L water/ha. (It is noted that the nominal application rate of 791 g a.s./ha is used for the EU- agreed endpoint (EFSA 2024a).) The formulated product YF7321A that was used in the test was considered to be comparable to Pirimor/A10788A (EC 2022, EFSA 2024a). Phytotoxicity was scored via semi-quantitative visual assessment and thus these results are not considered sufficiently robust for further use. Validity criteria to the OECD guideline were difficult to evaluate; the following was considered by the RMS:

	- Seedling emergence was above 70 % on average and in each replicate for nine species (sugar beet, oilseed rape, lettuce, cucumber, radish, maize, wheat, oats and purple nutsedge). For soybean, the average was > 70 % with one replicate below 70 %. For onion, in three replicates the emergence rate was below 70 % (50-60 %), but it is unclear if the average was above that. It was concluded that for nine species the validity criterion of at least 70 % emergence in the control was fulfilled (EC 2022). - There were some very slight to minor phytotoxicity effects in the controls of sugar beet, soybean, oilseed rape, cucumber, maize, purple nutsedge, lettuce and onion. For onion 13.3-16.7 % damage was reported. Altogether it was concluded that the phytotoxicity effects that were observed in the control replicates were within the natural variation. - Mean survival in the control was not reported in detail. In general, dead plants were reported for onion, maize and lettuce, but without the exact numbers. Due to the low phytotoxicity effects reported in the controls, the survival in the controls was deemed sufficient. Altogether the RMS reckoned that the validity criteria were met and the results were suitable for further use in the risk assessment. Considering the uncertainties above, the study is scored reliable with restrictions (R2) for nine species and not reliable (R3) for soybean and onion due to the < 70 % emergence rate in certain replicate(s).

3.2 Graphic representation of effect data

The lowest most 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 more values for the same endpoint from the same test are available (e.g. EC10 and NOEC), the statistically more robust one is shown in the figure. If both EC10 and NOEC are equally robust, EC10 is preferred (for further explanation, please refer to Appendix 1 Considerations for the evaluation of the studies). 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.

The data on earthworm show an approximately 8 times higher sensitivity for chronic as compared to acute exposure to pirimicarb (NOEC of 2.72 vs 21.3 mg a.s./kg for biomass/adult weight change after 28 vs 14 days, respectively). The chronic equal-to effect concentrations for collembolans and mites are in the same order of magnitude (11.4-75.5 mg a.s./kg) as the acute data for earthworms (21.3 mg a.s./kg), whereas the chronic data on earthworm (2.72 mg a.s./kg) indicates 3-30 times higher sensitivity. For terrestrial plants and microorganisms only unbound values are available (see triangles facing up or down in Figure 1).

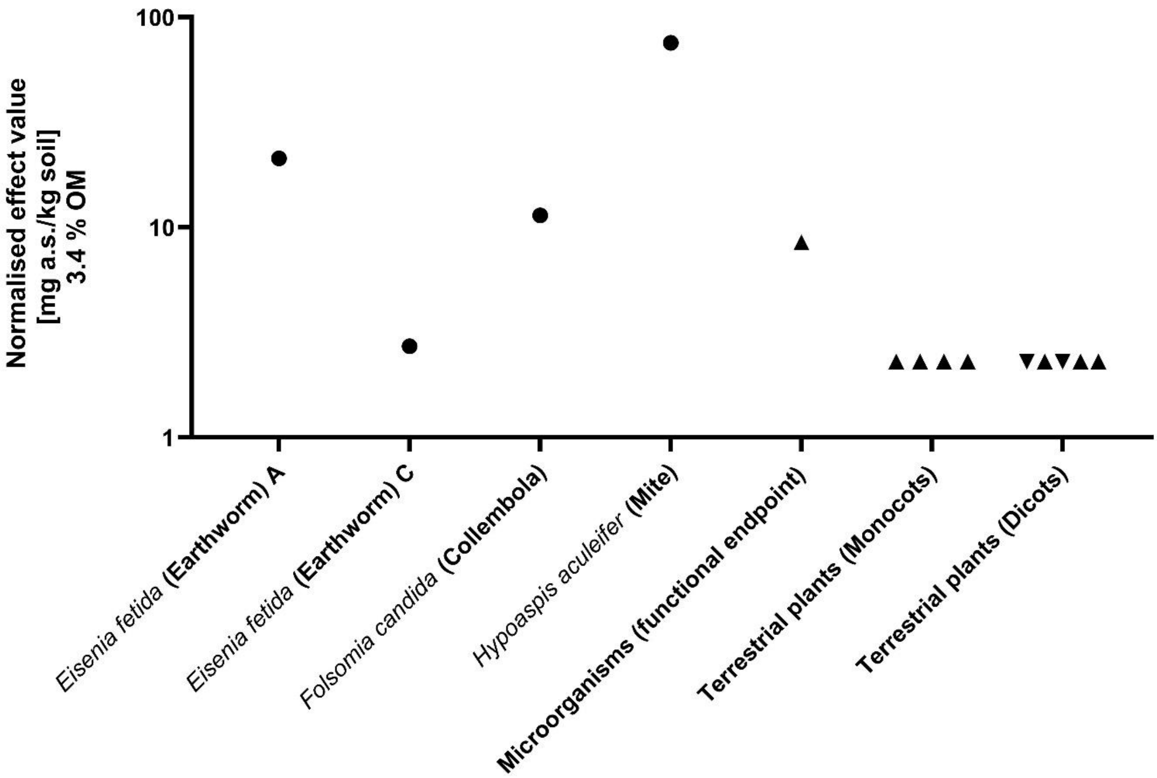


Figure 1: Effect data for pirimicarb after normalisation to a standard organic matter content of 3.4 % - the lowest effect values of the relevant and reliable endpoints per species per test setup. For earthworms the acute (A) and chronic (C) data are shown separately. For the other groups chronic data (NOEC/EC10) or equivalent to that (≤ 10 % effect) are presented. Triangles represent unbound data with the triangle facing up symbolising ≥ or > values and the triangle facing down symbolising ≤ or < values.

