REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product name: PYRIX 20SL

Chemical active substance(s):

PYRIPROXYFEN, 20 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: AGROFARM SP. z o.o.

Submission date: 7 November 2025, update July 2026

MS Finalisation date: July 2026 (initial Core Assessment)

September 2026 (final Core Assessment)

Version history

When	What
07.11.2025	Environmental fate
11.06.2026	Applicant's update all point - information and data from the EU review of pyriproxyfen changes are highlighted in green.
July 2026	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
September 2026	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

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8 Fate and behaviour in the environment (KCP 9)

Although mushroom cultivation has historically been classified under "greenhouse" cultivation (Reg. (EC) No 1107/2009, Article 3, Definition 27), recent regulatory guidance and the technical realities of mushroom farming strongly support its classification as a closed building use for the purpose and intended uses of our Plant Protection Product *Pyriproxyfen 20 SL*.
EFSA (2019) administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances explicitly lists "mushroom sheds" as an example of indoor use, alongside other enclosed environments such as silos and storage rooms.

> *"For indoor use the remarks column should contain an entry to clarify the use e.g. post-harvest storage room or silo, potato store, mushroom shed, witloof shed or rhubarb forcing house."*

This reflects a shift in regulatory understanding that mushroom cultivation occurs in fully enclosed, controlled environments, distinct from traditional greenhouses and as such, environmental exposure is negligible.

Mushroom growing houses are designed for efficient cultivation and are therefore located in buildings that are isolated from the external environment. Such buildings are fully closed with non-transparent walls and a non-transparent roof, with a tightly sealed, smooth concrete floor most often covered with ceramic tiles. The growing rooms are equipped with the necessary air conditioning and irrigation systems with a microclimate control system.
Unlike greenhouses, which often have transparent walls and roofs, soil or hydroponic systems with continuous water flow, and thus potential for environmental emissions, mushroom growing houses are:

- opaque, sealed structures,
- using composted substrate on solid, hole-free shelves arranged on several stacked levels,
- using computer-controlled low-water systems, where water is added only to maintain substrate humidity, and not to irrigate.

The solid, hole-free shelves as well as the computerised low-water systems prevent nutrients from being washed away, thus also preventing pyriproxyfen residues from flowing onto the lower shelves or onto the sealed floors.
These differences make mushroom cultivation chambers functionally and structurally distinct from greenhouses.This all points more towards CLOSED BUILDING.

There is no possibility of pyriproxyfen and his metabolites being released into the environment and having an impact on the environment (soil, water, surface water, air) and animals.
There is no need to carry out tests for pyriproxyfen and his metabolites in soil, water, surface waters, ground water and air . No need to conduct a risk assessment of the impact of pyriproxyfen on the environment.
Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025

Agrofarm's statemant on spent mushroom substrate and its use.

Information on the disposal of mushroom substrate:

> **Treat as waste. Spent mushroom substrate classified under code 02 01 99 (other waste not specified) is agricultural waste and is governed by the Polish Waste Act of 14 December 2012 regulations.**

Based on the physicochemical properties of pyripoxyfen, the timing of application of Pyrix 20SL (the probability of pyriproxyfen residues in the substrate is negligible) and the behavior of pyripoxyfen in soil and groundwater, handling mushroom substrate as waste is safe and does not pose a threat to the environment and humans.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

,	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
PL ; Climatic zone:Northern/authorization zone:Centraluses (greenhouses - mushroom cultivation in CLOSED BUILDING)														
1	PL	*Mushrooms (fungi) Agaricus bisporus* Code number: 0280010	I-indoor application- closed buildings (only professional use)	-sciarid fly (Sciaridae) -phyrid fly (Phoridae) Developmental stage: Adult insect	Spray/ manual sprayer	BBCH: overgrowth of cover by mushroom mycelium Spraying two days after applying a torf cover	a) 1 b) 1 for 1 cycle (3-4 throws= fruit harvest)	n.a.	a) 15ml/m2 b) 15 ml/m2 for 1 cycle (3-4 fruit harvest)	a) 0,3 g.s.a./m2 (3 kg/ha or 3000 g/ha) b) 0,3 g.s.a./m2 (3kg/ha or 3000 g/h) for 1 cycle (3-4 fruit harvest)	(10000 L/ha) 1L/m2	n.a.	n.a.	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of pyriproxyfen concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	PL	Mushrooms (fungi) Agaricus bisporus Code num-ber: 0280010	I-indoor application-closed buildings (only professional use)	-sciarid fly (Sciaridae) -phyrid fly (Phoridae) Developmental stage: Adult insect	Spray/ manual sprayer	BBCH: overgrowth of cover by mushroom mycelium Spraying two days after applying a torf cover	a) 1 b) 1 for 1 cycle (3-4 throws= fruit harvest)	n.a.	a) 15ml/m2 b) 15 ml/m2 for 1 cycle (3-4 fruit harvest)	a) 0,3 g.s.a./m2 (3 kg/ha or 3000 g/ha) b) 0,3 g.s.a./m2 (3kg/ha or 3000 g/h) for 1 cycle (3-4 fruit harvest)	(10000 L/ha) 1L/m2	n.a.	n.a.

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

~~Table 8.2-1: Metabolites of pyriproxyfen potentially relevant for exposure assessment~~

There is no possibility of pyriproxyfen and his metabolites being released into the environment and having an impact on the environment (soil, water, surface water, air) and animals when Pyrix 20 SL used in accordance with GAP in closed building and the spent mushroom substrate is agricultural waste, not intended as fertilizer.
No need to carry out tests for pyriproxyfen metabolites in soil, water, surface waters, ground water and air. We believe there is no need to conduct a risk assessment of the impact of pyriproxyfen metabolites on the environment.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025

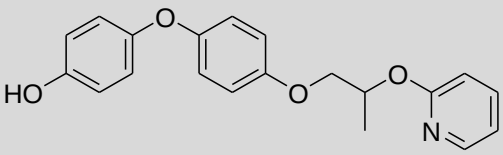
Available data from the EU-level review of pyriproxyfen from EFSA publications conclusion, opinion

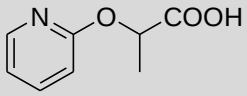
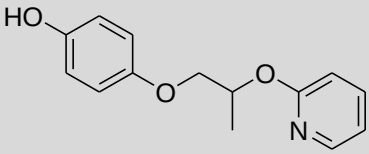
Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Pyriproxyfen was discussed at the Pesticides Peer Review TC 201 in January 2019.
Pyriproxyfen is a racemic mixture of an (R)-enantiomer and an (S)-enantiomer. The methods of analyses used in the radiolabelled soil and water studies in the dark were able to distinguish between the enantiomers and there was no significant change in the isomeric ratio over the duration of the studies. However, this information was not available for metabolites 4'-OH-Pyr, PYPAC and DPH-Pyr, which contain chiral carbon atom, and to address the specific environmental behaviour of the single isomers of pyriproxyfen under illuminated conditions. Therefore, for those processes in which microbial metabolism is involved, some degree of enantioselective transformation in the environment cannot be excluded. This is identified as a data gap (see Section 7). However, except for the chronic risk assessment to aquatic invertebrates for metabolite PYPAC, this data gap did not result in an assessment not finalised for parent pyriproxyfen (soil compartment) and metabolites DPH-Pyr (aquatic environment), 4'-OH-Pyr and PYPAC due to the margins of safety between hazard endpoints and PEC indicated in the available environmental risk assessments. For the aquatic risk assessment of pyriproxyfen, this uncertainty on the relative toxicity and contributions to the total residues levels of the isomers does not change the conclusion of high risk.

zRMS comments:

According to EFSA Journal 2019;17(6):5732 information regarding metabolites of pyriproxyfen are presented in table below:

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments
4'-OH-Pyr	337.4		Aerobic soil: 0.9-8.9% at 1-14 d (n=9) [phenyl-^{14}C] &-[pyridyl-^{14}C] labels Water/sediment: 4'-OH-Pyr – 9.2-15.9% at 2-50 d (max 14.8% at 7 d in the sediment) [phenyl-^{14}C] &-[pyridyl-^{14}C] labels

PYPAC	167.2		Aerobic soil: 1.0-13.9% at 1-30 d (n=9) [phenyl-^{14}C] &-[pyridyl-^{14}C] labels Soil photolysis: max 13.1% at 10 d (n=1) [pyridyl-^{14}C] label Water/sediment: PYPAC – 11.1-31.2% at 50-100 d (max 23.6% at 100 d in the water) [phenyl-^{14}C] &-[pyridyl-^{14}C] labels
DPH-pyr	245.3		Water/sediment: 3.4-12.7% at 2-14 d (max 11.8% at 2 d in the water). No reliable degradation/dissipation rates could be derived for metabolite DPH-Pyr. [phenyl-^{14}C] &-[pyridyl-^{14}C] labels

8.3 Rate of degradation in soil (KCP 9.1.1)

No need to carry out tests for pyriproxyfen and metabolites rate of degradation in soil when Pyrix 20 SL used in accordance with GAP in closed building and the spent mushroom substrate is agricultural waste, not intended as fertilizer.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Pyriproxyfen and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for piryproxyfen - laboratory studies
Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***
Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
Persistence endpoints

Parent	**Dark aerobic conditions**				
Soil type	**pH ($CaCl_2$)**	**Temp. (°C) / % MWHC**	**DT_{50} / DT_{90} (days)**	**χ^2 error (%)**	**Kinetics**
Hanford (sandy loam)					
Pyridyl	6.5[1]	25/ 75% ⅓ bar	7.34/35.1	2.26	FOMC
Phenyl	6.5[1]	25/ 75% ⅓ bar	7.10/30.7	5.62	FOMC
Geometric mean			7.22/32.83		
Noichi (sandy clay loam)					
Pyridyl	5.7[1]	25/ 75% ⅓ bar	5.96/88.8	5.1	DFOP
Phenyl	5.7[1]	25/ 75% ⅓ bar	5.9/79.7	3.1	DFOP
Geometric mean			5.93/84.1		
California (sandy loam)					
Pyridyl	7.6[2]	25/ 75% ⅓ bar	9.47/66.3	5.3	DFOP
Phenyl	7.6[2]	25/ 75% ⅓ bar	6.27/40.0	12.3	FOMC
Geometric mean			7.71/51.5		
PT102 (sandy loam)	6.7	20/ 45% MWHC	2.65/16.7	3.9	FOMC
PT103 (sandy loam)	4.9	20/ 45% MWHC	4.48/29.5	6.8	FOMC
SK15556090 (silt loam)	6.2	20/ 45% MWHC	1.35/10.8	4.9	FOMC
SK960087 (clay loam)	7.3	20/ 45% MWHC	1.17/14.0	5.4	FOMC
Brierlow (silt loam)	5.4	20/ pF2	1.9/25.2	5.0	DFOP
Longwoods (sandy loam)	7.5	20/ pF2	12.3/135	10.2	DFOP

