REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product name(s): Pyrix 20 SL

Chemical active substance:

Pyriproxyfen 20 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: AGROFARM SP z o.o.

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September 2026 (final Core Assessment)

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Version history

When	What
July 2025	Initial dRR – Agrofarm Sp. z o.o.
June 2026	Addressing of the chapter 3.3 (*Information on the occurrence or possible occurrence of the development of resistance*), by the applicant.
June 2026	Initial cMS 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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3.0 Efficacy Data and Information (including Value Data) on the Plant Protection Product

Introduction

This document summarises the information related to the efficacy of the plant protection product Pyrix 20 SL. Pyrix 20 SL is an insecticide, containing the active substance Pyriproxyfen (20 g/L) which was included into Annex I of Directive 91/414/EEC (2004/99/EC). The Commission Implementing Regulation (EU) 2018/113 renews the approval of the active substance in accordance with regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. The SANCO report for Pyriproxyfen (Commission working document, Review report for the active substance pyriproxyfen. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 March 2008 in view of the inclusion of pyriproxyfen in Annex I of Council Directive 91/414/EEC. SANCO/836/08 – final 11 May 2010) is considered to provide the relevant review information or a reference to where such information can be found.

This document complements the document Registration Report Part B Section 3: Efficacy Data and Information, base summary and summarises the information related to controlled Sciarid flies (*Sciaridae)*. The Annex I renewal for Pyriproxyfen provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No. 1107/2009, the conclusions of the renewal report on Pyriproxyfen, and in particular Appendices I and II thereof, shall be taken into account.
In their overall assessment Member States shall pay particular attention to:
- the risk to aquatic organism, bees and other non-target arthropods,
- the risk to birds and mammals,
- the risk to consumers,
- the risk to operators.

Conditions of use shall include risk mitigation measures, where appropriate. These concerns have been addressed within the current submission. Appendix 1 of this document contains the list of references included in this document for support of the evaluation. Information on the detailed composition of Pyrix 20 SL can be found in the confidential dossier of this submission (Registration Report - Part C).

Table 3- 1: Zonal rapporteur member state (zRMS) and concerned member states (cMS)

zRMS	Poland	PL
	Poland	PL

Description of the active substances and mode of action

The product Pyrix 20 SL comprises active substance Pyriproxyfen (20%). Pyriproxyfen is an insect growth regulator (IGR) that mimics juvenile hormone, a natural hormone in insects. Pyriproxyfen (4-phenoxyphenyl(RS)-2-(2-pyridyloxy)propyl ether) is a broad-spectrum insect growth regulator with activity against a variety of insects. It is used in a variety of flea control topical spot-on products. Pyriproxyfen is an insecticide classified as a juvenile hormone analog and insect growth regulator (IGR), specifically under IRAC group 7C. It disrupts insect development, preventing larvae from molting into adults and suppressing egg hatching. Pyriproxyfen acts as a juvenile hormone (JH) mimic, artificially maintaining the regulation of molting after natural JH levels have dropped; this arrests the development of ova and immature flea stages, which ultimately die. Pyriproxyfen interferes with the development of flea eggs, larvae, early pupae, and young adult fleas.

Table 3-2: Details of the active substance(s) in Pyrix 20 SL

Active substance	Pyriproxyfen
g/L	20
Chemical group	IRAC Group 7C
Mode of action	Juvenile hormone analog and insect growth regulator (IGR),

Description of the plant protection product

The GAP table of intended uses for Pyrix 20 SL is shown in table 6-1. The formulation of this product is a Soluble (liquid) concentrate (SL) and it comprises once active substance Pyriproxyfen (20 g/L).

Pyrix 20 SL is an insecticide used for the control of sciarid flies in mushroom. This product acts surface, subsurface and systemic on the plant and demonstrates contact and stomach action on the insects.

Abstract

This document summarises the information related to the efficacy of the plant protection product Pyrix 20 SL. The formulation of this product is a Soluble (liquid) concentrate (SL) and it comprises once active substance Pyriproxyfen (20 g/L). Pyrix 20 SL is an insecticide used for the control of sciarid flies in mushroom. This product acts surface, subsurface and systemic on the plant and demonstrates contact and stomach action on the insects. The formulation of this product is a Soluble (liquid) concentrate (SL) and it comprises once active substance Pyriproxyfen (20 g/L). Pyrix 20 SL is an insecticide used for the control of sciarid flies in mushroom. This product acts surface, subsurface and systemic on the plant and demonstrates contact and stomach action on the insects. This document summarises the results with ~~7~~ five efficacy reports from mushroom. This document summarises the information related to *Sciaridae* controlled in mushroom. Trials were conducted ~~in~~ with indoor application – in closed buildings (only professional use).

Table 3-3 Number of trials

Crop	Pest	Number of trials	Timing	Season			Kind of trials	Country	North East EPPO Climatic Zone
				2022	2023	2024		Poland	
Mushrooms	*Sciaridae*	~~7~~ 5	Overgrowth of cover by mushroom mycelium	2	~~3~~ 2	~~2~~ 1	Efficacy	~~7~~ 5	~~7~~ 5
Total		~~7~~ 5		**2**	~~3~~ **2**	~~2~~ **1**		~~7~~ 5	~~7~~ 5

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines PP 1/135(4) Phytotoxicity assessment, PP 1/152(4) Design and analysis of efficacy evaluation trials, PP 1/181(4) Conduct and reporting of efficacy evaluation trials including good experimental practice, PP 1/225(2) Minimum effective dose and PP 1/167(2) Insects and mites on mushrooms.

Table 3-4 Tested insecticide was applied at the following rates and timing

Crop	Rate of Pyrix 20 SL ml/m2	Timing of application	Nomber of application	Spray volume L/m2
Mushrooms	15	Overgrowth of cover by mushroom mycelium	1	1

There is no reference insecticide because there is no plant protection product approved for use in this area.

On the basis of submitted trials it is possible to state that product Pyrix 20 SL at the rate of 15 ml product per m2, effectively controls the following insects: sciarid fly and phorid fly. The efficacy amounted above 90% and protected mushrooms from sciarid flies.

Pyrix 20 SL demonstrated excellent crop tolerance to mushrooms in all trials. Therefore, it is concluded that the use of Pyrix 20 SL is safe ~~usage~~ at proposed rate and this supports the label claim for the use in mushrooms. Undesirable effects are not expected on crop, quality and quantity of yield and part of plants used for propagating purposes, on succeeding crops, adjacent crops and non-target organisms.

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS

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 is ~~struck-through and shaded~~, for clarity.
The **numbering of the chapters** has been corrected by zRMS evaluator, yet without marking the changes, for the sake of legibility. Some main points of the document, like the 3.1, had to be **restored** by the evaluator in order to retain the original layout of the dRR that is coherent with the template (2015), since they were originally postponed by the applicant. Changes in the **numbering of tables** followed respectively, along with the respective changes of table **references** in the text. For the sake of legibility of the document none of these had been marked visibly either.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract by zRMS

Introduction
Pyrix 20 SL is a liquid concentrate insecticide containing 20 g/ L pyriproxyfen. The active belongs to the group 7A IRAC: juvenile hormone analogs (JHAs). The mode of action of this group is based on mimicking high level of the JH by the active substance, with the result being the retention of the pest in its larval stage instead of going through metamorphosis and pupating into adult. Since pyriproxifen is far more persistent than the natural JH, the high level of the active maintained makes the pest go through next (supernumerary) larval moults, leading to abnormalities and to death. As the natural levels of JH are also of the key importance for egg maturation process in adults, the unnaturally high levels of the JH analog: pyriproxyfen, is also known to interfere with egg development, leading to females` laying sterile eggs.