4 Derivation of SGV

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

Table 5: The lowest relevant and reliable, statistically robust chronic data for pirimicarb 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 concentra tion	Effect concentration [mg a.s./kg soil]	Reference
Primary producers (terrestrial plants)	*Avena sativa* (Monocots)	NOEC	≥ 2.30	Fleming *et al.* (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295
	Cyperus rotundus (Monocots)	NOEC	≥ 2.30	
	Triticum aestivum (Monocots)	NOEC	≥ 2.30	
	Zea mays (Monocots)	NOEC	≥ 2.30	
	Beta vulgaris (Dicots)	NOEC	≥ 2.30	
	Brassica napus (Dicots)	NOEC	≥ 2.30	
	Cucumis sativus (Dicots)	NOEC	< 2.30	
	Lactuca sativa (Dicots)	NOEC	≥ 2.30	
	Raphanus sativus (Dicots)	NOEC	< 2.30	
Decomposers (nutrient transformers)	Microorganisms (Functional endpoints)	< 10 % effect	≥ 8.50*	Mason *et al.* (1991) cited in (EC 2022), Vol. 3CA B.9.5, p.288
Decomposers (litter transformers/ primary consumers)	*Eisenia fetida* (Earthworm)	EC10	2.72	Taylor & Joyce (2015) re-evaluating Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.242
	Folsomia candida (Collembola)	EC10	11.4	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
Secondary consumers	*Hypoaspis aculeifer* (Mite)	EC10	75.5	Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277

Notes: * Regulatory study with two test concentrations (0.5 and 5.0 mg a.s./kg soil, non-normalised) resulting in -7 and +1 % effects on nitrate-N transformation rates at the lower and higher concentrations, respectively, after 28 days. Effect concentrations with < 10 % effect are considered similar to NOEC/EC10 values.

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

The SGV_{AF} is determined by choosing an assessment factor and applying it to the lowest valid equal-to toxicity endpoint (e.g. NOEC, EC10) out of the long-term toxicity test results. 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).

Pirimicarb is an insecticide that acts as an inhibitor of the acetylcholinesterase (AChE) enzyme. Acetylcholine (ACh) is a neurotransmitter in many vertebrate and non-vertebrate species; in addition, it can also occur in taxonomically lower species, such as plants, fungi and microbes (Horiuchi *et al.* 2003, Fujita *et al.* 2024). In a recent study, soil microorganisms showed propensity of reacting to insecticides interfering with AChE (dimethoate) or the nicotinic ACh receptor (thiametoxam, imidacloprid) only with few exceptions (Jayaraj *et al.* 2023). Thus, it is plausible that any of these organisms, i.e.

microorganisms, fungi and plants as well as animals with a cholinergic nerve system can show high sensitivity to pirimicarb.

Cucumber (*Cucumis sativus*) and radish (*Raphanus sativus*) – **primary producers (terrestrial plant species)** – showed the highest sensitivity with NOEC values of < 2.30 mg a.s./kg soil (with 10 and 11 % decrease in plant dry weight as compared to the control, respectively; Fleming *et al*. (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295). It was noted in the renewal assessment report that the validity and the results of the study were not reported with sufficient details. Based on the additional information provided by the applicant during the EU review and the detailed consideration of the RMS, the study was still considered valid. However, as it was a limit test applying only one test concentration, the resulting unbound effect concentrations cannot be used for SGV derivation. As they appear to potentially be the lowest effect concentrations, a data gap for terrestrial plants needs to be considered.

The next lowest equal-to result is for earthworms, i.e. for **decomposers (litter transformers/primary consumers)**, it is an EC10 coming from a regulatory study with five test concentrations (Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238). In the original study evaluation there was no statistically significant effects at the highest test concentration, i.e. the NOEC was ≥ 7.43 mg a.s./kg soil (normalised value) for all measured effects. The statistical re-evaluation resulted in statistically robust normalised EC10 values of 3.88 and 2.72 mg a.s./kg soil for reproduction and adult biomass change, respectively (Taylor & Joyce (2015) re-evaluating Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.242). The results and the statistical re-evaluation could be confirmed via getting access to the respective study reports (EFSA 2024b). The lower value is considered suitable for SGV derivation (see also the respective uncertainty assessment in Section 7 below).

For microorganisms, **decomposers (nutrient transformers)** only an unbound effect concentration is available (≥ 8.50 mg a.s./kg; Mason *et al.* (1991) cited in (EC 2022), Vol. 3CA B.9.5, p.288). The threshold for long-term effects on nitrogen transformation in soils in this type of study (similar to and evaluated to OECD 216) is > 25 % difference in the nitrate formation rates between the control and the treatments. As the test resulted in < 10 % effects for the tested soil, the effect concentration is treated similarly to other NOEC/EC10 values (see Table 5 above). Since this unbound effect concentration indicates that the NOEC for microorganisms is higher than the EC10 for earthworms, the value can be used for considering the AF.

The relevant and reliable data indicate a lower sensitivity of collembolans (EC10 of 11.4 mg a.s./kg soil for reproduction; Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273), another representative of **decomposers (litter transformers/primary consumers)** and mite (EC10 of 75.5 mg a.s./kg soil for reproduction; Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277; **secondary consumers)**.

