REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: A23282A

Product name: **KAYAK ERA**

Chemical active substances:

Cyprodinil, 225 g/L
Prothioconazole, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New product authorization)

Applicant: XXXX

Submission date: July 2022

Evaluation date: March 2023

MS Finalisation date: December 2023

Version history

When	What
July 2022	dRR submitted
March 2023	Initial RR prepared by zRMS
December 2023	RR by zRMS after comments

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The applicant's dRR was not rewritten by the ZRMS and the RR resulting from the ZRMS' evaluation was prepared by an insertion on the grey background into the original dRR ZRMS' coments/corrections.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation A23282A are presented in Table 7.1-1. They have been selected from the individual GAPs in the EU Central zone for cereals. A list of all intended uses within the EU Central zone is given in Part B, Section 0.
The proposed intended GAP is definitely less critical than the representative GAPs from DARs and Sanco Appendices II (see next pages) of cyprodinil (SANCO/10014/2006 - 2010) and prothioconazole (SANCO/3923 /07 - 2021).
Moreover, to support the use of product A23282A consistently with the intended GAP 8 new wheat trials and 8 new barley trials of cyprodinil in northern Europe (1x450 g a.s./ha at BBCH 69; and 2x450 g a.s./ha up to BBCH 75, respectively) were submitted by the applicant.
For prothioconazole no new data were submitted in the framework of this application since 25 northern European wheat trials and 19 northern European barley trials with no longer protection are available to support the intended cGAP uses for the product A23282A (see Appendix 1 list).

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs as they are presented for prothioconazole and cyprodinil in the table below as laid down in Reg. (EU) 2019/552 and Reg. (EU) 2022/1435, respectively, is not expected.

Code number	Products to which the MRLs apply	Prothioconazole: prothioconazole-desthio (sum of isomers)	Cyprodinil
500010	**Barley**	**0,2**	**4**
500050	Oat	0,05	4
500070	Rye	0,05	0,5
500090	**Wheat**	**0,1**	**0,5**

The chronic and the short-term intakes of prothioconazole and cyprodinil residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS, agrees with the authorization of the intended uses.
According to SANTE/11956/2016 rev. 9 (14 September 2018) barley, wheat, oat, durum wheat, spelt and rye are considered to not possess melliferous capacity. No studies on honey are required.
According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

This cGAP covers all intended B0/part A GAPs of the applicant and is covered by the representative GAPs of prothioconazole, cyprodinil (2 next pages) and the sumitted new wheat and barley trials. The original large GAP table of the applicant, for convenience and clarity was removed here (it can be still seen on the next pages (crossed-out) and in part B section 0 of the present RR).

Use-No*	Zone	Crop	F, Etc.	Pests or Group of pests controlled	Application				Application rate				PHI (days)	Remarks:
					Method / Kind	Timing	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total	g **cyprodinil**/ha a) max. rate per appl. b) max. total rate	g **prothioconazole**/ha a) max. rate per appl. b) max. total rate	Water L/ha		
Major uses														
AT BE 1-12, 25,26, 29,30; AT 35-37; BE 31-33; DE 30; IE 35-37; LU 31-33; NL 31-33; SI 33-35 CZ HU 1-8, 25, 26, 29,30, 35, 36; PL 44, 45; HU 25-27; RO 27-29; SK 27-29	CEU	Wheat, durum wheat, rye, triticale, spelt	F	Target pests	foliar spray	BBCH 30-69	a) 1 b) 1	NA	a) 1.5 - 2 b) 1.5 - 2	a) 338 - **450** b) 338 - **450**	a) 113 - **150** b) 113 - **150**	100-400	N/A**	
AT BE DE IE LU NL SI 13-24, 27,28 CZ HU PL RO SKI 13-24, 27, 28		Barley, oat				BBCH 30-59								
Minor Uses														
AT-IE 31-34; BE 34-37; SI 9-12, 23-24, 27-28, 29-32; HU 28-31; LU 34-37; NL 34-37 PL 9-12, 31-43 HU-RO 9-12 RO-SK 23-26	CEU	Durum wheat; rye, triticale, spelt	F	Target pests	foliar spray	BBCH 30-69	a) 1 b) 1	NA	a) 1.5 - 2 b) 1.5 - 2	a) 338 - **450** b) 338 - **450**	a) 113 - **150** b) 113 - **150**	100-400	N/A**	
SI 25, 26 HU 23, 24		Oat				BBCH 30-59								

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 is 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
* * N/A stands for 'Not Applicable'; The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the commodity (e.g. harvest) and/or the setting of a PHI in days is not required
Explanation for Column 15 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

PROTHIOCONAZOLE - List of uses supported by available data SANCO/3923 /07 - final - 10 December 2007 /26 January 2021

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)** (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
wheat, rye, triticale	EU North South	Proline	F	Rusts, Eyespot, Fusarium spp., Powd. Mildew, Rhynchospor., Septoria,	EC	250 g/L	overall spray	start 26-29 up to BBCH69 (interval 14 - 21 d)#	1 – 3 #	ref. to growth stage		200 - 400	0.2	35	# timing , no. of applic. depends on national conditions
barley, oat	EU North South	Proline	F	Rusts, Eyespot, Pyren. teres, Powd. Mildew, Fusarium spp., Rhynchospor.	EC	250 g/L	overall spray	start 30 up to BBCH 61 (interval 14 - 21 d)#	1 – 2 #	ref. to growth stage		200 - 400	0.2	35	# timing , no. of applic. depends on national conditions

Cyprodinil - List of uses supported by available data SANCO/10014/2006 – final rev 1 - 9 July 2010

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Wheat, winter	EU	UNIX 75 WG	F	*Pseudocercosporella herpotrichoides* *Erysiphe graminis*	WG	cyprodinil (ISO draft) 750	foliar spray	BBCH 32	1		0.18-0.375	200 - 400	0.75	45	

The applicant's original GAP table:

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)															
AT1	Austria	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT2	Austria	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT3	Austria	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT4	Austria	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT5	Austria	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT6	Austria	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT7	Austria	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT8	Austria	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT9	Austria	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT10	Austria	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT11	Austria	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
AT12	Austria	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT13	Austria	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT14	Austria	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT15	Austria	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT16	Austria	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT17	Austria	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT18	Austria	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT19	Austria	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT20	Austria	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT21	Austria	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT22	Austria	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT23	Austria	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
AT24	Austria	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT25	Austria	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT26	Austria	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT27	Austria	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT28	Austria	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT29	Austria	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT30	Austria	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE1	Belgium	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE2	Belgium	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE3	Belgium	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE4	Belgium	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE5	Belgium	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE6	Belgium	winter wheat;	F	Puccinia striiformis;	foliar	BBCH30-69	a) 1	NA	a) 2	a) 450	a) 150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZAW		PUCCST	spray		b) 1		b) 2	b) 450	b) 150	400			
BE7	Belgium	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE8	Belgium	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE9	Belgium	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE10	Belgium	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE11	Belgium	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE12	Belgium	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE13	Belgium	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE14	Belgium	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE15	Belgium	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE16	Belgium	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE17	Belgium	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE18	Belgium	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
BE19	Belgium	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE20	Belgium	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE21	Belgium	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE22	Belgium	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE23	Belgium	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE24	Belgium	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE25	Belgium	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE26	Belgium	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE27	Belgium	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE28	Belgium	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE29	Belgium	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
BE30	Belgium	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
CZ1	Czech Republic	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	Including durum wheat and spelt	
CZ2	Czech Republic	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	Including durum wheat and spelt	
CZ3	Czech Republic	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	Including durum wheat and spelt	
CZ4	Czech Republic	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	Including durum wheat and spelt	
CZ5	Czech Republic	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ6	Czech Republic	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ7	Czech Republic	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ8	Czech Republic	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ13	Czech Republic	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ14	Czech Republic	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ15	Czech Republic	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ16	Czech Republic	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
CZ17	Czech Republic	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ18	Czech Republic	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ19	Czech Republic	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ20	Czech Republic	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ21	Czech Republic	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ22	Czech Republic	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ23	Czech Republic	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ24	Czech Republic	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ25	Czech Republic	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ26	Czech Republic	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ27	Czech Republic	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ28	Czech Republic	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
CZ29	Czech Republic	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ30	Czech Republic	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
CZ35	Czech Republic	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	Including durum wheat and spelt	
CZ36	Czech Republic	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
DE1	Germany	Wheat; TRZSS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring wheat, winter wheat, durum wheat and spelt	
DE2	Germany	Wheat; TRZSS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring wheat, winter wheat, durum wheat and spelt	
DE3	Germany	Wheat; TRZSS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring wheat, winter wheat, durum wheat and spelt	
DE4	Germany	Wheat; TRZSS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring wheat, winter wheat, durum wheat and spelt	
DE13	Germany	Barley; HORVX	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring barley and winter barley	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
DE14	Germany	Barley; HORVX	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring barley and winter barley	
DE15	Germany	Barley; HORVX	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring barley and winter barley	
DE16	Germany	Barley; HORVX	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring barley and winter barley	
DE17	Germany	Barley; HORVX	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring barley and winter barley	
DE18	Germany	Barley; HORVX	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring barley and winter barley	
DE25	Germany	Rye; SECCE	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring rye and winter rye	
DE27	Germany	Oat; AVESS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring oat and winter oat	
DE29	Germany	Triticale; TTLSS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring triticale and winter triticale	
HU1	Hungary	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU2	Hungary	spring wheat;	F	Puccinia striiformis;	foliar	BBCH30-69	a) 1	NA	a) 1.5-2	a) 338-450	a) 113-150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZAS		PUCCST	spray		b) 1		b) 1.5-2	b) 338-450	b) 113-150	400			
HU3	Hungary	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU4	Hungary	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU5	Hungary	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU6	Hungary	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU7	Hungary	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU8	Hungary	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU13	Hungary	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU14	Hungary	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU15	Hungary	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU16	Hungary	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU17	Hungary	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU18	Hungary	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
HU19	Hungary	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU20	Hungary	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU21	Hungary	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU22	Hungary	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
IE1	Ireland	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE2	Ireland	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE3	Ireland	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE4	Ireland	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE5	Ireland	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE6	Ireland	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE7	Ireland	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE8	Ireland	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE9	Ireland	durum wheat;	F	Zymoseptoria tritici;	foliar	BBCH30-69	a) 1	NA	a) 2	a) 450	a) 150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZDU		SEPTTR	spray		b) 1		b) 2	b) 450	b) 150	400			
IE10	Ireland	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE11	Ireland	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE12	Ireland	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE13	Ireland	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE14	Ireland	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE15	Ireland	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE16	Ireland	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE17	Ireland	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE18	Ireland	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE19	Ireland	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE20	Ireland	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE21	Ireland	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
IE22	Ireland	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE23	Ireland	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE24	Ireland	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE25	Ireland	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE26	Ireland	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE27	Ireland	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE28	Ireland	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE29	Ireland	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
IE30	Ireland	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU1	Luxembourg	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU2	Luxembourg	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU3	Luxembourg	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
LU4	Luxembourg	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU5	Luxembourg	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU6	Luxembourg	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU7	Luxembourg	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU8	Luxembourg	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU9	Luxembourg	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU10	Luxembourg	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU11	Luxembourg	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU12	Luxembourg	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU13	Luxembourg	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU14	Luxembourg	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU15	Luxembourg	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
LU16	Luxembourg	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU17	Luxembourg	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU18	Luxembourg	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU19	Luxembourg	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU20	Luxembourg	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU21	Luxembourg	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU22	Luxembourg	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU23	Luxembourg	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU24	Luxembourg	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU25	Luxembourg	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU26	Luxembourg	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU27	Luxembourg	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
LU28	Luxembourg	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU29	Luxembourg	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
LU30	Luxembourg	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL1	Netherlands	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL2	Netherlands	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL3	Netherlands	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL4	Netherlands	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL5	Netherlands	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL6	Netherlands	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL7	Netherlands	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL8	Netherlands	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL9	Netherlands	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL10	Netherlands	durum wheat;	F	Puccinia striiformis;	foliar	BBCH30-69	a) 1	NA	a) 2	a) 450	a) 150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZDU		PUCCST	spray	(April – July)	b) 1		b) 2	b) 450	b) 150	400			
NL11	Netherlands	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL12	Netherlands	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL13	Netherlands	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL14	Netherlands	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL15	Netherlands	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL16	Netherlands	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL17	Netherlands	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL18	Netherlands	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL19	Netherlands	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL20	Netherlands	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL21	Netherlands	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL22	Netherlands	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
NL23	Netherlands	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL24	Netherlands	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL25	Netherlands	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL26	Netherlands	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL27	Netherlands	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL28	Netherlands	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL29	Netherlands	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
NL30	Netherlands	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
PL1	Poland	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL2	Poland	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL3	Poland	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL4	Poland	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL5	Poland	winter wheat;	F	Zymoseptoria tritici;	foliar	BBCH30-69	a) 1	NA	a) 1.5-2	a) 338-450	a) 113-150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZAW		SEPTTR	spray		b) 1		b) 1.5-2	b) 338-450	b) 113-150	400			
PL6	Poland	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL7	Poland	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL8	Poland	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL13	Poland	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL14	Poland	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL15	Poland	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL16	Poland	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL17	Poland	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL18	Poland	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL19	Poland	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL20	Poland	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL21	Poland	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	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	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
PL22	Poland	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL23	Poland	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL24	Poland	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL25	Poland	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	Minor use under art. 33	
PL26	Poland	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL27	Poland	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL28	Poland	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL29	Poland	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL30	Poland	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
PL44	Poland	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL45	Poland	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO1	Romania	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO2	Romania	spring wheat;	F	Puccinia striiformis;	foliar	BBCH30-69	a) 1	NA	a) 1.5-2	a) 338-450	a) 113-150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZAS		PUCCST	spray		b) 1		b) 1.5-2	b) 338-450	b) 113-150	400			
RO3	Romania	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO4	Romania	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO5	Romania	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO6	Romania	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO7	Romania	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO8	Romania	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO13	Romania	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO14	Romania	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO15	Romania	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO16	Romania	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO17	Romania	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO18	Romania	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
RO19	Romania	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO20	Romania	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO21	Romania	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
RO22	Romania	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK1	Slovakia	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK2	Slovakia	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK3	Slovakia	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK4	Slovakia	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK5	Slovakia	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK6	Slovakia	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK7	Slovakia	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK8	Slovakia	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK9	Slovakia	durum wheat;	F	Zymoseptoria tritici;	foliar	BBCH30-69	a) 1	NA	a) 1.5-2	a) 338-450	a) 113-150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZDU		SEPTTR	spray		b) 1		b) 1.5-2	b) 338-450	b) 113-150	400			
SK10	Slovakia	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK11	Slovakia	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK12	Slovakia	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK13	Slovakia	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK14	Slovakia	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK15	Slovakia	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK16	Slovakia	spring barley; HORVS	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK17	Slovakia	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK18	Slovakia	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK19	Slovakia	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK20	Slovakia	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SK21	Slovakia	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
SK22	Slovakia	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
SI1	Slovenia	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI2	Slovenia	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI3	Slovenia	spring wheat; TRZAS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI4	Slovenia	spring wheat; TRZAS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI5	Slovenia	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI6	Slovenia	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI7	Slovenia	winter wheat; TRZAW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI8	Slovenia	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI13	Slovenia	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI14	Slovenia	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI15	Slovenia	spring barley; HORVS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI16	Slovenia	spring barley;	F	Puccinia hordei;	foliar	BBCH30-59	a) 1	NA	a) 2	a) 450	a) 150	100-	N/A*	-	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		HORVS		PUCCHD	spray		b) 1		b) 2	b) 450	b) 150	400			
SI17	Slovenia	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI18	Slovenia	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI19	Slovenia	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI20	Slovenia	winter barley; HORVW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI21	Slovenia	winter barley; HORVW	F	Puccinia hordei; PUCCHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI22	Slovenia	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT35	Austria	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
AT36	Austria	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
AT37	Austria	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
BE31	Belgium	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
BE32	Belgium	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
BE33	Belgium	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
DE30	Germany	Wheat; TRZSS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	Including spring wheat, winter wheat, durum wheat and spelt	
HU25	Hungary	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
HU26	Hungary	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
HU27	Hungary	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
IE35	Ireland	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
IE36	Ireland	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
IE37	Ireland	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
LU31	Luxembourg	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
LU32	Luxembourg	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
LU33	Luxembourg	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
NL31	Netherlands	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
NL32	Netherlands	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
NL33	Netherlands	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
RO27	Romania	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO28	Romania	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO29	Romania	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SK27	Slovakia	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SK28	Slovakia	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SK29	Slovakia	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SI33	Slovenia	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI34	Slovenia	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI35	Slovenia	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
Minor uses according to Article 51 (zonal uses)															
PL9	Poland	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL10	Poland	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
PL11	Poland	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL12	Poland	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL31	Poland	spring rye; SECCS	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL32	Poland	spring rye; SECCS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL33	Poland	spring rye; SECCS	F	Fusarium culmorum; FUSACU	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL34	Poland	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL35	Poland	durum wheat; TRZDU	F	Fusarium sp.; FUSASP	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL36	Poland	spring triticale; TTLSO	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL37	Poland	spring rye; SECCS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL38	Poland	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL39	Poland	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL40	Poland	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
PL41	Poland	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL42	Poland	spelt; TRZSP	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
PL43	Poland	spelt; TRZSP	F	Fusarium sp.; FUSASP	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
Minor uses according to Article 33 (zonal uses)															
AT31	Austria	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT32	Austria	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT33	Austria	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
AT34	Austria	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
HU9	Hungary	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU10	Hungary	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU11	Hungary	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU12	Hungary	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*	-	
HU23	Hungary	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
HU24	Hungary	Oat, winter; AVESW	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
IE31	Ireland	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
IE32	Ireland	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
IE33	Ireland	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
IE34	Ireland	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
RO9	Romania	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO10	Romania	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO11	Romania	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO12	Romania	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO23	Romania	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO24	Romania	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
RO25	Romania	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	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	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
RO26	Romania	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SK23	Slovakia	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SK24	Slovakia	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SK25	Slovakia	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SK26	Slovakia	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100-400	N/A*		
SI9	Slovenia	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI10	Slovenia	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI11	Slovenia	durum wheat; TRZDU	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI12	Slovenia	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*	-	
SI23	Slovenia	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI24	Slovenia	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI25	Slovenia	Oat, spring ; AVESP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI26	Slovenia	Oat, winter;	F	Blumeria graminis;	foliar	BBCH30-59	a) 1	NA	a) 2	a) 450	a) 150	100-	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		AVESW		ERYSGR	spray		b) 1		b) 2	b) 450	b) 150	400			
SI27	Slovenia	spring triticale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI28	Slovenia	winter triticale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI29	Slovenia	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI30	Slovenia	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI31	Slovenia	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
SI32	Slovenia	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
BE34	Belgium	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
BE35	Belgium	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
BE36	Belgium	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
BE37	Belgium	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
HU28	Hungary	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
HU29	Hungary	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14	15
Use-No.	**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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
HU30	Hungary	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
HU31	Hungary	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
LU34	Luxembourg	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
LU35	Luxembourg	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
LU36	Luxembourg	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
LU37	Luxembourg	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
NL34	Netherlands	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
NL35	Netherlands	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
NL36	Netherlands	spelt; TRZSP	F	Blumeria graminis; ERYSGR	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		
NL37	Netherlands	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69 (April – July)	a) 1 b) 1	NA	a) 2 b) 2	a) 450 b) 450	a) 150 b) 150	100-400	N/A*		