[1] in H_2O
[2] medium not stated

Modelling endpoints

Parent	**Dark aerobic conditions**				
Soil type	**pH ($CaCl_2$)**	**Temp. (ºC) / % MWHC**	**DT_{50} / DT_{90} (days)**	**$DT_{50\ MOD}$ 20°C / pF 2 (days) [a)]**	**χ^2 error (%)**
Hanford (sandy loam)					
Pyridyl	6.5[1]	25/ 75% ⅓ bar	8.26/27.5	6.66	5.04
Phenyl	6.5[1]	25/ 75% ⅓ bar	7.78 / 25.8	6.3	6.1
Geometric mean				6.46	
Noichi (sandy clay loam)					
Pyridyl	5.7[1]	25/ 75% ⅓ bar	5.96 / 88.8	13.9	5.1
Phenyl	5.7[1]	25/ 75% ⅓ bar	5.9 / 79.7	14.8	3.1
Geometric mean				14.3	
California (sandy loam)					
Pyridyl	7.6[2]	25/ 75% ⅓ bar	9.39/ 61.5	8.4	6.7
Phenyl	7.6[2]	25/ 75% ⅓ bar	6.27/ 40.0	5.3	12.3
Geometric mean				6.7	
PT102 (sandy loam)	6.7	20/ 45% MWHC	2.65 / 16.7	3.3	3.9
PT103 (sandy loam)	4.9	20/ 45% MWHC	4.48 / 29.5	5.3	6.8
SK15556090 (silt loam)	6.2	20/ 45% MWHC	1.35 / 10.8	1.7	4.9
SK960087 (clay loam)	7.3	20/ 45% MWHC	1.17 / 14.0	1.8	5.4
Brierlow (silt loam)	5.4	20/ pF2	2.0 / 24.3	7.3	6.1
Longwoods (sandy loam)	7.5	20/ pF2	19.7 / 65.3	19.7	14.3
Geometric mean				**5.5**	
pH dependence				No	

[1] in H_2O
[2] medium not stated
[a)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-2: Summary of aerobic degradation rates for metabolites - laboratory studies
Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
Persistence endpoints

4'-OH-Pyr	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was pyriproxyfen**				
Soil type	**pH ($CaCl_2$)**	**Temp. (°C) / % MWHC**	**DT_{50} / DT_{90} (days)**	**χ^2 error (%)**	**Kinetics**
Noichi (sandy clay loam) *Pyridyl*	5.7[1]	25/ 75% ⅓ bar	13.4 / 44.4	12.9	DFOP/SFO
Phenyl	5.7[1]	25/ 75% ⅓ bar	24.4 / 81.1	11.8	DFOP/SFO
Geometric mean			18.1/60.0		
California (sandy loam) *Pyridyl*	7.6[2]	25/ 75% ⅓ bar	13.1 / 107	9.2	FOMC
Phenyl	7.6[2]	25/ 75% ⅓ bar	38.0/148*	6.6	FOMC
			22.3/125.84		
PT102 (sandy loam)	6.7	20/ 45% MWHC	5.6 / 52.4	5.1	FOMC
SK15556090 (silt loam)	6.2	20/ 45% MWHC	7.6 / 46.1	7.8	DFOP
SK960087 (clay loam)	7.3	20/ 45% MWHC	9.3 / 71.8	6.4	FOMC
Brierlow (silt loam) *Parent dosed*	5.4	20/ pF2	7.4 / 24.5	16.6	DFOP/SFO
Brierlow (silt loam) *Metabolite dosed*	5.4	20/ pF2	0.1 / 2.0	3.6	FOMC
Longwoods (sandy loam)	7.5	20/ pF2	0.3 / 5.4	3.8	FOMC
Newhaven (silt loam)	5.4	20/ pF2	0.1 / 1.4	5.1	FOMC

* endpoint used for PECsoil calculations.

* both labels provide an FOMC fit. However for PECsoil calculation it is not feasible to ' average' the results to obtain average α and β values. Therefore the PECsoil calculation is based on the most conservative value (DT50 38.0, DT90 148 days)

Aerobic degradation rates for 4'-OH-Pyr - laboratory studies Modelling endpoints

4'-OH-Pyr	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was pyriproxyfen**						
Soil type	**pH ($CaCl_2$)**	**Temp. (°C) / % MWHC**	**DT_{50} / DT_{90} (days)**	**Formation fraction**	**$DT_{50\ MOD}$ 20°C / pF 2 (days) [a)]**	**χ^2 error (%)**	**Kinetics**
Noichi (sandy clay loam)	5.7[1]	25/ 75% ⅓ bar	13.4 / 44.4	0.10	19.1	12.9	DFOP/SFO
Pyridyl							
Phenyl	5.7[1]	25/ 75% ⅓ bar	24.4 / 81.1	0.06	34.8	11.8	DFOP/SFO
Geometric mean				0.08	25.8		
Arithmetic mean							
California (sandy loam)	7.6[2]	25/ 75% ⅓ bar	13.1 / 107	0.20	24.9	9.2	Decline from top: FOMC (α: 1.085, β: 14.6)
Pyridyl							
Phenyl	7.6[2]	25/ 75% ⅓ bar	40.9≛ / 136	0.06	31.6	6.9	SFO
Geometric mean				0.13	28.1		
Arithmetic mean							
PT102 (sandy loam)	6.7	20/ 45% MWHC	5.6 / 52.4	0.10	15.8	5.1	Decline from top: FOMC (α: 0.9713, β: 5.398)
SK15556090 (silt loam)	6.2	20/ 45% MWHC	7.6 / 46.1	0.05	13.9	7.8	Decline from top: DFOP (k_1: 0.1071, k_2: 0.003239, g: 0.8914)
SK960087 (clay loam)	7.3	20/ 45% MWHC	9.3 / 71.8	0.09	21.6	6.4	Decline from top: FOMC (α: 1.15, β: 11.22)
Brierlow (silt loam)				0.14	7.2		FOMC/SFO
Parent dosed	5.4	20/ pF2	7.4 / 24.5			14.3	
Brierlow (silt loam) *Metabolite dosed*	5.4	20/ pF2	0.1 / 2.0	-	0.6	3.6	FOMC (α: 0.7391, β: 0.09107)
Longwoods (sandy loam)	7.5	20/ pF2	0.3 / 5.4	-	1.6	3.8	FOMC (α: 0.66, β: 0.1691)
Newhaven (silt loam)	5.4	20/ pF2	0.1 / 1.4	-	0.4	5.1	FOMC (α: 0.6666, β: 0.04581)
Geometric mean					**5.96**		
Arithmetic mean				0.10			
pH dependence					No		

[1] in H_2O

[2] medium not stated

[a)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Aerobic degradation rates for PYPAC - laboratory studies Persistence endpoints

PYPAC	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was pyriproxyfen**				
Soil type	**pH ($CaCl_2$)**	**Temp. (°C) / % MWHC**	**DT_{50} / DT_{90} (days)**	**χ^2 error (%)**	**Kinetics**
Hanford (sandy loam)	6.5[1]	25/ 75% ⅓ bar	27.7/92.1	9.84	FOMC/SFO
California (sandy loam)	7.6[2]	25/ 75% ⅓ bar	7.1 / 23.4	18.9	SFO
PT103 (sandy loam)	4.9	20/ 45% MWHC	0.984/7.2	7.3	FOMC
SK960087 (clay loam)	7.3	20/ 45% MWHC	7.5 / 25.0	15.0	SFO
Brierlow (silt loam)	5.4	20/ pF2	2.6 / 8.7	10.0	SFO
Longwoods (sandy loam) *Parent dosed*	7.5	20/ pF2	35.4/118	25.6	DFOP/SFO
Longwoods (sandy loam) *Metabolite dosed*	7.5	20/ pF2	53.8/ 179	14.6	SFO
Newhaven (silt loam)	5.4	20/ pF2	8.5 / 28.1	5.4	SFO

Aerobic degradation rates for PYPAC - laboratory studies Modelling endpoints

PYPAC	**Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was pyriproxyfen**						
Soil type	**pH ($CaCl_2$)**	**Temp. (°C) / % MWHC**	**DT_{50} / DT_{90} (days)**	**Formation fraction**	**$DT_{50\ MOD}$ 20°C / pF 2 (days) [a)]**	**χ^2 error (%)**	**Kinetics**
Hanford (sandy loam)	6.5[1]	25/ 75% ⅓ bar	25.3/84.0	0.11	20.4	9.58	SFO
California (sandy loam)	7.6[2]	25/ 75% ⅓ bar	7.1 / 23.4	0.30	5.4	18.9	SFO
PT103 (sandy loam)	4.9	20/ 45% MWHC	1.7 / 5.5	0.47	1.7	8.9	SFO
SK960087 (clay loam)	7.3	20/ 45% MWHC	7.5 / 25.0	0.07	7.5	15.0	SFO
Brierlow (silt loam)	5.4	20/ pF2	2.6 / 8.7	-	2.6	10.0	SFO
Longwoods (sandy loam) *Parent dosed*	7.5	20/ pF2	24.7 / 82.1	0.33	24.7	22.6	SFO/SFO
Longwoods (sandy loam) *Metabolite dosed*	7.5	20/ pF2	53.8 / 179	-	53.8	14.6	SFO
Newhaven (silt loam)	5.4	20/ pF2	8.5 / 28.1	-	8.5	5.4	SFO
Geometric mean					**8.95**		
Arithmetic mean				0.26			
pH dependence					No		

[1]in H_2O
[2] medium not stated
[a)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

zRMS comments:

Soil degradation data presented in tables above are in line with EU agreed endpoints presented in EFSA Journal 2019;17(6):5732.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Metabolites	No data submitted, not required

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	Soil photolysis				
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d) irradiated, calculated at 43ºN*	St. (χ^2)	Method of calculation
Sandy loam	7.6	25 /75% field moisture capacity, measured at 0.33 bar	8.0/26.5 (pyridyl) 14.2/47.1 (phenyl)	8.3 9.3	SFO

a) medium unknown
* light intensity in the study was comparable to 70-74% of natural sunlight in July 15, 1991, at 43°N and 89°W

zRMS comments:

Provided information above is in line with this reported in EFSA Journal 2019;17(6):5732. No relevant pyriproxyfen metabolites were formed during degradation studies performed under anaerobic conditions.

