REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

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.-Poland

Submission date: 7 November 2025

MS Finalisation date: July 2026 (initial Core Assessment)

September 2026 (final Core Assessment)

Version history

When	What
07.11.2025	Initial version prepared by the Applicant.
July 2026	Initial zRMS assessment The report in the dRR format was prepared by the Applicant; therefore, all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes have been introduced directly into the text and highlighted in grey. Information that is not agreed or not relevant is ~~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.

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Reviewer comments:

This part of dossier has been submitted to support registration of the plant protection product Pyrix 20SL according art. 33 of 1107/2009.

Since the product Pyrix 20SL is intended for application in closed buildings, the groundwater exposure assessment is considered not relevant in accordance with the EFSA Journal (2014;12(3):3615) Therefore, groundwater exposure to the active substance pyripoxyfen and its metabolites is not expected, and the metabolites are not of concern with respect to groundwater leaching (see dRR, Section B.8).

The information presented in dRR Part B10 has been reviewed for the purposes of ongoing registration and also checked its compliance with the current guidelines. Information has been considered as sufficient and appropriate for concluding.

Explanation

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 and any metabolites being released into the environment and having an impact on the environment, especially for groundwater.
In fact, Polish regulations require that wastes be collected and disposed in an appropriate manner such that no residues can enter the soil, the drainage water and/or the sewage systems. Under Polish regulations, such wastes include any solid waste such as used soil and compost, and liquid waste such as water used to clean chambers. Such wastes must be disposed of by an authorised waste management company or a wastewater treatment system.
No need for an risk assessment for groundwater:

- **no soil contamination, as spent substrate is classified as waste and must be disposed of properly under Polish law.**
- **no drainage or leaching pathways from shelves to soil or groundwater,**

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

10 Relevance of metabolites in groundwater

10.1 General information

NOT APPLICABLE.

10.2 Relevance assessment of metabolite 1

NOT APPLICABLE.

10.2.1 STEP 1: Exclusion of degradation products of no concern

NOT APPLICABLE.

10.2.2 STEP 2: Quantification of potential groundwater contamination

NOT APPLICABLE.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

NOT APPLICABLE.

10.2.3.1 STEP 3, Stage 1: screening for biological activity

NOT APPLICABLE.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

NOT APPLICABLE.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

NOT APPLICABLE.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

NOT APPLICABLE.

10.2.5 STEP 5: Refined risk assessment

NOT APPLICABLE.

10.3 Relevance assessment of metabolite 2

NOT APPLICABLE.

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 points this Section 10 Relevance of metabolites in groundwater	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

NOT APPLICABLE.

List of data submitted by the applicant and not relied on

NOT APPLICABLE.

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

NOT APPLICABLE.

Appendix 2 Additional information

NOT APPLICABLE.