REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: GF-3308

Product name(s): Questar

Chemical active substance:

Fenpicoxamid (XDE-777), 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Corteva AgriScience

Submission date: August 2021

MS Finalisation date: April 2022 (initial Core Assessment)

October 2022 (final Core Assessment)

Version history

When	What
August 2021	Applicant initial dRR
April 2022	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~~.
October 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

Table of Contents

0 Product background, regulatory context and GAP information

0.1 Introduction

The application is made to fulfil the requirements of Article 29 of Regulation (EC) No 1107/2009 for the authorization of the product GF-3308. This is a new product submission in the Central zone.

This document describes the product background, regulatory context and GAP information required for the registration of GF-3308 containing 50 g/L of Fenpicoxamid.

0.1.1 Reason for application

This draft Registration Report (dRR) supports an application for the new product authorisation in the Central Zone, with Poland as the Rapporteur Member State. The product (development code GF-3308) is an emulsifiable concentrate (EC) containing Fenpicoxamid (50 g/L) as the active substance. The product is intended for use by professional users only to control cereal diseases.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.
Full data package was submitted by Corteva Agriscience.

0.1.2 Details of zRMS(s) and concerned MS

This is a new product submission with Poland as zRMS for CZ. Earlier submissions have been made in SZ and NZ. The concerned MSs are listed below in Table 0.1-1.

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	zRMS - Denmark Product code – GF-3308 Authorisation number – N/A	cMS1 – Estonia Authorisation number – N/A cMS2 – Latvia Authorisation number - N/A cMS3 – Lithuania Authorisation number - N/A cMS4 – Finland Authorisation number - N/A cMS5 – Sweden Authorisation number - N/A cMS6 – Norway Authorization number – N/A
Central zone	zRMS – Poland Product code – GF-3308 Authorisation number – N/A	cMS1 – Czech Republic Authorization number – N/A cMS2 – Slovakia Authorisation number - N/A cMS3 – Romania Authorisation number - N/A cMS4 – Austria Authorisation number - N/A
Southern zone	zRMS – France Product code – GF-3308 Authorisation number – 2200066	cMS1 – Croatia Authorisation number - N/A cMS2 – Bulgaria Authorization number – N/A cMS3 – Spain Authorization number – N/A cMS4 – Portugal

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
		Authorization number – N/A cMS5 – Italy Authorization number – N/A cMS6 – Greece Authorization number – N/A
Inter-zonal	Not applicable.	Not applicable.

0.1.3 Regulatory history of the active(s)

0.1.3.1 Fenpicoxamid

Table 0.1-2: Summary of regulatory history of CAS No: 517875-34-2

Status	
Approved in EU	Yes
Commission Implementing Regulation	2018/1265
RMS	UK (coRMS: France)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	11 October 2018
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	Not applicable
Date of final Commission (re-registration) deadline (Step 2)	Not applicable
Current expiration of approval	11 October 2028
Low risk substance or Candidate for Substitution?	Not applicable

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:

- the impact of processing on the consumer risk assessment,
- the protection of aquatic organisms.

The SANTE report for Fenpicoxamid was made available on 20 July 2018 (SANTE/10319/2018 Rev. 2). An EFSA Scientific Report was made available on 31 January 2018 (EFSA Journal 2018;16(1): 5146).

Table 0.1-3: Information on minimum purity of Fenpicoxamid

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 *, **
> 750 g/kg	Not Applicable

* 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.

EU agreed endpoints were used in the evaluation.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised in Poland.
The product has not been evaluated as the representative formulation.

0.2 zRMS conclusion

Authorisation of the product GF-3308 / Questar is recommended to the control of Zymoseptoria tritici, Puccinia recondita, Puccinia striiformis in wheat; Septoria spp., Puccinia striiformis in triticale and Rhynchosporium secalis, Puccinia recondita in rye. For some uses, due to no or limited efficacy data, Member States will need to make their own decision based on the available efficacy data and extrapolation possibility according to their national requirements.

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. 01, date: October 2022 ~~April 2021~~

PPP (product name/code):	GF-3308	Formulation type:	EC [a, b]
Active substance 1:	Fenpicoxamid	Conc. of as 1:	50 g/L [c]
Safener:	Not Applicable	Conc. of safener:	Not Applicable [c]
Synergist:	Not Applicable	Conc. of synergist:	Not Applicable [c]
Applicant:	Corteva Agriscience	Professional use:	☒
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes ~~no~~		
Field of use:	fungicide		

	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, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	**zRMS Conclusion**							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg ai/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 & bevaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP)	F	*Zymoseptoria tritici* (SEPTTR) *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) -100 fenpicoxamid b) -100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed. Lower doses to be used when lower disease pressure	A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios	A	A TRZAW Range 1.5-2.0 L/ha accepted for SEPTTR. Lower dose rate of 1,5 L/ha recommended under low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCST

																		R Bees A Remaining species		and PUCCRT. N TRZDU, TRZSP (possible registration under art. 51)
2	PL,	Winter triticale (TTLWI)	F	~~*Septoria* spp. (SEPTSP)~~ *Zymoseptoria tritici* (SEPTTR) *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) -100 fenpicoxamid b) -100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed. Lower doses to be used when lower disease pressure	A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	A Range 1.5-2.0 L/ha accepted for SEPTTR. Lower dose rate of 1,5 L/ha recommended under low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCST.
3	PL	Winter rye (SECCW)	F	*Rhynchosporium secalis* (RHYNSE) *Puccinia recondit*a (PUCCRE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) -100 fenpicoxamid b) -100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed. Lower doses to be used when lower disease pressure	A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	A Range 1.5-2.0 L/ha accepted for RHYNSE. Lower dose rate of 1,5 L/ha recommended under low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCRE.
4	PL	Spring wheat (TRZAS)	F	*Zymoseptoria tritici* (SEPTTR) *Puccinia recondita* (PUCCRT), *Puccinia striiformis*	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) -100 fenpicoxamid b) -100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed. Lower doses to be used when lower disease	A	A	R Operator PPE	A	A	N Aquatics R4	A	A SEPTTR, PUCCST Range 1.5-2.0 L/ha accepted for SEPTTR. Lower dose rate of 1,5 L/ha

				(PUCCST)									pressure			A Worker B&R			R Aquatics remaining scenarios R Bees A Remaining species		recommended under low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCST N PUCCRT
5	PL	Spring triticale (TTLSO)	F	*Septoria* spp. (SEPTSP) *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) -100 fenpicoxamid b) -100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed. Lower doses to be used when lower disease pressure	A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	N (possible registration of PUCCST under art. 51)
6	PL	Spring rye (SECCS)	F	*Rhynchosporium secalis* (RHYNSE) *Puccinia recondita* (PUCCRE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) -100 fenpicoxamid b) -100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed. Lower doses to be used when lower disease pressure	A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	N (possible registration under art. 51)
7	AT, CZ	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A	A	R Operator PPE	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees	A	A TRZAW (AT, CZ), TRZDU (CZ), TRZSP (CZ) C

															A Worker B&R			A Remaining species		TRZDU (AT), TRZSP (AT)
8	AT, CZ	Winter triticale (TTLWI)	F	*Septoria* spp. (SEPTSP) *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	A
9	AT, CZ	Winter rye (SECCW)	F	*Puccinia recondita* (PUCCRE) *Rhynchosporium secalis* (RHYNSE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	A
10	AT, CZ	Spring wheat (TRZAS)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	C
11	AT, CZ	Spring triticale	F	*Septoria* spp. (SEPTSP)	Tractor mounted	BBCH 30-69	a) 1	~~14~~	a) 2.0 L/ha	a) 100 fenpicoxamid	100-300	PHI F		A	A	R Operator	A	A	N Aquatics R4	A	C

		(TTLSO)		*Puccinia striiformis* (PUCCST)	spray		b) 1		b) 2.0 L/ha	b) 100 fenpicoxamid						PPE A Worker B&R			R Aquatics remaining scenarios R Bees A Remaining species		
12	AT, CZ	Spring rye (SECCS)	F	*Puccinia recondita* (PUCCRE) *Rhynchosporium secalis* (RHYNSE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	C
13	SK, RO	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Dose range proposed from 1.2-2.0 L/ha for SEPTTR. 1.5-2.0 L/ha for PUCCST and PUCCRT. Lower doses to be used when lower disease pressure	A	A	R Operator PPE A Worker B&R	A	A	N Aquatics R4 R Aquatics remaining scenarios R Bees A Remaining species	A	A TRZAW C TRZDU, TRZSP
14	SK, RO	Spring wheat (TRZAS)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia*	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Dose range proposed from 1.2-2.0 L/ha for SEPTTR. 1.5-2.0 L/ha for	A	A	R Operator PPE	A	A	N Aquatics R4 R Aquatics remaining scenarios	A	C

				striiformis (PUCCST)								PUCCST and PUCCRT. Lower doses to be used when lower disease pressure			A Worker B&R			R Bees A Remaining species		

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-pro fessional 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, Black well, 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
F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).
14 Remarks may include: Extent of use/economic importance/restrictions
15 Overall conclusions - explanation for the column 15 is below*

Column 15: zRMS conclusion.

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