8.4 Field studies (KCP 9.1.1.2)

No need to carry out tests for pyriproxyfen and metabolites dissipation in soil when Pyrix 20 SL used in accordance with GAP in closed building and the spent mushroom substrate is agricultural waste, not intended as fertilizer.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Pyriproxyfen and its metabolites

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Persistence endpoints

Parent	Aerobic conditions						
Soil	Location	pH	Depth (cm)	DT_{50} (days)	DT_{90} (days)	χ^2 error (%)	Kinetics
Ephrata (loamy sand)	Washington State, USA	7.6	7.5	9.47*	31.5	15.4	SFO
Lyons (loamy sand)	New York State, USA	6.0	7.5	9.15*	30.4	16.2	SFO

* since only two reliable field dissipation endpoint remain, and field studies were not triggered, the PECsoil concentrations will be calculated on the basis of the laboratory DT50 values (maximum DT50 and DT90, Longwoods DFOP fit)

Modelling endpoints

Parent	Aerobic conditions							
Soil	Location	pH	Depth (cm)	DT_{50} (days)	DT_{90} (days)	$DegT_{50\ MOD}$ 20°C / pF 2 (days) [a)]	χ^2 error (%)	Kinetics
Ephrata (loamy sand)	Washington State, USA	7.6	7.5	7.2	23.8	7.16	23.6	SFO
Lyons (loamy sand)	New York State, USA	6.0	7.5	7.8	25.9	7.78	10.1	SFO
Geometric mean						**7.5**		
pH dependence						No		

[a)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

zRMS comments:

Actual field soil degradation data for pyriproxyfen presented in tables above are in line with EU agreed endpoints presented in EFSA Journal 2019;17(6):5732.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

At this point, Agrofarm refers to data and information from the EU review of pyriproxyfen

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	No data submitted, not required

zRMS comments:

No EU agreed data from soil accumulation studies with pyriproxyfen are available in. EFSA Journal 2019;17(6):5732.

8.5 Mobility in soil (KCP 9.1.2)

No need to carry out tests for pyriproxyfen and metabolites mobility in soil when Pyrix 20 SL used in accordance with GAP in closed building and the spent mushroom substrate is agricultural waste, not intended as fertilizer.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

8.5.1 Pyriproxyfen and its metabolites

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent							
Soil Type	**OC %**	**Soil pH[a]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Sandy loam	1.0	8.0	-	-	123.7	12374	1.05
Silt loam	0.6	7.0	-	-	184.8	30807	1.17
Silty clay loam	0.8	7.8	-	-	285.8	35728	1.20
Clay loam	2.9	7.0	-	-	342.8	11820	1.20
Geometric mean						**20030**	
Arithmetic mean							1.16
pH dependence			No				

a)Medium not stated

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

4'-OH-Pyr							
Soil Type	**OC %**	**Soil pH[a)]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Sandy loam	0.6	6.9	-	-	21.38	3564.1	0.857
Silt loam	1.1	6.9	-	-	32.47	2951.9	0.771
Clay loam	1.2	7.9	-	-	11.44	953.1	1.00
Geometric mean						**2156.4**	
Arithmetic mean							0.876*
pH dependence			No				

a)Medium not stated

* in exposure assessment a value of 0.87(4) was used. For future assessments the correct value of 0.876 should be used

PYPAC							
Soil Type	**OC %**	**Soil pH[a)]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Sandy loam	0.6	6.9	-	-	0.119	19.90	1.05
Silt loam	1.1	6.9	-	-	0.345	31.35	1.00
Clay loam	1.2	7.9	-	-	0.109	9.08	1.17
Geometric mean						**17.82**	
Arithmetic mean							1.074
pH dependence			inconclusive, too few data. However based on the expected higher Koc for acidic soils (based on the estimated pKa) it was accepted by the peer review to use the geometric mean of the available values				

a)Medium not stated

DPH-Pyr							
Soil Type	**OC %**	**Soil pH[a)]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Clay loam	3.6	7.6	-	-	9.739	270.5	0.733
Silt loam	2.4	6.1	-	-	10.993	458.0	0.801
Loamy sand	1.2	5.5	-	-	7.176	598.0	0.713

Geometric mean			**420**	
Arithmetic mean				0.749
pH dependence	No			

a)Medium not stated

zRMS comments:

Soil sorption data for pyriproxyfen and its metabolites presented in tables above are in line with information presented in EFSA Journal 2019;17(6):5732.

8.5.2 Column leaching (KCP 9.1.2.1)

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)	
Column leaching	Elution (mm): 69 mm/day simulated rainfall Time period (d): 7.5 d
	Leachate: 0.1 and 2.8% total residues/radioactivity in leachate 0% active substance ~5% total residues/radioactivity retained in top 5 cm
Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)	
Column leaching	Aged for (d): 9 d Elution (mm): 782 mm/day simulated rainfall Time period (d): 15.6 hours
	Leachate: 1.0-7.6% total residues/radioactivity in leachate for [phenyl-^{14}C] and [pyridyl-^{14}C] labels respectively <0.8% active substance, <0.8% 4'-OH-Pyr, 6.5% PYPAC for [pyridyl-^{14}C] label only 88~89% total residues/radioactivity retained in top 9 cm

zRMS comments:

Results of column leaching and aged residues leaching of pyriproxyfen are reported in EFSA Journal 2019;17(6):5732, however are not necessary for purposes of evaluation of Pyrix 20 SL, as no unacceptable leaching of pyriproxyfen or its metabolites is expected for application of the product in closed buildings.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)	
Lysimeter/ field leaching studies	No data submitted, not required

zRMS comments:

The lysimeter studies were not required during the EU review of pyriproxyfen.

8.5.4 Field leaching studies (KCP 9.1.2.3)

No data available.

zRMS comments:

The field leaching studies were not required during the EU review of pyriproxyfen.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

NOT APPLICABLE.
No need to carry out tests for pyriproxyfen and metabolites degradation in the water/sediment when Pyrix 20 SL used in accordance with GAP in closed building and the spent mushroom substrate is agricultural waste, not intended as fertilizer.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

8.6.1 Pyriproxyfen and its metabolites

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent substance
Persistence endpoints

Parent	**Distribution: max in sediment 44.7-48.5% after 1-2 d**									
Water / sediment system	**pH water phase**	**pH sed [a)]**	**t. °C**	**DT_{50} /DT_{90} whole sys.**	**St. (χ^2)**	**$DisT_{50}$ /$DisT_{90}$ water**	**St. (χ^2)**	**$DisT_{50}$ /$DisT_{90}$ sed**	**St. (χ^2)**	**Method of calculation**
Mill stream pond	~8.5	~7.5	20	4.8 / 53.5	12.2	0.4 / 5.0	7.6	22.1 / 73.5	6.6	DFOP/ HS/ SFO
Emperor lake	~8.0	~6.5	20	5.7 / 61.0	8.0	0.9 / 7.5	5.3	36.8 /122	10.3	HS/ HS/ SFO
Worst-case [b)]				5.7 / 61.0		0.9 / 7.5		36.8 / 122		
Geometric mean [b)]				**5.2 / 57.1**		**0.6 / 6.1**		**28.5 / 94.7**		

[a)]Measured in unknown medium
[b)]Not normalised since study was at 20 °C

Modelling endpoints

Parent	**Distribution: max in sediment 44.7-48.5% after 1-2 d**									
Water / sediment system	**pH water phase**	**pH sed [a)]**	**t. °C**	**DT_{50} whole sys.**	**St. (χ^2)**	**$DisT_{50}$ water**	**St. (χ^2)**	**$DisT_{50}$ sed**	**St. (χ^2)**	**Method of calculation**
Mill stream pond	~8.5	~7.5	20	16.1	12.2	1.5	7.6	22.1	6.6	DFOP*/ HS*/ SFO
Emperor lake	~8.0	~6.5	20	18.4	8.0	2.3	5.3	36.8	10.3	HS*/ HS*/ SFO
Geometric mean [b)]				**17.2**		**1.9**		**28.5**		

[a)]Measured in unknown medium
[b)]Not normalised since study was at 20 °C

* DT50 values calculated from the k2 values of the slow phase

Metabolites

Persistence endpoints

Metabolite 4'-OH-Pyr	**Distribution: max in sediment 10.6-48.7% after 1-14 d** **Kinetic formation fraction: not applicable, kinetics determined from metabolite dosed study**									
Water / sediment system	**pH water phase**	**pH sed [a)]**	**t. °C**	**DT_{50} /DT_{90} whole sys.**	**St. (χ^2)**	**$DisT_{50}$ /$DisT_{90}$ water**	**St. (χ^2)**	**$DisT_{50}$ /$DisT_{90}$ sed**	**St. (χ^2)**	**Method of calculation**
Mill stream pond	~8.5	~7.2	20	1.2 / 30.6	13.2	0.4 / 1.3	6.0	3.5 / 55.9	11.9	HS/ SFO/ DFOP
Emperor lake	~8.0	~6.5	20	0.8 / 12.6	10.5	0.6 / 2.1	12.0	ND	ND	HS/ SFO/ -
Worst-case [b)]				1.2 / 30.6		0.6 / 2.1		3.5 / 55.9		
Geometric mean [b)]				**1.0 / 19.6**		**0.5 / 1.7**		**3.5 / 55.9**		

[a)]Measured in unknown medium
[b)]Not normalised since study was at 20 °C

Modelling endpoints

Metabolite 4'-OH-Pyr	**Distribution: max in sediment 10.6-48.7% after 1-14 d** **Kinetic formation fraction: not applicable, kinetics determined from metabolite dosed study**									
Water / sediment system	**pH water phase**	**pH sed [a)]**	**t. °C**	**DT_{50} whole sys.**	**St. (χ^2)**	**$DisT_{50}$ water**	**St. (χ^2)**	**$DisT_{50}$ Sed**	**St. (χ^2)**	**Method of calculation**
Mill stream pond	~8.5	~7.2	20	9.2	13.2	0.4	6.0	16.8	11.9	HS*/ SFO/ DFOP*
Emperor lake	~8.0	~6.5	20	3.8	10.5	0.6	12.0	ND	ND	HS*/ SFO/ -
Geometric mean [b)]				**5.9**		**0.5**		**16.8**		