The data set submitted by the applicant
The applicant has submitted five efficacy trial reports, two of which contain two series of the respective experiment carried out in line with the same, identical design and within the same time framework (planting date, application date and the assessment dates are the same for series 1 and for series 2). The whole data set is therefore considered as made of the total of 5 trials, instead of 7 as claimed by the applicant, with the two respective trials simply delivering more replications / datapoints than the other three. In light of the national arrangements the number of valid trials: 5 is sufficient for authorization in the category of minor crops, to which mushroom cultures belong. Fortunately enough, the proper test item Pyrix 20 SL had been used in all 5 trials, including 2 initial trials wherein Pyrix 100 EC had been tested as well.

Trial Methodology
The efficacy of the treatments has been defined by the applicant based on the number of adult sciarid flies trapped on the yellow sticky boards placed in the vicinity of plots, as described in EPPO PP1/167(2) *Insects and mites in mushrooms*. Plot size: 0.2 m^2 . Three assessments in each trial, or in a series within a trial, were carried out at 4 to 10-day intervals, starting 12 to 14 days after the treatment with the test item. Neither the incidence nor severity of infestation of the substrate by larvae were investigated. The quantity and quality of yield was recorded separately for each one of the 3 croppings.

Minimum Effective Dose

The dose rate of **0.3 L/m^2 of Pyrix 20 SL** can be considered the minimum effective dose in control of sciarid flies in mushroom cultures. The MED summaries had been postponed by the applicant. Instead, all the efficacy data are presented in bulk (although not summarized) in 3.2.3 *Efficacy tests* chapter.
The MED data summary by zRMS is presented and discussed in the commenting box following the *Minimum Effective Dose tests* point of the dRR.

Efficacy
The target dose rate shows the mean efficacy of **92**%, as averaged from 7 assessments carried out in the total of 5 trials, at mean PESSEV 154.3 (number of sciarid flies *per* m^2). The level of control concluded allows to assume that the use can be authorized. zRMS comments on efficacy

Yield
Only yield data from efficacy trials is presented (although not summarized) by the applicant. Based on the limited data presentation in the dRR as well as on the analysis of raw data and considerations and conclusions provided by the test unit (InHort) in trial reports, to the opinion of zRMS the yield data bring no important value to efficacy considerations since no significant differences between treated and untreated plots had been found.
However, for the minor crop status of the mushroom cultures in Poland the situation described does not affect negatively the authorization options.

Risk of Resistance

Selectivity
No dedicated selectivity trials had been carried out since this type of data is not required for insecticides, provided that no phytotoxicity was observed in efficacy trials, which is the case with the present submission. It is concluded by the applicant and accepted by zRMS that crop damage should not be expected following application of the test item at the target dose rate of 15 mL/m^2.

Impact on transformation processess
The non-submission of data accepted, see zRMS comments.

Impact on propagative material
The non-submission of data accepted, see zRMS comments.

Impact on succeeding crops
The non-submission of data accepted, see zRMS comments.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	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	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appl. (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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL ~~/~~ ~~Climatic zone: Northern authorization zone: Central~~	*Mushrooms (fungi) Agaricus bisporus*	I-indoor application-closed buildings (only professional use)	-sciarid fly (Sciaridae) - phorid fly ~~phyrid fly~~ (Phoridae) Developmental stage: Adult insect	Spray/ manual sprayer	BBCH: overgrowth of cover by mushroom mycelium Spraying two days after applying peat cover ~~a torf cover~~	a) 1 b) 1/1 cycle (3-4 throws= fruit harvest)	n.a.	a) 15 ml/m^2 b) 15 ml/m^2 for 1 cycle (3-4 fruit harvest)	a) 0,3 g ~~s.a.~~ a.s./m^2 (3 kg/ha or 3000 g/ha) b) 0,3 g ~~s.a.~~ a.s./m^2 (3kg/ha or 3000 g/h) for 1 cycle (3-4 fruit harvest)	(10000 L/ha)1L/m^2	-		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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data

Introduction

The product Pyrix 20 SL comprises active substance Pyriproxyfen (20%). Pyriproxyfen is an insect growth regulator (IGR) that mimics juvenile hormone, a natural hormone in insects. Pyriproxyfen (4-phenoxyphenyl(RS)-2-(2-pyridyloxy)propyl ether) is a broad-spectrum insect growth regulator with activity against a variety of insects. It is used in a variety of flea control topical spot-on products. Pyriproxyfen is an insecticide classified as a juvenile hormone analog and insect growth regulator (IGR), specifically under IRAC group 7C. It disrupts insect development, preventing larvae from molting into adults and suppressing egg hatching. Pyriproxyfen acts as a juvenile hormone (JH) mimic, artificially maintaining the regulation of molting after natural JH levels have dropped; this arrests the development of ova and immature flea stages, which ultimately die. Pyriproxyfen interferes with the development of flea eggs, larvae, early pupae, and young adult fleas.

Description of the plant protection product

The formulation of this product is a Soluble (liquid) concentrate (SL) and it comprises once active substance Pyriproxyfen (20 g/L). Pyrix 20 SL is an insecticide used for the control of sciarid flies in mushroom. This product acts surface, subsurface and systemic on the plant and demonstrates contact and stomach action on the insects.

This document summarises the results with 5 ~~7~~ efficacy reports from mushroom. This document summarises the information related to *Sciaridae* controlled in mushroom. Trials were conducted ~~in~~ indoor ~~application~~ – in closed buildings (only professional use).

Table 3.2-1 Number of trials

Crop	Pest	Number of trials	Timing	Season			Kind of trials	Country	North East EPPO Climatic Zone
				2022	2023	2024		Poland	
Mushrooms	*Sciaridae*	7	Overgrowth of cover by mushroom mycelium	2	~~3~~ 2	~~2~~ 1	Efficacy	~~7~~ 5	~~7~~ 5
Total		**7**		**2**	~~3~~ **2**	~~2~~ **1**		~~7~~ 5	~~7~~ 5

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines PP 1/135(4) Phytotoxicity assessment, PP 1/152(4) Design and analysis of efficacy evaluation trials, PP 1/181(4) Conduct and reporting of efficacy evaluation trials including good experimental practice, PP 1/225(2) Minimum effective dose and PP 1/167(2) Insects and mites on mushrooms.

Table 3.2-2 Tested insecticide was applied at the following rates and timing

Crop	Rate of Pyrix 20 SL ml/m2	Timing of application	Nomber of application	Spray volume L/m2
Mushrooms	15	Overgrowth of cover by mushroom mycelium	1	1

There is no reference insecticide because there is no plant protection product approved for use in this area. On the basis of submitted trials it is possible to state that product Pyrix 20 SL at the rate of 15 ml product per m2, effectively controls the following insects: sciarid fly and phorid fly. The efficacy amounted above 90% and protected mushrooms from flyes. Pyrix 20 SL demonstrated excellent crop tolerance to mushrooms in all trials. Therefore, concluded that Pyrix 20 SL is safe usage at proposed rate and this support the label claim for the use in mushrooms. Undesirable effects are not expected on

crop, quality and quantity of yield and part of plants used for propagating purposes, on succeeding crops, adjacent crops and non-target organisms.