7.1.2 Summary of the evaluation

The preparation A23282A is composed of cyprodinil and prothioconazole.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of cyprodinil and prothioconazole

Reference value	Source	Year	Value	Study relied upon	Safety factor
Cyprodinil - Parent compound					
ADI	Dir 06/64	2006	0.03 mg/kg bw/day	2 year rat study	100
ARfD	Dir 06/64	2006	not applicable		
Prothioconazole - Parent compound					
ADI	08/44/EC	2008	0.05	Chronic / carcinogenicity study in rats	100
ARfD	08/44/EC	2008	0.2	Oral developmental rats	100
Prothioconazole-desthio – Metabolite of prothioconazole					
ADI	SANCO/3923/07 - final	2007	0.01	Chronic / carcinogenicity study in rats	100
ARfD	SANCO/3923/07 - final	2007	0.01	Rat, developmental study	100
1,2,4-Triazole					
ADI	EFSA	2018a	0.023 mg/kg bw per day	Rat 12-month study	300
ARfD	EFSA	2018a	0.1 mg/kg bw	Rabbit developmental study	300
Triazole Alanine					
ADI	EFSA	2018a	0.3 mg/kg bw per day	Rabbit developmental study	100
ARfD	EFSA	2018a	0.3 mg/kg bw	Rabbit developmental study	100
Triazole Acetic Acid					
ADI	EFSA	2018a	1.0 mg/kg bw per day	Rat 2-generation and rabbit developmental studies	100
ARfD	EFSA	2018a	1.0 mg/kg bw	Rat 2-generation and rabbit developmental studies	100
Triazole Lactic Acid					
ADI	EFSA	2018a	0.3 mg/kg bw per day	Bridging from TA	100
ARfD	EFSA	2018a	0.3 mg/kg bw	Bridging from TA	100

7.1.2.1 Summary for cyprodinil

Table 7.1-3: Summary for cyprodinil

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
AT1-AT8, AT35-AT36, BE1-BE8, BE31-BE32, CZ1-CZ8, DE1-DE4, DE30, HU1-HU8, HU25-HU26, IE1-IE8, IE35-IE36, LU1-LU8, LU31-LU32, NL1-NL8, NL31-NL32, PL1-PL8, RO1-RO8, RO27-RO28, SK1-SK8, SK27-SK28, SI1-SI8, SI33-SI35	Wheat [0500090]	Yes	Yes (8)	Yes	Yes	Yes	No	No
AT9-AT12, AT37, BE9-BE12, BE33, HU9-HU12, HU27, IE9-IE12, IE37, LU9-LU12, LU33, NL9-NL12, NL33, PL9-PL12, PL34-PL35, RO9-RO12, RO29, SK9-SK12, SK29, SI9-SI12, SI35	Durum wheat [0500090-001]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT25-AT26, BE25-BE26, CZ25-CZ26, DE25, IE25-IE26, LU25-LU26, NL25-NL26, PL25-PL26, PL37, PL31-PL33, SI23-SI24	Rye [0500070]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT29-AT30, BE29-BE30, CZ29-CZ30, DE29, IE29-IE30, LU29-LU30, NL29-NL30, PL29-PL30, PL36, SI27-SI28	Triticale [0500090-006]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT31-AT34, BE34-37, HU28-31, IE31-IE34, LU34-LU37, NL35-NL37, PL38-PL43, RO23-RO26, SK23-SK26, SI29-SI32	Spelt [0500090-005]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT13-AT24, BE13-BE24, CZ13-CZ24, DE13-DE18, HU13-HU22, IE13-IE24, LU13-LU24, NL13-NL24, PL13-PL24, RO13-RO22, SK13-SK22, SI13-SI22	Barley [0500010]	Yes	Yes (8)	Yes	Yes	Yes		No
AT27-AT28, BE27-BE28, CZ27-CZ28, DE27, HU23-HU24, IE27-IE28, LU27-LU28, NL27-NL28, PL27-PL28, SI25-SI26	Oats [0500050]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The uses of A23282A have been adequately covered by the animal dietary burden calculation. It was done according to EFSA animal model 2017. Input data were taken from EFSA report (EJ 2013;11(10):3406) except for barley which was taken from the residue trials submitted to support the requested uses. The resulted trigger value of 0.1 mg/kg DM was exceeded. However, regarding available feeding data, there is no risk for animal MRL to be exceeded.

The data from processing studies are available. As residues of cyprodinil exceeding 0.1 mg/kg were expected in treated crops, investigation of magnitude of residues in processed commodities were performed. However, the available presented data shows insignificant residues expected in the relevant processed commodities.

New residue studies in succeeding crops have been submitted. The applied rate was approx. 2.5 or 3.3 x of the max rate of the requested GAP. The results indicate that residues of cyprodinil are not expected in succeeding crops. EFSA (2006) concluded that significant residues are not expected in rotational crops when the active substance was applied with the max rate of 750 g a.s./ha. The max rate of the intended GAP under consideration is 450 a.s./ha. It can be concluded that cyprodinil residues are not expected in rotational crops.

7.1.2.2 Summary for prothioconazole

Table 7.1-4: Summary for prothioconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
AT1-AT8, AT35-AT36, BE1-BE8, BE31-BE32, CZ1-CZ8, DE1-DE4, DE30, HU1-HU8, HU25-HU26, IE1-IE8, IE35-IE36, LU1-LU8, LU31-LU32, NL1-NL8, NL31-NL32, PL1-PL8, RO1-RO8, RO27-RO28, SK1-SK8, SK27-SK28, SI1-SI8, SI33-SI35	Wheat [0500090]	Yes	Yes (25)	Yes	Yes	Yes	No	No
AT9-AT12, AT37, BE9-BE12, BE33, HU9-HU12, HU27, IE9-IE12, IE37, LU9-LU12, LU33, NL9-NL12, NL33, PL9-PL12, PL34-PL35, RO9-RO12, RO29, SK9-SK12, SK29, SI9-SI12, SI35	Durum wheat [0500090-001]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT25-AT26, BE25-BE26, CZ25-CZ26, DE25, IE25-IE26, LU25-LU26, NL25-NL26, PL25-PL26, PL37, PL31-PL33, SI23-SI24	Rye [0500070]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT29-AT30, BE29-BE30, CZ29-CZ30, DE29, IE29-IE30, LU29-LU30, NL29-NL30, PL29-PL30, PL36, SI27-SI28	Triticale [0500090-006]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT31-AT34, BE34-37, HU28-31, IE31-IE34, LU34-LU37, NL35-NL37, PL38-PL43, RO23-RO26, SK23-SK26, SI29-SI32	Spelt [0500090-005]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No
AT13-AT24, BE13-BE24, CZ13-CZ24, DE13-DE18, HU13-HU22, IE13-IE24, LU13-LU24, NL13-NL24, PL13-PL24, RO13-RO22, SK13-SK22, SI13-SI22	Barley [0500010]	Yes	Yes (19)	Yes	Yes	Yes		No
AT27-AT28, BE27-BE28, CZ27-CZ28, DE27, HU23-24, IE27-IE28, LU27-LU28, NL27-NL28, PL27-PL28, SI25-SI26	Oats [0500050]	Yes	Yes (extrapolation)	Yes	Yes	Yes		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The uses of A23282A are adequately covered by the animal dietary burden calculations previously presented in the Article 12 confirmatory data Reasoned Opinion (see EFSA Journal 2020;18(2):5999).