[a)]Measured in unknown medium
[b)]Not normalised since study was at 20 °C

* DT50 values calculated from the k2 values of the slow phase

Persistence endpoints

Metabolite PYPAC	**Distribution: max in sediment 13.4-31.2% after 3-7 d** **Kinetic formation fraction: not applicable, kinetics determined from metabolite dosed study**									
Water / sediment system	**pH water phase**	**pH sed [a)]**	**t. °C**	**DT_{50} /DT_{90} whole sys.**	**St. (χ^2)**	**$DisT_{50}$ /$DisT_{90}$ water**	**St. (χ^2)**	**$DisT_{50}$ /$DisT_{90}$ sed**	**St. (χ^2)**	**Method of calculation**
Mill stream pond	~7.5	~7.2	20	53.8 / 179	6.0	19.0 / 117	10.8	89.9 / 299	14.5	SFO/ DFOP/ SFO

Emperor lake	~7.5	~6.5	20	11.2 / 37.1	7.6	8.5 / 28.3	5.1	13.5 / 44.9	18.2	SFO/ SFO/ SFO
Worst-case [b)]				53.8 / 179		19.0 / 117		89.9 / 299		
Geometric mean [b)]				**24.5 / 81.5**		**12.7 / 57.5**		**34.8 / 116**		

[a)]Measured in unknown medium
[b)]Not normalised since study was at 20 °C

Modelling endpoints

Metabolite PYPAC	**Distribution: max in sediment 13.4-31.2% after 3-7 d Kinetic formation fraction: not applicable, kinetics determined from metabolite dosed study**									
Water / sediment system	**pH water phase**	**pH sed [a)]**	**t. °C**	**DT_{50} whole sys.**	**St. (χ^2)**	**$DisT_{50}$ water**	**St. (χ^2)**	**$DisT_{50}$ Sed**	**St. (χ^2)**	**Method of calculation**
Mill stream pond	~7.5	~7.2	20	53.8	6.0	32.0	17.3	89.9	14.5	SFO/ SFO/ SFO
Emperor lake	~7.5	~6.5	20	11.2	7.6	8.5	5.1	13.5	18.2	SFO/ SFO/ SFO
Geometric mean [b)]				**24.5**		**16.5**		**34.8**		

[a)]Measured in unknown medium
[b)]Not normalised since study was at 20 °C

Summary of the mineralisation and non-extractable residues in water/sediment

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	**pH water phase**	**pH sed**	**Mineralisation x % after n d. (end of the study).**	**Non-extractable residues in sed. max x % after n d**	**Non-extractable residues in sed. max x % after n d (end of the study)**
Mill stream pond	~8.5	~7.5	52.5% after 100 d, [phenyl-^{14}C] 35.9% after 100 d, [pyridyl-^{14}C]	38.5% after 50 d, [phenyl-^{14}C] 36.7% after 100 d, [pyridyl-^{14}C]	36.8% after 100 d, [phenyl-^{14}C] 36.7% after 100 d, [pyridyl-^{14}C]
Emperor lake	~8.0	~6.5	24.6% after 100 d, [phenyl-^{14}C] 11.0% after 100 d, [pyridyl-^{14}C]	51.4% after 100 d, [phenyl-^{14}C] 30.9% after 100 d, [pyridyl-^{14}C]	51.4% after 100 d, [phenyl-^{14}C] 30.9% after 100 d, [pyridyl-^{14}C]
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)			4'-OH-Pyr – 9.2-15.9% at 2-50 d (max 14.8% at 7 d in the sediment) PYPAC – 11.1-31.2% at 50-100 d (max 23.6% at 100 d in the water) DPH-Pyr – 3.4-12.7% at 2-14 d (max 11.8% at 2 d in the water). No reliable degradation/dissipation rates could be derived for metabolite DPH-Pyr. [phenyl-^{14}C] &-[pyridyl-^{14}C] labels		

zRMS comments:

Information presented in tables above is in line with data for pyriproxyfen presented in EFSA Journal 2019;17(6):5732.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

NOT APPLICABLE.
When using Pyrix 20SL in accordance with GAP in closed buildings, the presence or release of pryriproxyfen and metabolites into the soil is not expected. PEC soil Calculations are no needed.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

8.7.1 Justification for new endpoints

NOT APPLICABLE

8.7.2 Active substance(s) and relevant metabolite(s)

8.7.2.1 Pyriproxyfen and its metabolites

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Parent Method of calculation	DT_{50} (d): 12.3 days (DT90 135 days) Kinetics: DFOP (k1 0.1349, k2 0.01118, g 0.5465) Field or Lab: representative worst case from laboratory studies. (since only two reliable field dissipation endpoints remain, and field studies were not triggered, the PECsoil concentrations will be calculated on the basis of the laboratory DT50 values (Longwoods))
Application data	Crop: ornamentals (as risk envelope) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 60 (vines, BBCH 14-69, used as surrogate crop) Number of applications: 2 Interval (d): 10 Application rate(s): 112.5 g a.s./ha

8.7.2.2 PECsoil of formulation pyriporxyfen

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	–		0.1043	–
Short term 24h	–	–	0.1011	0.1027
2d	–	–	0.0981	0.1011
4d	–	–	0.0926	0.0982
Long term 7d	–	–	0.0854	0.0942
28d	–	–	0.0561	0.0755
50d	–	–	0.0439	0.0652
100d	–	–	0.0319	0.0525
Plateau concentration	–			

Metabolite 4' OH Pyr Method of calculation	Molecular weight relative to the parent: 1.050 DT_{50} (d): 38.0 days Kinetics: FOMC (α 1.627 and β 12.19) Worst-case lab value
Application data	Application rate assumed: 10.51 g/ha (assumed 4' OH Pyr is formed at a maximum of 8.9% of the applied dose)

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time-weighted average	Multiple application Actual	Multiple application Time-weighted average
Initial	–		0.0077	–
Short-term – 24h	–	–	0.0069	0.0073
——————2d	–	–	0.0062	0.0069
——————4d	–	–	0.0051	0.0063
Long-term – 7d	–	–	0.0040	0.0055
——————28d	–	–	0.0014	0.0031
——————50d	–	–	0.0007	0.0022
——————100d	–	–	0.0003	0.0013
Plateau concentration	–			

Metabolite PYPAC Method of calculation	Molecular weight relative to the parent: 0.520 DT_{50} (d): 53.8 days Kinetics: SFO Worst-case lab value
Application data	Application rate assumed: 8.136 g/ha (assumed PYPAC is formed at a maximum of 13.9% of the applied dose)

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time-weighted average	Multiple application Actual	Multiple application Time-weighted average
Initial	–		0.0082	–
Short-term – 24h	–	–	0.0080	0.0081
——————2d	–	–	0.0079	0.0080
——————4d	–	–	0.0077	0.0079
Long-term – 7d	–	–	0.0074	0.0078
——————28d	–	–	0.0057	0.0068
——————50d	–	–	0.0043	0.0060
——————100d	–	–	0.0022	0.0046
Plateau concentration	–			

zRMS comments:

The PEC soil results presented by the Applicant in tables above refer to the application to vine and are therefore not relevant for the intended use of the product Pyrix 20 SL. Therefore, presented results were not validated by the zRMS and have been struck through and shaded for transparency.

According to the critical Central Zone GAP table 8.1-1, the product Pyriproxyfen 02 SL is intended for use only by professional users as indoor application in closed buildings without contact with the soil surface.

According to the critical Central Zone GAP table 8.1-1, the product Pyriproxyfen 02 SL is intended for use only by professional users as indoor application in closed buildings without contact with the soil surface

In addition the Applicant states that:
Mushroom growing houses are designed for efficient cultivation and are therefore located in buildings that are isolated from the external environment. Such buildings are fully closed with non-transparent walls and a non-transparent roof, with a tightly sealed, smooth concrete floor most often covered with ceramic tiles. The growing rooms are equipped with the necessary air conditioning and irrigation systems with a microclimate control system. Unlike greenhouses, which often have transparent walls and roofs, soil or hydroponic systems with continuous water flow, and thus potential for environmental emissions, mushroom growing houses are:

- *opaque, sealed structures,*
- *using composted substrate on solid, hole-free shelves arranged on several stacked levels,*
- *using computer-controlled low-water systems, where water is added only to maintain substrate humidity, and not to irrigate.*

The solid, hole-free shelves as well as the computerised low-water systems prevent nutrients from being washed away, thus also preventing pyriproxyfen residues from flowing onto the lower shelves or onto the sealed floors.
These differences make mushroom cultivation chambers functionally and structurally distinct from greenhouses.This all points more towards CLOSED BUILDING.

Since the application of the product will be conducted in sealed, non-transparent closed buildings with smooth, impermeable floors (often tiled concrete or ceramic) and computer-controlled irrigation and spraying systems that use minimal water, no soil contamination is expected. In accordance with the *EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments* (EFSA Journal 2014;12(3):361, Table 1, page 5) a soil exposure assessment for the application in closed buildings is considered not relevant.