When long-term test results (NOEC or EC10 values) are available for at least three species 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 pirimicarb, altogether four effect concentrations for three species and microorganisms at three trophic levels are available with the lowest endpoint of 2.72 mg a.s./kg soil for earthworms. To account for the uncertainties in the available data, an AF of 10 is applied to the lowest appropriate equal-to effect value:

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

$$SGV_{AF} = \frac{2.72\left(\frac{mg\ a.s.}{kg\ soil}\right)}{10} = 0.27\left(\frac{mg\ a.s.}{kg\ soil}\right)$$

The application of an AF of 10 to the lowest equal to chronic datum results in a SGV_{AF} of **0.27 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

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 pirimicarb, exact data are available for Annelida (*Eisenia fetida*), Hexapoda (*Folsomia candida*), and Chelicerata (*Hypoaspis aculeifer*). In total, equal-to values for three species are available from three taxonomic groups. 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 utilizing aquatic toxicity data can be used to estimate the SGV_{EqP} (EC TGD 2003). In the case of pirimicarb, sufficient amount of data is available for soil organisms to cover a range of different types of physiology and behaviour at two trophic levels. Therefore, the derivation of SGV_{EqP} using the equilibrium partitioning approach is not required.

4.4 Determination of SGV using mesocosm/field data

Two field studies on earthworms, and soil micro- and macroarthropods could be obtained and were considered in the EU renewal assessment (Wilkinson (1973) cited in (EC 2022), Vol. 3CA B.9.4.1, p.244 and Frampton (1999) further evaluated in Frampton & van den Brink (2007); also cited in (EC 2022), Vol. 3CA B.9.4.2, p.282; see Table A2 in Appendix 2). Both studies suffered from various substantial deficiencies that prevented further consideration. These include but are not limited to the following: lacking analytical verification, lacking site history and weather conditions, no toxic standard treatment, too small plot sizes, lacking efficiency assessment of the earthworm extraction method, no pre-treatment sampling for earthworms, too rare sampling of earthworms, erratic results with strongly fluctuating species abundance throughout the study (Wilkinson 1973) as well as missing history of the applied chemicals more than a year before the study (despite the reported conventional crop growing that took place at that time), application of the test item in winter wheat canopy with unknown amount of test substance reaching the soil, sampling of ground and leaf-dwelling arthropods rather than soil-dwelling organisms and lack of analytical verification (Frampton 1999, Frampton & van den Brink 2007). Altogether no meaningful quantitative endpoints could be derived from these studies (for further details, please refer to Table A2 in Appendix 2).

5 Toxicity of major transformation products

Four major soil metabolites were determined during the degradation studies of pirimicarb (for details, please refer to Table 2 in Section 1.5.1). For two of them – R31805 and R34865 – with using the highest maximum percentage of formation, the results on acute earthworm studies were listed (Moser & Römbke (2001a) and (2001b) cited in (EC 2022), Vol. 3CA B.9.4, p.235, without providing the study summaries). Also, these metabolites were included together in combination in a nitrogen and carbon transformation study (McMurray (2001) cited in (EC 2022), Vol. 3CA B.9.4, p.293). In the absence of sufficient details of the methods and the results, no reliable endpoints could be derived from these studies.

It is noted that the limited data on the metabolites was not an issue during the EU review as in the absence of actual metabolite data it was assumed that the metabolites were ten times more toxic than the parent. When data on some of the metabolites were available for a certain group of organisms, the lowest effect concentration was used for all metabolites in the respective risk assessment. This conservative approach did not highlight any potential issues in the prospective risk assessment.

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 pirimicarb, only the assessment factor (AF) method could be applied for deriving an SGV. Since the dataset included enough relevant and reliable data and the AF does not exceed 50, the SGV is considered definitive.

A definitive **SGV of 0.27 mg a.s./kg soil for pirimicarb** is suggested.

7 Protection of soil organisms and uncertainty analysis

The SGV of 0.27 mg a.s./kg soil for pirimicarb has been derived based on a dataset containing relevant and reliable values for earthworms (*Eisenia fetida*), collembolans (*Folsomia candida*), mites (*Hypoaspis aculeifer*) and microorganisms.

Pirimicarb is an insecticide, thus according to its mode of action, it is expected that organisms with a cholinergic nerve system would be the most sensitive taxonomic groups although ACh was shown to be present in taxonomically lower species as well. Based on the relevant and reliable data suitable for SGV derivation, earthworms are the most sensitive group of species.

For terrestrial plants only results from a limit test are available. Out of four monocot and five dicot species, cucumber and radish showed statistically significant effects regarding seedling biomass growth (with 10 and 11 % lower plant dry weight as compared to the control) at the normalised test concentration of 2.30 mg a.s./kg soil. As the data are critical with regard to possible adverse effects, these unbound values cannot be used for SGV derivation and the data for primary producers (terrestrial plants) is considered as a data gap. Acetylcholine has also been measured in plants, and it was linked with the regulation of differentiation, water homeostasis and photosynthesis (Horiuchi *et al.* 2003) that could explain the observed effects in the study with pirimicarb. However, statistically significant decrease occurred only for two species and with low effect sizes (10 and 11 %) at a similar effect concentration as for earthworms (2.30 vs 2.72 mg a.s./kg soil, respectively). Therefore the derived SGV is considered protective also of terrestrial plants.

There are some indications that higher adsorption of pirimicarb may occur in soils with high clay content that can potentially lower the bioavailability of pirimicarb (see results and discussion in Section 1.5.3 and 1.6). In Switzerland the clay content ranges between 5 and 50 % and the highest clay content in the soil mobility tests resulting in higher adsorption was 47 % (see details in Section 1.5.3 above). No ecotoxicological tests with pirimicarb were conducted with soil out of the Swiss clay content range. However, with regard to the occasional occurrence of higher clay content and in turn higher possible adsorption along with lower bioavailability in certain Swiss soils, this property needs to be considered in site-specific evaluations and risk assessments performed in Switzerland.

According to the current analytical methods described in Section 2, the concentration range around the proposed SGV for pirimicarb is possible to be detected and quantified during the national soil monitoring (SGV of 0.27 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.

Only few and not-assignable data on two of the four major soil metabolites are available. However, the existing – non-normalised – data do not indicate higher toxicity to earthworm and microorganisms than the active substance pirimicarb.