3.2.1 Preliminary tests

In 2022, two efficacy studies were conducted with two formulation of insecticide: Pyrix 20 SL and Pyrix 100 EC. The tested products were use in following rates: Pyrix 20 SL 15, 25 and 34 ml/m2 and Pyrix 100 EC 3, 5 , 7 ml/m2. Both formulations effectively controlled *Sciaridae* (table 3.2.1-1). After the first series of tests, the Pyrix 100 EC formulation was resigned. In subsequent studies, the Pyrix 20 SL insecticide was tested at the following doses: 12, 15, and 25 ml/m2.

Table 3.2.1-1. The efficacy of Pyrix 20 SL and Pyrix 100 EC on mushroom (number of *Sciaridae per* m^2)

				Trial ID					
	Treatment	Application	rate ml/ m2	ZBZNBH/12/2022/1/I			ZBZNBH/12/2022/1/II		
				I	II	III	I	II	III
1	Untreated*			20,8	213,5	294,8	16,3	142,5	254,8
2	Pyrix 20 SL	A	15	100	91,6	83,4	100	90,5	84,8
3	Pyrix 20 SL	A	25	100	83,2	78,2	100	93,5	89,2
4	Pyrix 20 SL	A	34	100	96,5	94,1	100	90,7	91,3
5	Untreated*			32,3	289,0	310,0	10,3	95,3	252,8
6	Pyrix 100 EC	A	3	100	97,2	90,4	100	92,6	89,7
7	Pyrix 100 EC	A	5	100	96,9	90,3	100	77,4	84,8
8	Pyrix 100 EC	A	7	100	96,8	91,0	100	81,8	83,3

*number of Sciaridae szt/m2

More information on preliminary range-finding tests can be found in point 3.2.3 Efficacy tests.

3.2.2 Minimum effective dose tests

In 2023 and 2024, tested insecticide Pyrix 20 SL at the following rates: 12. 15 and 25 ml/m^2. More information on minimum effective dose tests can be found in point 3.2.3 Efficacy tests.

Comments of zRMS on the Minimum Effective Dose data:

Next to designing two out of five trials with two identical series of the experiment, the applicant had used another formulation of pyriproxifen (Pyrix 100 EC, with different active content) in two initial trials of 2022. Some of the dose rates higher than the targeted 0.3 g/m^2 a.s. (15.0 mL/m^2 f.p. 20 SL) were used only in these two trials, *e.g.* the 0.70 g/m^2 a.s. (7.0 mL/m^2 f.p. 100 EC respectively). On the other hand, only two trials with the proper test item Pyrix 20 SL had used the dose rate of 0.68 g/m^2 a.s. (34 mL/m^2 f.p. 20 SL). As the result, the data set became fragmented by formulation type and by the fact that not all the dose rates are present in each trial, making it challenging a task to summarize while following the necessary assumption that efficacy of particular dose of particular formulation should be calculated based on PESSEV observed in the same trial in which that dose of that particular formulation were actually applied.
The summary presented below by zRMS shows averaged data of 3 assessments in each trial; where the number of assessments shown in brackets is higher than the number of trials averaged, this difference only accounts for trials with two series of experiment.

treatment	Dose rate mL/m^2 f.p.	Dose rate g/m^2 a.s.	Trials (assessments)	mean efficacy (%) across 3 assessments:	Min.	Max.
Pyrix 20 SL	12	0.24	3 (5)	89.99	81,63	94,59
Pyrix 20 SL	15	**0.30**	5 (7)	**91.97****	84,02	99,02
Pyrix 20 SL	25	0.50	5 (7)	92.80	86,04	98,88
Pyrix 20 SL	34	0.68	2	95.43	92,69	100,00
Pyrix 100 EC	3	**0.30**	2	**94.99****	90,06	100,00
20 SL (100 EC)*	15 (3)	**0.30**	5 (9)	**93.48****	87,04	99,51
20 SL (100 EC)*	25 (5)	0.50	5 (9)	92.18	86,79	99,44
Pyrix 100 EC	5	0.50	2	91.57	87,17	100,00
Pyrix 100 EC	7	0.70	2	92.16	87,15	100,00
SL (EC)	34 (7)	0.68 (0.70)	2	93.79	89,92	100,00

*efficacy of the respective dose averaged between the formulations, where additionally some data from Pyrix 100 EC are available
**efficacy of the target dose rate 0,3 mL/m2 highlighted

While the "dose response" between 0.24 and 0.30 g/m^2 for Pyrix 20 SL is **1.98**% (n=5, n=7, respectively), the "response" between 0.30 and 0.50 g/m^2 for Pyrix 20 SL is only **0.83**% (n=7). Then the efficacy response to dose increased from 0.50 to 0.68 g/m^2 is **2.63**% and the distance between the 0.30 and 0.68 g/m^2 is **3.46**%, thereby suggesting that it is perhaps 25 mL/m^2 and not 15, that should be claimed MED?

Although the differences between the means of all the dose rates tested are negligible anyway and the results are fairly erratic, demonstrating no clear-cut value that could be easily assumed as MED, the efficacy of any rate was never below the critical 80% while only the lowest dose, 0.24 g/m^2, shows the efficacy on average <90%. Therefore the dose rate of **15 L/m^2 of Pyrix 20 SL**, the one targeted by the applicant can be judiciously considered the minimum effective dose in control of sciarid flies in mushroom cultures.

Even though summarized for the sake of completeness, the data averaged between SL and EC formulations are irrelevant taken that Pyrix 100 EC had been abandoned by the applicant after 2022 and that only 2 trials are available.

zRMS comments on efficacy
#zRMSAbstract

3.2.3 Efficacy tests

Materials and methods

This document summarises the results with 5 ~~7~~ efficacy reports from mushrooms. This document summarises the information related to *Sciaridae* controlled in mushrooms. (List of these reports is contained in Appendix 1).

Site
Trials were conducted ~~in~~ indoor, in closed buildings. According to the above, the insecticide was tested under conditions typical of mushroom production - mushroom farms.

Table 3.2.3-1. List of supporting trials conducted in Poland

Crop	Pest	Trial Code	Year	Remarks
Mushroom AGABI *Agaricus bisporus*	*Sciaridae* *Sciarid flies* Muchówki - ziemiórki	ZBZNBH/12/2022/1/I	2022	PL
		ZBZNBH/12/2022/1/II	2022	PL
		*ZBZNBH/4/2023/1/I Series 1, Series 2	2023	PL
		ZBZNBH/4/2023/2/I	2023	PL
		*ZBZNBH/4/2024/1/I Series 1, Series 2	2024	PL

*shaded table cells: rows combined by zRMS, in order to represent single trial in a single line.

Testing units
The experiments of the insecticide Pyrix 20 SL were carried out by Institute of Horticulture – National Research Institute**,** Horticultural Plant Cultivation and Fertilization Facility, Laboratory Cultivation of Vegetables and Edible Mushrooms. All testing units have been mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP (Good Experimental Practice) recognised.