However, according to the information provided by the Applicant, the spent mushroom substrate will be disposed of as waste and subsequently used as compost. According to polish Waste Act of 14 December 2012, and in accordance with the European Waste Catalogue (EWC), spent mushroom substrate is classified as agricultural waste under EWC code 02 01 99 "wastes not otherwise specified".
The use of the spent mushroom substrate as compost may result in indirect exposure of soil to residues of the active substance and its metabolites. Nevertheless, the pyripoxyfen and its relevant soils metabolites are not considered to be persistent in soil (the DT_{50} values are below 120 days, and DT_{90} values are below 365 days). Therefore, no further assessment of soil exposure is required for the substrate further used as a compost.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

NOT APPLICABLE.
When using Pyrix 20SL in accordance with GAP in closed buildings, the presence or release of pryriproxyfen and metabolites in groundwater is not expected. PEC_{gw} Calculations are no needed.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

8.8.1 Justification for new endpoints

NOT APPLICABLE

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

8.8.2.1 Pyriproxyfen and its metabolites

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Field uses	
Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUSgw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL (version 4.4.4), FOCUS PELMO (version 5.5.3) and FOCUS MACRO (version 5.5.4) * Crops: citrus fruit, pome fruit, tomatoes and ornamentals Pyriproxyfen Water solubility at 20°C: 0.101 mg/L Vapour pressure at 20°C: 9.2×10^{-6} Pa Geometric mean DT_{50} soil at 20°C and pF 2: 5.83 days (combined lab and field soil DT50s) Geometric mean K_{FOC}: 20030 Arithmetic mean 1/n: 1.16 Crop uptake factor: 0 4'-OH-Pyr Water solubility at 20°C: 1×10^{6} mg/L Vapour pressure at 20°C: 0 Pa Geometric mean DT_{50} soil at 20°C and pF 2: 5.96 d Formation fraction from parent: 0.10 Geometric mean K_{FOC}: 2156.4 Arithmetic mean 1/n: 0.876 Crop uptake factor: 0 PYPAC Water solubility at 20°C: 1×10^{6} mg/L Vapour pressure at 20°C: 0 Pa Geometric mean DT_{50} soil at 20°C and pF 2: 8.95 d

	Formation fraction from parent: 0.26 Geometric mean K_{FOC}: 17.82) Arithmetic mean 1/n: 1.074 Crop uptake factor: 0
Application rate	Gross application rate: citrus fruit 225 g/ha, pome fruit 60 g/ha, tomatoes and ornamentals 112.5 g/ha Crop growth stage: citrus fruit BBCH 85-89, pome fruit BBCH 59 pre-flowering, tomatoes BBCH 88 and ornamentals beginning of infestation Canopy interception: citrus fruit 80%, pome fruit 60%, tomatoes 80% and ornamentals 60% Application rate net of interception: citrus fruit 45 g/ha, pome fruit 24 g/ha, tomatoes 22.5 g/ha and ornamentals 45 g/ha No. of applications: citrus fruit and pome fruit 1, tomatoes and ornamentals 2 Time of application (absolute application dates): citrus fruit 1 Oct, pome fruit 1 Apr (C,H,J,K,N) or 1 Mar (P,O,S,T), tomatoes 1 Jun, 11 Jun, and ornamentals early 1 March, 11 March, ornamentals late 1 Jun, 11 Jun For the protected use in tomatoes and ornamentals (walk-in tunnel and greenhouse) the Pistoia modified leaching scenario was used, see input box below the field uses.

* please note that for MACRO calculations the final revision of the endpoints was not taken into account. MACRO was never critical. Modelling is performed using the applicant initial values (see modelling box PECgw protected uses). For future calculations the following endpoints should be used: parent DT50 soil 5.8 days, 4' OH Pyr soil 6.0 days, PYPAC soil DT50 9.0 days, in combination with a formation fraction of 0.26.

PEC(gw) – FOCUS modelling results (80th percentile annual average concentration at 1m)

Citrus fruit	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH-Pyr	PYPAC
PEARL	Piacenza	<0.001	<0.001	0.071
	Porto	<0.001	<0.001	0.044
	Sevilla	<0.001	<0.001	0.021
	Thiva	<0.001	<0.001	0.039
PELMO	Piacenza	<0.001	<0.001	0.057
	Porto	<0.001	<0.001	0.027
	Sevilla	<0.001	<0.001	0.001
	Thiva	<0.001	<0.001	<0.001

Pome fruit	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH-Pyr	PYPAC
PEARL	Châteaudun	<0.001	<0.001	0.004
	Hamburg	<0.001	<0.001	0.009
	Jokioinen	<0.001	<0.001	0.005
	Kremsmünster	<0.001	<0.001	0.003
	Okehampton	<0.001	<0.001	0.004
	Piacenza	<0.001	<0.001	0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001
PELMO	Châteaudun	<0.001	<0.001	0.020
	Hamburg	<0.001	<0.001	0.021

Pome fruit	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH-Pyr	PYPAC
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	0.021
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	0.042
	Porto	<0.001	<0.001	0.025
	Sevilla	<0.001	<0.001	0.031
	Thiva	<0.001	<0.001	0.002
MACRO	Châteaudun	<0.001	<0.001	<0.001

Tomatoes (field)	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH-Pyr	PYPAC
PEARL	Châteaudun	<0.001	<0.001	0.004
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001
PELMO	Châteaudun	<0.001	<0.001	0.003
	Piacenza	<0.001	<0.001	0.014
	Porto	<0.001	<0.001	0.007
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001
MACRO	Châteaudun	<0.001	<0.001	0.001

Ornamentals EARLY (field)	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH-Pyr	PYPAC
PEARL	Châteaudun	<0.001	<0.001	0.008
	Hamburg	<0.001	<0.001	0.010
	Kremsmünster	<0.001	<0.001	0.009
	Piacenza	<0.001	<0.001	0.004
	Porto	<0.001	<0.001	0.002
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001
PELMO	Châteaudun	<0.001	<0.001	0.015
	Hamburg	<0.001	<0.001	0.018
	Kremsmünster	<0.001	<0.001	0.022
	Piacenza	<0.001	<0.001	0.044
	Porto	<0.001	<0.001	0.025
	Sevilla	<0.001	<0.001	0.003
	Thiva	<0.001	<0.001	0.001
MACRO	Châteaudun	<0.001	<0.001	0.002

Ornamentals LATE (field)	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH-Pyr	PYPAC
PEARL	Châteaudun	<0.001	<0.001	0.009
	Hamburg	<0.001	<0.001	0.023
	Kremsmünster	<0.001	<0.001	0.012
	Piacenza	<0.001	<0.001	0.002
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	0.001
	Thiva	<0.001	<0.001	<0.001
PELMO	Châteaudun	<0.001	<0.001	0.012
	Hamburg	<0.001	<0.001	0.030

~~Ornamentals LATE (field)~~	~~Scenario~~	~~Parent (µg/L)~~	~~Metabolite (µg/L)~~	
			~~4' OH Pyr~~	~~PYPAC~~
	~~Kremsmünster~~	~~<0.001~~	~~<0.001~~	~~0.033~~
	~~Piacenza~~	~~<0.001~~	~~<0.001~~	~~0.009~~
	~~Porto~~	~~<0.001~~	~~<0.001~~	~~0.002~~
	~~Sevilla~~	~~<0.001~~	~~<0.001~~	~~0.001~~
	~~Thiva~~	~~<0.001~~	~~<0.001~~	~~0.001~~
~~MACRO~~	~~Châteaudun~~	~~<0.001~~	~~<0.001~~	~~0.001~~

zRMS comments:

The groundwater modelling presented in tables above refer to the applications to citrus fruit, pome fruit, tomatoes and ornamentals and are therefore not relevant for the intended use of the product Pyrix 20 SL. Therefore, presented results of groundwater modelling were not validated by the zRMS and have been struck through and shaded for transparency.

According to the critical Central Zone GAP table 8.1-1, the product Pyriproxyfen 02 SL is intended for use only by professional users as indoor application in closed buildings without contact with the soil surface.

In addition the Applicant states that:
Mushroom growing houses are designed for efficient cultivation and are therefore located in buildings that are isolated from the external environment. Such buildings are fully closed with non-transparent walls and a non-transparent roof, with a tightly sealed, smooth concrete floor most often covered with ceramic tiles. The growing rooms are equipped with the necessary air conditioning and irrigation systems with a microclimate control system. Unlike greenhouses, which often have transparent walls and roofs, soil or hydroponic systems with continuous water flow, and thus potential for environmental emissions, mushroom growing houses are:

- *opaque, sealed structures,*
- *using composted substrate on solid, hole-free shelves arranged on several stacked levels,*
- *using computer-controlled low-water systems, where water is added only to maintain substrate humidity, and not to irrigate.*

The solid, hole-free shelves as well as the computerised low-water systems prevent nutrients from being washed away, thus also preventing pyriproxyfen residues from flowing onto the lower shelves or onto the sealed floors.
These differences make mushroom cultivation chambers functionally and structurally distinct from greenhouses.This all points more towards CLOSED BUILDING.

Since the application of the product will be conducted in sealed, non-transparent closed buildings with smooth, impermeable floors (often tiled concrete or ceramic) and computer-controlled irrigation and spraying systems that use minimal water, no ground water contamination is expected. In accordance with the *EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments* (EFSA Journal 2014;12(3):361, Table 1, page 5) the ground water exposure assessment for the application in closed buildings is considered not relevant.

However, according to the information provided by the Applicant, the spent mushroom substrate will be disposed of as a waste and subsequently used as compost. According to polish Waste Act of 14 December 2012, and in accordance with the European Waste Catalogue (EWC), spent mushroom substrate is classified as agricultural waste under EWC code 02 01 99 "wastes not otherwise specified".
The use of the spent mushroom substrate as compost may result in indirect exposure of ground water to residues of the active substance and its metabolites. Nevertheless, the pyripoxyfen and its relevant soils metabolites are not considered to be persistent in soil (the DT_{50} values are below 120 days, and DT_{90} values are below 365 days). Therefore, no further assessment of ground water exposure is required for the substrate further used as a compost, and leaching of pyriproxyfen or its metabolites is considered insignificant.

