REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product name(s): PYRIX 20 SL

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 June 2026

MS Finalisation date: July 2026 (initial Core Assessment)

September 2026 (final Core Assessment)

Version history

When	What
November 2025	Initial dRR performed by the Applicant.
June 2026	Applicant's correction the point 9.13: Classification and labelling
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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9 Ecotoxicology (KCP 10)

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*.
In fact, the 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 modernly 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 being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

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 202025

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Climatic zone:Northern/authorization zone:Central (greenhouses - mushroom cultivation in CLOSED BUILDING)																				
1	PL	Mushrooms (fungi) Agaricus bisporus	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	A	A	A	A	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 – 21 “Conclusion”

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

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) 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
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. There is no need for a risk assessment. Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.
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.

zRMS comments:

The Applicant provided the following classification of Indoor Mushroom Cultivation for intended uses performed in the GAP Table for ppp Pyrix 20 SL.

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*.
In fact, the 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 modernly 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''.

zRMS agrees with the Applicant argumentation that the specificity of spraying mushrooms (classified as Closed building) excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants.
Therefore there is no need to perform a risk assessment for all group non-target organism according to recommendation given in: ,,EFSA Supporting publication 2015:EN-924:,,Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, Table 2, category permanent greenhouse) and in EFSA Journal 2014;12(3):3615: ,,EFSA Guidance Document on clustering and ranking of emissions of actives 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''.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to birds and mammals is expected and therefore, no risk assessment, including risk from drinking water exposure and from secondary poising is required for birds and mammals. This is in line with the recommendations given in the EFSA Technical Report (2015).

Therefore, overall, an acceptable risk to birds and mammals is concluded for all intended use of Pyrix 20 SL.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to aquatic organism is expected and therefore, no risk assessment is required for aquatic organism. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2) and EFSA Journal 2014;12(3):3615 (Table 1).

Therefore, overall, an acceptable risk to aquatic organism concluded for all intended use of Pyrix 20 SL.

9.1.1.3 Effects on bees (KCP 10.3.1)

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to bees is expected and therefore, no acute and chronic risk assessment, is required for aquatic organism. This is in line with the recommendations of the EFSA Technical Report (2015, Table 2).

Therefore, overall, an acceptable risk to bees is concluded for all intended use of Pyrix 20 SL.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to non-target arthropods is expected and therefore, risk assessment in-field or off-field, is required for NTA. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2).
Therefore, overall, an acceptable risk to non-target arthropods is concluded for all intended use of Pyrix 20 SL.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to non-target soil meso- and macrofauna is expected and therefore, no risk assessment, is required for these species. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2) and EFSA Journal 2014;12(3):3615 (Table 1).

Therefore, overall, an acceptable risk to non-target soil meso-and macrofauna concluded for all intended use of Pyrix 20 SL.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to non-target plants is expected and therefore, no risk assessment, is required. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2).

Therefore, overall, an acceptable risk to NTTP concluded for all intended use of Pyrix 20 SL.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to other terrestrial organism is expected and therefore, no risk assessment, on other terrestrial organism. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2).

Therefore, overall, an acceptable risk on other terrestrial organism to concluded for all intended use of Pyrix 20 SL.

9.1.2 Grouping of intended uses for risk assessment

~~NOT APPLICABLE~~

The following table documents the grouping of the intended uses to support application (according to SANCO/11244/2011).

Table 9.1-2: Critical use pattern of Pyrix 20 SL grouped according to application rate and growth stage

Grouping according to application rate and growth stage			
Use	**Intended uses #**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
1	Mushrooms (fungi) Agaricus bisporus I-indoor application- closed buildings (only profession-al use)	Crop group (mushrooms) Application rate: 1 x 15ml/m^2 Application timing: BBCH: overgrowth of cover by mushroom mycelium	Application rate: 1 x 15ml/m2 Application rate: 1 x 15ml/m^2 Application timing: BBCH: overgrowth of cover by mushroom mycelium.

9.1.3 Consideration of metabolites

NOT APPLICABLE.