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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 labs. A 15-cm pot usually has a depth of approx. 13-14 cm and – based on photos of the test in contract labs (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.* 2015b, 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.* 2015a). 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 does 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 (Moermond *et al.* 2016, Marti-Roura *et al.* 2023, Casado-Martinez *et al.* 2024). 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 (Moermond *et al.* 2016, Marti-Roura *et al.* 2023). 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 and not considered further 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 regard 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), but also the wide range of DT50 values for pirimicarb in Section 1.5.2 above). 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 (Toschki *et al.* 2020, Anderson *et al.* 2010).

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; Moermond *et al.* 2016, Casado-Martinez *et al.* 2024).

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 pirimicarb 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; CFU – colony forming units. 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 A1).

Species (Taxonomic group)[5]	Test substance	Measured effect[6]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida (Earthworm)	Pirimicarb 50 % WG `YF7321A`	adult mortality	14 d	LC50	> 60	n.r.	n.a.	n.r.	A	R4/C2	Yearsdon *et al*. (1990) cited in (EC 2022), Vol. 3CA B.9.4, p.235
Eisenia fetida (Earthworm)	Pirimicarb 50 % WG `YF7321A`	adult mortality	14 d	NOEC	≥ 60	n.r.	n.a.	n.r.	A	R4/C2	Yearsdon *et al*. (1990) cited in (EC 2022), Vol. 3CA B.9.4, p.235
Eisenia fetida andrei (Earthworm)	Pirimicarb (a.s.)	adult mortality	14 d	LC50	653	10	222	Artificial soil: 10% sphagnum peat, 20% kaolin clay, 69.5% industrial quartz sand, 0.5 % calcium carbonate, pH 5.99-6.24, 56.3-55.9 % MWHC	B	R3/C2	Friedrich (2011) cited in (EC 2022), Vol. 3CA B.9.4, p.236
Eisenia fetida andrei (Earthworm)	Pirimicarb (a.s.)	adult mortality	14 d	NOEC	125	10	42.5	Artificial soil: 10% sphagnum peat, 20% kaolin clay, 69.5% industrial quartz sand, 0.5 % calcium carbonate, pH 5.99-6.24, 56.3-55.9 % MWHC		R1/C2	Friedrich (2011) cited in (EC 2022), Vol. 3CA B.9.4, p.236
***Eisenia fetida andrei* (Earthworm)**	**Pirimicarb (a.s.)**	**biomass (adult weight change)**	**14 d**	**NOEC**	**62.5**	**10**	**21.3**	**Artificial soil: 10% sphagnum peat, 20% kaolin clay, 69.5% industrial quartz sand, 0.5 % calcium carbonate, pH 5.99-6.24, 56.3-55.9 % MWHC**	**F**	**1 (R1/C2)**	**Friedrich (2011) cited in (EC 2022), Vol. 3CA B.9.4, p.236**

5 M – monocotyledonous, D – dicotyledonous plant species
6 DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Species (Taxonomic group)[5]	**Test substance**	**Measured effect[6]**	**Duration**	**Type of effect concentration**	**Effect concentration [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	adult mortality	28 d	NOEC	≥ 10.92	5	≥ 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23, 57.1-58.2 % MWHC	C	R1/C2	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	biomass (adult weight change)	28 d	NOEC	≥ 10.92	5	≥ 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23, 57.1-58.2 % MWHC	C, F	1 (R1/C2)	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	reproduction	56 d	EC50	> 10.92	5	> 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23, 57.1-58.2 % MWHC	C, F	1 (R1/C2)	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	reproduction	56 d	NOEC	≥ 10.92	5	≥ 7.43	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23, 57.1-58.2 % MWHC	C	R1/C1	Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.238
Eisenia fetida (Earthworm)	Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)	reproduction	56 d	EC10	5.71	5	3.88	Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23, 57.1-58.2 % MWHC	C, F	1 (R1/C1)	Taylor & Joyce (2015) re-evaluating Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.242; confirmed via (EFSA 2024b)

Species (Taxonomic group)[5]	Test substance	Measured effect[6]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
***Eisenia fetida* (Earthworm)**	**Pirimicarb WG (A10788A, actual 50.8 % a.s. w/w)**	**biomass (adult weight change)**	**28 d**	**EC10**	**4.00**	**5**	**2.72**	**Artificial soil: 5% sphagnum peat, 20 % kaolin clay, 0.5 % calcium carbonate, 74.7 % industrial quartz sand, pH 5.54-6.23, 57.1-58.2 % MWHC**	**C**	**1 (R1/C2)**	**Taylor & Joyce (2015) re-evaluating Friedrich (2010) cited in (EC 2022), Vol. 3CA B.9.4, p.242; confirmed via (EFSA 2024b)**
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	adult mortality	28 d	NOEC	29.5	5	20.1	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium, carbonate, pH 6.4-6.9, 48.3-59.6 % MWHC	E	R1/C2	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	adult mortality	28 d	LC10	18.2	5	12.4	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9, 48.3-59.6 % MWHC	E	R4/C2	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	adult mortality	28 d	LC50	76.6	5	52.2	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9, 48.3-59.6 % MWHC	E	R4/C2	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	reproduction (number of juveniles)	28 d	NOEC	16.2	5	11.0	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9, 48.3-59.6 % MWHC	E, F	1 (R1/C2)	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
***Folsomia candida* (Collembola)**	**Pirimicarb WG (A10788A,**	**reproduction (number of juveniles)**	**28 d**	**EC10**	**16.7**	**5**	**11.4**	**Artificial soil: 5 % sphagnum peat, 20 % kaolin clay,**	**E, F**	**1 (R1/C1)**	**Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273**