Please note that according to polish requirements, wastewater after cleaning the chambers were the product has been used must be collected and disposed of appropriately, to prevent that no residues can enter the drainage water and/or sewage system. The wastewater should be transfer to an entity authorized to collect and manage hazardous waste.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

NOT APPLICABLE.
When using Pyrix 20SL in accordance with GAP in closed buildings, the presence or release of pyriproxyfen and metabolites in surface water is not expected. PEC_{SW} Calculations are no needed.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

8.9.1 Justification for new endpoints

NOT APPLICABLE

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

8.9.2.1 Pyriproxyfen and its metabolites

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent and metabolites Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Steps 1-2 in FOCUS (version 3.2) Please note that STEP 1-2 calculations are performed on the original input parameters. As a STEP 3 assessment using the final agreed endpoints is available STEP 1-2 calculations were not revised. Pyriproxyfen Molecular weight: 321.4 g/mol Water solubility: 0.101 mg/L K_{OC}: 18 897 mL/g DT_{50} soil: 8.7 d DT_{50} water/sediment system: 17.2 d DT_{50} water: 17.2 d DT_{50} sediment: 17.2 d 4'-OH-Pyr Molecular weight: 337.4 g/mol Water solubility: 1×10^6 mg/L K_{OC}: 2207 mL/g DT_{50} soil: 6.8 d DT_{50} water/sediment system: 5.9 d DT_{50} water: 5.9 d DT_{50} sediment: 5.9 d Maximum occurrence in soil: 8.9% Maximum occurrence in water/sediment: 15.9% PYPAC Molecular weight: 167.2 g/mol Water solubility: 1×10^6 mg/L K_{OC}: 18.2 mL/g DT_{50} soil: 7.3 d DT_{50} water/sediment system: 24.5 d DT_{50} water: 24.5 d DT_{50} sediment: 24.5 d

	Maximum occurrence in soil: 13.9% Maximum occurrence in water/sediment: 31.2%* DPH-Pyr Molecular weight: 245.3 g/mol Water solubility: 1×10^6 mg/L K_{OC}: 420 mL/g DT_{50} soil: 1000 d DT_{50} water/sediment system: 1000 d DT_{50} water: 1000 d DT_{50} sediment: 1000 d Maximum occurrence in soil: 0.6% Maximum occurrence in water/sediment: 12.7% Crop interception: citrus fruit, pome fruit and tomatoes (field) full canopy, ornamentals (field) average crop cover For tomatoes and ornamentals (walk-in tunnel) the method was set to soil incorporation hence no interception.
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH (version 5.3), SPIN (version 2.2), MACRO (version 5.5.4), PRZM (version 4.3.1), TOXSWA (version 4.4.3) and SWAN (version 4.01) NB STEP 4 calculations for parent are based on preliminary endpoints using a DT50 of 8.7 days, a Koc value of 18897 L/kg and a 1/n value of 1.15. Since these endpoints lead to a conservative assessment the simulation was not redone. For future calculations the endpoints as below should be followed. All other input parameters are as below. Pyriproxyfen Water solubility at 20°C: 0.101 mg/L Vapour pressure at 20°C: 9.2×10^{-6} Pa DT_{50} soil at 20°C and pF 2: 5.83 d (combined lab and field soil DT50s) K_{FOC}: *20030) L/kg* 1/n: 1.16) DT_{50} water: 1000 d DT_{50} sediment: 17.2 d Crop uptake factor: 0 4'-OH-Pyr Water solubility at 20°C: 1×10^6 mg/L Vapour pressure at 20°C: 0 Pa DT_{50} soil at 20°C and pF 2: 5.96 d Formation fraction in soil from parent: 0.10 K_{FOC}: 2156.4) L/kg 1/n: 0.876 DT_{50} water: 1000 d DT_{50} sediment: 5.9 d Formation fraction in water from parent: 1.0 (conservative default) Formation fraction in sediment from parent: 1.0 (conservative default) Crop uptake factor: 0 PYPAC Water solubility at 20°C: 1×10^6 mg/L Vapour pressure at 20°C: 0 Pa DT_{50} soil at 20°C and pF 2: 8.95 d Formation fraction in soil from parent: 0.26 K_{FOC}: 17.82 L/kg) 1/n: 1.07 (*RMS:* 1.074) DT_{50} water: 24.5 d DT_{50} sediment: 1000 d Formation fraction in water from parent: 1.0 (conservative default) Formation fraction in sediment from parent: 1.0 (conservative default) Crop uptake factor: 0

Application rate	Crop and growth stage: citrus fruit BBCH 85-89, pome fruit BBCH 59 pre-flowering, tomatoes BBCH 88 and ornamentals beginning of infestation Number of applications: citrus fruit and pome fruit 1, tomatoes and ornamentals 2 Interval (d): tomatoes and ornamentals 10 Application rate: citrus fruit 225 g/ha, pome fruit 60 g/ha, tomatoes and ornamentals 112.5 g/ha Application window: citrus fruit 1 Oct – 1 Dec, pome fruit (early and late application) 1 Apr – 1 Jun (D3,D4,D5,R1) or 1 Mar – 1 May (R2,R3,R4), tomatoes and ornamentals 1 Jun – 1 Aug For walk-in tunnels, the Step 3 approach is followed using the FOCUS Step 3 D scenarios. Additionally the application method was set to soil incorporation hence disabling the drift entry route **(hence the use is restricted to closed walk-in tunnels)** For greenhouse use, see assessment with GEM below

* Maximum observed percentage of PYPAC is 31.2% (total system). Since this occurred at the final time point the experts agreed that a value of 100% should be used for STEP 1-2 (TC 201, January 29th 2019). As there is a STEP 3 assessment available in which the formation fraction in water and sediment is set to 1, there is no need to recalculate. For future STEP 1-2 calculations a percentage of 100% should be used.

8.9.2.2 $PEC_{sw/sed}$ of pyriproxyfen formulation

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

FOCUS STEP 1	Max PECSW (µg/L)	Max PECSED (µg/kg)
Citrus fruit (citrus)		
Pyriproxyfen	14.66	601.37
4'-OH-Pyr	6.92	109.30
PYPAC	19.86	3.50
DPH-Pyr	6.02	23.56
Pome fruit (pome/stone, early appl.)		
Pyriproxyfen	6.56	179.4
4'-OH-Pyr	2.32	30.6
PYPAC	5.53	0.95
DPH-Pyr	1.87	6.98
Pome fruit (pome/stone, late appl.)		
Pyriproxyfen	3.91	160.37
4'-OH-Pyr	1.85	29.15
PYPAC	5.29	0.93
DPH-Pyr	1.61	6.28
Tomatoes (vegetables, fruiting)		
Pyriproxyfen	4.93	541.03
4'-OH-Pyr	5.30	109.30
PYPAC	18.28	3.27
DPH-Pyr	5.08	21.02
Ornamentals (hand appl., crop > 50 cm)		
Pyriproxyfen	8.88	561.38
4'-OH-Pyr	5.96	109.30
PYPAC	18.92	3.34
DPH-Pyr	5.46	22.05

FOCUS STEP 2	Max PEC_{SW} (µg/L)		Max PEC_{SED} (µg/kg)	
	North Europe	South Europe	North Europe	South Europe
Citrus fruit (citrus)				
Pyriproxyfen	11.79	11.79	109.64	101.77
4'-OH-Pyr	1.97	1.97	13.79	12.25
PYPAC	2.96	2.70	0.52	0.48
DPH-Pyr	1.19	1.14	4.58	4.28
Pome fruit (pome/stone, early appl.)				
Pyriproxyfen	5.84	5.84	51.80	68.68
4'-OH-Pyr	0.97	0.97	6.17	9.08
PYPAC	1.30	1.76	0.22	0.30
DPH-Pyr	0.57	0.67	2.06	2.61
Pome fruit (pome/stone, late appl.)				
Pyriproxyfen	3.15	3.15	26.09	33.43
4'-OH-Pyr	0.52	0.52	3.06	4.50
PYPAC	0.69	0.93	0.12	0.16
DPH-Pyr	0.30	0.36	1.10	1.38
Tomatoes (vegetables, fruiting)[‡]				
Pyriproxyfen	1.03	1.03	26.25	34.81
4'-OH-Pyr	0.19	0.27	3.90	5.54
PYPAC	0.78	1.05	0.14	0.19
DPH-Pyr	0.29	0.37	1.15	1.48
Ornamentals (hand appl., crop > 50 cm)[‡]				
Pyriproxyfen	3.01	3.01	55.20	69.47
4'-OH-Pyr	0.50	0.50	7.28	10.01
PYPAC	1.58	2.04	0.28	0.36
DPH-Pyr	0.64	0.78	2.51	3.07

[‡] Worst case of single or multiple applications

FOCUS STEP 3	Pyriproxyfen				
	Max PEC_{SW} (µg/L)	Main route of entry	7 d TWA PEC_{SW} (µg/L)	21 d TWA PEC_{SW} (µg/L)	Max PEC_{SED} (µg/kg)
Citrus fruit (citrus)					
D6 ditch	**8.250**	Spray Drift	5.635	2.499	**19.06**
R4 stream	5.692	Spray Drift	0.076	0.037	2.187
Pome fruit (pome/stone, early appl.)					
D3 ditch	4.628	Spray Drift	0.698	0.237	3.029
D4 pond	0.282	Spray Drift	0.255	0.224	1.371
D4 stream	4.352	Spray Drift	0.029	0.010	0.156
D5 pond	0.282	Spray Drift	0.255	0.226	1.362
D5 stream	4.592	Spray Drift	0.026	0.009	0.140
R1 pond	0.282	Spray Drift	0.254	0.221	1.290
R1 stream	3.744	Spray Drift	0.090	0.030	0.470
R2 stream	4.959	Spray Drift	0.057	0.019	0.304
R3 stream	5.270	Spray Drift	0.205	0.068	1.031
R4 stream	3.745	Spray Drift	0.091	0.030	0.473
Pome fruit (pome/stone, late appl.)					
D3 ditch	2.184	Spray Drift	0.330	0.112	1.410
D4 pond	0.098	Spray Drift	0.089	0.079	0.450
D4 stream	1.942	Spray Drift	0.013	0.004	0.069
D5 pond	0.098	Spray Drift	0.089	0.080	0.447
D5 stream	2.049	Spray Drift	0.012	0.004	0.062
R1 pond	0.098	Spray Drift	0.089	0.078	0.423
R1 stream	1.671	Spray Drift	0.040	0.013	0.209
R2 stream	2.213	Spray Drift	0.026	0.009	0.135
R3 stream	2.352	Spray Drift	0.091	0.031	0.457
R4 stream	1.671	Spray Drift	0.041	0.014	0.210
Tomatoes (vegetables, fruiting)[‡]					
D6 ditch	0.705	Spray Drift	0.060	0.033	0.232

FOCUS STEP 3	Pyriproxyfen				
	Max PEC_{SW} (µg/L)	Main route of entry	7 d TWA PEC_{SW} (µg/L)	21 d TWA PEC_{SW} (µg/L)	Max PEC_{SED} (µg/kg)
R2 stream	0.629	Spray Drift	0.019	0.009	1.243
R3 stream	0.662	Spray Drift	0.040	0.025	1.972
R4 stream	0.469	Spray Drift	0.038	0.024	0.669
Ornamentals (vines, late appl.)[1]					
D6 ditch	1.928	Spray Drift	1.310	0.953	5.228
R1 pond	0.106	Spray Drift	0.098	0.087	0.475
R1 stream	1.404	Spray Drift	0.050	0.028	0.357
R2 stream	1.888	Spray Drift	0.031	0.019	0.161
R3 stream	1.977	Spray Drift	0.096	0.031	0.537
R4 stream	1.408	Spray Drift	0.042	0.012	0.215