EFSA calculated the livestock dietary burden considering the new residue data submitted on rapeseeds, wheat and carrots as well as taking into account residues in all crops that can be potentially fed to livestock and for which the existing EU MRLs are set above the LOQ. The requested uses have no impact on the dietary burdens calculated. The animal MRLs are not expected to be exceeded.

For TDMs the maximum and median dietary burdens were agreed in the Addendum for the TDM Confirmatory Data (UK, 2018). The contribution of wheat, triticale, rye, spelt and durum wheat to the TMDI is <10% and the estimated daily intake is <10% of the ARfD. The requested uses have no impact on the dietary burdens calculated in that Addendum.

The data from processing studies are available. However, as residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops and the contribution of wheat and barley to the estimated daily intake is <10% of the ARfD, investigation of the magnitude of residues in processed commodities is not required. Based on the data residues of TDMs in processed commodities are expected on the level similar to prothioconazole.

Residues in succeeding crops have been sufficiently investigated. Based on the available data it can be concluded, that for the intended uses on cereals no residues are expected in rotational crops and seting up a plant back interval is not necessary.

No TDMs residue data from supervised residue trials are necessary in the present section. Use pattern in this submission is less critical than the critical GAP used to generate the TDM data previously submitted by the TDMG and can be considered covered by the assessment published in November 2015 and February 2018 as the RMS's draft addendum (United Kingdom, 2015 and 2018: Addendum – Confirmatory Data, addressing sections B.5, B.6, B.7). Although residue trials on wheat and barley analysing for TDMs have been submitted in dRAR (UK/Poland, 2020), it was shown that TDM residues found in these trials were much lower than presented in TDM Confirmatory Data Addendum. Therefore, it is not considered necessary to include these data in the current dRR.

Also therefore the separate consumer risk assessment for TMDs was performed sufficiently by EFSA (see EFSA Journal 2020;18(2):5999) and Addendum UK (2018) in the context of critical EU GAPs. The TDM residues produced from GAPs for this submission of A23282A are less critical than residue inputs already evaluated as part of the TDM review. Therefore, the Applicant considers worst case TDM risk assessment to cover the uses considered in this submission of A23282A. The zRMS agrees that the requested GAP have no impact on the consumer risk assessment for TMDs.

7.1.2.3 Summary for A23282A

Table 7.1-5: Information on A23282A (KCA 6.8)

Crop	PHI for A23282A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for A23282A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Cyprodinil	Prothioconazole		
Wheat [0500090]	n/a	Yes	Yes	n/a	-
Durum wheat [0500090-001]	n/a	Yes	Yes	n/a	
Barley [0500010]	n/a	Yes	Yes	n/a	
Rye [0500070]	n/a	Yes	Yes	n/a	
Oat [0500050]	n/a	Yes	Yes	n/a	
Triticale [0500090-006]	n/a	Yes	Yes	n/a	
Spelt [0500090-005]	n/a	Yes	Yes	n/a	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for A23282A
Crop group	Led by cyprodinil	Led by prothioconazole	
…	NR	NR	NR

NR: not relevant

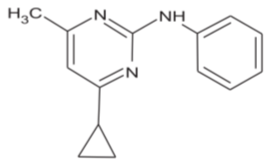
Assessment

This submission document provides data to support the review of the registration of the foliar application of product A23282A in Europe.

7.2 Cyprodinil

General data on cyprodinil are summarised in the table below (last updated 2021/03/23)

Table 7.2-1: General information on cyprodinil

Active substance (ISO Common Name)	Cyprodinil (CGA 219417)
IUPAC	4-cyclopropyl-6-methyl-N-phenylpyrimidin-2-amine or (4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenyl-amine
Chemical structure	
Molecular formula	$C_{14}H_{15}N_3$
Molar mass	225.3 g/mol
Chemical group	Pyrimidinamines (or anilinopyrimidines)
Mode of action (if available)	Inhibition of the biosynthesis of the amino acid methionine and possible repressing secretion of extracellular hydrolytic enzymes involved in pathogenesis.
Systemic	Yes
Company (ies)	XXXX
Rapporteur Member State (RMS)	France
Approval status	Approved (01/05/2007) COMMISSION DIRECTIVE 2006/64/CE REGULATION (EU) No 540/2011 REGULATION (EU) No 2020/421
Restriction (e.g. is restricted to use as "...")	Restricted to uses as fungicide
Review Report	SANCO/10014/2006 – final rev. 1 09/07/2010
Current MRL regulation	Regulation (EC) No 2021/1810
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA, 2013)
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2006) The process of renewal of the first approval in accordance with Regulation (EC) No 1107/2009 is currently ongoing.
Current MRL applications on intended uses	No

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Two new stability studies have been submitted by the applicant in the framework of this application. Results are summarised in the table below. The detailed assessments of these studies are presented in Appendix 2.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High Water Content	Peaches	26 months	104/92 ABR-97114	France, 2005a
	Apple	26 months	104/92 ABR-97114	France, 2005a
High Starch Content	Wheat ears	24 months	104/92 ABR-97114	France, 2005a
	Potato	24 months	104/92 ABR-97114	France, 2005a
High Acid Content	Grapes	24 months	104/92 ABR-97114	France, 2005a
	Strawberries	24 months	104/92 ABR-97114	France, 2005a
No group	Wheat stalks	24 months	104/92 ABR-97114	France, 2005a
	Wine	24 months	104/92	France, 2005a
Animal Products				
Cyprodinil				
Animal Meat	Ruminant	18-19 months	ABR-97115	France, 2005a
Animal Liver	Ruminant	18-19 months	ABR-97115	France, 2005a
Milk	Ruminant	18-19 months	ABR-97115	France, 2005a
Eggs	Poultry	18-19 months	ABR-97115	France, 2005a
CGA 304075 (free and conjugated) - achieved at ≤ 20°C				
Animal Liver	Ruminant	6 months	T001784-05	France, 2010
Animal Kidney	Ruminant	6 months	T001784-05	France, 2010
Milk	Ruminant	3 months	T008935-03	France, 2010
New data				
Plant products				
High Oil Content	Canola	9 months	Sagan, K., 2009 CER04169/07 (VV-117239)	XXXX

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
	Tree nuts	10 months	Mazlo, J., 2010 T003062-07 (VV-467356)	XXXX

Summary of storage stability studies reported in the EU

Reference: France, 2005a, 2010, EFSA, 2013

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review (EFSA, 2006) and the MRL review (EFSA, 2013) for cyprodinil. Storage stability of residues of cyprodinil (CGA 219417) and its metabolite CGA 304075 was demonstrated for the following periods in the commodities listed in the table above when frozen (approximately -18°C for cyprodinil and approximately -20 °C for CGA 304075).

Conclusion on stability of residues during storage

The storage stability of cyprodinil has been investigated in different groups, including high starch and high water content commodities and cereal straw (= wheat stalk), animal tissues, eggs and milk. Residues of cyprodinil were found to be stable at ≤ -18°C for up to 26 months in high water content commodities (peaches, apples) and 24 months in high acid content commodities (grapes, strawberries) and in dry/high starch content commodities (wheat). Furthermore, new storage stability studies have been submitted as part of this application, in which residues of cyprodinil were found to be stable at ≤ -18°C for up to 10 months in high oil commodities (canola and tree nuts). These studies have also been submitted to France, as part of the ongoing AIR review process for cyprodinil. Residues of cyprodinil were also found to be stable at -20°C for up to 18-19 months in animal commodities (meat, liver, milk and eggs). The storage stability of CGA 304075 (free and conjugated) has been investigated in animal tissues and milk. Residues of CGA 304075 (free and conjugated) were found to be stable at ≤ -20°C for up to 6 months in the liver and kidney and for 3 months in milk. Therefore for wheat and barley grain, classified as a crop with high starch content, sufficient stability has been demonstrated to support the residue data presented in the submission.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of cyprodinil and CGA 304075 (free and conjugated) in sample extracts and fully support the residue data presented in the submission.

Conclusion on stability of residues in sample extracts

Sufficient stability has been demonstrated to support the residue data presented in the submission.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label Position	Application and Sampling Details				Report Reference	Source
			Method, F or G(a)	Rate (kg a.s./ha)	No	Sampling (DAT)		
EU Reviewed Data								
Fruits and fruiting vegetable	Apple	2-^{14}C-pyrimidine	Foliar, F	0.05*	3 (b)	61 (fruits and foliage at harvest) (c)	4/93	France, 2005a
	Peach	U-^{14}C-phenyl or 2-^{14}C-pyrimidine	Foliar, F	0.27 and 2.7	4 (d)	1 (fruits and foliage)	ABR-97002	
	Tomato	U-^{14}C-phenyl or 2-^{14}C pyrimidine	Foliar, G	0.75	2 (e)	14 (fruits and foliage at harvest) (f)	20/92 21/92	
Root and tuber vegetables	Potato	U-^{14}C-phenyl or 2-^{14}C-pyrimidine	Foliar, G	0.56	3 (g)	14 (tubers and foliage at harvest) (h)	PMR 03/96 PMR 05/96	France, 2005a
Cereals	Wheat	U-^{14}C-phenyl	Foliar, G	0.75	1 (i)	Whole plant autoradiography and samples taken at 0-35 days	18/92	France, 2005a
	Wheat	U-^{14}C-phenyl or 2-^{14}C-pyrimidine	Foliar, F	0.75 + 0.50	2 (j)	41 (straw, husk and grain at harvest) (k)	18/92 19/92 7/94	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Application intervals of ca. 8 and 5 weeks
(c): Additionally sampling of foliage, post each application.
(d): Application to individual branches of separate fruit trees, 21 to 1 day PHI (7 day intervals approx.)
(e): First application when fruits 2 cm diameter; second application 28 days later (14 days before harvest)
(f): Additionally sampling of fruit and foliage after 1st application and after 2nd application
(g): Application intervals of 19/20 days
(h): Additionally foliage sampled day of 1st and 3rd application and tubers sampled after final application
(i): Application at 5-6 leaf stage
(j): 1st application BBCH 16-18 (6-8 leaf stage); 2nd application 22 days later
(k): Additionally whole plant material sampled (after each application and 41 days after 1st application)
*: kg a.s./hL

Summary of plant metabolism studies reported in the EU

Reference: France, 2005a; EFSA, 2013

Primary crop metabolism of cyprodinil was investigated for foliar application on cereals (wheat), on fruits and fruiting vegetables (peach, tomato and apple), and on root and tuber vegetables (potato), using U-^{14}C-phenyl or 2-^{14}C-pyrimidine labelled cyprodinil. The studies demonstrate that where there is a direct contact of cyprodinil with the edible part, cyprodinil represents the largest part of the residue, and that metabolism proceeds mainly via hydroxylation of the phenyl and pyrimidine rings followed by sugar conjugation. It was concluded that metabolism is similar in all crops and the residue definition for all the considered uses for both risk assessment and enforcement should be established as cyprodinil (parent compound only).

Conclusion on metabolism in primary crops

The metabolism of cyprodinil in plants following foliar application is sufficiently addressed to support the proposed uses of the product A23282A on cereals.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop Group	Crop	Label Position	Application and Sampling Details				Report Reference	Source
			Method, F or G[(a)]	Rate (kg a.s./ha)	Sowing Interval (DAT)	Harvest Interval (DAT)		
EU Reviewed Data								
Leafy vegetables	Lettuce	U-^{14}C-phenyl	F[(b)]	0.75 + 0.5	43	Not reported	28-92	France, 2005a
Root and tuber vegetables	Sugar beet				272			
Cereals	Wheat Maize				106 302			
Leafy vegetables	Lettuce	U-^{14}C-pyrimidine	F[(b)]	0.75 + 0.5	43	77 96	28-92 29-92	France, 2005a
Root and tuber vegetables	Sugar beet				272	365 398 483		
Cereals	Wheat Maize				106 302	317 365 398 365 398 483		
Pulses and oilseeds	Mustard	U-^{14}C-phenyl and 2-^{14}C-pyrimidine	F[(c)]	3.2 - 3.6	42 130 283 365	Not reported	135-96	France, 2005a
Root and tuber vegetables	Radish							
Cereals	Wheat							
Leafy vegetables	Lettuce	2-^{14}C-pyrimidine	F[(c)]	1.25	29 124 365	'maturity'	97DG56	France, 2005a
Root and tuber vegetables	Radish				29 124 365	'maturity'		
Cereals	Wheat				29 180 365	'interim samples and maturity'		

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) Application of cyprodinil to a primary crop of spring wheat

(c) Application of cyprodinil to bare soil

Summary of metabolism studies in rotational crops reported in the EU

Reference: France, 2005a; EFSA, 2013

The metabolism of cyprodinil in rotational crops was investigated in lettuce, sugar beet, wheat, maize, mustard and radish using U-^{14}C-phenyl, U-^{14}C-pyrimidine or 2-^{14}C-pyrimidine labelled cyprodinil. Four confined rotational crop studies investigating the nature of residues following different plant-back intervals are available to address the potential for residues to occur in rotational crops. In these studies, cyprodinil radiolabeled in phenyl or pyrimidinyl rings was applied to bare soil or crops at application rates ranging from 1.25-3.6 kg a.s./ha (0.83N/1.1N to approximately 3N the intended total seasonal application rate reported in the article 12 review of cyprodinil (EFSA 2013), or 2.78N to approximately 8N of the total seasonal application rate intended for the crops under consideration in this dossier). Studies on the magnitude of residues in rotational crops confirmed the presence of the plant metabolites NOA 422054 and CGA 321915 at the earliest replanting interval of 30 DAT. However, as none of these metabolites were found to be of toxicological concern, it was concluded in the peer review not to include these metabolites in the residue definition for plants assuming that short plant-back intervals were not expected to occur in practice for the crops supported in the framework of the peer review. These studies are summarised in the table above.

Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found not to be similar. However, as none of the metabolites were found to be of toxicological concern, it was concluded in the peer review not to include these metabolites in the residue definition for rotated plants. Consequently, a specific residue definition for rotational crops is not deemed necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
Pasteurisation (20 minutes, 90°C, pH 4)	^{14}C-pyrimidine-labelled cyprodinil (100)	00MO07	France, 2005a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	^{14}C-pyrimidine-labelled cyprodinil (100)		
Sterilisation (20 minutes, 120°C, pH 6)	^{14}C-pyrimidine-labelled cyprodinil (100)		

Summary of high temperature studies reported in the EU

Reference: France, 2005a

The effect of processing on the nature of cyprodinil was investigated in the framework of the peer review. Studies were conducted with ^{14}C-pyrimidine-labelled test substance simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). The results are summarised in the table above.

Conclusion on nature of residues in processed commodities

The nature of residues of cyprodinil in processed products has been investigated. Cyprodinil is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruit (Peach, Tomato, Apple) Root and tuber vegetables (Potato) Cereals (Wheat)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	No As none of the metabolites were found to be of toxicological concern, it was concluded in the peer review not to include these metabolites in the residue definition for plants.
Processed commodities	Cyprodinil is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Cyprodinil (Regulation n° (EC) 2021/1810)
Plant residue definition for risk assessment	Cyprodinil (EFSA, 2013)
Conversion factor from enforcement to RA	Not applicable

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label Position	No of Animals	Application Details		Sampling Details		Report Reference	Source
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	U-^{14}C-phenyl	2	0.2, 9.94 [a]	4	Milk	Twice daily	5/94 9050	France, 2005a
						Urine & faeces	Daily		
						Tissues	At sacrifice [f]		
		2-^{14}C-pyrimidine	2	0.2, 9.8 [b]	4	Milk	Twice daily	5/94 9050	France, 2005a
						Urine & faeces	Daily		
						Tissues	At sacrifice [f]		
		U-^{14}C-phenyl	2	4.11 [c]	4	Milk	Twice daily	17/96	France, 2005a
						Urine & faeces	Daily		
						Tissues	At sacrifice [f]		
Laying Poultry	Hen	U-^{14}C-phenyl	6	0.4, 18.9 [d]	4	Eggs	Daily	6/94 9055	France, 2005a
						Excreta	Daily		
						Tissues	At sacrifice [f]		
		2-^{14}C-pyrimidine	6	0.4, 19.2 [e]	4	Eggs	Daily		
						Excreta	Daily		
						Tissues	At sacrifice [f]		

Group	Species	Label Position	No of Animals	Application Details		Sampling Details		Report Reference	Source
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
New data									
Lactating Ruminant	Goat	2-^{14}C-pyrimidine	1	4	4	Milk	Twice daily	Anderson, W., 2006, T019338-04 (VV-501913)	XXXX
						Urine and faeces	Daily		
						Blood	Prior to sacrifice		
						Tissues	After sacrifice		

(a): U-^{14}C-phenyl cyprodinil was administered to a single goat at a dose level of 0.2 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and a second goat at a dose level of 9.94 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(b): 2-^{14}C-pyrimidine cyprodinil was administered to a single goat at a dose level of 0.2 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and a second goat at a dose level of 9.8 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(c): U-^{14}C-phenyl cyprodinil was administered to a single goat at a dose level of 4.11 mg/kg bw (nominal dose rate of 100 mg/kg in the diet). Review of the existing MRLs for cyprodinil EFSA Journal 2013;11(10):3406 40
(d): U-^{14}C-phenyl cyprodinil was administered to two hens at a dose level 0.4 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and to four hens at a dose level of 18.9 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(e): 2-^{14}C-pyrimidine cyprodinil was administered to two hens at a dose level of 0.4 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and to four hens at a dose level of 19.2 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(f): 6 h after the last dose

Summary of animal metabolism studies reported in the EU

Reference: France, 2005a; EFSA, 2013

The metabolism of cyprodinil was investigated in lactating goats and laying hens using U-^{14}C- phenyl and 2-^{14}C-pyrimidine labelled cyprodinil. Both studies show that cyprodinil is extensively metabolised and proceeds predominantly via hydroxylation of the phenyl and pyrimidine rings and conjugation with sulphate or glucuronic acid. The main metabolites identified in the livestock metabolism were all found in the rat metabolism study and the residue definition for enforcement and risk assessment is defined as the sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil, aside from milk where the conjugated form of the metabolite needs to be included both for enforcement and risk assessment purposes. These studies are summarised in the table above.

Summary of new animal metabolism studies

The following study has also been submitted to France, as part of the ongoing AIR review process for cyprodinil. The metabolism of cyprodinil was investigated in lactating goats using 2-^{14}C-pyrimidine labelled cyprodinil. This study, intended only to produce tissue samples containing incurred radioactive residues of CGA 304075 for method-development purposes, gave tissue concentrations of CGA 304075 and its conjugates lower than the metabolism studies in lactating goats.

Despite this quantitative difference, the overall distribution of residues was sufficiently consistent with the metabolism studies, and tissues for method development were successfully generated.

Conclusion on metabolism in livestock

The metabolism of cyprodinil in livestock is sufficiently addressed to support the proposed uses of the product A23282A.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

Endpoints	
Animals covered	Lactating goats, laying hens
Time needed to reach a plateau concentration	No plateau in milk reported; no residues expected No plateau reached in egg, but cyprodinil shown to be extensively metabolised and radioactivity excreted
Animal residue definition for monitoring	The sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil except milk, sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil (Regulation n° (EC) 2021/1810)
Animal residue definition for risk assessment	The sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil except milk, sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil Residue definition (EFSA 2013)
Conversion factor	not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes No for CGA 304075 according to its distribution in tissues (not fat soluble)

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

Cyprodinil: New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarised in the table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A23282A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Wheat (extrapolation to triticale, rye, durum wheat and spelt)	**Zonal cGAP** (Art. 12; EFSA, 2013)	**N-EU**	**2 x 750 g a.s./ha, BBCH 30-65, interval between applications 21d, PHI 42d**	Grain: 0.11 Straw: 0.42	Grain: 0.32 Straw: 2.57	-	0.5	Yes
	Zonal cGAP (Art. 12; EFSA, 2013)	**S-EU**	**1 x 750 g a.s./ha, BBCH 30-65, PHI 42d**	Grain: 0.13 Straw: 0.58	Grain: 0.32 Straw: 5.78	-	0.5	Yes
	Intended cGAP	**N-EU**	**1 x 450 g a.s./ha, BBCH 30-69**	N/A				
	Intended cGAP	**S-EU**	**1 x 450 g a.s./ha, BBCH 30-69**	N/A				
	New trials KCA1 6.3.1	N-EU	Trials GAP: 1 x 450 g a.s./ha, BBCH 30-69 Grain: 2 x 0.03, 2 x 0.04, 2 x 0.05, 0.07, 0.10 Straw: 0.07, 0.10, 0.16, 0.23, 0.25, 0.35, 0.58, 0.88	Grain: 0.045 Straw: 0.240	Grain: 0.10 Straw: 0.88	Grain: 0.154	0.5	Yes
	~~**New trials**~~	~~S-EU~~	~~Trials GAP: 1 x 450 g a.s./ha, BBCH 30-69~~ ~~Grain: 3 x 0.02, 0.03, 0.07, 0.08, 0.09, 0.11~~ ~~Straw: 0.02, 0.05, 0.23, 0.31, 0.94, 1.00, 1.02, 3.90~~	Grain: 0.050 Straw: 0.625	Grain: 0.11 Straw: 3.90	Grain: 0.202	0.5	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
	Overall supporting data for intended cGAP (formulation A23282A)	N-EU + S-EU The datasets are merged, because the Student test 5% and Mann-Whitney U-test (α=5%) show statistical similarity	Grain: 3 x 0.02, 3 x 0.03, 2 x 0.04, 2 x 0.05, 2 x 0.07, 0.08, 0.09, 0.10, 0.11 Straw: 0.02, 0.05, 0.07, 0.10, 0.16, 2 x 0.23, 0.25, 0.31, 0.35, 0.58, 0.88, 0.94, 1.00, 1.02, 3.90	Grain: 0.045 Straw: 0.280	Grain: 0.11 Straw: 3.90	Grain: 0.172	0.5	Yes
Barley (extrapolation to oats)	**Zonal cGAP** (Art. 12; EFSA, 2013)	**N-EU**	**2 x 750 g a.s./ha, BBCH 30-65, interval between applications 21d, PHI 42d**	Grain: 0.75 Straw: 0.36	Grain: 1.74 Straw: 1.99	-	4	Yes
	Zonal cGAP (Art. 12; EFSA, 2013)	**S-EU**	**2 x 750 g a.s./ha, BBCH 30-65, interval between applications 21d, PHI 42d**	Grain: 0.61 Straw: 0.46	Grain: 1.81 Straw: 2.45	-	4	Yes
	Intended cGAP	**N-EU**	**1 x 450 g a.s./ha, BBCH 30-59**	N/A				
	Intended cGAP	**S-EU**	**1 x 450 g a.s./ha, BBCH 30-59**	N/A				
	New trials KCA1 6.3.2	N-EU	Trials GAP: 2 x 450 g a.s./ha, BBCH 24-75 Grain: 0.26, 0.29, 0.3, 0.43, 0.61, 0.79, 0.88, 0.92 Straw: 2 x 0.16, 0.33, 0.55, 0.61, 0.96, 1.32, 1.51	Grain: 0.52 Straw: 0.58	Grain: 0.92 Straw: 1.51	Grain: 1.680	4	Yes
	~~**New trials**~~	~~S-EU~~	~~Trials GAP: 2 x 450 g a.s./ha, BBCH 30-77~~ ~~Grain: <0.01, 0.38, 0.74, 1.0, 1.05, 1.1, 1.36, 2.2~~ ~~Straw: 0.45, 0.56, 0.61, 0.98, 1.34, 1.75, 2.56, 2.7~~	Grain: 1.025 Straw: 1.16	Grain: 2.2 Straw: 2.7	Grain: 3.603	4	Yes
		N-EU	Straw: 2 x 0.16, 0.33, 0.55, 0.61, 0.96, 1.32, 1.51	Straw: 0.58	Straw: 1.51	-	-	-

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
	Overall supporting data for intended cGAP (formulation A23282A)	S-EU	Straw: 0.45, 0.56, 0.61, 0.98, 1.34, 1.75, 2.56, 2.7	Straw: 1.16	Straw: 2.7	-	-	-
		N-EU + S-EU For grain, the datasets are merged, because the Student test 5% and Mann-Whitney U-test (α=5%) show statistical similarity	Grain: <0.01, 0.26, 0.29, 0.3, 0.38, 0.43, 0.61, 0.74, 0.79, 0.88, 0.92, 1.0, 1.05, 1.1, 1.36, 2.2	Grain: 0.765	Grain: 2.2	Grain: 2.900	4	Yes

(a) Definition of residue for enforcement and risk assessment are the same: cyprodinil
(b) Source of EU MRL: Reg. (EU) 2021/1810

7.2.3.2 Conclusion on the magnitude of residues in plants

A23282A is used as a foliar treatment on field grown cereals (wheat, triticale, rye, spelt, durum wheat, barley and oat).

Wheat

Wheat is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for wheat can be extrapolated to rye, triticale, spelt and durum wheat (SANTE/2019/12752).

The intended cGAP is 1 x 450 g a.s./ha, BBCH 30-69, field.

The intended cGAP is less critical than the zonal cGAP (2 x 750 g a.s./ha, BBCH 30-65, interval between applications 21d, PHI 42d).

Eight new trials in northern Europe were conducted to support the intended cGAP use on wheat. In each trial one application at a nominal rate of 450 g a.s./ha at BBCH 69 was made. The actual application rate was within ±25% acceptance range. In these trials residues of cyprodinil in wheat grain taken at harvest were in the range of 0.03 – 0.10 mg/kg. Residues of cyprodinil in wheat straw taken at harvest were in the range of 0.07 – 0.88 mg/kg. All cyprodinil residues in grain are within the current MRL of 0.5 mg/kg.