Species (Taxonomic group)[5]	Test substance	Measured effect[6]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
	actual 49.2 % a.s. w/w)							**74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9, 48.3-59.6 % MWHC**			
Folsomia candida (Collembola)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	reproduction (number of juveniles)	28 d	EC50	27.6	5	18.8	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74 % fine quartz-sand, < 1 % calcium carbonate, pH 6.4-6.9, 48.3-59.6 % MWHC	E, F	1 (R1/C2)	Kimmel (2015a) cited in (EC 2022), Vol. 3CA B.9.4, p.273
Hypoaspis aculeifer (Mite)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	adult mortality	14 d	NOEC	≥ 1000	10	≥ 340	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 70 % fine quartz-sand, < 1 % calcium carbonate, pH 6.0-6.9	F	1 (R1/C2)	Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277
Hypoaspis aculeifer (Mite)	Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)	reproduction	14 d	NOEC	309	10	105	Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 70 % fine quartz-sand, < 1 % calcium carbonate, pH 6.0-6.9	G	R1/C1	Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277
***Hypoaspis aculeifer* (Mite)**	**Pirimicarb WG (A10788A, actual 49.2 % a.s. w/w)**	**reproduction**	**14 d**	**EC10**	**222**	**10**	**75.5**	**Artificial soil: 10 % sphagnum peat, 20 % kaolin clay, 70 % fine quartz-sand, < 1 % calcium carbonate, pH 6.0-6.9**	**F, G**	**1 (R1/C1)**	**Kimmel (2015b) cited in (EC 2022), Vol. 3CA B.9.4, p.277**
Microorganisms	Pirimicarb WG (YF7321A, nominal 50 % a.s. w/w)	Carbon transformation[FE]	n.r.	NOEC	≥ 3.33	n.r.	n.a.	A sandy loam soil and a loam soil	H	R4/C1	Tarry *et al*. (1990) cited in (EC 2022), Vol. 3CA B.9.4, p.288
Microorganisms	**Pirimicarb WG (YF7321A, actual 47.5 % a.s. w/w)**	**Nitrogen transformation[FE]**	**28 d**	**< 10 % effect**	**≥ 5.00**	**2**	**≥ 8.50**	**Frensham soil: sandy loam, 11 % clay, 14 % silt, 75 % sand, pH 6.7**	**F, J**	**1 (R1/C1)**	**Mason *et al*. (1991) cited in (EC 2022), Vol. 3CA B.9.5, p.288**

Species (Taxonomic group)[5]	Test substance	Measured effect[6]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Microorganisms	Pirimicarb WG (YF7321A, actual 47.5 % a.s. w/w)	Nitrogen transformation[FE]	28 d	< 10 % effect	≥ 5.00	4.1	≥ 4.15	18-Acres soil: sandy clay loam, 23 % clay, 24 % silt, 53 % sand, pH 7.5	J	R3/C1	Mason *et al.* (1991) cited in (EC 2022), Vol. 3CA B.9.5, p.288
Microorganisms	Pirimicarb WG (YF7321A, actual 47.5 % a.s. w/w)	Carbon transformation[FE]	28 d	NOEC	≥ 0.5	2	≥ 0.850	Frensham soil: sandy loam, 11 % clay, 14 % silt, 75 % sand, pH 6.7	V	R4/C1	Mason *et al.* (1991) cited in (EC 2022), Vol. 3CA B.9.5, p.288
Microorganisms	Pirimicarb WG (YF7321A, actual 47.5 % a.s. w/w)	Carbon transformation[FE]	28 d	NOEC	≥ 0.5	4.1	≥ 0.415	18-Acres soil: sandy clay loam, 23 % clay, 24 % silt, 53 % sand, pH 7.5	V	R4/C1	Mason *et al.* (1991) cited in (EC 2022), Vol. 3CA B.9.5, p.288
Beta vulgaris[D] *Brassica napus*[D] *Cucumis sativus*[D] *Lactuca sativa*[D] *Raphanus sativus*[D] *Avena sativa*[M] *Cyperus rotundus*[M] *Triticum aestivum*[M] *Zea mays*[M] (Terrestrial plants)	Pirimicarb DF (dry flowables, YF7904B, actual 52.37 % a.s. w/w)	seedling emergence	21 d	NOEC	≥ 0.676 (710 g a.s./ha) ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676 ≥ 0.676	1	≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30	SC compost: loamy sand soil, 88 % sand, 6 % silt, 6 % clay, pH 6.1-6.4	L	R2/C1	Fleming *et al.* (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295
Glycine max[D] *Allium cepa*[M] (Terrestrial plants)	Pirimicarb DF (dry flowables, YF7904B, actual 52.37 % a.s. w/w)	seedling emergence	21 d	NOEC	≥ 0.676 ≥ 0.676		≥ 2.30 ≥ 2.30	SC compost: loamy sand soil, 88 % sand, 6 % silt, 6 % clay, pH 6.1-6.4	L	R3/C1	Fleming *et al.* (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295
Beta vulgaris[D] *Brassica napus*[D] *Cucumis sativus*[D] *Glycine max*[D] *Lactuca sativa*[D] *Raphanus sativus*[D] *Avena sativa*[M] *Allium cepa*[M]	Pirimicarb DF (dry flowables, YF7904B, actual 52.37 % a.s. w/w)	phytotoxicity (visual scoring)	21 d	NOEC	≥ 0.676 (710 g a.s./ha)	1	≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30 ≥ 2.30	SC compost: loamy sand soil, 88 % sand, 6 % silt, 6 % clay, pH 6.1-6.4	L	R3/C2	Fleming *et al.* (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295