Experimental methods
The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:
PP 1/225(2) Minimum effective dose;
PP 1/135(4) Phytotoxicity assessment;
PP 1/152(4) Design and analysis of efficacy evaluation trials;
PP 1/181(4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
They were carried out ~~in the field in~~ under the conditions of natural pest infestation. The efficacy trials were conducted according to the EPPO standard PP 1/167(2) Insects and mites on mushrooms.

Assessment methods
The evaluation of insecticide efficacy ~~effectiveness~~ was carried out according to EPPO guidelines ~~and established~~. On the basis of these results, the percent of effectiveness of insecticides was calculated according to Abbott's formula.

3.2.3.1 Control of Sciaridae in mushroom

For the control of *Sciaridae* in mushroom a dose rate of 15 ml/m2 Pyrix 20 SL with single application ~~once applications~~ is intended.

Material and methods

A total of five ~~7~~ trials, with 2 of them including two series each, is available to investigate the efficacy of 15 ml/m2 Pyrix 20 SL for control of *Sciaridae* in mushroom. Trials were carried out in Poland in the North-East EPPO zone in 2022 (2 trials), 2023 (~~3~~ 2 trials) and 2024 (~~2~~ 1 trial). All trials were performed under GEP conditions, with four or five replications in a completely randomized block system and according to EPPO guidelines (see above). Summary of the data from efficacy ~~effectiveness~~ trials in mushroom can be found in table 3.2.3.1-1 and 3.2.3.1-2.

Table 3.2.3.1-1. Details on trial methodology

Test report / research number (1)	Trial location(2); Crop cultivar ; F/G (3); N/A (4)	Testing Unit (5)	Test method (6); Plot size; Sample Size (7)	Treatment			
				Growth stage (8)	Interval	Total number	Spray volume (L/ha)
ZBZNBH/12/2022/1/I	Skierniewice Łódź Poland Mushroom V. Sylvan 737 G A	Institute of Horticulture – National Research Institute	EPPO PP 1/167(2) EPPO PP 1/225(2) EPPO PP 1/181(4) EPPO PP 1/152(4) EPPO PP 1/135(4) 6,4 m^2	A: BBCH: overgrowth of cover by mushroom mycelium	not applicable	1	10000 (1 L/m2)
ZBZNBH/12/2022/1/II	Skierniewice Łódź Poland Mushroom V. Sylvan 737 G A	Institute of Horticulture – National Research Institute	EPPO PP 1/167(2) EPPO PP 1/225(2) EPPO PP 1/181(4) EPPO PP 1/152(4) EPPO PP 1/135(4) 6,4 m^2	A: BBCH: overgrowth of cover by mushroom mycelium	not applicable	1	10000 (1 L/m2)
ZBZNBH/4/2023/1/I Seria 1	Skierniewice Łódź Poland Mushroom V. Triple X G	Institute of Horticulture – National Research Institute	EPPO PP 1/167(2) EPPO PP 1/225(2) EPPO PP 1/181(4) EPPO PP 1/152(4) EPPO PP 1/135(4) 4 m^2	A: BBCH: overgrowth of cover by mushroom mycelium	not applicable	1	10000 (1 L/m2)

	A						
ZBZNBH/4/2023/1/I Seria 2	Skierniewice Łódź Poland Mushroom V. Triple X G A	Institute of Horticulture – National Research Institute	EPPO PP 1/167(2) EPPO PP 1/225(2) EPPO PP 1/181(4) EPPO PP 1/152(4) EPPO PP 1/135(4) 4 m^2	A: BBCH: overgrowth of cover by mushroom mycelium	not applicable	1	10000 (1 L/m2)
ZBZNBH/4/2023/2/I	Skierniewice Łódź Poland Mushroom V. Sylvan 737 G A	Institute of Horticulture – National Research Institute	EPPO PP 1/167(2) EPPO PP 1/225(2) EPPO PP 1/181(4) EPPO PP 1/152(4) EPPO PP 1/135(4) 4 m^2	A: BBCH: overgrowth of cover by mushroom mycelium	not applicable	1	10000 (1 L/m2)
ZBZNBH/4/2024/1/I Seria 1	Skierniewice Łódź Poland Mushroom V. Triple X G A	Institute of Horticulture – National Research Institute	EPPO PP 1/167(2) EPPO PP 1/225(2) EPPO PP 1/181(4) EPPO PP 1/152(4) EPPO PP 1/135(4) 4 m^2	A: BBCH: overgrowth of cover by mushroom mycelium	not applicable	1	10000 (1 L/m2)

ZBZNBH/4/2024/1/I Seria 2	Skierniewice Łódź Poland Mushroom V. Triple X G A	Institute of Horticulture – National Research Institute	EPPO PP 1/167(2) EPPO PP 1/225(2) EPPO PP 1/181(4) EPPO PP 1/152(4) EPPO PP 1/135(4) 4 m^2	A: BBCH: overgrowth of cover by mushroom mycelium	not applicable	1	10000 (1 L/m2)

Notes: (1): test report number including the year of establishing the trial (e.g. PM 96/1).
(2): precise place of the trial followed by the country (e.g. Rheims, FR.)
(3): F = field trial, G = protected crop, specify (e.g. glasshouse).
(4): N = Natural infestation, A = Artificial inoculation.
(5): Trial responsible entity / officially recognized organization.
(6): Test guideline used (e.g. EPPO PP 1/32).
(7): Sample size per plot.
(8): Crop growth stage at application timing (e.g. BBCH 31-BBCH 50) / target growth stage (e.g. egg, adult, pre-emergence, post-emergence).

Table 3.2.3.1-2. Details on trial application and efficacy assessment

Test report (1)	Crop Harmful organism/ weed species or intended use	Assessed part and variable (2)	Untreated (3) Pest before application	Efficacy treatments (4)				Remarks (5)
				Product		Standard (s)		
				name	dose ml/m2	name	dose l, kg/ha	
ZBZNBH/12/2022/1/I	Mushroom harmful organism*:* *Sciaridae* *Lycoriella ingenua*	The average number of pest on m2 % Efficacy	The average number of pest on m2	Pyrix 20 SL Pyrix 20 SL Pyrix 20 SL Pyrix 100 EC Pyrix 100 EC Pyrix 100 EC	15 25 34 3 5 7	No reference PPP		Application date: A: 12.11.2022 Assessment date: 25.11.2022 02.12.2022 09.12.2022 16.12.2022
ZBZNBH/12/2022/1/II	Mushroom harmful organism*:* *Sciaridae* *Lycoriella ingenua*	The average number of pest on m2 % Efficacy	The average number of pest on m2	Pyrix 20 SL Pyrix 20 SL Pyrix 20 SL Pyrix 100 EC Pyrix 100 EC Pyrix 100 EC	15 25 34 3 5 7	No reference PPP		Application date: A: 22.10.2022 Assessment date: 04.11.2022 10.11.2022 18.11.2022 25.11.2022
ZBZNBH/4/2023/1/I Seria 1	Mushroom harmful organism*:* *Sciaridae* *Lycoriella ingenua*	The average number of pest on m2 % Efficacy	The average number of pest on m2	Pyrix 20 SL Pyrix 20 SL Pyrix 20 SL	15 25 34	No reference PPP		Application date: A: 02.06.2023 Assessment date: 14.06.2023 23.06.2023 30.06.2023 06.07.2023