Therefore, sufficient trials are available to support the proposed uses on wheat, rye, triticale, spelt and durum wheat, and to conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

Barley

Barley is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for barley can be extrapolated to oats (SANTE/2019/12752).

The intended cGAP is 1 x 450 g a.s./ha, BBCH 30-59, field.

The intended cGAP is less critical than the zonal cGAP (2 x 750 g a.s./ha, BBCH 30-65, interval between applications 21d, PHI 42d).

Eight new trials in northern Europe conducted with A14325E, an emulsifiable concentrate (EC) formulation containing 300 g/L cyprodinil, are available to support the use of product A23282A (EC formulation) on barley. These studies have also been submitted to France, as part of the ongoing AIR review process for cyprodinil. In each trial two applications at a nominal rate of 450 g a.s./ha at BBCH 24-75 were made. The actual application rates were within ±25% acceptance range. The trials GAP was more critical than the intended GAP, thus covering the intended use. In these trials residues of cyprodinil in barley grain taken at harvest were in the range of 0.26 – 0.92 mg/kg. Residues of cyprodinil in barley straw taken at harvest were in the range of 0.16 – 1.51 mg/kg. All cyprodinil residues in grain are within the current MRL of 4 mg/kg.

Therefore, sufficient trials are available to support the proposed uses on barley and oats and conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The use of A23282A may result in residues of cyprodinil in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations and feeding studies undertaken are provided below.

Input values for the dietary burden calculation (EFSA animal model 2017) have been taken from the article 12 MRL review of cyprodinil (EFSA, 2013), except for barley for which the input values derive from the residue trials presented in this dossier. However, as the animal dietary burden calculator model has changed since the publication of the article 12 MRL review of cyprodinil, the feed commodities are different and carrot, brewer's grain dried (barley and oats), canola meal, rape meal, wheat gluten meal and wheat milled by-products are now included. Moreover, an input value for the sunflower meal is also included, which originates from the MRL application on the setting of an Import Tolerance for cyprodinil in sunflowers submitted to RMS France in September 2021. Default processing factors were used for all processed commodities where appropriate to consider the potential concentration of residues, with the exception of apple pomace, wet where the processing factor (PF) of 1.3 and wheat milled by-products where the PF of 2.2 (based on wheat bran PF) were used (EFSA, 2013).

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cyprodinil				
Barley straw	1.16	Median residue (barley Southern zone residue trials)	2.7	Highest residue (barley Southern zone residue trials)
Oat straw	1.16	Median residue (barley Southern zone residue trials)	2.7	Highest residue (barley Southern zone residue trials)
Rye straw	0.58	STMR (EFSA, 2013)	5.78	HR (EFSA, 2013)
Triticale straw	0.58	STMR (EFSA, 2013)	5.78	HR (EFSA, 2013)
Wheat straw	0.58	STMR (EFSA, 2013)	5.78	HR (EFSA, 2013)
Carrot (culls)	0.45	STMR (EFSA, 2013)	1.04	HR (EFSA, 2013)
Barley grain	0.765	Median residue (barley residue trials, Northern and Southern zone merged)	0.765	Median residue (barley residue trials, Northern and Southern zone merged)
Bean seed (dry)	0.06	STMR (EFSA, 2013)	0.06	STMR (EFSA, 2013)
Lupin seed	0.02	STMR (EFSA, 2013)	0.02	STMR (EFSA, 2013)
Oat grain	0.765	Median residue (barley residue trials, Northern and Southern zone merged)	0.765	Median residue (barley residue trials, Northern and Southern zone merged)
Pea seed (dry)	0.02	STMR (EFSA, 2013)	0.02	STMR (EFSA, 2013)
Rye grain	0.13	STMR (EFSA, 2013)	0.13	STMR (EFSA, 2013)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Triticale grain	0.13	STMR (EFSA, 2013)	0.13	STMR (EFSA, 2013)
Wheat grain	0.13	STMR (EFSA, 2013)	0.13	STMR (EFSA, 2013)
Apple pomace (wet)	0.61	STMR (0.49) x PF (1.25) (EFSA, 2013)	0.61	STMR (0.49) x PF (1.25) (EFSA, 2013)
Brewer’s grain (dried)	2.52	STMR (0.765) x PF (3.3) (Median residue (barley residue trials in this submission))	2.52	STMR (0.765) x PF (3.3) (Median residue (barley residue trials in this submission))
Canola (rape seed) meal	0.04	STMR (0.02) x PF (2) (FAO, 2016)	0.04	STMR (0.02) x PF (2) (FAO, 2016)
Distiller’s grain (dried)	0.43	STMR (0.13) x PF (3.3) (EFSA, 2013)	0.43	STMR (0.13) x PF (3.3) (EFSA, 2013)
Lupin seed meal	0.02	STMR (0.02) x PF (1.1) (EFSA, 2013)	0.02	STMR (0.02) x PF (1.1) (EFSA, 2013)
Rape meal	0.04	STMR (0.02) x PF (2) (FAO 2016)	0.04	(STMR) (0.02) x PF (2) (FAO 2016)
Sunflower meal	0.06	STMR (0.03) x PF (2) (Art. 6 for sunflower seeds submitted to France in Sep 2021)	0.06	STMR (0.03) x PF (2) (Art. 6 for sunflower seeds submitted to France in Sep 2021)
Wheat gluten meal	0.23	STMR (0.13) x PF (1.8) (EFSA, 2013)	0.23	STMR (0.13) x PF (1.8) (EFSA, 2013)
Wheat milled by-products	0.29	STMR (0.13) x PF (2.2) (EFSA, 2013)	0.29	STMR (0.13) x PF (2.2) (EFSA, 2013)

Cyprodinil falls under old data requirements, therefore the only categories considered are dairy and beef cattle, laying poultry and pig. The results of the calculations are reported in (see Table 7.2-11) and compared to the previous assessment published in the Article 12 Reasoned Opinion (EFSA, 2013). The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)	Previous assessment Maximum burdens (mg/kg DM)
Residue definition for risk assessment: the sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil except milk, sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil						

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)	Previous assessment Maximum burdens (mg/kg DM)
Beef cattle*	0.038	0.079	Carrot culls	3.31	Yes	4.30
Dairy cattle*	0.066	0.130	Carrot culls	3.37	Yes	2.00
Ram/ewe	-	-	-	-	-	-
Lamb	-	-	-	-	-	-
Breeding swine	-	-	-	-	-	-
Finishing swine*	0.053	0.090	Carrot culls	3.01	Yes	0.71
Broiler poultry	-	-	-	-	-	-
Layer poultry*	0.092	0.165	Carrot culls	2.41	Yes	0.63
Turkey	-	-	-	-	-	-

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The maximum dietary burden calculated in this dossier is approximately 2.1 times lower than the lowest dose level of the poultry metabolism studies (see 0). With the exception of kidney and liver, total residues (TRRs) were <0.01 mg/kg in eggs and tissues at the lowest dose of 5 mg/kg DM diet in the hen metabolism study. Therefore the residue levels at the maximum animal dietary burden would be below 0.01 mg/kg in poultry muscle, fat and eggs. The total residues (TRRs) in kidney and liver were up to 0.04 and 0.12 mg/kg, respectively at the lowest dose of 5 mg/kg DM diet. Since all identified metabolites in liver and kidney were ≤0.01 mg/kg (the most abundant metabolite was a sulfate conjugate of CGA 304075 in the liver at 0.01 mg/kg), residues of these metabolites would also be below 0.01 mg/kg at the calculated maximum animal dietary burden. Therefore, no MRL exceedance in poultry is expected. Hence, no livestock feeding study is needed. Therefore, the residue levels in poultry commodities are expected to remain below the enforcement LOQ of 0.02 mg/kg.

For sheep, cattle and swine products, the dietary burdens calculated in this submission were compared to the previous assessment published in the Article 12 Reasoned Opinion (EFSA, 2013; Table above).

The MRLs for animal products were automatically calculated by the EFSA (2017) livestock tool, considering the calculated dietary burden and the livestock feeding data. Equations within the EFSA (2017) livestock are unable to scale residue values (Transfer Factor (TF) approach) when a Feeding Level (FL) only has <LOQ residue data. In such cases, the TF residues to replace the tool's default use of LOQ values have been manually calculated.

The uses of A23282A are adequately covered by meat ruminants (beef cattle) animal dietary burden calculations previously presented in the Article 12 Reasoned Opinion (EFSA, 2013; 3.31 vs 4.3 mg/kg DM in diet). Moreover, the MRL estimates for cattle and sheep generated by the EFSA (2017) livestock tool are within existing MRL proposals (Reg. (EU) 2021/1810). As a consequence, the proposed EU MRLs for cyprodinil in cattle and sheep products remain valid for the proposed uses and the residue data for their edible commodities do not require detailed assessment as part of this submission.

The dietary burdens for cattle milk and swine are higher than the previously calculated value presented in the Article 12 Reasoned Opinion (EFSA, 2013). However, MRL estimates for cattle milk, swine muscle and fat generated by the EFSA (2017) livestock tool are within existing MRL proposals (Reg. (EU)

2021/1810). Therefore the residue data for these edible commodities do not require detailed assessment as part of this submission. For swine liver and kidney, the MRL estimates differ when compared to existing MRLs. The estimated cyprodinil MRLs for swine liver and kidney are 0.02 mg/kg compared to 0.02* mg/kg in Reg. (EU) 2021/1810. Therefore the swine residue data have been reviewed in detail.

With regards to swine liver, all residues are <LOQ at the feeding level closest to the maximum dietary burden (FL1). Therefore the TF residue based on the >LOQ FL closest to the maximum dietary burden has been selected (0.005 mg/kg at FL2) and as a result an MRL of 0.02* mg/kg is proposed for swine liver. The same approach has been taken for swine kidney, with the TF residue at FL2 equating to 0.007 mg/kg. Therefore an MRL of 0.02* mg/kg can also be proposed for swine kidney. Consequently, no MRL exceedance in swine liver and kidney is expected.

A summary of the values derived for swine commodities and ruminant milk from the ruminant feeding study is presented in the Table 7.2-12.

Table 7.2-12: Summary of the outcome of pig/ruminants feeding studies

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	CF for RA
Enforcement and risk assessment residue definition: the sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil except milk, sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil				
Pig muscle	0.02	0.02	0.02*	1.00
Pig fat	0.02	0.02	0.02*	1.00
Pig liver	0.003	0.01	0.02*	1.00
Pig kidney	0.004	0.01	0.02*	1.00
Ruminant milk	0.02	0.02	0.02*	1.00

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009). For pig liver and kidney the median residue has been refined dusing the transer factor approach as described above.
(b): Highest residue value (tissues) according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for maximum dietary burden between the relevant feeding groups of the study (FAO, 2009). For pig liver and kidney the highest residue value has been refined dusing the transer factor approach as described above.
(*): Indicates that the MRL is set at the limit of analytical quantification.

Available data

No new data were submitted in the framework of this application.

Table 7.2-13: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU reviewed data (France, 2010; EFSA, 2013)												
Enforcement and risk assessment residue definition: the sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil except milk, sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil												
Pig muscle/meat[e]	0.053	0.090	0.0720	3	n.r.	n.r.	n.r.	n.r.	0.02	0.02	0.02*	1.00
			0.5450	3	n.r.	n.r.	n.r.	n.r.				
			1.8100	3	<0.02	<0.02	<0.02	<0.02				
Pig fat	0.053	0.090	0.0720	3	n.r.	n.r.	n.r.	n.r.	0.02	0.02	0.02*	1.00
			0.5450	3	n.r.	n.r.	n.r.	n.r.				
			1.8100	3	<0.02	<0.02	<0.02	<0.02				
Pig liver	0.053	0.090	0.0720	3	<0.02	<0.02	<0.02	<0.02	0.003	0.01	0.02*	1.00
			0.5450	3	0.03	0.03	0.03	0.03				
			1.8100	3	0.09	0.03	0.09	0.09				
Pig kidney	0.053	0.090	0.0720	3	<0.02	<0.02	<0.02	<0.02	0.004	0.01	0.02*	1.00
			0.5450	3	0.04	0.04	0.04	0.04				
			1.8100	3	0.13	0.13	0.13	0.13				
Milk	0.066	0.130	0.0720	84[f]	n.r.	n.a.	n.r.	n.a.	0.02	0.02	0.02*	1.00
			0.5450	84[f]	n.r.	n.a.	n.r.	n.a.				
			1.8100	84[f]	<0.02	n.a	<0.02	n.a				

n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk
n.r.: Not reported but residues at higher dosing levels were already demonstrated to be <0.02 mg/kg

(a): Based on a 550 kg animal consuming 20 kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009). For pig liver and kidney the median residue has been refined dusing the transer factor approach as described above.
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009). For pig liver and kidney the highest residue value has been refined dusing the transer factor approach as described above..
(d): The median conversion factor for enforcement to risk assessment.
(e): While the results of the livestock feeding study refer to the muscle, the MRL proposal and risk assessment values are applicable to the meat.
(f): Mean residue level from day 0 until day 28 (3 cows, 28 sampling days).
(*): Indicates that the MRL is set at the limit of analytical quantification.