Species (Taxonomic group)[5]	**Test substance**	**Measured effect[6]**	**Duration**	**Type of effect concentration**	**Effect concentration [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
Cyperus rotundus[M] *Triticum aestivum*[M] *Zea mays*[M] (Terrestrial plants)							≥ 2.30 ≥ 2.30				
***Beta vulgaris*[D]** ***Brassica napus*[D]** ***Cucumis sativus*[D]** ***Lactuca sativa*[D]** ***Raphanus sativus*[D]** ***Avena sativa*[M]** ***Cyperus rotundus*[M]** ***Triticum aestivum*[M]** ***Zea mays*[M]** **(Terrestrial plants)**	**Pirimicarb DF (dry flowables, YF7904B, actual 52.37 % a.s. w/w)**	**biomass (plant dry weight)**	**21 d**	**NOEC**	**≥ 0.676 (710 g a.s./ha)** **≥ 0.676** **< 0.676** **≥ 0.676** **< 0.676** **≥ 0.676** **≥ 0.676** **≥ 0.676** **≥ 0.676**	**1**	**≥ 2.30** **≥ 2.30** **< 2.30** **≥ 2.30** **< 2.30** **≥ 2.30** **≥ 2.30** **≥ 2.30** **≥ 2.30**	**SC compost: loamy sand soil, 88 % sand, 6 % silt, 6 % clay, pH 6.1-6.4**	**L**	**R2/C1**	**Fleming *et al*. (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295**
Glycine max[D] *Allium cepa*[M] (Terrestrial plants)	Pirimicarb DF (dry flowables, YF7904B, actual 52.37 % a.s. w/w)	biomass (plant dry weight)	21 d	NOEC	≥ 0.676 ≥ 0.676		≥ 2.30 ≥ 2.30	SC compost: loamy sand soil, 88 % sand, 6 % silt, 6 % clay, pH 6.1-6.4	L	R3/C1	Fleming *et al*. (1996a) cited in (EC 2022), Vol. 3CA B.9.6.1, p.295

Table A2: Soil effect data for pirimicarb from field studies. Abbreviations: n.r. – not reported; n.a. – not applicable; MWHC – maximum water holding capacity; OC – organic carbon; OM – organic matter; CFU – colony forming units. Values resulting from calculations are rounded to three significant figures.

Species (Taxonomic group)	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Earthworms	JF2130 (50 % Dispersible Powder (DP)) and JF2538 (50 % DP)	abundance (number of earthworms)	2-5 years	NOEC	n.a.	1) 2-4 2) 5-7 3) 2	n.a.	Field study/natural soils: 1) sandy loam over clay (17 % clay, 17 % silt, 66 % sand, 2 – 4 % organic matter, pH 5.5 – 6.5) 2) loam over limestone (21 % clay, 48 % silt, 31 % sand, 5 – 7 % organic matter, pH 8.0) 3) loamy sand (9 % clay, 8 % silt, 83 % sand, 2 % organic matter, pH 6.6)	D	3	Wilkinson (1973) cited in (EC 2022), Vol. 3CA B.9.4.1, p.244
Earthworms	JF2130 (50 % Dispersible Powder (DP)) and JF2538 (50 % DP)	biomass (weight)	2-5 years	NOEC	n.a.	1) 2-4 2) 5-7 3) 2	n.a.	Field study/natural soils: 1) sandy loam over clay (17 % clay, 17 % silt, 66 % sand, 2 – 4 % organic matter, pH 5.5 – 6.5) 2) loam over limestone (21 % clay, 48 % silt, 31 % sand, 5 – 7 % organic matter, pH 8.0) 3) loamy sand (9 % clay, 8 % silt, 83 % sand, 2 % organic matter, pH 6.6)	D	3	Wilkinson (1973) cited in (EC 2022), Vol. 3CA B.9.4.1, p.244
Microarthropods	JF2130 (50 % Dispersible Powder (DP)), JF2538 (50 % DP)	abundance (number of arthropods)	2-5 years	NOEC	n.a.	1) 2-4 2) 5-7 3) 2	n.a.	Field study/natural soils: 1) sandy loam over clay (17 % clay, 17 % silt, 66 % sand, 2 – 4 % organic matter, pH 5.5 – 6.5) 2) loam over limestone (21 % clay, 48 % silt, 31 % sand, 5 – 7 % organic matter, pH 8.0)	D	3	Wilkinson (1973) cited in (EC 2022), Vol. 3CA B.9.4.1, p.244

[7] DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Species (Taxonomic group)	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
								3) loamy sand (9 % clay, 8 % silt, 83 % sand, 2 % organic matter, pH 6.6)			
Collembola and macroarthropod community	Aphox (500 g/kg Soluble Granule (SG))	abundance, taxonomic richness	44 d	NOEC	n.a. (40 g a.s./ha)	4.4 6.2 6.8 8.8	n.a.	Field study/natural soils: 21.9-34.7 % coarse sand, 29.1-38.0 % fine sand, 15.6-21.0 % silt, 9.8-15.5 % clay, pH 6.3-6.9	M	(2) R4/C4	Frampton (1999) further evaluated in Frampton & van den Brink (2007); also cited in (EC 2022), Vol. 3CA B.9.4.2, p.282

Notes A1: Notes on soil studies for pirimicarb.