[1] Worst case of single or multiple applications

FOCUS STEP 3	4' OH Pyr			
	Max PEC_{SW} (µg/L)	7 d TWA PEC_{SW} (µg/L)	21 d TWA PEC_{SW} (µg/L)	Max PEC_{SED} (µg/kg)
Citrus fruit (citrus)				
D6 ditch	**0.114**	0.113	0.100	**3.275**
R4 stream	0.016	0.008	0.002	0.369
Pome fruit (pome/stone, early appl.)				
D3 ditch	0.001	0.001	0.001	0.199
D4 pond	0.011	0.011	0.011	0.375
D4 stream	0.002	<0.001	<0.001	0.006
D5 pond	0.013	0.013	0.013	0.384
D5 stream	0.002	<0.001	<0.001	0.007
R1 pond	0.010	0.010	0.010	0.349
R1 stream	0.002	<0.001	<0.001	0.026
R2 stream	0.001	<0.001	<0.001	0.018
R3 stream	0.004	<0.001	<0.001	0.056
R4 stream	0.001	<0.001	<0.001	0.023
Pome fruit (pome/stone, late appl.)				
D3 ditch	<0.001	<0.001	<0.001	0.092
D4 pond	0.003	0.003	0.003	0.127
D4 stream	0.001	<0.001	<0.001	0.003
D5 pond	0.004	0.004	0.004	0.130
D5 stream	0.001	<0.001	<0.001	0.003
R1 pond	0.003	0.003	0.003	0.118
R1 stream	0.002	<0.001	<0.001	0.011
R2 stream	0.001	<0.001	<0.001	0.008
R3 stream	0.002	<0.001	<0.001	0.024
R4 stream	0.001	<0.001	<0.001	0.010
Tomatoes (vegetables, fruiting)[1]				
D6 ditch	<0.001	<0.001	<0.001	0.033
R2 stream	0.003	<0.001	<0.001	0.242
R3 stream	0.007	0.001	0.001	0.410
R4 stream	0.016	0.002	0.002	0.172
Ornamentals (vines, late appl.)[1]				
D6 ditch	0.037	0.036	0.030	1.250
R1 pond	0.004	0.004	0.004	0.142
R1 stream	0.008	0.001	<0.001	0.076
R2 stream	0.002	<0.001	<0.001	0.031
R3 stream	0.006	0.001	<0.001	0.096
R4 stream	0.002	<0.001	<0.001	0.021

[1] Worst case of single or multiple applications

FOCUS STEP 3	PYPAC			
	Max PEC_{SW} (µg/L)	7-d TWA PEC_{SW} (µg/L)	21-d TWA PEC_{SW} (µg/L)	Max PEC_{SED} (µg/kg)
Citrus fruit (citrus)				
D6 ditch	0.191	0.183	0.143	**0.325**
R4 stream	0.037	0.009	0.003	0.069
Pome fruit (pome/stone, early appl.)				
D3 ditch	0.002	0.002	0.001	0.020
D4 pond	0.020	0.020	0.020	0.063
D4 stream	0.001	<0.001	<0.001	0.001
D5 pond	0.022	0.022	0.022	0.066
D5 stream	0.001	<0.001	<0.001	0.001
R1 pond	0.018	0.018	0.018	0.058
R1 stream	0.012	0.001	0.001	0.003
R2 stream	0.005	0.001	<0.001	0.002
R3 stream	0.024	0.004	0.001	0.006
R4 stream	0.018	0.002	0.001	0.003
Pome fruit (pome/stone, late appl.)				
D3 ditch	0.001	0.001	0.001	0.009
D4 pond	0.007	0.007	0.007	0.022
D4 stream	0.001	<0.001	<0.001	<0.001
D5 pond	0.007	0.007	0.007	0.023
D5 stream	0.001	<0.001	<0.001	<0.001
R1 pond	0.006	0.006	0.006	0.020
R1 stream	0.012	0.001	0.001	0.002
R2 stream	0.005	0.001	<0.001	0.001
R3 stream	0.024	0.004	0.001	0.004
R4 stream	0.018	0.002	0.001	0.002
Tomatoes (vegetables, fruiting)[1]				
D6 ditch	<0.001	0.004	0.004	0.004
R2 stream	0.236	0.087	0.084	0.088
R3 stream	0.235	0.175	0.168	0.179
R4 stream	**0.259**	0.068	0.066	0.077
Ornamentals (vines, late appl.)[1]				
D6 ditch	0.078	0.074	0.061	0.158
R1 pond	0.008	0.008	0.008	0.023
R1 stream	0.113	0.013	0.004	0.019
R2 stream	0.158	0.021	0.007	0.018
R3 stream	0.156	0.023	0.008	0.023
R4 stream	0.061	0.008	0.003	0.008

[1] Worst case of single or multiple applications

FOCUS STEP 4	Scenario	Pyriproxyfen – max PEC_{SW} (µg/L) *Based on soil DT50 of 8.7 days and Koc value of 18897 L/kg and 1/n of 1.15*						
	Vegetative strip (m)	None	None	None	None	None	None	None
Nozzle reduction	No spray buffer (m)	None	5	10	15	20	25	30
Citrus fruit (citrus)								
None	D6 ditch	-		2.491	1.259	0.7696	0.5241	
50 %				1.246	0.630	*		
75%				0.623	*			
None	R4 stream	-		1.987	1.004	0.6139	0.4182	
50 %				0.994	0.502	0.307		
75%				0.497	*			
Pome fruit (pome/stone, early appl.)								
None	D3 ditch	-				0.512	0.302	*
50 %						0.256		
75%		2.872		0.559		*		
None	D4 pond	-				0.056	0.038	0.027

FOCUS STEP 4	Scenario	Pyriproxyfen – max PEC_{sw} (µg/L) *Based on soil DT50 of 8.7 days and Koc value of 18897 L/kg and 1/n of 1.15*						
	Vegetative strip (m)	None	None	None	None	None	None	None
Nozzle reduction	No spray buffer (m)	None	5	10	15	20	25	30
50 %						0.028		
75%		0.152		0.0436		*		
None	D4 stream	-				0.526	0.310	*
50 %						0.263		
75%		2.953		0.575		*		
None	D5 pond	-				0.056	0.038	0.027
50 %						0.028		
75%		0.152		0.044		*		
None	D5 stream	-				0.555	0.328	*
50 %						0.278		
75%		3.116		0.607		*		
None	R1 pond	-				0.056	0.038	0.027
50 %						0.028		
75%		0.152		0.044		*		
None	R1 stream	-				0.453	0.267	*
50 %						0.226		
75%		2.541		0.495		*		
None	R2 stream	-				0.599	0.354	*
50 %						0.300		
75%		3.365		0.655		*		
None	R3 stream	-				0.637	0.376	*
50 %						0.319		
75%		3.576		0.697		*		
None	R4 stream	-				0.453	0.267	*
50 %						0.226		
75%		2.541		0.495		*		
Pome fruit (pome/stone, late appl.)								
None	D3 ditch	-	1.474	0.659	0.333			
50 %		1.093	0.738	0.330				
75%		0.547						
None	D4 pond	-	0.113	0.062	0.040			
50 %		0.049	0.056	0.031				
75%		0.025						
None	D4 stream	-	1.516	0.678	0.342			
50 %		0.972	0.758	0.339				
75%		0.486						
None	D5 pond	-	0.113	0.062	0.040			
50 %		0.049	0.056	0.031				
75%		0.025						
None	D5 stream	-	1.600	0.715	0.361			
50 %		1.025	0.800	0.358				
75%		0.513						
None	R1 pond	-	0.113	0.062	0.040			
50 %		0.049	0.056	0.031				
75%		0.025						
None	R1 stream	-	1.305	0.583	0.295			
50 %		0.836	0.653	0.292				
75%		0.418						
None	R2 stream	-	1.728	0.773	0.390			
50 %		1.107	0.864	0.386				
75%		0.554						
None	R3 stream	-	1.836	0.821	0.415			
50 %		1.177	0.919	0.411				
75%		0.589						
None	R4 stream	-	1.305	0.583	0.295			
50 %		0.836	0.653	0.292				
75%		0.418						

FOCUS STEP 4	Scenario	Pyriproxyfen – max PECsw (µg/L) *Based on soil DT50 of 8.7 days and Koc value of 18897 L/kg and 1/n of 1.15*						
	Vegetative strip (m)	None	None	None	None	None	None	None
Nozzle reduction	No spray buffer (m)	None	5	10	15	20	25	30
Tomatoes (vegetables, fruiting)[1]								
None	D6 ditch	-	0.191					
50 %		0.353						
75%								
None	R2 stream	-	0.230					
50 %		0.315						
75%								
None	R3 stream	-	0.242					
50 %		0.331						
75%								
None	R4 stream	-	0.258					
50 %		0.258						
75%								
Ornamentals (vines, late appl.)[1]								
None	D6 ditch	-	1.163	0.421	0.229			
50 %		0.967	0.584	0.211				
75%		0.485						
None	R1 pond	-	0.123	0.068	0.046			
50 %		0.053	0.062	0.034				
75%		0.027						
None	R1 stream	-	1.024	0.371	0.202			
50 %		0.703	0.512	0.186				
75%		0.352						
None	R2 stream	-	1.376	0.499	0.271			
50 %		0.944	0.688	0.250				
75%		0.472						
None	R3 stream	-	1.441	0.522	0.284			
50 %		0.989	0.721	0.261				
75%		0.495						
None	R4 stream	-	1.026	0.372	0.202			
50 %		0.705	0.513	0.186				
75%		0.353						

[1] Worst case of single or multiple applications

* values achieved on the basis of spray drift mitigation exceeding the maximum cap of 95% set in FOCUS Landscape & Mitigation,

