

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: FGF11

Product name(s): Telaron Alpha / Patton Alpha
Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC

Chemical active substance(s):

Azoxystrobin, 160 g/L

Prothioconazole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT/

(new authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024

MS Finalisation date: March 2025 (initial Core Assessment)

August 2025 (final Core Assessment)

Version history

When	What
November 2024	dRR Part B – Section 10; Version 1 submitted by applicant
March 2025	Initial assessment by the 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 are ~~struck through~~ and shaded for transparency.
August 2025	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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10 Relevance of metabolites in groundwater

Reviewer comments:

This part of dossier has been submitted to support registration of the plant protection product FGF11 according art. 33 of 1107/2009.mDocument refers data related to the forming of metabolites in the environment (for details see dRR B8):

Input parameters for azoxystrobin and its metabolites presented in dRR B8 and used in the modelling are in line with EU agreed endpoints as reported in EFSA Journal 2010; 8(4):1542 and in Addendum with confirmatory data for azoxystrobin (September, 2014).

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2023).

The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06.

In line with information presented in Addendum with confirmatory data for azoxystrobin (September, 2014) the degradation of azoxystrobin was modelled using two separate simulations. The first simulations assumed that azoxystrobin degraded via microbial degradation to R234886, whilst the second assumed that azoxystrobin degraded due to photolysis to form metabolites: R401553 and R402173 (subsequently degrading to R401553).

Obtained results from zRMS modelling were in good agreement with these derived by the Applicant for azoxystrobin and its metabolites presented in Table 8.8-4 to 8.8-7. Performed simulations indicate that unacceptable leaching of azoxystrobin and its metabolites R401553 and R402173 is expected following application of FGF11 according to the intended use pattern.

The PEC_{gw} values for metabolite R234886 in acidic soils were <0.1 µg/L in all scenarios and crops.

The PEC_{gw} values for metabolite R234886 in alkaline soils were above 0.1 µg/L, with the maximum value of 0.138 µg/L in the Hamburg scenario (PEARL model) following application to spring cereals at BBCH 30-69. According to EFSA Journal 2010; 8(4):1542 metabolite R234886 is toxicologically not relevant. Since PEC_{GW} values do not exceeded the threshold concentration of 0.75 µg/L for non-relevant metabolites, no further assessment is thus necessary.

Overall, no unacceptable leaching of azoxystrobin and its metabolites is expected following application of FGF11 according to the intended use pattern.

Input parameters for prothioconazole and its metabolites presented in the dRR B8 and used in the modelling are in general in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 106.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2023). The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06.

Obtained results were in good agreement with these derived by the Applicant for prothioconazole and its metabolites presented in Table 8.8-9 to 8.8-12.

Overall, no unacceptable leaching of prothioconazole and its metabolites is expected following application of FGF11 according to the intended use pattern.

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 (see point 10.1) and appropriate for concluding.

10.1 General information

The metabolite R234886 of azoxystrobin is predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B8, section 8.8.2). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is therefore required.

General information on the metabolite is provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

The following metabolites have been considered for PEC_{GW} risk assessment:

Metabolites of azoxystrobin potentially relevant for exposure assessment

Metabolite	Molar mass [g/mol]	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
R401553	213.2		Soil: >10 % of a.s.	PEC _{GW} , PEC _{SOIL} , PEC _{SW/SED}
R402173	333.3		Soil: >10 % of a.s.	PEC _{GW} , PEC _{SOIL} , PEC _{SW/SED}
R234886	389.4		Soil: >10 % of a.s. Water/Sediment: >10 % of a.s.	PEC _{GW} , PEC _{SOIL} , PEC _{SW/SED}

The metabolite R234886 of azoxystrobin is predicted to occur in groundwater at concentrations above 0.1 µg/L when the product is applied to alkaline soils (see dRR Part B, Section 8.8.2).

With FOCUS PEARL 5.5.5, the PEC_{GW} for R234886 are above 0.1 µg/L for spring and winter cereals, with application from BBCH 30 to BBCH 69, for the Hamburg scenario. The PEC_{GW} is above 0.1 µg/L for winter oilseed rape at BBCH 61 for the Hamburg scenario.

With FOCUS PELMO 6.6.4, the PEC_{GW} for R234886 are above 0.1 µg/L for spring and winter cereals, with application from BBCH 30 to BBCH 69, for the Hamburg scenario. The PEC_{GW} are above 0.1 µg/L for spring oilseed rape at BBCH 61 for the Okehampton scenario, and for winter oilseed rape at BBCH 61 for the Hamburg, Okehampton and Porto scenarios.

With FOCUS MACRO 5.5.4, no PEC_{GW} above 0.1 µg/L were observed.

The PEC_{GW} of the other metabolites of azoxystrobin did not exceed 0.1 µg/L in any scenario for any use.

Metabolites of prothioconazole potentially relevant for exposure assessment

Metabolite	Molar mass [g/mol]	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
JAU 6476-S-methyl (M01)	358.3		Soil: >10 % of a.s. Water/Sediment: >10 %	PEC _{GW} , PEC _{SOIL} , PEC _{SW/SED}
JAU 6476-desthio (M04)	312.2		Soil: >10 % of a.s. Water/Sediment: >10 %	PEC _{GW} , PEC _{SOIL} , PEC _{SW/SED}

For the metabolites of prothioconazole, all PEC_{GW} were $< 0.001 \mu\text{g/L}$ for all uses and all scenarios. Therefore, no exceedances were observed.

Summary of maximum PEC_{GW} for azoxystrobin metabolite R234886

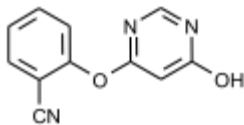
Substance	80 th Percentile PEC_{GW} ($\mu\text{g/L}$)	Crop	Application rate (g a.s./ha)	BBCH code	Model and Version Number	Scenario
R234886 (alkaline)	0.138	Spring Cereals	1×160	30	PEARL 5.5.5	Hamburg

Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.11 is therefore required.

No other metabolites of azoxystrobin or prothioconazole are predicted to occur in groundwater at concentrations above $0.1 \mu\text{g/L}$ for the uses under consideration.

General information on the metabolite is provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

Table 10.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Azoxystrobin	R234886		Max PEC_{gw} Based on:	$0.138 \mu\text{g/L}$ PEARL 5.5.5, Hamburg scenario (alkaline substance inputs) Spring Cereals, $1 \times 160 \text{ g a.s./ha}$ from BBCH 30

10.2 Relevance assessment of R234886

Summary:

The relevance of the groundwater metabolite R234886 has already been assessed and the assessment agreed at EU level (see **Azoxystrobin, EFSA Journal 2010; 8(4):1542** and **Addendum, EC, 2014**), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). R234886 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.11. A summary of the relevance assessment is given in Table 10.2-1 and the corresponding studies are listed in the corresponding sections.

Table 10.2-1: Summary of the relevance assessment for R234886

	Assessment step	Result of assessment	
	STEP 1	Metabolite of no concern?	No
Q u a n t i f i	STEP 2	Max PEC_{gw}	$0.138 \mu\text{g/L}$

			Based on	PEARL 5.5.5, Hamburg scenario (alkaline substance inputs) Spring Cereals, 1×160 g a.s/ha from BBCH 30
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Acute Tox. Cat.3, H331 Toxic if inhaled
			Classification of metabolite	N/A
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable (<0.75 µg/L and below 0.02 µg/kg body weight/day)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
			ADI based on	N/A*

* N/A: not applicable

10.2.1 STEP 1: Exclusion of degradation products of no concern

R234886 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.2.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for R234886 were performed (see Part B, Section 8, chapter 8.8.2). The uses for which concentrations of R234886 were considered to exceed 0.1 µg/L are listed in Table 10.2-1. Details are given in Part B, Section 8, chapter 8.8.2.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Data from the document “**Azoxystrobin – Volume 3, Annex B.6: Toxicology and Metabolism**”, May 2009 - B6.8.1.3 Groundwater relevance assessment of R234886

The notifier has presented a study (Grayson & Schneider 2008 - TMJ/5077B) comparing the fungicidal activity of azoxystrobin and R234886. The test organisms were *Phytophthora infestans* (late blight - test crop potato); *Puccinia recondita* (brown rust - test crop wheat); *Cercospora arachidicola* (early leaf spot - test crop peanut); & *Alternaria solani* (early blight - test crop tomato).

Azoxystrobin gave good control (>60% control at 2ppm) against *Phytophthora infestans*, *Puccinia recondita* & *Alternaria solani*; R234886 gave zero control against these species at 2 - 6ppm. Against *Cercospora arachidicola* azoxystrobin surprisingly gave minimal control (<10%) and R234886 gave 3.1% control - the commercial control of difenoconazole gave >90% control at 0.6 ppm.

These results show R234886 has no significant fungicidal activity against the four species tested.

For the non-relevance assessment of the groundwater metabolite R234886 reference is made to the EFSA Conclusion (EFSA Journal 2010; 8(4):1542).

Moreover, an addendum to the DAR (**Confirmatory Information – Azoxystrobin, December 2014**) provided an assessment of the relevance of R234886:

“An assessment of the relevance of R234886 in groundwater is presented in Davies (2011), submitted for this confirmatory data assessment. This assessment (following the stepwise relevance assessment approach but using an incorrect maximum PEC_{gw} value) has not been presented as part of this confirmatory data evaluation since the PEC_{gw} values calculated are below those considered during the renewal assessment (maximum of 4.10 vs 22 µg/L), whereby R234886 was considered to be not-relevant. No new data or information were submitted as part of the confirmatory data submission therefore the conclusions from the review are unchanged and metabolite **R234886 is considered not relevant at the levels predicted to occur in groundwater.**”

This conclusion was confirmed by the EFSA technical reports (**Outcome of the consultation with Member States, applicant and EFSA on the pesticide risk assessment of confirmatory data for the active substance azoxystrobin**, EFSA supporting publication 014:EN-718)

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS' assessment of confirmatory data
4(15)	Addendum-confirmatory information, B.8.8.5.1 groundwater, pages 39 and 70.	EFSA: A reference is made to Davies (2011) an assessment of the relevance of R234886 in groundwater, having been submitted. An assessment of what was contained in this report is not presented? Though this may not be an issue because (as indicated by the RMS), R234886 was already concluded as being a non relevant groundwater metabolite in the EFSA conclusion, when exposure estimates in groundwater were higher at up to 22µg/L. However at the very least, the RMS should have given a brief outline of what was included in this report and confirmed that it did not contain any adverse information or important additional information, to that which had already been used to conclude on the groundwater non relevance of R234886 in the EFSA conclusion.	RMS: Noted. Text has been added to a revised Addendum dated November 2014 to explain the relevance of the metabolite. The assessment presented in Davies 2011 has not been presented in in the confirmatory data evaluation since the PEC _{gw} values calculated are below those considered during the renewal assessment (maximum of 4.10 vs 22 µg/L), whereby R234886 was considered to be not-relevant. No new data were submitted as part of the confirmatory data submission therefore the conclusions from the review are unchanged and metabolite R234886 is considered not relevant at the levels predicted to occur in groundwater.	Addressed

R234886 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

The biological activity of R234886 does not have comparable target activity as the parent active compound as shown in biological screening data. R234886 is considered not relevant and is further evaluated in Stage 2 / relevant.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

R234886 is considered not relevant and is further evaluated in Stage 3.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

The parent, azoxystrobin, to R234886 is classified as acutely toxic (classification in accordance to CLP 1272/2008). R234886 has not been tested for acute toxicity. R234886 is considered not relevant and is further evaluated in Step 4.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

The PEC_{gw} for R234886 was < 0.75 µg/L. There is no consumer exposure via other routes. R234886 is not considered to exceed the toxicological threshold of concern as defined in EC guidance document

SANCO/221/2000 –rev.10.

PEC: 0.138 µg/L

Water consumption: 2.0 L/day

Body weight: 60 kg (adult)

Calculation:

$0.138 \times 2/60 = 0.0046 \text{ µg/kg body weight/day}$

A further assessment in Step 5 is not required.

10.2.5 STEP 5: Refined risk assessment

R234886 has a $PEC_{gw} < 0.75 \text{ µg/L}$ and the threshold of concern approach in Step 4 is acceptable. No refined assessment of the potential toxicological significance including the selected ADI is required.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4.1/01	Worthington, M.	2024a	Azoxystrobin – A leaching assessment for azoxystrobin and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe. Company report No.: S24-101230-02-002 Eurofins Agrosience Services Regulatory GmbH Eutinger Strasse 24, 75223 Niefern, Germany non GLP Unpublished	N	UPL Europe
KCP 9.2.4.1/02	Worthington, M.	2024b	Prothioconazole – A leaching assessment for prothioconazole and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe Company report No.: S24-101230-02-003 Eurofins Agrosience Services Regulatory GmbH Eutinger Strasse 24, 75223 Niefern, Germany non GLP Unpublished	N	UPL Europe

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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
-	-	-	-	-	-

Appendix 2 Additional information

No additional information.

Comments of zRMS:	No further comments.
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