ZBZNBH/4/2023/1/I Seria 2	Mushroom harmful organism*:* *Sciaridae* *Lycoriella ingenua*	The average number of pest on m2 % Efficacy	The average number of pest on m2	Pyrix 20 SL Pyrix 20 SL Pyrix 20 SL	15 25 34	No reference PPP		Application date: A: 02.06.2023 Assessment date: 14.06.2023 23.06.2023 30.06.2023 06.07.2023
ZBZNBH/4/2023/2/I	Mushroom harmful organism*:* *Sciaridae* *Lycoriella ingenua*	The average number of pest on m2 % Efficacy	The average number of pest on m2	Pyrix 20 SL Pyrix 20 SL Pyrix 20 SL	15 25 34	No reference PPP		Application date: A: 16.06.2023 Assessment date: 30.06.2023 07.07.2023 17.07.2023 22.07.2023
ZBZNBH/4/2024/1/I Seria 1	Mushroom harmful organism*:* *Sciaridae* *Lycoriella ingenua*	The average number of pest on m2 % Efficacy	The average number of pest on m2	Pyrix 20 SL Pyrix 20 SL Pyrix 20 SL	15 25 34	No reference PPP		Application date: A: 13.07.2024 Assessment date: 26.07.2024 05.08.2024 09.08.2024 16.08.2024
ZBZNBH/4/2024/1/I Seria 2	Mushroom harmful organism*:* *Sciaridae* *Lycoriella ingenua*	The average number of pest on m2 % Efficacy	The average number of pest on m2	Pyrix 20 SL Pyrix 20 SL Pyrix 20 SL	15 25 34	No reference PPP		Application date: A: 13.07.2024 Assessment date: 26.07.2024 05.08.2024 09.08.2024 16.08.2024

Notes: (1): Test report number including the year of establishing the trial (e.g. PM 96/1).
(2): Plant part assessed and criteria for assessment (frequency or intensity).
(3): Severity of incidence of harmful organisms and the growth stage of weeds (BBCH monograph) of the untreated.

(4): Efficacy (control) or intended effect.
(5): Relevant conclusions on effectiveness (see also table 3).

Results

North-East EPPO zone – indoor application – closed buildings

The efficacy ~~efficiency~~ of Pyrix 20 SL against Sciaridae (*Lycoriella ingenua)* was investigated in 5 ~~7~~ trials in 2022 (2), 2023 (2 ~~3~~) and 2024 (1 ~~2~~) with single application ~~once application~~. Summarized results are shown in Table 3.2.3.1-3. The tested product was applied at the following rates: ~~of~~ 12, 15, 25 ml per m^2 once per season at the growth stage: overgrowth of cover by mushroom mycelium. In all trials assessments were conducted 3-4 days before first mushroom yield, after the first, second and third harvest. The results showed high level of efficacy in these trials, irrespective of used dose. After product used at the rate 0,12 ml/m^2 effectiveness fluctuated from 80,5% to 100%. Pyrix 20 SL at the rate 15 ml/m^2 effectively controlled Sciaridae and efficacy fluctuated from 81,1% to 100 % (see table 3.2.3.1-3, 3.2.3.1-4, 3.2.3.1-5 and 3.2.3.1-6). The insecticide Pyrix 20SL effectively protected the mushrooms against the pest, even under very high pest pressure. No reference product was used in the study because there was no insecticide approved for use in this area at that time.

Table 3.2.3.1-3. The efficacy of Pyrix 20 SL and Pyrix 100 EC on mushroom (number of *Sciaridae per* m^2)

				Trial ID					
	Treatment	Application	rate ml/ m2	ZBZNBH/12/2022/1/I			ZBZNBH/12/2022/1/II		
				I	II	III	I	II	III
1	Untreated*			20,8	213,5	294,8	16,3	142,5	254,8
2	Pyrix 20 SL	A	15	100	91,6	83,4	100	90,5	84,8
3	Pyrix 20 SL	A	25	100	83,2	78,2	100	93,5	89,2
4	Pyrix 20 SL	A	34	100	96,5	94,1	100	90,7	91,3
5	Untreated*			32,3	289,0	310,0	10,3	95,3	252,8
6	Pyrix 100 EC	A	3	100	97,2	90,4	100	92,6	89,7
7	Pyrix 100 EC	A	5	100	96,9	90,3	100	77,4	84,8
8	Pyrix 100 EC	A	7	100	96,8	91,0	100	81,8	83,3

~~*number of Sciaridae szt/m2~~

Table 3.2.3.1-4. The efficacy of Pyrix 20 SL on mushroom (number of *Sciaridae per* m^2)

				Trial ID					
	Treatment	Application	rate ml/ m2	ZBZNBH/4/2023/1/I Seria 1			ZBZNBH/4/2023/1/I Seria 2		
				I	II	III	I	II	III
1	Untreated*			58,0	179,8	429,4	82,0	140,3	310,0
2	Pyrix 20 SL	A	12	96,2	92,2	81,9	95,1	90,0	76,2
3	Pyrix 20 SL	A	15	98,3	95,5	88,7	96,3	91,1	82,1
4	Pyrix 20 SL	A	25	99,0	96,5	90,8	95,4	91,8	84,6

*number of Sciaridae szt/m2

Table 3.2.3.1-5. The efficacy of Pyrix 20 SL on mushroom (number of *Sciaridae per* m^2)

				Trial ID		
	Treatment	Application	rate ml/ m2	ZBZNBH/4/2023/2/I		
				I	II	III
1	Untreated*			27,0	169,2	487,3
2	Pyrix 20 SL	A	12	95,6	91,8	80,5
3	Pyrix 20 SL	A	15	98,5	92,7	83,5
4	Pyrix 20 SL	A	25	97,8	91,9	82,6

*number of Sciaridae szt/m2

Table 3.2.3.1-6. The efficacy of Pyrix 20 SL on mushroom (number of *Sciaridae per* m^2)

				Trial ID					
	Treatment	Application	rate ml/ m2	ZBZNBH/4/2024/1/I Seria 1			ZBZNBH/4/2024/1/I Seria 2		
				I	II	III	I	II	III
1	Untreated*			13,2	85,4	132,2	15,8	60,3	108,8
2	Pyrix 20 SL	A	12	92,4	96,7	84,1	93,7	98,0	85,5
3	Pyrix 20 SL	A	15	100	95,3	85,5	100,0	93,4	81,1
4	Pyrix 20 SL	A	25	100	99,1	91,5	100,0	98,3	85,3

*number of Sciaridae szt/m2

Summary and conclusion

This document summarises the results with 7 efficacy reports from mushrooms. This document summarises the information related to *Sciarid fly* controlled in mushroom. Trials were conducted in closed buildings in Poland in North East EPPO Climatic Zone. Trials were carried out in Institute of Horticulture – National Research Institute in Skierniewice. The efficacy trials were designed, conducted and reported according to the following EPPO guidelines PP 1/225(2) Minimum effective dose, PP 1/135(4) Phytotoxicity assessment; PP 1/152(4) Design and analysis of efficacy evaluation trials; PP 1/181(4) Conduct and reporting of efficacy evaluation trials including good experimental practice and PP 1/167(2) Insects and mites on mushrooms.
On the basis of submitted trials it is possible to state that product Pyrix 20 SL at the rate of 15 ml product per m^2, effectively controls the *Sciaridae* on mushroom. Pyrix 20 SL demonstrated excellent crop tolerance to mushrooms in all trials. Therefore, concluded that Pyrix 20 SL is safe usage at proposed rate and this support the label claim for the use in mushroom. Undesirable effects are not expected on crop, quality and quantity of yield and part of plants used for propagating purposes, on succeeding crops, adjacent crops and non-target organisms.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

The tested product Pyrix 20 SL had a positive effect on crop yield quality. For more information, see point 6.4.2 Effect on the yield of treated plants or plant product.