A	The study results are listed without study summary.
B	LC50 is extrapolated outside of the tested concentrations of 31.25-500 mg a.s./kg
C	For the Friedrich (2010) study, the RMS considered the statistically non-significant second highest test concentration as an endpoint for the reproduction NOEC as the highest test concentration included 24.1 % reduction in reproduction, while the second highest concentration only 9.4 %. It should be noted though that the coefficient of variation (CV) for reproduction in the control was 18.1, at the second highest concentration 18.4 and at the highest test concentration 24.4 %. (The OECD 222 guideline requires CV of < 30 % in the control, i.e. the occurred CVs were not exceptionally high.) This means that with this level of variation, no observed effect concentrations with < 10 % difference from the control cannot be statistically demonstrated. Following the evaluation requirements for SGV derivation (see Appendix 1), the statistically robust endpoint, i.e. the highest test concentration has been chosen here and listed as reproduction NOEC. Taylor and Joyce (2015) conducted a statistical re-evaluation of Friedrich (2010). As the effects did not exceeded 50 %, only EC10 and EC20 values could be calculated both for reproduction and adult biomass change. The reproduction EC10 had a “fair”, the biomass EC10 a “good” normalised width of the confidence interval (EFSA 2019). In both cases the confidence intervals of the EC10 do not overlap with the confidence intervals of the EC20, i.e. the latter are clearly higher. The detailed experimental results and their statistical re-evaluation could be confirmed via access to the full study reports (EFSA 2024b). Altogether the EC10 values are considered robust and suitable for further use (and preferred over the NOEC values – see explanation in Appendix 1). The results in terms of active substance were re-calculated with the actual active substance concentration of 50.8 % (w/w) of the applied product and shown to three significant figures. Thus they can slightly differ here from the values listed in the EU dossier (where they stated that the ECx values as mg a.s./kg soil were based on the actual a.s. content of the product, but they were based on the nominal a.s. content).
E	The confidence interval (CI) of the calculated mortality EC10 is too wide (normalised width of CI falls into the “bad” category (EFSA 2019)) and the EC20low falls below the EC10 median. Altogether the calculated mortality EC10 is not considered statistically robust and scored as unreliable. Both the reproduction NOEC and EC10 are considered statistically robust and reliable. Following our evaluation approach (see Appendix 1), the EC10 is preferred over the NOEC. The results in terms of active substance were re-calculated with the actual active substance concentration of 49.2 % (w/w) of the product and given to three significant figures. Thus they can slightly differ here from the values listed in the EU dossier.
D	Field study conducted at three locations in the UK for 2-5 years with yearly application of 0.5 and 5 kg a.s./ha to follow effects on earthworms and soil microarthropods.

	There were several shortcomings of the study thus no effect concentrations could be derived. The most important deficiencies: no analytical verification of the applied amount of a.s., no site history or weather conditions reported, no toxic standard included, too small plot sizes, efficiency of the earthworm extraction method not reported, no pre-treatment sampling for earthworms, too rare sampling of earthworms, erratic results with strongly fluctuating species abundance throughout the study.
F	The assessment from the renewal assessment report was adopted and accepted without additional assessment (i.e. at face value). The results were re-calculated according to the actual measured active substance content of the applied formulation (if it was available) thus slight differences to the EU-listed endpoints may occur (if they used the nominal a.s. content).
G	It is noted that the ECx results in Table B.9.4.2-3 in Vol. 3CA B.9.4.2 (EC 2022) were erroneously reported, but in the RMS comments it is clearly stated that the reproduction EC10 is 452 mg test item/kg soil. Also, that the reproduction NOEC was originally reported as 628 mg test item/kg soil, but that was not accepted by the RMS (as it could potentially be the beginning of the dose-response relationship and as such it was not considered reliable). From the size of the effect concentrations it can be understood that the EC10, EC20 and EC50 were 452 (367-524), 547 (464-622) and 789 (699-894) mg test item/kg soil, respectively. – The EC10 is considered accordingly: the normalised width of the EC10 falls into the "good" category, the EC20low is higher than the median EC10 and the steepness of the fitted curve (EC10/EC50) seems to be neither too steep nor too shallow (EFSA 2019). Altogether the reproduction EC10 is considered statistically robust and preferred over the reproduction NOEC (see Appendix 1).
H	The study is not fully summarised in the renewal assessment report (EC 2022), it is not clear if the missing information was not reported or just not included in the summary.
J	Although the Mason *et al*. study was dated to 1991, it was evaluated to the relevant OECD 216 guideline from 2000. The original study report did not contain the results per replicate and thus the RMS could not check the fulfilment of the validity criterion. For further request the applicant sent the detailed results that showed that the validity criterion (i.e. < 15 % CV in the control) for both soils was met. However, neither the applicant nor the RMS calculated the nitrate formation rate as it is required in the OECD (2000) guideline. In case of the **18-acres soil**, no nitrate formation occurred in 28 days in any treatments including the control. This indicates that the microbial community in this soil was not suitable to show potential effects of the test substance on nitrate formation. Therefore the results for this test is not considered reliable for further use (R3). In the **Frensham soil**, the differences of the nitrate transformation rates to the control were -7 and +1 % at 0.5 and 5.0 mg a.s./kg concentration, respectively. This implies a ≥ 5.0 mg a.s./kg non-normalised effect concentration (with < 10 % effects) for this soil.
L	A limit test was conducted to a US EPA guideline (Subdivision J, Series 122-1(s) (New Series 850.4100) Seedling Emergence Tier I (undated)) rather than the OECD 208 guideline. However, the RMS evaluated the study according to the OECD 208 guideline validity criteria (see below). For this seedling emergence test disposable plastic seed trays (11 cm x 15 cm x 7 cm with base holes) rather than pots were used. For calculating the concentration from the applied rate, the 7 cm depth of the trays was used. The measured concentration in the stock solution corresponded to 710 g a.s./100 L water/ha. (It is noted that the nominal application rate of 791 g a.s./ha is used for the EU- agreed endpoint (EFSA 2024a).) The formulated product YF7321A that was used in the test was considered to be comparable to Pirimor/A10788A (EC 2022, EFSA 2024a). Phytotoxicity was scored via semi-quantitative visual assessment and thus these results are not considered sufficiently robust for further use. Validity criteria to the OECD guideline were difficult to evaluate; the following was considered by the RMS: - Seedling emergence was above 70 % on average and in each replicate for nine species (sugar beet, oilseed rape, lettuce, cucumber, radish, maize, wheat, oats and purple nutsedge). For soybean, the average was > 70 % with one replicate below 70 %. For onion, in three replicates the emergence rate was below 70 % (50-60 %), but it is unclear if the average was above that. It was concluded that for nine species the validity criterion of at least 70 % emergence in the control was fulfilled (EC 2022). - There were some very slight to minor phytotoxicity effects in the controls of sugar beet, soybean, oilseed rape, cucumber, maize, purple nutsedge, lettuce and onion. For onion 13.3-16.7 % damage was reported. Altogether it was concluded that the phytotoxicity effects that were observed in the control replicates were within the natural variation. - Mean survival in the control was not reported in detail. In general, dead plants were reported for onion, maize and lettuce, but without the exact numbers. Due to the low phytotoxicity effects reported in the controls, the survival in the controls was deemed sufficient. Altogether the RMS reckoned that the validity criteria were met and the results were suitable for further use in the risk assessment. Considering the uncertainties above, the study is scored reliable with restrictions (R2) for nine species and not reliable (R3) for soybean and onion due to the < 70 % emergence rate in certain replicate(s).