Walk-in tunnel

FOCUS STEP 3	Scenario	Max PECsw (µg/L)	7-d TWA PECsw (µg/L)	21-d TWA PECsw (µg/L)	Max PECSED (µg/kg)
Tomatoes (vegetables, fruiting) – walk-in tunnel					
Pyriproxyfen	D6 ditch	<0.001	<0.001	<0.001	<0.001
4'-OH-Pyr	D6 ditch	<0.001	<0.001	<0.001	<0.001
PYPAC	D6 ditch	<0.001	<0.001	<0.001	<0.001
Ornamentals (vines, late appl.) – walk-in tunnel					
Pyriproxyfen	D6 ditch	<0.001	<0.001	<0.001	<0.001
4'-OH-Pyr	D6 ditch	<0.001	<0.001	<0.001	<0.001
PYPAC	D6 ditch	<0.001	<0.001	<0.001	<0.001

Greenhouse

Parent and metabolites
Parameters used in GEM

Version control no. of GEM 3.3.2

Pyriproxyfen
Molecular weight: 321.4 g/mol
Water solubility: 0.101 mg/L
KOM: 11618 mL/g

1/n: 1.16
DT50 soil: 8.8 d *
DT50 water/sediment system: 17.2 d
DT50 water: 1000 d
DT50 sediment: 17.2 d
DT50 circulation water: 14.0 days
DT50 hydroponic substrate: 8.8 days *
DT50 greenhouse floor: 100 days
DT50 air (25 C): 0.1 d

4' OH Pyr
Molecular weight: 337.4 g/mol
Water solubility: 1 × 106 mg/L
KOM: 1251 mL/g
1/n: 0.874
DT50 soil: 6.8 d *
DT50 water/sediment system: 5.9 d
DT50 water: 1000 d
DT50 sediment: 5.9 d
DT50 circulation water: 1000 days
DT50 hydroponic substrate: 6.8 days *
DT50 greenhouse floor: 100 days
DT50 air (25 C): 1000 d
Formation fraction soil: 0.10
Formation fraction water: 1 (conservative default)
Formation fraction sediment: 1 (conservative default)
Formation fraction recirculation water: 1 (conservative default)

PYPAC
Molecular weight: 167.2 g/mol
Water solubility: 1 × 106 mg/L
KOM: 10.3 mL/g
1/n: 1.074
DT50 soil: 7.4 d *
DT50 water/sediment system: 24.5 d
DT50 water: 24.5 d
DT50 sediment: 1000 d
DT50 circulation water: 1000 days
DT50 hydroponic substrate: 7.4 days *
DT50 greenhouse floor: 100 days
DT50 air (25 C): 1000 d
Formation fraction soil: 0.41 *
Formation fraction water: 1 (conservative default)
Formation fraction sediment: 1 (conservative default)
Formation fraction recirculation water: 1 (conservative default)

DPH Pyr
Molecular weight: 337.4 g/mol
Water solubility: 1 × 106 mg/L
KOM: 243.6 mL/g
1/n: 0.749
DT50 soil: 1000 d
DT50 water/sediment system: 1000 d
DT50 water: 1000 d
DT50 sediment: 1000 d
DT50 circulation water: 1000 days
DT50 hydroponic substrate: 1000 days
DT50 greenhouse floor: 100 days
DT50 air (25 C): 1000 d
Formation fraction soil: 0
Formation fraction water: 1 (conservative default)
Formation fraction sediment: 1 (conservative default)
Formation fraction recirculation water: 1 (conservative default)

Crop interception:

Application rate	For tomatoes (soilless) this was calculated internally by the model and for ornamentals (soil-bound) this was set at 60% (based on vines as surrogate crop for interception). Crop and growth stage: tomatoes BBCH 88 and ornamentals beginning of infestation Number of applications: tomatoes and ornamentals 2 Interval (d): tomatoes and ornamentals 10 Application rate: tomatoes and ornamentals 112.5 g/ha Application dates: to deal with sensitivity of the model to the application date the following approach was taken - for substrate cultivation of tomatoes and ornamentals, simulations are performed for the 15th of every month, supplemented with a calculation a week before and a week after the 15th of the month that provided the highest result. - for soil-bound cultivation of ornamentals application was set to May 20th and May 30th to include the default date based on sensitivity analysis, in combination with an assessment factor of 2 on the model outcome.

* please note that as a result of expert consultation the final endpoints have changed. No new assessment has been performed, since changes are small and to lower DT50 values, except for PYPAC, for which DT50 in soil increases marginally but the final agreed formation fraction is lower than used. For future calculations the following endpoints should be used: parent DT50 soil (and substrate) **5.8** days, 4'-OH-Pyr soil (and substrate) **6.0** days, PYPAC soil (and substrate) DT50 **9.0** days, in combination with a formation fraction of **0.26**.

Results

Soil-bound

Use	Crop scenario GEM	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)
		pyriproxyfen		4'-OH-Pyr		PYPAC		DPH-Pyr	
Ornamentals	Cut flowers	0.193	0.0921	0.0049	0.0041	0.0145	0.0125	0.0076	0.0061

Soilless (only results for the date yielding the maximum PEC values are presented, for details see Volume 3 CP B.8)

Crop scenario GEM	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)	Max PEC_{sw} (µg/L)	21-d $PEC_{sw,twa}$ (µg/L)
	pyriproxyfen		4'-OH-Pyr		PYPAC		DPH-Pyr	
Tomato	0.1857	0.1180	0.3060	0.1950	0.6435	0.3531	0.7208	0.3987
Cut flowers	0.6215	0.3981	0.9217	0.6185	1.560	0.9664	1.790	1.092

zRMS comments:

The surface water modelling presented in tables above refer to the applications to citrus fruit, pome fruit, tomatoes and ornamentals and are therefore not relevant for the intended use. Therefore, presented results of surface water modelling were not validated by the zRMS and have been struck through and shaded for transparency.

According to the critical Central Zone GAP table 8.1-1, the product Pyriproxyfen 02 SL is intended for use only by professional users as indoor application in closed buildings without contact with the soil surface.

In addition the Applicant states that:
Mushroom growing houses are designed for efficient cultivation and are therefore located in buildings that are isolated from the external environment. Such buildings are fully closed with non-transparent walls and a non-transparent roof, with a tightly sealed, smooth concrete floor most often covered with ceramic tiles. The growing rooms are equipped with the necessary air conditioning and irrigation systems with a microclimate control system. Unlike greenhouses, which often have transparent walls and roofs, soil or hydroponic systems with continuous water flow, and thus potential for environmental emissions, mushroom growing houses are:

- *opaque, sealed structures,*

- *using composted substrate on solid, hole-free shelves arranged on several stacked levels,*
- *using computer-controlled low-water systems, where water is added only to maintain substrate humidity, and not to irrigate.*

The solid, hole-free shelves as well as the computerised low-water systems prevent nutrients from being washed away, thus also preventing pyriproxyfen residues from flowing onto the lower shelves or onto the sealed floors.
These differences make mushroom cultivation chambers functionally and structurally distinct from greenhouses.This all points more towards CLOSED BUILDING.

Since the application of the product will be conducted in sealed, non-transparent closed buildings with smooth, impermeable floors (often tiled concrete or ceramic) and computer-controlled irrigation and spraying systems that use minimal water, no surface water contamination is expected. In accordance with the *EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments* (EFSA Journal 2014;12(3):361, Table 1, page 5) a surface water exposure assessment for the application in closed buildings is considered not relevant.

According to polish requirements, wastewater after cleaning the chambers were the product has been used must be collected and disposed of appropriately, to prevent that no residues can enter the drainage water and/or the sewage system. The wastewater should be transfer to an entity authorized to collect and manage hazardous waste.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

NOT APPLICABLE.
When using Pyrix 20SL in accordance with GAP in closed buildings, the presence or release of pyriproxyfen and metabolites in air is not expected.

Please see the appendix attached to this document:
Expert Statement on the Classification of Indoor Mushroom Cultivation [Author: Marielle Fortin-McCuaig / EUROFINS Agroscience regulatory/ Completion date: 26 June 2025]

However, there are available data from the EU-level review of pyriproxyfen from EFSA publications, which we present below.

Source: ***Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732]***

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied – no data requested
Photochemical oxidative degradation in air	DT_{50} of 2.5 hours derived by the Atkinson model (AOPWIN version 1.92). OH· (12 h) concentration assumed = 1.5×10^6 OH· cm^{-3}
Volatilisation	from plant surfaces: no data submitted, not required (v.p. <1.33×10^{-5} Pa at 22.8°C)
	from soil surfaces: no data submitted, not required (v.p. <1.33×10^{-5} Pa at 22.8°C)
Metabolites	-

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5	
Soil (indicate location and type of study)	No data submitted, not required
Surface water (indicate location and type of study)	No data submitted, not required
Ground water (indicate location and type of study)	No data submitted, not required
Air (indicate location and type of study)	No data submitted, not required

zRMS comments:

Provided above information regarding fate and behaviour of pyriproxyfen in the air is in line with EU agreed data reported in EFSA Journal 2019;17(6):5732.

The vapour pressure of the active substance pyriproxyfen is <1.33×10^{-5} Pa at 22.81 °C, whereas the mushroom growing temperature is 13-16°C, and therefore likely to be < 1×10^{-5} Pa at 20°C, thus the active substance pyriproxyfen can be considered non-volatile. Thus, contamination of the atmosphere with pyriproxyfen from the intended uses of Pyrix 20SL is considered to be negligible, and the exposure of adjacent surface waters by the active substance pyriproxyfen due to volatilization with subsequent deposition not need to be considered.

8.11 Classification and Labelling

zRMS comments:

The plant protection product Pyrix 20 SL was assessed for compliance with Commission Delegated Regulation (EU) 2023/707. The evaluation included verification of active substance and relevant co-formulants against the new hazard classes (ED HH, ED ENV, PBT, vPvB, PMT, vPvM). No change in classification and labelling of the product was identified.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9 ALL	Marielle Fortin-McCuaig / EUROFINS	2025	Expert Statement on the Classification of Indoor Mushroom Cultivation EUROFINS Agroscience regulatory GLP-non Unpublished	N	Agrofarm Sp. z o.o.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9 ALL	EFSA	2019	Peer review of the pesticide risk assessment of the active substance pyriproxyfen [EFSA Journal 2019;17(7):5732] Published	N	EFSA Public access

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
There were no data submitted by the Applicant and not relied on.					

~~NOT APPLICABLE~~

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
There were no data relied on and not submitted by the Applicant.					

~~NOT APPLICABLE~~

Appendix 2 Detailed evaluation of the new Annex II studies

NOT APPLICABLE.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

NOT APPLICABLE.