Comments of zRMS on Efficacy data:

The same set of trials has been used by the applicant in order to determine the minimum effective dose and to demonstrate the efficacy of the targeted dose of 15 mL/m^2 f.p. Pyrix 20 SL.

Efficacy of Pyrix 20 SL at 15 mL/m^2; summary of 5 (7)* trials

n (no. of assessments)	no. of adults / m^2 UNCK			mean efficacy (%) across 3 assessments:		
	mean	Min.	Max.	mean	Min.	Max.
15 (21)*	154.3	13.2	487.3	**91.97**	84.02	99.02

*for each trial (or a series of experiment within a trial) the assessments were carried out 3 times on consecutive days; these have been averaged for the summary.

The target dose rate shows the mean efficacy of **92**%, as averaged from 7 assessments carried out in the total of 5 trials, at PESSEV 154.3 (number of adult *Sciaridae per* m^2). The level of control concluded allows to assume that the use can be authorized.

#zRMSAbstract

3.3 Information on the occurrence or possible occurrence of the development of resistance

Pyriproxyfen is classified under IRAC (Insecticide Resistance Action Committee) group 7C. It is a juvenile hormone analog and an insect growth regulator. It works by mimicking a natural insect hormone, disrupting the insect's growth and development, particularly affecting immature stages and eggs. Pyriproxyfen is used to control various pests, including whiteflies, scales, fleas, and other insects.

RESISTANCE RISK ANALYSIS

Active Substance: Pyriproxyfen (20 g/L)
This resistance risk analysis has been conducted in accordance with EPPO Standard PP 1/213 (4), "Resistance Risk Analysis" (European and Mediterranean Plant Protection Organization; fourth revision, approved in September 2015), and to fulfil the requirement laid down in Commission Regulation (EU) No 284/2013, Section 6 (Efficacy Data), point 6.3 ~~6.6~~, "Information on the occurrence or possible occurrence of the development of resistance." The assessment also takes into account the Uniform Principles for Evaluation and Authorisation established in Commission Regulation (EU) No 546/2011 and the general requirements of Regulation (EC) No 1107/2009.

3.3.1. Background Information

The analysis is based on proprietary data contained in the product dossier and on verified external sources listed in the references section.

Item	Value / Characteristic
Active substance (a.s.)	Pyriproxyfen; CAS No. 95737-68-1; content 20 g/L
Formulation type	Soluble concentrate (SL)
Mode of action (MoA)	Insect Growth Regulator (IGR); juvenile hormone analogue/mimic (JHA)
IRAC classification	Group 7C (juvenile hormone mimics)
Crop	Button mushroom Agaricus bisporus (EPPO code: AGARBI); indoor cultivation
Target pest	Larvae of dipteran flies: *Lycoriella ingenua* (Sciaridae) and/or *Megaselia halterata* (Phoridae)
GAP(Good Agricultural Practice)	One application per crop cycle; application rate 15 mL/m² = 3 000 g a.s./ha; timing: on day 2 after casing colonisation by mycelium

Editorial note: The target fly species was not specified in the field trial report. For resistance risk assessment purposes, the target species should be clearly identified. The species listed above represent the two principal insect pests of cultivated mushrooms.

3.3.2. Assessment According to EPPO PP 1/213 (4)

3.3.2.1 Intrinsic Risk – Active Substance

Pyriproxyfen has a single, specific mode of action (modulation of the juvenile hormone receptor; IRAC Group 7C), which inherently increases resistance risk due to the absence of multiple target-site activity. Practical resistance to pyriproxyfen has been documented. The best-described case involves *Bemisia tabaci*, in which high levels of resistance evolved approximately one year after the introduction of pyriproxyfen for greenhouse use and after only three consecutive applications. Resistance has also been reported in the greenhouse whitefly *Trialeurodes vaporariorum*, involving a metabolic mechanism associated with cytochrome P450 overexpression. Furthermore, some resistant strains exhibit limited or no significant fitness costs, indicating that resistance, once selected, may persist within populations. Cross-resistance within IRAC Group 7 has also been documented among juvenile hormone mimics, including methoprene (7A), fenoxycarb (7B), and pyriproxyfen (7C).

Interim conclusion: The intrinsic resistance risk associated with pyriproxyfen is assessed as moderate to high. The *Bemisia tabaci* precedent is particularly relevant because resistance evolved under protected cultivation conditions (greenhouses), which are partially analogous to enclosed mushroom-growing facilities.

3.3.2.2 Intrinsic Risk – Target Organism

The biological characteristics of sciarid and phorid flies indicate an elevated intrinsic resistance risk associated with the target organisms:
Short life cycle (approximately 3–4 weeks for Lycoriella spp. under mushroom-house conditions) and multiple overlapping generations per year (multivoltine species);
High fecundity and sexual reproduction, resulting in substantial genetic variability upon which selection may act;
Large population sizes within cultivation facilities.
A mitigating factor is the absence of documented resistance of these species to pyriproxyfen. Searches of resistance databases (resistance.eppo.int and the Arthropod Pesticide Resistance Database, pesticideresistance.org), together with a review of the scientific literature, did not reveal any confirmed cases of practical resistance in *Lycoriella ingenua* or *Megaselia halterata*. On the contrary, available studies demonstrate effective control of sciarid flies in mushroom cultivation using pyriproxyfen. The absence of resistance reports should be documented explicitly (including search date, search terms, and absence of records) rather than omitted.

3.3.2.3 Modified and Agronomic Risk

Risk-Increasing Factors
Isolated, enclosed pest populations – limited immigration of susceptible individuals from outside sources (lack of refuges diluting resistance alleles) may facilitate resistance fixation. The same mechanism contributed to the rapid evolution of resistance in *Bemisia tabaci* under greenhouse conditions.
Continuous production systems – mushroom cultivation is conducted year-round; successive fly populations within the same growing room may be exposed repeatedly to the same mode of action across crop cycles, resulting in cumulative selection pressure despite only one application per cycle.

Risk-Reducing Factors
Only one application per crop cycle (GAP) – low selection pressure within a single production cycle, in clear contrast to the *Bemisia* scenario involving three consecutive applications within a season.
Availability of alternative modes of action for rotation, including benzoylureas (diflubenzuron – IRAC Group 15), Bacillus thuringiensis var. israelensis (Bti – IRAC Group 11), and spinosad (IRAC Group 5), where authorised.
Integration into an Integrated Pest Management (IPM) programme, including hygiene measures, substrate pasteurisation (Phase II/III), facility sealing and air filtration, fly monitoring (traps), and biological control agents such as *Steinernema feltiae* nematodes and predatory mites (*Stratiolaelaps scimitus* / *Hypoaspis miles*).

3.3.2.4 Overall Risk Conclusion

Taking all factors into account, the risk of resistance development cannot be considered negligible. However, provided that the proposed resistance-management measures are implemented, the overall resistance risk is assessed as low to moderate. The GAP profile (single application per crop cycle) and the IPM context contribute favourably, whereas the single-site mode of action with a documented history of resistance development and the enclosed, multigenerational pest population contribute unfavourably. The analysis therefore supports the implementation of risk-mitigation measures as described in Section 3.3.3.

3.3.3. Resistance Management Measures

The following measures are proposed for inclusion in the dossier and, in abbreviated form, on the product label:
A maximum of one pyriproxyfen application per crop cycle (in accordance with GAP) – a key component of the anti-resistance strategy.
Rotation of modes of action between crop cycles – pyriproxyfen and other juvenile hormone mimics from IRAC Group 7 (e.g. methoprene, fenoxycarb) should not be used in consecutive crop cycles; alternate with products having a different mode of action.
Use of the full recommended dose and uniform application coverage – sublethal exposure may promote resistance selection.
Integration of non-chemical measures (hygiene, insect exclusion, substrate pasteurisation, biological control) as the foundation of pest management; pyriproxyfen should be used as one component of an integrated programme rather than as a stand-alone solution.
Monitoring of field performance and reporting of control failures.
Inclusion of resistance-management statements on the label consistent with IRAC recommendations and EPPO PP 1/213 (4).

~~4.~~ Minimum Required Content of Section 6.3. ~~6.6~~
Even where the overall risk assessment is favourable, Section 6.3. ~~6.6~~ (Regulation (EU) No 284/2013) should include:
Classification of the mode of action (IRAC Group 7C), including reference to known resistance cases within the group;
Documented searches of resistance databases (EPPO, APRD/pesticideresistance.org), including search date and results for the target species;
Assessment of the three EPPO risk components (intrinsic risk of the active substance, intrinsic risk of the target organism, and modified/agronomic risk);
Overall resistance risk conclusion;
Proposed resistance-management measures.
Omission of any of these elements is a common reason for requests for additional information (deficiencies) by the evaluating authority.

3.3.4. References

EPPO (2015). PP 1/213 (4) Resistance Risk Analysis. EPPO Bulletin 45(3), 371–387.
IRAC Mode of Action Classification – Group 7C (Juvenile Hormone Mimics): Pyriproxyfen.
Regulation (EC) No 1107/2009 of the European Parliament and of the Council.
Commission Regulation (EU) No 284/2013 – Data Requirements for Plant Protection Products (Section 6, Point 6.6).
Commission Regulation (EU) No 546/2011 – Uniform Principles for Evaluation and Authorisation.
Horowitz, A.R. et al. (2002). Dynamics of Insecticide Resistance in Bemisia tabaci: A Case Study with the Insect Growth Regulator Pyriproxyfen. Pest Management Science.
Erler, F., Polat, E. et al. (2011). Control of Mushroom Sciarid Fly Lycoriella ingenua Populations with Insect Growth Regulators Applied by Soil Drench. Journal of Economic Entomology, 104(3), 839–844.

Comments of zRMS on resistance risk issue:

In the face of absence of virtually any content relating to 3.3 in the dRR, in the course of evaluation the applicant was requested to state his position on the main assessment points, in the order in which they are described in the EPPO guidance PP 1/213 (4). The above content is the result of the update and it has been accepted by zRMS as sufficient.

No alternative plant protection products, like once-available molting disruptors of benzoylurea group (IRAC 15), are currently authorized in Poland for control of sciarid flies in mushrooms (PPP register by MAaRD, ver. 16.06.2026 accessed 24.06.2026), except for biological products delivering nematode and acarine natural

enemies, as listed by the applicant. Consequently, the claim of risk mitigating factor of *rotation of mode of action* is unrealistic if chemical products are meant. Likewise, the single application per crop cycle is alone insufficient a measure when continuous production is caried out inside the same object for a long period of time. The remining risk-mitigating measures proposed by the applicant are considered valid and should be placed in the product label along with the requirement of MoA rotation, so that they are in place when possibly other chemical PPPs are available in the future.

#zRMSAbstract

3.4 Adverse effects on treated crops

3.4.1 Phytotoxicity to host crop

No significant phytotoxicity of any kind was observed following treatment of crops with Pyrix 20 SL. In addition to this, there were no significant symptoms of any kind seen on yield, or on any other parameters of quality. Overall, across 5 ~~7~~ efficacy trials carried out in mushroom in Poland, no symptoms of phytotoxicity or any other adverse effects on crop growth and development were observed at any of the assessment timings following ~~once~~ single application of Pyrix 20 SL at the proposed label rate of 12, 15 and 25 ml product/m^2. Overall, it is therefore concluded that there is no risk to mushrooms crops following treatment with the test product - Pyrix 20 SL.

3.4.2 Effect on the yield of treated plants or plant product

This document summarises the results with ~~7~~ 5 efficacy reports from mushrooms. In all studies, the yield of mushrooms was assessed.
The tested insecticide had no significant effect on the yield, but had a positive effect on the yield quality.

See table below: 3.4.2-1, 3.4.2-2, 3.4.2-3, 3.4.2-4.

Tab. 3.4.2-1 Influence of Pyrix 20 SL on yield of mushroom [kg/m2]

				Trial ID					
	Treatment	Application	rate ml/ m2	ZBZNBH/12/2022/1/I			ZBZNBH/12/2022/1/II		
				I class	II class	Total yield	I class	II class	Total yield
1	Untreated*			31,80a	3,92a	35,72	31,80a	3,92a	35,72
2	Pyrix 20 SL	A	15	32,27a	3,35a	35,62	32,27a	3,35a	35,62
3	Pyrix 20 SL	A	25	32,97a	2,83a	35,8	32,97a	2,83a	35,8
4	Pyrix 20 SL	A	34	33,51a	2,89a	36,4	33,51a	2,89a	36,4
5	Untreated*			32,82a	1,94b	34,76	32,82a	1,94b	34,76
6	Pyrix 100 EC	A	3	33,23a	3,23a	36,46	33,23a	3,23a	36,46
7	Pyrix 100 EC	A	5	32,95a	2,49a	35,44	32,95a	2,49a	35,44
8	Pyrix 100 EC	A	7	34,99a	1,16b	36,15	34,99a	1,16b	36,15

Tab. 3.4.2-2 Influence of Pyrix 20 SL on yield of mushroom [kg/m2]

				Trial ID					
	Treatment	Application	rate ml/ m2	ZBZNBH/4/2023/1/I Seria 1			ZBZNBH/4/2023/1/I Seria 2		
				I class	II class	Total yield	I class	II class	Total yield
1	Untreated*			39,8a	3,0a	42,8	37,7a	3,4a	41,1
2	Pyrix 20 SL	A	12	36,4a	3,0a	39,4	36,4a	3,4a	39,8
3	Pyrix 20 SL	A	15	39,7a	2,9a	42,6	38,7a	2,9a	41,6
4	Pyrix 20 SL	A	25	39,2a	1,5a	40,7	39,7a	1,8a	41,5

Tab. 3.4.2-3 Influence of Pyrix 20 SL on yield of mushroom [kg/m2]