Summary of livestock studies reported in the EU

Reference: France, 2005a, 2010; EFSA, 2013

EFSA concluded: *"According to the (...)hen metabolism studies, it is concluded that, after exposure to the maximum dietary burden (at least 10 times lower than the lowest dose level of the metabolism studies; see also section 3.2.1), residue levels in poultry commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg in poultry products, including muscle, fat, eggs, liver and kidney. Hence, no livestock feeding study for poultry is needed; MRLs and risk assessment values for the relevant commodities in poultry can be established at the LOQ level.*

Regarding other types of livestock, the magnitude of cyprodinil residues in ruminants was investigated during the peer review under Directive 91/414/EEC in a feeding study with lactating cows (France, 2003). However the metabolite CGA 304075 was not determined and it was not possible to propose MRLs on the basis of this study. In an addendum to the DAR an additional feeding study with lactating cows was reported (France, 2010) where the magnitude of residues of cyprodinil and CGA 304075 were investigated.

Four groups of lactating cows, one group consisting of a control and a back-up animal and the remaining three groups consisting of three cow each, were dosed for 29-30 consecutive days with cyprodinil at levels of 2 (1X), 15 (7.5X) and 50 (25X) mg/kg in the diet (equivalent to 0.07, 0.54 and 1.81 mg/kg bw per d). The samples were analysed for cyprodinil and the metabolite CGA 304075. [...] In milk, residues of cyprodinil and CGA 304075 were <LOQ at the 25 X dose level. When found in liver and kidney (at the 7.5X and 25X dose rates only), residues were mostly analysed as CGA 304075, although parent cyprodinil was still found as an isolated occurrence at the highest dosing rate in liver (where a residue of 0.02 mg/kg cyprodinil and a residue of 0.07 mg/kg CGA 304075 was analysed)

Consequently, the available data are considered sufficient for deriving MRLs in ruminants and pigs."

Note: In the DAR, a ruminant feeding study was assessed but metabolite CGA 304075 was not determined and it was not possible to propose MRLs on the basis of this study. This study is therefore not summarised here.

Conclusion on feeding studies

The requested uses and the new mode of calculation modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

zRMS' statement on residues in fish

No MRLs in fish are currently set for cyprodinil. The detectable residues of cyprodinil in cereal grain that can be used for fish feeding are in trials consistent with the intended GAP much lower than the MRLs in cereal grain. Thus, as the trials in fish are not currently available for the applicant as the data source, the relevant mitigation measures can be applied. On the other hand, EFSA in 2022 reports (EFSA Journal 2022;20(3):7215) that in that year 962 fish samples were reported covering an analytical scope of 318 pesticides. Sixty-one samples (6.3%) were reported to have pesticide residue levels quantified at or above the limit of quantification in five different pesticides (47 results in DDT (RD) mainly in sea bass, Pacific salmon and herrings), six determinations in pendimethalin (RD) mainly in Rainbow trout, four determinations in hexachlorobenzene (RD) in herrings, three determinations in BAC (RD) and one determination in glyphosate (RD)). These results make the risk for fish from the use of cyprodinil consistently with the intended GAP unlikely.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

As quantifiable residues of cyprodinil are expected in the treated crops, a study investigating the nature in processed commodities is required. As residues of cyprodinil exceeding 0.1 mg/kg are expected in the treated crops, investigation of the magnitude of residues in processed commodities is required.

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

Table 7.2-14: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
EU reviewed data (EFSA, 2013)						
Enforcement residue definition - Cyprodinil						
Processing factors recommended (sufficiently supported by data)						
Barley, brewing malt	25	1.15	1		OF95151/DE93 9810301 9810302 9810401 9810402 9715402 9715801 9715401 9715802 9715001 9715002 9715702 OF96142/DE11 OF95151/KJ30 2023/99 2025/99 2026/99 gr 44496 gr 42298 gr 44598 gr 41198 gr 43498 971064026 971047027 9715701	EFSA, 2013
Barley, beer	19	0.03	1	-		
Barley, pot/pearl	7	0.48	1	-		
Wheat, white flour	4	0.49	1		2013/00 IF-96/07964-00 IF-97/09998-00	EFSA, 2013
Wheat, bran	4	2.20	1			
Indicative processing factors (limited dataset)						
Wheat, wholemeal flour	1	0.87	1		2013/00	EFSA, 2013

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
Wheat, wholemeal bread	1	0.50	1		2013/00	EFSA, 2013

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

Summary of processing studies reported in the EU

Reference: France, 2005a and EFSA, 2013

Processing studies for cyprodinil have been conducted for apples (juice, wet pomace). They were reviewed during the approval process and are considered to be acceptable.

In the Article 12 evaluation of cyprodinil new processing studies in plums (dried), table grapes (dried), wine grapes (juice, must, unheated red wine, wet pomace), strawberries (jam, canned), barley (brewing malt, beer, pot/pearl), wheat (white flour, bran, wholemeal flour, wholemeal bread), tomatoes (unpeeled and canned, paste, juice) and beans (cooked), reviewed by JMPR, were presented.

The results relevant for crops under consideration in this submission are summarised in the table above.

7.2.5.2 Conclusion on processing studies

Processing factors were derived for barley and wheat processed products.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarised hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

New studies for residues in succeeding crops have been submitted by the applicant in the framework of this application. These studies are summarised in the table below. The detailed results are presented in Appendix 2.

Table 7.2-15: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
EU Reviewed data						
Bare soil (California, USA)	2.24 (4 x 0.56)	Leafy vegetables	Lettuce	30 90 150 210	174-97	France, 2005a
		Root and tuber vegetables	Turnips			
		Cereals	Wheat grain and straw			
Wheat (UK)	0.75 (BBCH 30)	Leafy vegetables	Lettuce	35-37	209/99 210/99	France, 2005a
		Root and tuber vegetables	Radish tops and whole plant	35-37 112-114		
		Cereals	Wheat ears, grain and stalks	35-37 135 314-316		
Wheat (Switzerland and Germany)	0.75 (BBCH 30)	Leafy vegetables	Lettuce	30 120	201/00 gr33800	France, 2005a
		Root and tuber vegetables	Radish leaves and whole plant	30 120		
		Cereals	Spring Wheat	30 55 331 - 370		
New data						
Bare soil (Austria and UK)	1.5	Leafy vegetables	Lettuce	30 56-63 365-383	Chambers J., 2015, 37SRX09R03 (VV-696953)	XXXX
		Root and tuber vegetables	Carrot tops and roots			
		Cereals	Wheat grain and straw	30 56-63 212-216 365-383		
Bare soil (Italy and France)	1.5	Leafy vegetables	Lettuce	30 60 323-384	Chambers J., 2015, 37SRX09R04 (VV-696952)	XXXX

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
		Root and tuber vegetables	Carrot tops and roots			
		Cereals	Wheat grain and straw	30 60 201-204 323-384		
Bare soil (Germany, UK, Italy and Spain)	1.13	Oily Crop	Winter and Spring oil seed rape	29-30 59-62 169-171	Ziske J., Bodsch J., 2016, IF-14/03024493 (VV-465458)	XXXX

Summary of field rotational crop studies in the EU

References: France, 2005a, EFSA, 2013

In addition to the confined rotational crop study, five rotational crop field trials were evaluated in the framework of the peer review. In the first field study cyprodinil was applied on bare soil and in the other four studies it was applied on wheat and the magnitude of residues was investigated on several succeeding crops (lettuce, turnips, radish and wheat) sown at different plant-back intervals following application of cyprodinil.

The RMS concluded: *"The residue data obtained from field studies even though variable, confirm the results from the confined rotational crop studies regarding the possible occurrence of the two plant metabolites NOA 442054 and CGA 321915 in crop rotations in some situations and that cyprodinil itself will very rarely occur.*

Overall residues of NOA 422054 ranged from <0.01-0.14 mg/kg in radish tops, <0.01-0.04 mg/kg in lettuce and <0.01-0.07 mg/kg in wheat forage, but the values > LOQ are generally found in the samples from the short plant back interval. Metabolite NOA 442054 in its free form is not stable in roots under deep frozen storage conditions. But no significant residues of NOA 442054 are expected in radish roots, as NOA 442054 sugar conjugate form was predominant in radish root and further, largest stability of the conjugate was suggested.

Overall residues of CGA 32915 were <0.01 mg/kg or low in rare situations; in wheat forage (0.01 and 0.02 mg/kg) and radish leaves (0.03 mg/kg) from the short plant back interval, in lettuce whole plant (0.01 mg/kg).

On the basis on these findings, no significant residues of these two metabolites are expected in relevant rotational crops of wheat in the year of treatment nor in the following year, following treatment of winter wheat at stage BBCH 32.

It is not considered necessary to include these metabolites in the residue definition for plants because firstly they occur in very specific crops/conditions and also because these metabolites are considered not toxicologically relevant."

EFSA concluded: *"Although CGA 321915 and NOA 422054 are not expected to be of any particular toxicological concern compared to the parent compound, the possibility of residues of these metabolites arising in rotational crops is likely to be dependent on the specific crop use and whether close cropping will occur as a result of normal agricultural practice. In order to address all possible crop rotations with primary* *crops, Member States granting authorisations for cyprodinil should consider the need to take the appropriate risk mitigation measures (e.g. definition of pre-plant intervals of at least 120d) in order to avoid the presence of cyprodinil metabolites residues in rotational crops."*

Summary of new field rotational crop studies

The new studies have also been submitted to France, as part of the ongoing AIR review process for cyprodinil. Cyprodinil was applied to bare soil at 1.13 or 1.5 kg a.s./ha (approx 2.5 or 3.3 X of the total seasonal application rate intended for the crops under consideration in this dossier). The results indicate that residues of cyprodinil are not expected in succeeding crops. Where residues of cyprodinil were found in rotational crops planted 30-60 days after application, values were very low (0.01 – 0.03 mg/kg).