9.2 Effects on birds (KCP 10.1.1)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

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

9.2.1 Toxicity data

~~NOT APPLICABLE~~

Table 9.2-1: Endpoints and effect values relevant for birds

Species	Substance	Exposure System	Results	Reference
Mallard duck	Pyriproxyfen	Acute	**LD_{50} > 1906 mg a.s./kg bw**	EFSA Journal 2019;17(6):5732
Bobwhite quail	Pyriproxyfen	Acute	**LD_{50} > 1906 mg a.s./kg bw**	EFSA Journal 2019;17(6):5732
Mallard duck	Pyriproxyfen	Short-term	LC_{50} > 1261 mg a.s./kg bw/d	EFSA Journal 2019;17(6):5732
Bobwhite quail	Pyriproxyfen	Short-term	LC_{50} > 863 mg a.s./kg bw/d	EFSA Journal 2019;17(6):5732
Mallard duck/ Bobwhite quail	Pyriproxyfen	Long-term	$LD_{50}/10$ >190.6 mg a.s./kg bw/d	EFSA Journal 2019;17(6):5732
Mallard duck	Pyriproxyfen	Long-term	**NOEC = 70.2 mg a.s./kg bw/d**	EFSA Journal 2019;17(6):5732
Bobwhite quail	Pyriproxyfen	Long-term	NOEC = 85.0 mg a.s./kg bw/d (males) NOEC = 82.8 mg a.s./kg bw/d (females)	EFSA Journal 2019;17(6):5732

zRMS comments:

Birds toxicity data in Table 9.2-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732.

9.2.1.1 Justification for new endpoints

NOT APPLICABLE.

9.2.2 Risk assessment for spray applications

~~NOT APPLICABLE.~~

9.2.2.1 First-tier assessment (screening/generic focal species)

~~NOT APPLICABLE.~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to birds is expected and therefore, no risk assessment, including risk from drinking water exposure and from secondary poising is required for birds. This is in line with the recommendations given in the EFSA Technical Report (2015).

Therefore, overall, an acceptable risk to birds is concluded for all intended use of Pyrix 20 SL.

9.2.2.2 Higher-tier risk assessment

NOT APPLICABLE.

9.2.2.3 Drinking water exposure

NOT APPLICABLE.

~~When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).~~

Leaf scenario

NOT APPLICABLE

Puddle scenario

NOT APPLICABLE

9.2.2.4 Effects of secondary poisoning

NOT APPLICABLE.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.5 Biomagnification in terrestrial food chains

NOT APPLICABLE.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

NOT APPLICABLE.

9.2.4 Overall conclusions

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to birds is expected and therefore, no risk assessment, including risk from drinking water exposure and from secondary poising is required

for birds. This is in line with the recommendations of the EFSA Technical Report (2015).
Therefore, overall, an acceptable risk to birds is concluded for all intended use of Pyrix 20 SL.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

Please see the appendix attached to this document:
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9.3.1 Toxicity data

~~NOT APPLICABLE~~

Table 9.3-1: Endpoints and effect values for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Pyriproxyfen	Acute	**LD_{50} > 5000 mg a.s./kg bw**	EFSA Journal 2019; 17(6):5732
Rat	Pyriproxyfen	Long-term	**NOAEL = 13.3 mg a.s./kg bw/d**	EFSA Journal 2019; 17(6):5732

4'-OH-pyriproxyfen is the only major plant metabolite (> 10%) of the active substance. As this degradation product was also found in rat, mouse goat and hen (refer to the EU DAR), 4'-OH-pyriproxyfen can be assumed to have been tested with the parent. Also, other minor metabolites (i.e. DPH-pyriproxyfen, POP, POPA, PYPA and PYPAC, see DAR) have been found in vertebrate metabolism studies and are therefore considered to be covered with data for pyriproxyfen.

zRMS comments:

Mammalian toxicity data in Table 9.3-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732.

9.3.1.1 Justification for new endpoints

NOT APPLICABLE.

9.3.2 Risk assessment for spray applications

~~NOT APPLICABLE.~~

9.3.2.1 First-tier assessment (screening/generic focal species)

~~NOT APPLICABLE.~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to mammals is expected and therefore, no risk assessment, including risk from drinking water exposure and from secondary poising is required for mammal. This is in line with the recommendations given in the EFSA Technical Report (2015, Table 2). In addition, it should be noted that formulation study for Pyrix 20 SL is not required as toxicity of the product to mammals can be estimated based a.s. toxicity data according to EU Reg. 284/2013.

Therefore, overall, an acceptable risk to mammals is concluded for all intended use of Pyrix 20 SL.

9.3.2.2 Higher-tier risk assessment

NOT APPLICABLE.

9.3.2.3 Drinking water exposure

NOT APPLICABLE.

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

NOT APPLICABLE.

9.3.2.4 Effects of secondary poisoning

NOT APPLICABLE.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.5 Biomagnification in terrestrial food chains

NOT APPLICABLE.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

NOT APPLICABLE.

9.3.4 Overall conclusions

NOT APPLICABLE

zRMS comments:

Overall, an acceptable risk to mammals is concluded for all intended use of Pyrix 20 SL.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

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

zRMS comments:

As currently there are no agreed rules or criteria for evaluation of the risk to other terrestrial vertebrates like reptiles and amphibians, this issue should be addressed once respective guidance is available and EU agreed endpoints concluded.

9.5 Effects on aquatic organisms (KCP 10.2)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

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

9.5.1 Toxicity data

~~NOT APPLICABLE~~

Table 9.5-1: Endpoints and effect values for aquatic organisms – pyriproxyfen and relevant metabolites

Species	Substance	Exposure System	Results [µg a.s./L]	Reference
Lepomis macrochirus	Pyriproxyfen	96 h (f-t)	**LC_{50} > 270 mm**	EFSA Journal 2019; 17(6):5732
Oncorhynchus mykiss	Pyriproxyfen	96 h (f-t)	LC_{50} > 325 mm	EFSA Journal 2019; 17(6):5732
Cyprinodon variegatus	Pyriproxyfen	96 h (f-t)	LC_{50} > 1020 mm	EFSA Journal 2019; 17(6):5732
Oryzias latipes	Pyriproxyfen	189 d (f-t)	**NOEC = 2.7 mm**	EFSA Journal 2019; 17(6):5732
Oncorhynchus mykiss	Pyriproxyfen	95 d (f-t), ELS	NOEC = 4.3 mm	EFSA Journal 2019; 17(6):5732

Species	Substance	Exposure System	Results [µg a.s./L]	Reference
Oncorhynchus mykiss	4'-OH-Pyr	96 h (f-t)	**LC_{50} = 270 mm**	EFSA Journal 2019; 17(6):5732
Oncorhynchus mykiss	PYPAC	96 h (s)	LC_{50} > 93000 mm	EFSA Journal 2019; 17(6):5732
Oncorhynchus mykiss	DPH-PYR	96 h (s)	**LC_{50} = 5100 mm**	EFSA Journal 2019; 17(6):5732
Oncorhynchus mykiss	PYPA	96 h (s)	LC_{50} > 105000 mm	EFSA Journal 2019; 17(6):5732
Daphnia magna	Pyriproxyfen	48 h (f-t)	EC_{50} = 400 mm	EFSA Journal 2019; 17(6):5732
Daphnia magna	Pyriproxyfen	21 d (f-t)	NOEC = 0.015 mm **EC_{10} = 0.0088 mm**	EFSA Journal 2019; 17(6):5732
Mysidopsis bahia	Pyriproxyfen	48 h (f-t)	**EC_{50} = 65 mm**	EFSA Journal 2019; 17(6):5732
Mysidopsis bahia	Pyriproxyfen	28 d (f-t)	NOEC = 0.81 mm	EFSA Journal 2019; 17(6):5732
Crassostrea virginica	Pyriproxyfen	96 h (f-t)	EC_{50} = 92 mm LC_{50} > 110 mm	EFSA Journal 2019; 17(6):5732
Daphnia magna	4'-OH-Pyr	48 h (f-t)	**EC_{50} = 1800 mm**	EFSA Journal 2019; 17(6):5732
Daphnia magna	4'-OH-Pyr	21 d (f-t)	**NOEC = 2.9 mm**	EFSA Journal 2019; 17(6):5732
Daphnia magna	PYPAC	48 h (s)	EC_{50} > 95000 mm	EFSA Journal 2019; 17(6):5732
Daphnia magna	PYPAC	21 d (f-t)	NOEC = 4.74 mm	EFSA Journal 2019; 17(6):5732
Daphnia magna	PYPA	48 h (s)	EC_{50} > 110000 mm	EFSA Journal 2019; 17(6):5732
Daphnia magna	DPH-PYR	48 h (s)	**EC_{50} > 9800 mm**	EFSA Journal 2019; 17(6):5732
Daphnia magna	DPH-PYR	21 d (s-s)	**NOEC = 3900 mm** 4000 mm	EFSA Journal 2019; 17(6):5732
Chironomus riparius	Pyriproxyfen	28 d (s, spiked water)	NOEC = 10 nom **NOEC = 3.1 mm**	EFSA Journal 2019; 17(6):5732
Hyalella azteca	Pyriproxyfen	42 d (s-s, spiked sediment)	NOEC = 41 mm	EFSA Journal 2019; 17(6):5732
Selenastrum capricornutum	Pyriproxyfen	72 h (s)	EbC_{50} = 64 mm **ErC_{50} = 111 mm**	EFSA Journal 2019; 17(6):5732
Pseudokirchneriella subcapitata	4'-OH-Pyr	72 h (s)	EbC_{50} > 2180 mm **ErC_{50} > 2180 mm**	EFSA Journal 2019; 17(6):5732
Pseudokirchneriella subcapitata	PYPAC	72 h (s)	EbC_{50} = 26000 mm ErC_{50} = 30000 mm	EFSA Journal 2019; 17(6):5732
Pseudokirchneriella subcapitata	PYPA	72 h (s)	EbC_{50} > 105000 mm ErC_{50} > 105000 mm	EFSA Journal 2019; 17(6):5732
Pseudokirchneriella subcapitata	DPH-PYR	72 h (s)	EbC_{50} > 9500 mm ErC_{50} **> 9500 mm**	EFSA Journal 2019; 17(6):5732
Lemna gibba	Pyriproxyfen	14 d (s-s)	EC_{50} **> 180 mm**	EFSA Journal 2019; 17(6):5732

Species	Substance	Exposure System	Results [µg a.s./L]	Reference
Higher-tier studies (micro- or mesocosm studies)				
Indoor laboratory plankton-dominated microcosms study with Pyriproxyfen 10 EC: Based on the effect class 1 concentration of 1.2 µg a.s./L(B), and using an assessment factor of 2, the ETO-RAC is 0.6 µg a.s./L. To derive the ETO-RAC using the effect class 2 concentration, an assessment factor of 3 is considered appropriate, since less than 8 of the potentially most sensitive taxa were present in the indoor microcosm study. Based on the effect class 2 concentration of 5 µg a.s./L(B), and using an assessment factor of 3, the ETO-RAC is 1.7 µg a.s./L. The lower of the two values (**ETO-RAC = 0.6 µg a.s./L**) is used for risk assessment, in a conservative approach, which is considered justified by the fact that less than 8 of the potentially most sensitive taxa were present in the indoor microcosm study.				
s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations				

zRMS comments:

Aquatic toxicity data in Table 9.5-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732. The formulation the studies for aquatic organisms have not been performed for Pyrix 20 SL.

According to EU Reg 284/2013 , Point 10.2: Possible effects on aquatic species (fish, aquatic invertebrates, algae and in the case of herbicides and plant growth regulators, aquatic macrophytes) shall be investigated except where the possibility that aquatic species will be exposed can be ruled out.

For proposed uses of Pyrix 20 SL the exposure to aquatic organism is not expected (close buildings) and the lack of formulation studies for Pyrix 20 SL is justified.

9.5.1.1 Justification for new endpoints

NOT APPLICABLE.

9.5.2 Risk assessment

NOT APPLICABLE.

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to aquatic organism is expected and therefore, no risk assessment, is required for aquatic organism. This is in line with the recommendations of the EFSA Technical Report (2015, Table 2) and EFSA Journal 2014;12(3):3615, Table 1) and information given by e-fate expert, confirmed that no exposure of active substance in surface water is expected from intended use of Pyrix 20 SL (please see Section 8 for details).

Therefore, overall, an acceptable risk to aquatic organism concluded for all intended use of Pyrix 20 SL.

9.5.3 Overall conclusions

~~NOT APPLICABLE.~~

zRMS comments:

Overall, an acceptable risk to aquatic organism concluded for all intended use of Pyrix 20 SL.

9.6 Effects on bees (KCP 10.3.1)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

Please see the appendix attached to this document:
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9.6.1 Toxicity data

~~NOT APPLICABLE.~~

Table 9.6-1: Endpoints and effect values for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Pyriproxyfen 10 EC	Oral, acute	LD_{50} = 74 µg a.s./bee	EFSA Journal 2019; 17(6):5732
Apis mellifera	Pyriproxyfen 10 EC	Contact, acute	LD_{50} > 100 µg a.s./bee	EFSA Journal 2019; 17(6):5732
Apis mellifera	Pyriproxyfen	Oral, chronic, 10 d	LDD_{50} = 100 µg/bee/day*	EFSA Journal 2019; 17(6):5732
Apis mellifera	Pyriproxyfen	Oral, chronic, 4 d (Bee brood development)	$NOEC_{larvae}$ = 0.046 µg/larva/developmental period	EFSA Journal 2019; 17(6):5732
Bombus terrestris	Pyriproxyfen	Oral, acute	LD50 > 72.8 µg a.s./bee	EFSA Journal 2019; 17(6):5732
Bombus terrestris	Pyriproxyfen	Contact, acute	LD50 > 100 µg a.s./bee	EFSA Journal 2019; 17(6):5732
Higher-tier studies (tunnel test, field studies)				
Field study (Barth, 2003, NNW-0167; EU DAR 2017): In a study in Germany, 1 x 75 g a.s./ha Pyriproxyfen 10 EC did not affect mortality of adults or juvenile stages, overall colony performance or survival and development of egg and larvae through to adult emergence. Field study (Bakker 2011, NNW-0208; EU DAR 2017): In a study in France, 2 x 112.5 g a.s./ha Pyriproxyfen 10 EC with a 10-day-interval did not affect flight intensity, bee mortality, colony strength and brood development.				

* Test concentrations in feeding solutions were not analytically verified. The lack of analytical verification of the feeding solutions is not considered to affect the validity of the study, as pyriproxyfen is stable in water and the report did not indicate that undissolved material was observed

zRMS comments:

Bee toxicity data in Table 9.6-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732. The formulation's studies for bees have not been performed for Pyrix 20 SL.
According to EU Reg 284/2013, Point 10.3.1: The possible effects on bees shall be investigated except where the plant protection product is for exclusive use in situations where bees are not likely to be exposed such as:
(a) food storage in enclosed spaces; (b) non-systemic plant protection products for application to soil, except granules; (c) non-systemic dipping treatments for transplanted crops and bulbs; (d) wound sealing and healing treatments; (e) non-systemic rodenticidal baits; (f) **use in greenhouses without bees as pollinators.**

For proposed uses of Pyrix 20 SL the exposure to bees is not expected (close buildings) and the lack of formulation studies to bees for Pyrix 20 SL is justified.

9.6.1.1 Justification for new endpoints

NOT APPLICABLE.

9.6.2 Risk assessment

~~NOT APPLICABLE~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to bees is expected and therefore, no acute and chronic risk assessment, is required for bees. This is in line with the recommendations of the EFSA Technical Report (2015, (Table 2).

Therefore, overall, an acceptable risk to bees is concluded for all intended use of Pyrix 20 SL.

9.6.2.1 Hazard quotients for bees

NOT APPLICABLE.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

NOT APPLICABLE.

9.6.3 Effects on bumble bees

NOT APPLICABLE.

9.6.4 Effects on solitary bees

NOT APPLICABLE.

9.6.5 Overall conclusions

~~NOT APPLICABLE~~

zRMS comments:

Overall, an acceptable risk to bees is concluded for all intended use of Pyrix 20 SL.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

Please see the appendix attached to this document:
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9.7.1 Toxicity data

~~NOT APPLICABLE.~~

Table 9.7-1: Endpoints and effect values for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	Pyriproxyfen 10 EC	Laboratory test glass plates (2D)	LR_{50} = 17.21 g a.s./ha **ER_{50} = 8.1 g a.s./ha**	EFSA Journal 2019; 17(6):5732
	Pyriproxyfen 10 EC	Extended laboratory test with aged residues on potted grape plant leaves (3D)	LR_{50} > 225 g a.s./ha (0/ 7/ 14 days) **ER_{50} = 205 g a.s./ha (0 days)** ER_{50} > 225 g a.s./ha (7/ 14 days)	EFSA Journal 2019; 17(6):5732
Aphidius rhopalosiphi (adults)	Pyriproxyfen 10 EC	Laboratory test glass plates (2D)	LR_{50} = 213.1 g a.s./ha **ER_{50} = 81 g a.s./ha**	EFSA Journal 2019; 17(6):5732
	Pyriproxyfen 10 EC	Extended laboratory test with aged residues on potted barley plants (3D)	LR_{50} > 225 g a.s./ha ER_{50} > 225 g a.s./ha	EFSA Journal 2019; 17(6):5732
Orius laevigatus (4-5 day old nymphs)	Pyriproxyfen 10 EC	Laboratory test Glass plates (2D)	LR_{50} > 450 g a.s./ha ER_{50} > 450 g a.s./ha	EFSA Journal 2019; 17(6):5732
Chrysoperla carnea	Pyriproxyfen 10 EC	Extended laboratory test with aged residues on potted grape plant leaves (3D)	LR_{50} > 225 g a.s./ha (0/ 7/ 14 days) ER_{50} > 225 g a.s./ha (0/ 7/ 14 days)	EFSA Journal 2019; 17(6):5732

zRMS comments:

NTA toxicity data in Table 9.7-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732. The formulation's studies for non-target terrestrial arthropods have not been performed for Pyrix 20 SL.
According to EU Reg 284/2013 Point 10.3.2: Effects on non-target terrestrial arthropods shall be investigated for all plant protection products except where plant protection products containing the active substance are for exclusive use in situations where non-target arthropods are not exposed such as: (a) food storage in enclosed spaces that preclude exposure; (b) wound sealing and healing treatments; (c) enclosed spaces with rodenticidal baits.
In the same time according to recommendations of the EFSA Technical Report (2015, (Table 2) the risk to NTA is excluded.
For proposed uses of Pyrix 20 SL the exposure to NTA is not expected (close buildings) and the lack of formulation studies to non-target terrestrial arthropods for Pyrix 20 SL is justified.

9.7.1.1 Justification for new endpoints

~~NOT APPLICABLE.~~

9.7.2 Risk assessment

~~NOT APPLICABLE.~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to non-target terrestrial arthropods is expected and therefore, no in-field or off-field risk assessment, is required for non-target terrestrial arthropods. This is in line with the recommendations of the EFSA Technical Report (2015, (Table 2).

Therefore, overall, an acceptable risk to is non-target terrestrial arthropods concluded for all intended use of Pyrix 20 SL.

9.7.2.1 Risk assessment for in-field exposure

NOT APPLICABLE.

9.7.2.2 Risk assessment for off-field exposure

NOT APPLICABLE.

9.7.2.3 Additional higher-tier risk assessment

NOT APPLICABLE.

9.7.2.4 Risk mitigation measures

NOT APPLICABLE

9.7.3 Overall conclusions

~~NOT APPLICABLE.~~

zRMS comments:

Overall, an acceptable risk to is non-target terrestrial arthropods concluded for all intended use of Pyrix 20 SL.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.
Please see the appendix attached to this document:
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9.8.1 Toxicity data

NOT APPLICABLE

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Earthworms	Pyriproxyfen	5% peat, chronic	NOEC = 50 mg a.s./kg d.w.soil $NOEC_{corr}$ = 25 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
	PYPAC	5% peat, chronic	NOEC ≥ 100 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
	4'-OH-Pyr	5% peat, chronic	NOEC ≥ 100 mg a.s./kg d.w.soil $NOEC_{corr}$ ≥ 50 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
Folsomia candida	Pyriproxyfen	5% peat, chronic	NOEC = 12.5 mg a.s./kg d.w.soil $NOEC_{corr}$ = 6.25 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
	PYPAC	5% peat, chronic	NOEC ≥ 100 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
	4'-OH-Pyr	5% peat, chronic	NOEC ≥ 100 mg a.s./kg d.w.soil $NOEC_{corr}$ ≥ 50 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
Hypoaspis aculeifer	Pyriproxyfen	5% peat, chronic	NOEC = 50 mg a.s./kg d.w.soil $NOEC_{corr}$ = 25 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
	PYPAC	5% peat, chronic	NOEC ≥ 100 mg a.s./kg d.w.soil	EFSA Journal 2019; 17(6):5732
	4'-OH-Pyr	5% peat, chronic	NOEC ≥ 100 mg a.s./kg d.w.soil **$NOEC_{corr}$ ≥ 50 mg a.s./kg d.w.soil**	EFSA Journal 2019; 17(6):5732
Field studies				
No data.				
Litter bag test				
No data.				

zRMS comments:

Meso and macro-fauna toxicity data in Table 9.8-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732.

According to EU Reg 284/2013 Point 10.4.1: The possible impact on earthworms shall be reported unless the applicant shows that it is not likely that earthworms are exposed, directly or indirectly.
and
Point 10.4.2 : Effects on soil organisms (other than earthworms) shall be investigated for all plant protection products, except in situations where soil organisms are not exposed such as: (a) food storage in enclosed spaces that preclude exposure; (b) wound sealing and healing treatments; (c) enclosed spaces with rodenticidal baits.

For proposed uses of Pyrix 20 SL the exposure to soil meso- and macro fauna is not expected (close buildings) and the lack of formulation studies for Pyrix 20 SL is justified.

9.8.1.1 Justification for new endpoints

NOT APPLICABLE.

9.8.2 Risk assessment

~~NOT APPLICABLE.~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to soil meso- and macro fauna is expected and therefore, no risk assessment, is required. This is in line with the recommendations of the EFSA Technical Report (2015, Table 2) and EFSA Journal 2014;12(3):3615, Table 1) and information given by e-fate expert, confirmed that no exposure of active substance in surface water and soil is expected from intended use of Pyrix 20 SL (please see Section 8 for details).

Therefore, overall, an acceptable risk to soil meso- and macro fauna concluded for all intended use of Pyrix 20 SL.

9.8.2.1 First-tier risk assessment

~~NOT APPLICABLE.~~

9.8.2.2 Higher-tier risk assessment

~~NOT APPLICABLE.~~

9.8.3 Overall conclusions

~~NOT APPLICABLE.~~

zRMS comments:

Overall, an acceptable risk to soil meso- and macro fauna is concluded for all intended use of Pyrix 20 SL.

9.9 Effects on soil microbial activity (KCP 10.5)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

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9.9.1 Toxicity data

~~NOT APPLICABLE.~~

Table 9.9-1: Endpoints and effect values for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Pyriproxyfen	46 d, loamy sand	No adverse effects up to 1.5 mg a.s./kg dry soil	EFSA Journal 2019; 17(6):5732

zRMS comments:

Soil microorganism toxicity data in Table 9.9-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732. The formulation the studies for soil microorganism have not been performed for Pyrix 20 SL.
According to EU Reg 284/2013, Point 10.5: The effects of plant protection products on soil microbial function shall be investigated if the toxicity of the plant protection product cannot be predicted on the basis of data for the active substance, unless the applicant shows that no exposure occurs.

For proposed uses of Pyrix 20 SL the exposure to soil microorganism is not expected (close buildings) and the lack of formulation studies for Pyrix 20 SL is justified.

9.9.1.1 Justification for new endpoints

~~NOT APPLICABLE.~~

9.9.2 Risk assessment

~~NOT APPLICABLE.~~

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to soil microorganism is expected and therefore, no risk assessment, is required. This is in line with the recommendations of the EFSA Technical Report (2015, Table 2) and EFSA Journal 2014;12(3):3615, Table 1) and information given by e-fate expert, confirmed that no exposure of active substance in surface water and soil is expected from intended use of Pyrix 20 SL (please see Section 8 for details).

Therefore, overall, an acceptable risk to soil microorganism is concluded for all intended use of Pyrix 20 SL.

9.9.3 Overall conclusions

~~NOT APPLICABLE~~

zRMS comments:

Overall, an acceptable risk to soil microorganism is concluded for all intended use of Pyrix 20 SL.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

There is no possibility of pyriproxyfen being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on

birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods, non-target soil meso- and macrofauna, microbial organisms, and non-target terrestrial plants. No need for a risk assessment.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

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9.10.1 Toxicity data

NOT APPLICABLE

Table 9.10-1: Endpoints and effect values for non-target terrestrial plants (screening data)

Species	Substance	Exposure System	Results	Reference
Echinochloa crusgalli. m *Avena sativa.* m *Abuliton theoprasti* d *Raphanus sativus.* d	Pyriproxyfen 10 EC	Screening test	Effects below 50% at 8000 g a.s./ha.	EFSA Journal 2019; 17(6):5732
A. cepa *L. perenne* *B. vulgaris* *B. napus* *B. oleracea* *L. sativa* *L. esculentum* *T. aestivum* *Z. mays* *G. max*	Pyriproxyfen 10 EC	Laboratory dose response tests	**ER_{50} > 448 g a.s./ha vegetative vigour** **ER_{50} > 448 g a.s./ha emergence**	EFSA Journal 2019; 17(6):5732

m: monocotyledonous; d: dicotyledonous

Screening data were obtained for 4 plants species exposed to a maximum rate of 8 kg Pyriproxyfen 10 EC/ha. In contrast, 6 species are required according to the Draft Working Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO 2002). However, the EU experts agreed that pyriproxyfen poses an acceptable risk to non-target terrestrial plants, as it is a non-herbicidal active substance and as additional data indicate that no effects have been observed on fungi (7 species).

zRMS comments:

NTTP toxicity data in Table 9.10-1 for a.s Pyriproxyfen were confirmed by zRMS that they are in line with EFSA Journal 2019;17(6):5732.