	Treatment	Application	rate ml/ m2	Trial ID		
				ZBZNBH/4/2023/2/I		
				I class	II class	Total yield
1	Untreated*			37,4a	2,2a	39,6
2	Pyrix 20 SL	A	12	39,5a	3,3a	42,8
3	Pyrix 20 SL	A	15	38,8a	3,0a	41,8
4	Pyrix 20 SL	A	25	38,8a	2,3a	41,1

Tab. 3.4.2-4 Influence of Pyrix 20 SL on yield of mushroom [kg/m2]

	Treatment	Application	rate ml/ m2	Trial ID					
				ZBZNBH/4/2024/1/I Seria 1			ZBZNBH/4/2024/1/I Seria 2		
				I class	II class	Total yield	I class	II class	Total yield
1	Untreated*			36,5a	1,5a	38,0	32,1a	5,5a	37,6
2	Pyrix 20 SL	A	12	35,2a	2,7a	37,9	34,5a	1,8b	36,3
3	Pyrix 20 SL	A	15	34,1a	3,1a	37,2	32,0a	2,4b	34,4
4	Pyrix 20 SL	A	25	33,1a	3,0a	36,1	31,8a	3,1ab	34,9

Comments of zRMS on yield data:

In the submitted trial reports the proportion of document space allocated to pest data *vs* yield data are approximately as 1 to 4. The total yield is recorded as split into fruiting bodies in classes I and II, and separately for each cropping. Moreover, the number of fruiting bodies *per* kg yield had been recorded as a measure of quality.
On the contrary, the yield data presented in the dRR are just the total weight values with only the quality class I and class II shown separately. No comments from the applicant have been provided in spite of the fact that the test unit (InHort) had delivered extensive commenting to the results obtained, in all five trial reports.
In light of the inconclusive data on insect incidence and severity, the yield data might have represented an important support of the applicant`s claim of efficacy in general, should they had been analysed carefully. Instead, the short summary provided below by zRMS may only confirm the predominant course of conclusions drawn by the test unit: no important differences had been observed in the yield quantity or quality, between the treated containers and their untreated counterparts.

treatment	Dose rate mL/m^2	Class I, kg/m^2	Class II, kg/m^2	Total yield, kg/m^2	n
Untreated for 20 SL	0	**31,80**	**3,92**	**35,72**	2
Pyrix 20 SL	15	**32,27**	**3,35**	**35,62**	2
Untreated for 100 EC	0	32,82	1,94	34,76	2
Pyrix 100 EC	3	33,23	3,23	36,46	2
Untreated for 20 SL	0	34,86	3,42	38,28	8
Pyrix 20 SL	15	**35,01**	**3,04**	**38,06**	8

#zRMSAbstract

3.4.3 Effects on the quality of plants or plant products

Information on effects on quality of plants can be found in the point 3.4.2.

Comments of zRMS: See the zRMS comments above.

3.4.4 Effects on transformation processes

Lack of data.

Comments of zRMS:

Accepted within the efficacy context. Mushrooms are rarely consumed raw. Although they are typically not subjected to biological transformation, they are usually cooked or pickled, both categorized at least as processing. There is no necessity to discuss this issue within efficacy part of dossier, but it should be addressed by the applicant (and evaluated) within other, relevant sections.

#zRMSAbstract

3.4.5 Impact on treated plants or plant products to be used for propagation

Not applicable.

Comments of zRMS:

Accepted: the active substance is neither a fungicide, nor is the fruiting body the propagating material. Furthermore, and to the knowledge of zRMS no guidance exists which would stipulate collecting data on condition of mycelium following application of insecticides to the substrate.

3.5 Observations on other undesirable or unintended side-effects

3.5.1 Impact on succeeding crops

Not applicable.

Comments of zRMS:

Accepted within the efficacy context and as pertaining exclusively to the authorization options of the claimed use. Nonetheless, the issue should be addressed by the applicant and then be evaluated by other sections, namely Fate and Behavior and Residues, which may express their view depending on the intended use of the spent substrate that had been previously treated with the test item.

3.5.2 Impact on other plants including adjacent crops

Not applicable.

Comments of zRMS: Accepted.

3.5.3 Effects on beneficial and other non-target organisms

An adverse impact on beneficial organisms was not observed in the course of efficacy experiments. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

Comments of zRMS: Accepted.

3.6 Other/special studies

Not applicable.

Comments of zRMS: Noted.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
Institute of Horticulture – National Research Institute, Horticultural Plant Cultivation and Fertilization Facility, Laboratory Cultivation of Vegetables and Edible Mushrooms.	Rybickiego 15/17, 96-100 Skierniewice	No 8/2022

Appendix 1: List of data submitted in support of the evaluation

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
6.2 6.4.2	Szumigaj-Tarnowska J.	2022	Ocena skuteczności biologicznej preparatów Pyrix 20 SL i Pyrix 100 EC (piryproksyfen) w zwalczaniu muchówek (Sciaridae) w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL and Pyrix 100 EC (pyriproxyfen) in the control of flies (Sciaridae) in the mushrooms cultivation *Agaricus bisporus.* Trial No. ZBZNBH/12/2022/1/I Institute of Horticulture – National Research Institute GEP – yes Unpublished	Y	Agrofarm Sp. z o.o.
6.2 6.4.2	Szumigaj-Tarnowska J.	2022	Ocena skuteczności biologicznej preparatów Pyrix 20 SL i Pyrix 100 EC (piryproksyfen) w zwalczaniu muchówek (Sciaridae) w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL and Pyrix 100 EC (pyriproxyfen) in the control of flies (Sciaridae) in the mushrooms cultivation *Agaricus bisporus.* Trial No. ZBZNBH/12/2022/1/II Institute of Horticulture – National Research Institute GEP – yes Unpublished	Y	Agrofarm Sp. z o.o.
6.2 6.4.2	Szumigaj-Tarnowska J.	2023	Ocena skuteczności biologicznej preparatów Pyrix 20 SL (piryproksyfen) w zwalczaniu muchówek w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL (pyriproxyfen) in the control of flies in the mushroom cultivation *Agaricus bisporus*. Trial No. ZBZNBH/4/2023/1/I Seria 1; Seria 2 Institute of Horticulture – National Research Institute GEP – yes Unpublished	Y	Agrofarm Sp. z o.o.
6.2 6.4.2	Szumigaj-Tarnowska J.	2023	Ocena skuteczności biologicznej preparatów Pyrix 20 SL (piryproksyfen) w zwalczaniu muchówek w uprawie pieczarki *Agaricus bisporus* Evaluation of the biological effectiveness of Pyrix 20 SL (pyriproxyfen) in the control of flies in the mushroom cultivation *Agaricus bisporus*. Trial No. ZBZNBH/4/2023/2/I Institute of Horticulture – National Research Institute GEP – yes Unpublished	Y	Agrofarm Sp. z o.o.
6.2 6.4.2	Szumigaj-Tarnowska J.	2024	Ocena skuteczności biologicznej preparatów Pyrix 20 SL (piryproksyfen) w zwalczaniu muchówek w uprawie pieczarki *Agaricus bisporus*	Y	Agrofarm Sp. z o.o.

			Evaluation of the biological effectiveness of Pyrix 20 SL (pyriproxyfen) in the control of flies in the mushroom cultivation *Agaricus bisporus*. Trial No. ZBZNBH/4/2024/1/I Seria 1; Seria 2 Institute of Horticulture – National Research Institute GEP – yes Unpublished		