Conclusion on rotational crops studies

EFSA (2006) concluded that significant residues are not expected in rotational crops when the active substance is applied on primary crops up to a total annual dose rate of 750 g a.s./ha (EFSA, 2006). Since the maximum annual application rate intended for the crops under consideration in this dossier is lower - i.e 450 a.s./ha , it can be concluded that cyprodinil residues are not expected to be present in rotational crops, provided that the active substance is applied according to the proposed GAPs.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A23282A. Therefore, other special studies are not needed. According to SANTE/11956/2016 rev. 9 (14 September 2018) barley, wheat, oat, durum wheat, spelt and rye are considered to not possess melliferous capacity. No studies on honey are required.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-16: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: cyprodinil		
Almonds	0.02	STMR-RAC (FAO, 2004)
Brazil nuts	0.01	STMR-RAC (FAO, 2018)
Cashew nuts	0.01	STMR-RAC (FAO, 2018)
Chestnuts	0.01	STMR-RAC (FAO, 2018)
Coconuts	0.01	STMR-RAC (FAO, 2018)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Hazelnuts/cobnuts	0.01	STMR-RAC (FAO, 2018)
Macadamia	0.01	STMR-RAC (FAO, 2018)
Pecans	0.01	STMR-RAC (FAO, 2018)
Pine nut kernels	0.01	STMR-RAC (FAO, 2018)
Walnuts	0.01	STMR-RAC (FAO, 2018)
Other tree nuts	0.01	STMR-RAC (FAO, 2018)
Apples	0.48	STMR-RAC (FAO, 2014)
Pears	0.48	STMR-RAC (FAO, 2014)
Quinces	0.48	STMR-RAC (FAO, 2014)
Medlar	0.48	STMR-RAC (FAO, 2014)
Loquats/Japanese medlars	0.48	STMR-RAC (FAO, 2014)
Other pome fruit	0.48	STMR-RAC (FAO, 2014)
Apricots	0.68	STMR-RAC (FAO, 2004)
Cherries (sweet)	0.68	STMR-RAC (FAO, 2004)
Peaches	0.68	STMR-RAC (FAO, 2004)
Plums	0.68	STMR-RAC (FAO, 2004)
Other stone fruit	0.68	STMR-RAC (FAO, 2004)
Table grapes	0.68	STMR-RAC (EFSA, 2013)
Wine grapes	0.67	STMR-RAC (EFSA, 2013)
Strawberries	0.99	STMR-RAC (EFSA, 2013)
Blackberries	0.81	STMR-RAC (EFSA, 2013)
Raspberries (red and yellow)	0.81	STMR-RAC (EFSA, 2013)
Blueberries	1.02	STMR-RAC (EFSA, 2021)
Cranberries	1.02	STMR-RAC (EFSA, 2021)
Currants (red, black and white)	1.02	STMR-RAC (EFSA, 2021)
Gooseberries (green, red and yellow)	1.02	STMR-RAC (EFSA, 2021)
Rose hips	0.69	STMR-RAC (EFSA, 2013)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Mulberries (black and white)	0.69	STMR-RAC (EFSA, 2013)
Azarole/Mediteranean medlar	0.69	STMR-RAC (EFSA, 2013)
Elderberries	0.69	STMR-RAC (EFSA, 2013)
Other small fruit & berries	0.69	STMR-RAC (EFSA, 2013)
Kaki/Japanese persimmons	0.48	STMR-RAC (FAO, 2014)
Avocados	0.26	STMR-RAC (FAO, 2014)
Granate apples/pomegranates	3.3	STMR-RAC (FAO, 2018)
Guavas	0.485	STMR-RAC (FAO, 2018)
Beetroots	0.45	STMR-RAC (EFSA, 2013)
Carrots	0.45	STMR-RAC (EFSA, 2013)
Celeriacs/turnip rooted celeries	0.08	STMR-RAC (EFSA, 2013)
Horseradishes	0.45	STMR-RAC (EFSA, 2013)
Parsnips	0.45	STMR-RAC (EFSA, 2013)
Parsley roots/Hamburg roots parsley	0.45	STMR-RAC (EFSA, 2013)
Radishes	0.023	STMR-RAC (EFSA, 2013)
Salsifies	0.45	STMR-RAC (EFSA, 2013)
Garlic	0.02	STMR-RAC (EFSA, 2013)
Onions	0.07	STMR-RAC (FAO, 2004)
Shallots	0.02	STMR-RAC (EFSA, 2013)
Spring onions/green onions and Welsh onions	0.17	STMR-RAC (EFSA, 2013)
Tomatoes	0.17	STMR-RAC (EFSA, 2013)
Sweet peppers/bell peppers	0.24	STMR-RAC (EFSA, 2013)
Aubergines/egg plants	0.17	STMR-RAC (EFSA, 2013)
Cucumbers	0.13	STMR-RAC (EFSA, 2013)
Gherkins	0.13	STMR-RAC (EFSA, 2013)
Courgettes	0.13	STMR-RAC (EFSA, 2013)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Other cucurbits - edible peel	0.13	STMR-RAC (EFSA, 2013)
Melons	0.016	STMR-RAC (0.08) (EFSA, 2013) x PeF (0.2)
Pumpkins	0.016	STMR-RAC (0.08) (EFSA, 2013) x PeF (0.2)
Watermelons	0.016	STMR-RAC (0.08) (EFSA, 2013) x PeF (0.2)
Other cucurbits - inedible peel	0.016	STMR-RAC (0.08) (EFSA, 2013) x PeF (0.2)
Broccoli	0.27	STMR-RAC (FAO, 2014)
Cauliflowers	0.27	STMR-RAC (FAO, 2014)
Other flowering brassica	0.27	STMR-RAC (FAO, 2014)
Head cabbages	0.03	STMR-RAC (FAO, 2014)
Lamb's lettuce/corn salads	3.1	STMR-RAC (EFSA, 2013)
Lettuces	3.1	STMR-RAC (EFSA, 2013)
Escaroles/broad-leaved endives	3.1	STMR-RAC (EFSA, 2013)
Cress and other sprouts and shoots	3.1	STMR-RAC (EFSA, 2013)
Land cress	3.1	STMR-RAC (EFSA, 2013)
Roman rocket/rucola	3.1	STMR-RAC (EFSA, 2013)
Red mustards	3.1	STMR-RAC (EFSA, 2013)
Baby leaf crops (including brassica species)	3.1	STMR-RAC (EFSA, 2013)
Other lettuce and other salad plants	3.1	STMR-RAC (EFSA, 2013)
Spinaches	3.1	STMR-RAC (EFSA, 2013)
Purslanes	3.1	STMR-RAC (EFSA, 2013)
Chards/beet leaves	3.1	STMR-RAC (EFSA, 2013)
Other spinach and similar	3.1	STMR-RAC (EFSA, 2013)
Witloofs/Belgian endives	0.02	STMR-RAC (EFSA, 2013)
Chervil	5.05	STMR-RAC (FAO, 2014)
Chives	5.05	STMR-RAC (FAO, 2014)
Celery leaves	5.05	STMR-RAC (FAO, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Parsley	5.05	STMR-RAC (FAO, 2014)
Sage	5.05	STMR-RAC (FAO, 2014)
Rosemary	5.05	STMR-RAC (FAO, 2014)
Thyme	5.05	STMR-RAC (FAO, 2014)
Basil and edible flowers	5.05	STMR-RAC (FAO, 2014)
Laurel/bay leaves	5.05	STMR-RAC (FAO, 2014)
Tarragon	5.05	STMR-RAC (FAO, 2014)
Other herbs	5.05	STMR-RAC (FAO, 2014)
Beans (with pods)	0.6	STMR-RAC (EFSA, 2013)
Beans (without pods)	0.02	STMR-RAC (EFSA, 2013)
Peas (with pods)	0.6	STMR-RAC (EFSA, 2013)
Peas (without pods)	0.02	STMR-RAC (EFSA, 2013)
Lentils (fresh)	0.07	STMR-RAC (EFSA, 2010)
Asparagus	0.02	STMR-RAC (EFSA, 2013)
Celeries	8.45	STMR-RAC (FAO, 2018)
Florence fennels	0.77	STMR-RAC (EFSA, 2019a)
Globe artichokes	1.2	STMR-RAC (FAO, 2018)
Rhubarbs	0.43	STMR-RAC (EFSA, 2019b)
Beans	0.06	STMR-RAC (EFSA, 2013)
Peas	0.02	STMR-RAC (EFSA, 2013)
Lupins/lupini beans	0.02	STMR-RAC (EFSA, 2013)
Sunflower seeds	0.03	STMR-RAC (Art. 6 for sunflower submitted to France in September 2021)
Rapeseeds/canola seeds	0.02	STMR-RAC (FAO, 2016)
Barley	0.765	STMR-RAC (barley residue trials, Northern and Southern zone merged)
Oat	0.765	STMR-RAC (barley residue trials, Northern and Southern zone merged)
Rye	0.13	STMR-RAC (EFSA, 2013)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Wheat	0.13	STMR-RAC (EFSA, 2013)
Valerian root	0.45	STMR-RAC (EFSA, 2013)
Ginseng root	0.45	STMR-RAC (EFSA, 2013)
Other herbal infusions (dried roots)	0.45	STMR-RAC (EFSA, 2013)
Liquorice	0.45	STMR-RAC (EFSA, 2013)
Turmeric/curcuma	0.45	STMR-RAC (EFSA, 2013)
Other spices (roots)	0.45	STMR-RAC (EFSA, 2013)
Bovine: Liver	0.02	STMR-RAC (EFSA, 2013)
Bovine: Kidney	0.02	STMR-RAC (EFSA, 2013)
Sheep: Liver	0.02	STMR-RAC (EFSA, 2013)
Sheep: Kidney	0.02	STMR-RAC (EFSA, 2013)
Goat: Liver	0.02	STMR-RAC (EFSA, 2013)
Goat: Kidney	0.02	STMR-RAC (EFSA, 2013)
Equine: Liver	0.02	STMR-RAC (EFSA, 2013)
Equine: Kidney	0.02	STMR-RAC (EFSA, 2013)
Other farmed animals: Liver	0.02	STMR-RAC (EFSA, 2013)
Other farmed animals: Kidney	0.02	STMR-RAC (EFSA, 2013)
Other crops/commodities	Default MRL (LOQ), according to Reg. (EU) 2021/1810	

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	Not available
IEDI (% ADI) according to EFSA PRIMo 3.1	58% (based on NL toddler)
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1*	Not applicable (no ARfD)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1*	Not applicable (no ARfD)

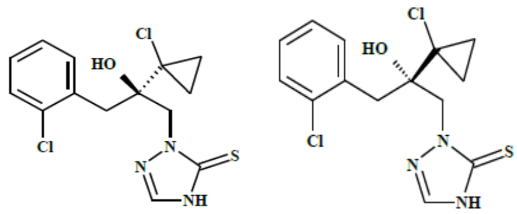
* include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of cyprodinil in A23282A do not represent unacceptable chronic risks for the consumer.

7.3 Prothioconazole

General data on prothioconazole are summarised in the table below (last updated 2021/02/21)

Table 7.3-1: General information on prothioconazole

Active substance (ISO Common Name)	Prothioconazole
IUPAC	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione (ISO)
Chemical structure	 Racemate (50:50)
Molecular formula	$C_{14}H_{15}Cl_2N_3OS$
Molar mass	344.26 g/mol
Chemical group	Triazole compounds
Mode of action (if available)	Steroid demethylation in the ergosterol biosynthesis pathway
Systemic	Yes
Company (ies)	Bayer CropScience AG*
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved 01/08/2008, Commission Directive 2008/44/EC - Regulation (EU) No 540/2011 & 2019/707
Restriction	Only uses as fungicide may be authorised.
Review Report	SANCO/3923/07 – final 10/12/2007 updated on 26/01/2021 following confirmatory data
Current MRL regulation	Regulation (EU) 2019/552
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA, 2014 - see list of references)
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2007 - see list of references) New request (EFSA-Q-2015-00521)
Current MRL applications on intended uses	None (EFSA Register of Questions)

* Notifier in the EU process to whom the a.s. belong(s)

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Prothioconazole

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High water content	Wheat forage	36 months 1)	MR-354/01	UK/Poland, 2020
	Spinach Sugar beet Tomato	24 months 1)	MR-07/282	
	Tomato	25 months 2)	MR-08/024	
High oil content	Canola seed	24 months 1)	MR-07/282	
	Oilseed rape seed Soya bean	25 months 2)	MR-08/024	
High protein content	Field pea (dried)	24 months 1)	MR-07/282	
High starch content	Wheat grain	36 months 1)	MR-354/01	
	Potato	25 months 2)	MR-08/024	
High acid content	Orange	25 months 2)	MR-08/024	
Other	Wheat straw	36 months 1)	MR-354/01	
Animal Products				
Not required				UK/Poland, 2020

1) Prothioconazole-desthio
2) Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio

TDMs

Table 7.3-3: Summary of stability data for Triazole Acetic Acid (TAA) achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High oil content	Oilseed rape seed	24 months	RJ1932B Kwiatowski A.S., Robinson N.R., 1995	United Kingdom, 2018 EFSA, 2018a

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
		48 months	RAJAY2006 Murphy I., 2008	
	Oilseed rape oil	48 months	RAJAY2006 Murphy I., 2008	
	Peanut butter	12 months	USTTF-1511 Memmel A.C., 2005	
	Soybean seed	26 months	138232 Saha M., 2010	
High water content	Cabbage head	24 months	RJ1932B Kwiatowski A.S., Robinson N.R., 1995	
	Sugar beet root	24 months		
	Apple	12 months	USTTF-1511 Memmel A.C., 2005	
	Radish tops	12 months	138232 Saha M., 2010	
	Radish roots	26 months		
	Wheat forage	48 months	RAJAY2006 Murphy I., 2008	
	Turnip roots			
	Tomato fruits			
	Mustard leaves			
High starch content	Wheat grain	24 months	RJ1932B Kwiatowski A.S., Robinson N.R., 1995	
	Barley grain	36 months	2285 Zini G., Crisippi T., 2003	
	Wheat flour	12 months	USTTF-1511 Memmel A.C., 2005	
		48 months	RAJAY2006 Murphy I., 2008	
	Wheat grain	26 months	138232 Saha M., 2010	
		48 months	RAJAY2006 Murphy I., 2008	
High protein content	Dry pea seed	24 months	RJ1932B Kwiatowski A.S., Robinson N.R., 1995	

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
Cereal straw	Wheat straw	24 months	RJ1932B Kwiatowski A.S., Robinson N.R., 1995	
		48 months	RAJAY2006 Murphy I., 2008	
	Barley straw	36 months	2285 Zini G., Crisippi T., 2003	

Table 7.3-4: Summary of stability data for Triazole Alanine (TA) achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High oil content	Oilseed rape seed	15 months	TMJ4481B Lister N et al, 2000	United Kingdom, 2018 EFSA, 2018a
		48 months	RAJAY2006 Murphy I., 2008	
	Oilseed rape oil	8 months	RAJAY2006 Murphy I., 2008	
	Peanut butter	12 months	USTTF-1511 Memmel A.C., 2005	
	Soybean seed	26 months	138232 Saha M., 2010	
High water content	Cabbage head	15 months	RJ1932B Kwiatowski A.S., Robinson N.R., 1995	
	Apple	12 months	USTTF-1511 Memmel A.C., 2005	
	Radish tops	26 months	138232 Saha M., 2010	
	Radish roots	26 months		
	Wheat forage	36 months	RAJAY2006 Murphy I., 2008	
	Turnip roots	48 months		
	Tomato fruits	48 months		
	Mustard leaves	48 months		

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
	Sugar beet root	15 months	TMJ4481B Lister N et al, 2000	
High starch content	Barley grain	36 months	2284 Zini G., Crisippi T., 2003	
	Wheat flour	12 months	USTTF-1511 Memmel A.C., 2005	
		48 months	RAJAY2006 Murphy I., 2008	
	Wheat grain	26 months	138232 Saha M., 2010	
		48 months	RAJAY2006 Murphy I., 2008	
		15 months	TMJ4481B Lister N et al, 2000	
High protein content	Dry pea seed	15 months	TMJ4481B Lister N et al, 2000	
Cereal straw	Wheat straw	15 months	TMJ4481B Lister N et al, 2000	
		48 months	RAJAY2006 Murphy I., 2008	
	Barley straw	36 months	2284 Zini G., Crisippi T., 2003	

