

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: GF-3307 (S7K-3-3)

Product name(s): QUEEN

Chemical active substances:

Fenpicoxamid (XDE-777), 50 g/L

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(extension of use)

Applicant: Corteva Agriscience

Submission date: March 2025, update June 2025, July 2025

MS Finalisation date: August 2025 (initial Core Assessment),

March 2026 (final Core Assessment)

Version history

When	What
March 2025	Submission of GF-3307 (S7K-3-3) Sugar beet/Fodder beet Extension of Use in the Central Zone – Corteva Agriscience
June 2025	GAP table updated as per zRMS request – amendments highlighted in turquoise – Corteva Agriscience
July 2025	GAP update – change in the number of applications per use - change indicated by the applicant in response to the email – E-V-A
August 2025	<p>Initial zRMS assessment</p> <p>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.</p> <p>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.</p>
March 2026	<p>Final report (Core Assessment updated following the commenting period)</p> <p>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. Not agreed or not relevant information are struck through and shaded for transparency.</p>

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)	5
0.1.3.1	Fenpicoxamid	5
0.1.3.2	Prothioconazole	5
0.1.4	Regulatory history of the product	7
0.2	zRMS conclusion.....	8
Appendix 1	ALL intended uses	9

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-3307 on sugar beet/fodder beet in the Central zone.

This document describes the product background, regulatory context and GAP information required for the registration of GF-3307 containing 50 g/L of Fenpicoxamid, 100 g/L of Prothioconazole.

0.1.1 Reason for application

This draft Registration Report (dRR) supports an application for the extension of use in the Central Zone, with Poland as the Rapporteur Member State. The product (development code GF-3307, new code S7K-3-3) is an emulsifiable concentrate (EC) containing Fenpicoxamid (50 g/L) and Prothioconazole (100 g/L) as the active substances. The product is intended for use by professional users only to control sugar beet/fodder beet diseases.

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

In addition to the submission of studies as listed in sections B1 to 10, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009 for prothioconazole. Letter of Access is provided and relevant studies are highlighted accordingly in the sections appendix 1.

0.1.2 Details of zRMS(s) and concerned MS

This is a label extension submission with Poland as zRMS. 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	N/A for this label extension dossier	N/A for this label extension dossier
Central zone	<u>zRMS – Poland</u> Product code – GF-3307 Authorisation number - R-140/2023	<u>cMS1 – Belgium</u> Authorization number – 11179P/B <u>cMS2 – Czech Republic</u> Authorization number – 5977-0 <u>cMS3 – Austria</u> Authorization number – 4340-0 <u>cMS4 – Netherlands</u> Authorization number – 16560N <u>cMS5 – Hungary</u> Authorization number – 6300/2610-1/2022 <u>cMS6 – Romania</u> Authorization number – 970PC <u>cMS7 – Slovakia</u> Authorization number – 24-01735-AU
Southern zone	<u>zRMS – France</u> Product code – GF-3307 Authorisation number - 2210013	<u>cMS1 – Italy</u> Authorization number – 18181 and clone registrations 18525, 18526 <u>cMS2 – Spain</u> Authorization number – ES-01386
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	Commission Implementing Regulation (EU) No 2018/1265
RMS	UK (co-RMS: France) for first approval, SE (co-RMS : BG) for renewal
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 risk to 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 2018.¹

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.

0.1.3.2 Prothioconazole

Table 0.1-4: Summary of regulatory history of CAS No: 178928-70-6

Status	
Approved in EU	Yes
Original Inclusion Directive Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, amended by Reg. (EU) No 2019/707 of 7 May 2019
RMS	PL (co-RMS: France)

¹ EFSA Journal 2018;16(1):5146

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01 August 2008
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	Deadline for Article 43 not yet known (Active renewal ongoing)
Date of final Commission (re-registration) deadline (Step 2)	N/A (Active renewal ongoing)
Current expiration of approval	15.08.2025 (Reg. (EU) No 2023/918)
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 operator safety in spray applications. Conditions of use should include adequate protective measures.
- The protection of aquatic organisms. Risk mitigation measures such as buffer zones should be applied, where appropriate.
- The protection of birds and small mammals. Risk mitigation measures should be applied, where appropriate.

The SANCO report for Prothioconazole (SANCO/3923 /07 – 10/12/2007) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 12/07/2007².

² EFSA Scientific Report (2007) 106, 1-98

Table 0.1-5: Information on minimum purity of Prothioconazole

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 *, **
> 970 g/kg	N/A Annex I source

* 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

The product has not been evaluated as the representative formulation.

GF-3307 (S7K-3-3) has been approved in Poland on 11th September, 2023. Authorization number is R-140/2023 and product name, QUEEN.

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-6: Summary of regulatory history of the product GF-3307.

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
GF-3307 (S7K-3-3)	Univoq	FR	2210013	14/04/2021	N/A
GF-3307 (S7K-3-3)	Univoq	HR	UP/I-320-20/19-03/29	21/03/2022	N/A
GF-3307 (S7K-3-3)	Univoq	BG	11-1586	25/10/2021	N/A
GF-3307 (S7K-3-3)	Univoq	EL	61051	20/12/2021	N/A
GF-3307 (S7K-3-3)	Univoq	CY	3928	24/01/2022	N/A
GF-3307 (S7K-3-3)	Univoq	ES	ES-01386	01/07/2022	N/A
GF-3307 (S7K-3-3)	Univoq	IT	18181 and clone registrations 18525, 18526	08/03/2023	N/A
GF-3307 (S7K-3-3)	Univoq	AT	4340-0	27/12/2021	N/A
GF-3307 (S7K-3-3)	Univoq	BE	11179P/B	19/11/2021	N/A
GF-3307 (S7K-3-3)	Univoq	LU	L02384-066	23/07/2021	N/A
GF-3307 (S7K-3-3)	Univoq	DE	00A278-00	22/02/2022	N/A
GF-3307 (S7K-3-3)	Univoq	IE	PCS 06462	26/10/2022	N/A
GF-3307 (S7K-3-3)	Queen	HU	6300/2610-1/2022	18/10/2022	N/A
GF-3307 (S7K-3-3)	Queen	NL	16560N	26/07/2023	N/A
GF-3307 (S7K-3-3)	Queen	PL	R-140/2023	11/09/2023	N/A
GF-3307 (S7K-3-3)	Queen	CZ	5977-0	10/01/2024	N/A
GF-3307 (S7K-3-3)	Queen	SK	24-01735-AU	16/02/2024	N/A
GF-3307 (S7K-3-3)	Univoq	LT	AS2-13F	15/03/2023	N/A
GF-3307 (S7K-3-3)	Univoq	SE	5954	14/03/2024	N/A
GF-3307 (S7K-3-3)	Univoq	LV	0888	24/05/2024	N/A
GF-3307 (S7K-3-3)	Univoq	EE	00894	15/11/2024	N/A
GF-3307 (S7K-3-3)	Queen	RO	970PC	07/11/2024	N/A

0.2 zRMS conclusion

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

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

PPP (product name/code): GF-3307 (S7K-3-3)
Active substance 1: Fenpicoxamid
Active substance 2: Prothioconazole
Safener: Not Applicable
Synergist: Not Applicable
Applicant: Corteva Agriscience
Zone(s): Central ^(d)
Verified by MS: yes ~~no~~
Field of use: Fungicide

GAP, rev. 3 ~~2~~ date: November ~~August~~ March 2025
Formulation type: EC ^(a, b)
Conc. of as 1: 50 g/L ^(c)
Conc. of as 2: 100g/L ^(c)
Conc. of safener: Not Applicable ^(c)
Conc. of synergist: Not Applicable ^(c)
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
Use- No. *	Mem- ber state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, G, Gn, or I **	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syn- ergist per ha, other dose rate expres- sion, dose range (min-max)	zRMS Conclusion								
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. num- ber a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	kg or L product / ha a) max. rate per appl. b) max. to- tal rate per crop/sea- son	g or kg ai/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy	
Zonal uses (field or outdoor uses, certain types of protected crops)																						
1	PL	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CERCBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2 + b) 2	21 days	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicox- amid + 150 Prothio- conazole b) 150 Fen- picoxamid + 300 Prothio- conazole	150- 300	21	Range 1.2- 1.5 L/ha	A	A	A	A	A	R Aquatics	A	A BEAVA: CERCBE, RAMUBE	
																			A Remaining species		N BEAVA: UROMBE BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE	

[illegible]

				<i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)						+ 300 Prothioconazole									Remaining species		C BEAVA: UROMBE, ERYSBE, RAMUBE BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE	
5	BE	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CERCBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2 $\frac{1}{2}$ b) 2	21 days	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21		A	A	A	A	A	R Aquatics	A	A BEAVA: CERCBE, UROMBE, ERYSBE, RAMUBE	
																			C Bees			C BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE
																			A Remaining species			
6	CZ	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CERCBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2 $\frac{1}{2}$ b) 2	21 days	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21		A	A	A	A	A	R Aquatics	A	A BEAVA: CERCBE, UROMBE, ERYSBE, RAMUBE	
																			C Bees			C BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE
																			A Remaining species			
7	AT	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CERCBE) <i>Uromyces betae</i> (UROMBE)	Tractor mounted spray	BBCH 39-49	a) 2 $\frac{1}{2}$ b) 2	21 days	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid	150-300	21		A	A	A	A	A	R Aquatics	A	A BEAVA, BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE	
																			C Bees			

				<i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)					+ 300 Prothioconazole										A Remaining species		
8	NL	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CERCBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2 + b) 2	21 days	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21		A	A	A	A	A	R Aquatics C Bees A Remaining species	A	A BEAVA, BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE

* 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

*** Final decision is left at the Authority discretion – for details, see point 5 part A

- | | |
|--|---|
| <p>Remarks table heading:</p> <p>(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008</p> <p>(c) g/kg or g/l</p> | <p>(d) Select relevant</p> <p>(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1</p> <p>(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.</p> |
|--|---|
-
- | | |
|--|---|
| <p>Remarks columns:</p> <p>1 Numeration necessary to allow references.</p> <p>2 Use official codes/nomenclatures of EU Member States.</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p> | <p>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.</p> <p>8 The maximum number of application possible under practical conditions of use must be provided.</p> <p>9 Minimum interval (in days) between applications of the same product.</p> <p>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.</p> <p>11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".</p> <p>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).</p> <p>14 Remarks may include: Extent of use/economic importance/restrictions.</p> |
|--|---|

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