M	Non-target effects on terrestrial arthropod communities of the broad-spectrum insecticides chlorpyrifos and cypermethrin and the selective insecticide pirimicarb were investigated separately in winter wheat fields in summer. The pirimicarb treatment took place at 40 g a.s./ha rate. The arthropods were sampled on day 6, 10, 17, 27 and 44 days after the treatment. Pesticide treatments were reported only from less than one year before the study (winter wheat: carboxin, thiobendazole, chlorotoluron, micoprop-p, chlormequat, choline chloride, imazaquin, cyproconazole 2x, flusilazole and fenpropidin). The history of cropping was listed for another six years including field beans, winter wheat, linseed, winter wheat, spring peas and winter cereal. The pesticides applied in these previous crops were not reported. The treatment took place on 23rd June in winter wheat that was harvested on15th August. Due to the growing plant canopy, it is unclear how much of the test substance reached the soil and if there was any exposure through the soil. No analytical verification of the treatment took place. Also, the sampling method using a Ryoby suction sampler meant that ground and leaf-dwelling arthropods were targeted and not soil-dwelling organisms. Based on the above detailed deficiencies, the study is not considered relevant and reliable for SGV derivation. (It is noted that the study was scored in the EU review as reliable with reservations.)
V	The validity criteria as specified in the relevant guideline were not included in the study summary, therefore it is not clear if the criteria were met.

It is noted that the following studies were considered potentially relevant but did not meet the most important requirement with regard to the way of exposure through soil and/or the treatment was not applied as a single substance (and they may have other deficiencies as well), thus they have not been evaluated and listed in detail (not relevant; C3). Furthermore, there were studies that were not reported detailed enough with regard to the methods and/or the results to be able to derive a reliable quantitative endpoint (not assignable; R4).

- Ahtiainen *et al.* (2003)
- Álvarez-Martín *et al.* (2016)
- Bunn *et al.* (1996)
- Ekelund & Christensen (1994)
- Fleming *et al*. (1996b) cited in (EC 2022), Vol. 3CA B.9.6.1, p.300
- Gutiérrez *et al.* (2008)
- Mazzia *et al.* (2018)
- Schuster & Schröder (1990)
- Wiles & Frampton (1996)

Appendix 3 Data on the metabolites

Table A3: Soil effect data for R31805, a major soil metabolite of pirimicarb. 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; CFU – colony forming units. For notes, please refer to the end of Appendix 3 (Notes A2).

Species (Taxonomic group)	**Measured effect[8]**	**Duration**	**Type of effect concentration**	**Effect value [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
Eisenia andrei (Earthworm)	mortality	14 d	LC50	> 1000	n.r.	n.a.	n.r.	A	R4/C2	Moser & Römbke (2001a) cited in (EC 2022), Vol. 3CA B.9.4, p.235
Eisenia andrei (Earthworm)	biomass (bodyweight)	14 d	NOEC	300	n.r.	n.a.	n.r.	A	R4/C2	Moser & Römbke (2001a) cited in (EC 2022), Vol. 3CA B.9.4, p.235
Microorganisms	nitrogen transformation[FE]	28 d	< 25 % effect	R31805: 1.75 (1312 g/ha) R34865: 1.61 (1207 g/ha)	n.r.	n.a.	n.r.	K	R4/C1	McMurray (2001) cited in (EC 2022), Vol. 3CA B.9.4, p.293
Microorganisms	carbon transformation[FE]	28 d	< 25 % effect	R31805: 1.75 (1312 g/ha) R34865: 1.61 (1207 g/ha)	n.r.	n.a.	n.r.	K	R4/C1	McMurray (2001) cited in (EC 2022), Vol. 3CA B.9.4, p.293

[8] DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Table A4: Soil effect data for R34865, a major soil metabolite of pirimicarb. 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; CFU – colony forming units. For notes to the studies, please refer to the end of Appendix 3 (Notes A2).

Species (Taxonomic group)	**Measured effect**[9]	**Duration**	**Type of effect concentration**	**Effect value [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
Eisenia andrei (Earthworm)	mortality	14 d	LC50	> 1000	n.r.	n.a.	n.r.	A	R4/C2	Moser and Römbke (2001b) cited in (EC 2022), Vol. 3CA B.9.4, p.235
Eisenia andrei (Earthworm)	n.r.	14 d	NOEC	≥ 1000	n.r.	n.a.	n.r.	A	R4/C2	Moser and Römbke (2001b) cited in (EC 2022), Vol. 3CA B.9.4, p.235
Microorganisms	nitrogen transformation[FE]	28 d	< 25 % effect	R31805: 1.75 (1312 g/ha) R34865: 1.61 (1207 g/ha)	n.r.	n.a.	n.r.	K	R4/C1	McMurray (2001) cited in (EC 2022), Vol. 3CA B.9.4, p.293
Microorganisms	carbon transformation[FE]	28 d	< 25 % effect	R31805: 1.75 (1312 g/ha) R34865: 1.61 (1207 g/ha)	n.r.	n.a.	n.r.	K	R4/C1	McMurray (2001) cited in (EC 2022), Vol. 3CA B.9.4, p.293

Notes A2: Notes on soil effect data for pirimicarb metabolites.

A	The study results are listed without study summary.
K	The study was conducted with a mixture of metabolites R31805 and R34865. However, it was poorly summarised with missing information on the methods and the results. The study is potentially relevant, but the reliability cannot be evaluated (R4) and no normalised effect concentrations can be derived.

9 DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint