REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product name(s): Pyrix 20 SL

Chemical active substance(s):

Pyriproxyfen 20 g/L

Central Zone

Zonal Rapporteur Member State: Poland

Applicant: AGROFARM SP Z O.O.

Submission date: November 2025

MS Finalisation date: July 2026 (initial Core Assessment)

September 2026 (final Core Assessment)

Version history

When	What
July 2025	Initial dRR – Agrofarm Sp. z o.o.
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.
September 2026	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

Table of Contents

0 Product background, regulatory context and GAP information 4
0.1 Introduction 4
0.1.1 Reason for application 4
0.1.2 Details of zRMS(s) and concerned MS 4
0.1.3 Regulatory history of the active(s) 4
0.1.3.1 Active substance Pyriproxyfen 4
0.1.4 Regulatory history of the product (if relevant) 5
0.2 zRMS conclusion 5

Appendix 1 ALL intended uses 7

0 Product background, regulatory context and GAP information

0.1 Introduction

This document presents the regulations and basic information for pyriproxyfen and the plant protection product Pyrix 20 SL for the purpose of its registration under Article 33 of Regulation 1907/2006.

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	Not relevant	Not applicable
Central zone	Not relevant	Not applicable
Southern zone	Not relevant	Not applicable
Inter-zonal	Not relevant	Not applicable

0.1.3 Regulatory history of the active(s)

0.1.3.1 Active substance Pyriproxyfen

Table 0.1-2: Summary of regulatory history of CAS No: 95737-68-1

Status	
Approved in EU	YES
Original Inclusion Directive or Commission Implementing Regulation	Old legislation: Dir 2010/39/EU Reg.(EU)2018/1796; Reg.(EU)2019/1589 Legislation: Reg. (EU) No 540/2011 Reg. (EU) 2020/968
RMS	ES/ BE. RMS responsible for the last approval: NL
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	Date of approval 01/01/2009 Date of most recent renewal: 01.10.2020 Date of Regulation to be applied: 01.10.2020
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	N/A
Date of final Commission (re-registration) deadline (Step 2)	N/A
Current expiration of approval	Expiration of approval : 31/07/2035
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.
In this overall assessment Member States must pay particular attention to:

In this overall assessment Member States shall pay particular attention to:

— the dietary exposure of consumers to residues of pyriproxyfen,
— the protection of sediment-dwelling organisms and aquatic organisms,
— the protection of bees.

As regards the protection of sediment-dwelling organisms and aquatic organisms, for outdoor use of the plant protection products containing pyriproxyfen Member States shall include in the specific conditions appropriate risk mitigation measures, e.g. no-spray buffer zones and/or spray drift reduction, to achieve a low risk for sediment-dwelling organisms and aquatic organisms.

As regards the protection of bees, for outdoor use of plant protection products containing pyriproxyfen Member States shall include in the specific conditions a restriction of application to periods outside of the flowering of bee attractive crops, and appropriate risk mitigation measures, e.g. no-spray buffer zones and/or spray drift reduction, to achieve a low risk for bees and bee larvae.

The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water is abstracted for drinking water.
The applicant shall submit the requested confirmatory information within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

Final Renewal report for the active substance Pyriproxyfen Finalised by the Standing Committee on Plants, Animals, Food and Feed on 19 May 2020 - **Pyriproxyfen SANTE/11426/2019, Rev 2** and EFSA Scientific Report - **EFSA Journal 2019; 17(7): 5732** are considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Table 0.1-3: Information on minimum purity of active substance Pyriproxyfen

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity 970 g/kg.	Agrofarm Sp. z o.o. has data access to Pyriproxyfen active concentrate which has been approved at the EU level[1]

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).
** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

1) See PART C- Confidential Information:

- Letter of Supply and data Access to Pyriproxyfen active concentrate Issued to Agrofarm Sp. z o.o., Dzika 41/48, 00-194 Warszawa, Poland – 14 October 2025.
- Letter form EU DG-Animals, Plants and Food Plant Protection Product and Fertilisers: Evaluation of the equivalence of new source of the active substance pyriproxyfen. Ref.:41.500/16/256945 ; 01-08-2016.

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 1, date: 2026-07 ~~2025-07-10~~

PPP (product name/code):	PYRIX 20 SL	Formulation type:	SL
Active substance 1:	pyriproxyfen	Conc. of as 1:	20 g/L
Safener:	No	Conc. of safener:	n.a.
Synergist:	No	Conc. of synergist:	n.a.
Applicant:	Agrofarm Sp. z o.o.	Professional use:	☒
Zone(s):	Climatic zone: Northern / authorization zone: Central	Non professional use:	☐
Verified by MS:	No		
Field of use:	Insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
Use-No. (e)	**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 (f)	**zRMS Conclusions**							
					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			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Climatic zone: Northern/authorization zone: Central (use in greenhouses or other closed places of plant production)																						
1	PL~~/ Climatic zone: Northern~~	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/m2 b) 15 ml/m2 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	n.a.		A	R	A	R	A	A	A	A

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when 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
15 zRMS conclusions*

* Explanation for column 15 “Overall conclusions”

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