According to EU Reg 284/2013 Point 10.6.1. The effects of plant protection products on non-target plants shall be reported, if the toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance, unless the applicant shows that no exposure occurs.

For proposed uses of Pyrix 20 SL the exposure to NTTP is not expected (close buildings) and the lack of formulation studies is justified.

9.10.1.1 Justification for new endpoints

NOT APPLICABLE.

9.10.2 Risk assessment

NOT APPLICABLE.

zRMS comments:

As the intended use of Pyrix 20 SL is indoors (classified as closed buildings), no exposure to soil microorganism is expected and therefore, no risk assessment, is required. This is in line with the recommendations of the EFSA Technical Report (2015, Table 2).

Therefore, overall, an acceptable risk to NTTP is concluded for all intended use of Pyrix 20 SL.

9.10.2.1 Tier-1 risk assessment (based screening data)

NOT APPLICABLE.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

NOT APPLICABLE.

9.10.2.3 Higher-tier risk assessment

NOT APPLICABLE.

9.10.2.4 Risk mitigation measures

NOT APPLICABLE.

9.10.3 Overall conclusions

NOT APPLICABLE.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

NOT APPLICABLE.

9.12 Monitoring data (KCP 10.8)

NOT APPLICABLE.

9.13 Classification and Labelling

NOT APPLICABLE.

There is no possibility of Pyrix 20SL being released into the environment and having an impact on the environment and animals. The specificity of spraying mushrooms excludes the effect of pyriproxyfen on birds and other terrestrial vertebrates, aquatic organisms, bees, arthropods and non-target terrestrial plants.

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. However, the Regulations allow the use of the spent mushroom substrate for growing plants.

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 spent mushroom substrate as waste is safe and does not pose a threat to the environment, especially on non-target soil meso- and macrofauna, microbial organisms.
Mushrooms (champignons) are not intended for animal feed. No need for a risk assessment for drinking water exposure, for secondary exposure, for baits, pellets, granules, prills or treated seed.

Based on the :

- GAP for Pyrix 20 SL, the application site (closed building),
- timing of application of Pyrix 20SL (the probability of pyriproxyfen residues in the substrate is negligible)
- behavior of pyripoxyfen in soil and groundwater,
- fact that pyriproxyfen does not meet the criteria to be classified as a PBT (Persistent, Bioaccumulative, and Toxic) or vPvB (very Persistent, very Bioaccumulative) substance and not classified as a PMT (Persistent, Mobile, Toxic) or vPvM (very Persistent, very Mobile) chemical,

no toxic or adverse effects on flora and fauna, short and long term, when used in accordance with GAP.

We propose the following classification for Pyrix 20 SL :

Precautionary statement(s):	P273 - Avoid release to the environment. P280 - Wear protective gloves, protective clothing P391 - Collect spillage. P501 - Dispose of contents/container and deliver it to authorized disposal points.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

zRMS comments:

zRMS doesn't agree with the Applicant's approach. The classification of the product Pyrix is based on the % of active substance in the product and acute and chronic toxicity of active substance according to recommendation CLP classification. The classification of a plant protection product (PPP) under the CLP Regulation does not depend on whether the preparation is used in a greenhouse, closed building or in the field.

Formulant (chemical name, CAS No.)	**Content %w/w**	**Classification**	**Consequence for the product classification (Y/N)**
Pyriproxyfen (99.3%) CAS-No. 95737-68-1 EC-No.429-800-1	2.015	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor - Aquatic Acute: 10 M-Factor – Aquatic Chronic: 1000	YES  GHS 09 **H410 - Very toxic to aquatic life with long lasting effects.**

None of toxicity of the each co-formulant has consequence for the product classification (for detail see in PART C) Finaly in the label **H410 is proposed.**

In conclusion:

Hazard statement(s):	**H410 - Very toxic to aquatic life with long lasting effects**
Precautionary statement(s):	P280 - Wear protective gloves, protective clothing P391 - Collect spillage. P501 - Dispose of contents/container and deliver it to authorized disposal points.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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
All KCP 10	Marielle Fortin-McCuaig	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
No studies are submitted.					

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
No studies are submitted					

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
No data relied on not submitted by the applicant but necessary for evaluation.					

Appendix 2 Detailed evaluation of the new studies

NOT APPLICABLE.

zRMS comments:

According EU Reg 284/2013 the formulation study is not required for proposed use of Pyrix 20 SL.