Table 7.3-5: Summary of stability data for Triazole Lactic Acid (TLA) achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High oil content	Oilseed rape seed	48 months	366867 Perez R., et al, 2015	United Kingdom, 2018 EFSA, 2018a
High water content	Lettuce	48 months	366867 Perez R., et al, 2015	
High starch content	Wheat flour	12 months	USTTF-1511 Memmel A.C., 2005	

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
	Wheat grain	48 months	366867 Perez R., et al, 2015	
High protein content	Navy bean	48 months	366867 Perez R., et al, 2015	
High acid content	Orange fruit	48 months	366867 Perez R., et al, 2015	

Table 7.3-6: Summary of stability data for 1,2,4-Triazole (1,2,4-T) achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High oil content	Oilseed rape seed	76 days	RAJAY2006 Murphy I., 2008	United Kingdom, 2018 EFSA, 2018a
	Oilseed rape oil	48 months	RAJAY2006 Murphy I., 2008	
	Peanut butter	12 months	USTTF-1511 Memmel A.C., 2005	
	Soybean seed	12 months	138232 Saha M., 2010	
High water content	Apple	12 months	USTTF-1511 Memmel A.C., 2005	
	Radish tops	26 months	138232 Saha M., 2010	
	Radish roots	26 months		
	Wheat forage	36 months	RAJAY2006 Murphy I., 2008	
	Turnip roots	36 months		
	Tomato fruits	36 months		
	Mustard leaves	4 months		
High starch content	Wheat flour	12 months	USTTF-1511 Memmel A.C., 2005	
		48 months	RAJAY2006 Murphy I., 2008	
	Wheat grain	26 months	138232 Saha M., 2010	

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
		48 months	RAJAY2006 Murphy I., 2008	
Cereal straw	Wheat straw	36 months	RAJAY2006 Murphy I., 2008	
Animal Products				
Milk	Ruminant	18 months	Zini.,1997	United Kingdom, 2018 EFSA, 2018a
		12 months	Memmel AC., 2005	
Eggs	Poultry	12 months	Memmel AC., 2005	
Liver	Ruminant	12 months	Zini G., 1998	
Muscle	Ruminant	12 months	Zini G., 1998	
Fat	Ruminant	12 months	Zini G., 1998	

Summary of storage stability studies reported in the EU

Prothioconazole

Reference: EFSA, 2014

"In the framework of the peer review, storage stability of prothioconazole-desthio *residues was demonstrated at -18 °C for 18 months in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw (EFSA, 2007b; United Kingdom, 2004, 2007). Furthermore, storage stability of prothioconazole-desthio residues was subsequently demonstrated for a period of 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw (EFSA, 2009, 2010a, 2010b, 2012; Netherlands, 2007). According to the RMS and the Member States which submitted additional data during the MS consultation, all residue trial samples reported in the PROFile were stored in compliance with the storage conditions reported above. Degradation of prothioconazole-desthio residues during storage of the trial samples is therefore not expected. However, storage stability was demonstrated for prothioconazole and prothioconazole-desthio only, while further metabolites are included in the residue definition for risk assessment. Therefore, further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition are still required in the relevant commodity groups."*

Reference: UK/Poland, 2020

The relevant metabolites of prothioconazole are regarded as stable in a range of crop matrices for the following storage intervals: Prothioconazole-desthio for 1088 days in commodities with high water and high starch content as well as wheat straw, and for 734 days in commodities of high oil and high protein content; prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio for 759 days in commodities with high water, high oil, high starch and high acid content.

Storage stability of prothioconazole is not presented as this compound is not part of the residue definition for enforcement and risk assessment.

TDMs

References: United Kingdom, 2018 and EFSA, 2018a

A total of 11 studies were submitted to UK in August 2014, by the triazole derivative metabolite group (TDMG) member companies, to assess the stability of residues of 1,2,4-triazole, triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in a range of frozen crop and animal commodities.

Taking into account all studies, acceptable storage stability was observed for all TDMs in several commodity categories, as summarised in the table below (EFSA, 2018a):

Table 7.3-7: Summary of Stability Data for TDMs in Plant and Animal Commodities agreed within the EU (EFSA, 2018a)

Plant products (Category)	Commodity	Storage stability (Months)			
		1,2,4-Triazole	**TA**	**TAA**	**TLA**
High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnip roots, sugar beet roots, cabbages, lettuces	6	53	53	48 (lettuce only)
High starch content	Barley, wheat	12	26	26	48
High oil content	Rapeseeds, soyabeans	12 (soyabean only; not stable in rapeseed)	26 (soyabean only; not stable in rapeseed)	53	48
High protein content	Peas, dry; Navy beans	No data	15	25	48
High acid content	Oranges	No data	No data	No data	48
Cereal straw	Barley, wheat	12	53	40	No data[(a)]
Animal products	Milk	18	No data	No data	No data
	Eggs	No data	No data	No data	No data
	Liver	12	No data	No data	No data
	Muscle	12	No data	No data	No data
	Fat	12	No data	No data	No data

(a) UK 2018 stated "*No data are available for TLA. However, given the stability data available for all other categories no further data are required.*"

Reference: EFSA, 2018a

"From the submitted storage stability data it can be concluded that the residue trials analysing TA, TAA and TLA residues in high water-, high oil-, high protein- and high starch-content commodities were supported by acceptable storage stability data on these compounds, except for TA (raspberries, peas, rapeseeds) and TAA (raspberries). The residue trials analysed 1,2,4-triazole residues in most of the crops within a time interval for which acceptable storage stability of this compound could not be demonstrated, except for stone fruit, stem vegetables, soya beans and oats grain. Storage stability data were not provided and are required for 1,2,4-triazole, TA and TAA in high acid-content commodities, for 1,2,4-triazole in high protein-content commodities and for TLA in cereal straw to cover the maximum storage time interval of all residue trials in primary and rotational crops (data gap). For products of animal origin, the available storage stability data demonstrated acceptable freezer storage stability of 1,2,4-triazole in milk for 18 months and in liver, muscle and fat for 12 months. Additional storage stability data analysing for the residues of 1,2,4-triazole, TA and TAA in milk and eggs were also provided but were not considered as acceptable since the homogenised samples of milk and eggs were fortified with a mixture of TA and TAA and not with the individual compound, respectively."

Further work to address the data gaps identified within the EFSA Peer Review (2018) are ongoing within the TDMG. As per an agreement with EU Commission, any newly generated TDMG data will be part of a centralised EU review process. All new ancillary TDM data are addressed via the TDMG, and as agreed by the European Commission, evaluated by the Austrian Authority AGES in parallel to the AIR evaluation of Paclobutrazol.

Conclusion on stability of residues during storage

The storage stability of the relevant prothioconazole metabolite prothioconazole-desthio has been investigated in different groups, including commodities of high water, high oil, high protein and high starch content and cereal straw. The storage stability of the relevant prothioconazole metabolites prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio has been investigated in different groups, including commodities of high water, high oil, high starch and high acid content, and is therefore considered to be also given in cereal straw.
The storage stability of the triazole derivative metabolites has been investigated in different groups, including commodities of high water, high oil, high protein, high starch, high acid content and cereal straw. Sufficient stability has been demonstrated to support the residue data presented in this submission.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of prothioconazole-desthio in sample extracts and fully support the residue data presented in the submission.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-8: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)		
EU reviewed data								
Root and tuber vegetables	Sugar beet	[U-^{14}C-phenyl] prothio-conazole	Foliar, F	0.29	4 (14 days interval)	Roots & tops/leaves: 7	200466	UK/Poland, 2020, EFSA, 2014
		[3,5-^{14}C-triazole] prothio-conazole	Foliar, F	0.29	4 (14 days interval)	Roots & tops/leaves: 7	200467	
Pulses and oilseeds	Peanut	[U-^{14}C-phenyl] prothio-conazole	Foliar, G	0.30	3 (21 days interval)	Hay & nuts without shells: 14	MR-193/01	United Kingdom, 2004, 2007 EFSA, 2014

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)		
					(BBCH 66-75)			
		[3,5-^{14}C-triazole] prothioconazole	Foliar, G	0.30	3 (21 days interval) (BBCH 66-75)	Hay & nuts without shells: 14	MR-194/02	UK/Poland, 2020, EFSA, 2014
Cereals	Wheat	[U-^{14}C-phenyl] prothioconazole	Foliar, G (spring wheat)	0.22	2 (BBCH 32-65)	Forage: 6 Hay: 26 Grain & straw: 48	MR-198/99	United Kingdom, 2004, 2007 EFSA, 2014
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G (summer wheat)	0.25	2 (27 days interval) (BBCH 31-59)	Forage: 0, 14 Grain & straw: 48	PF3906	
		[3,5-^{14}C-triazole] prothioconazole	Foliar, F (spring wheat)	0.18 and 0.29	2 (BBCH 32-65)	Forage, hay, grain, straw: according to normal farming practice	200733	UK/Poland, 2020, EFSA, 2014
		[U-^{14}C-phenyl] prothioconazole	Seed, G (spring wheat)	0.02 or 0.10 kg/100 kg seeds (ca. 220 kg seeds/ha)	1	Forage: 57 Hay: 110 Grain & straw: 153	110881 (MR-467/99)	United Kingdom, 2004, 2007 EFSA, 2014

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2014

"In the foliar treated wheat samples, the TRR levels accounted for 0.08 and 5 mg eq/kg in grain, 10 and 8 mg eq/kg in forage, 8.9 and 11.2 mg eq/kg in hay and 27 and 7.9 mg eq/kg in straw, respectively for the phenyl and the triazole labelling forms of prothioconazole. The level of metabolites identification accounted for 73% and 66% of the TRR in forage, 65% and 75% of the TRR in hay, 66% and 61% of the TRR in straw and 34% and 94% TRR in grain, respectively for the phenyl and triazole labellings. In all the wheat matrices, prothioconazole was extensively metabolized.

Prothioconazole-desthio was the major compound of the total residues in all wheat plant parts for the phenyl labelling form: 35.4% of the TRR (3.70 mg eq/kg) in forage, 18.5% of the TRR (1.64 mg eq/kg) in hay, 22.3% of the TRR (5.95 mg eq/kg) in straw and 16% of the TRR (0.014 mg eq/kg) in grain. The hydroxylated derivative metabolites of prothioconazole-desthio (M14, M15, M17) and their glucoside conjugates were also identified in forage (13.4% of the TRR, 1.42 mg eq/kg), hay (19.5% of the TRR, 1.74 mg eq/kg), grain (9.5% of the TRR, 0.007 mg eq/kg) and straw (14.8% of the TRR, 3.93 mg eq/kg). The parent compound and other minor metabolites were identified in all matrices and accounted each for less than 10% TRR.

For the triazole labelling form, a similar metabolic pattern as for the phenyl labelling was observed in all wheat plant parts with the parent prothioconazole being also extensively metabolised (< 10% TRR). Besides, cleavage of the triazole moiety of the prothioconazole-desthio occurred in all wheat matrices resulting in the formation of the following 'triazole derivative metabolites' (TDMs): triazole alanine and triazole acetic acid mainly recovered in grain at proportions of 71% and 19% of the TRR, respectively. It is noted that these compounds are common, unspecific metabolites of triazole fungicides.

In wheat after foliar application using [3,5-^{14}C-triazole]-prothioconazole-desthio, the highest total residues levels were identified in straw (28.67 mg eq/kg), in forage (10.87 mg eq/kg) and to a minor extent in grain (2.85 mg eq/kg). Prothioconazole-desthio constituted the major compound of the total radioactive residues in forage (up to 86.8% TRR, 8.94 mg eq/kg in green material) and in straw (71.9% TRR, 20.61 mg eq/kg) whilst the triazole alanine and triazole acetic acid metabolites were significantly translocated to wheat grains, where they both represented 92.1% of the TRR (2.63 mg eq/kg).

Following seed treatment on wheat with the phenyl labelled prothioconazole, very low levels of radioactive residues were recovered in wheat grain (TRR <0.01 mg/kg) and no metabolites' identification could be attempted. In straw, forage and hay, TRR accounted for 0.03 - 0.28, 0.02 - 0.07 and 0.02 - 0.09 mg eq/kg, after the 1X and 5X experiments, respectively. Identification procedures in these matrices were performed in the 5X experiment and showed that the metabolic pattern of prothioconazole in the wheat plant parts after seed treatment was similar to the one depicted following foliar applications. Indeed, parent compound was extensively metabolised: prothioconazole-desthio and its hydroxylated forms (including their glucosides) (M14, M15, M17) constituted the major compounds in all crop parts. Prothioconazole-desthio represented 10.9% of the TRR (0.008 mg eq/kg) in forage, 6.6% of the TRR (0.019 mg eq/kg) in straw and 6.4% of the TRR (0.005 mg eq/kg) in hay. Its hydroxylated metabolites and their corresponding glucosides amounted together to 19.7% of the TRR (0.055 mg eq/kg) in straw, 13.5% of the TRR (0.011 mg eq/kg) in fodder and 5.6% of the TRR (0.005 mg eq/kg) in hay. Parent and all other metabolites were below 10% of the TRR.

In peanuts, following both labelling applications, the highest total radioactive residues were identified in peanut hay (47.4 - 107.5 mg eq/kg). In nutmeat, the total residues accounted for only 0.29 to 1.40 mg eq/kg. The level of identification of the total residues in hay and nutmeat for both labels ranged from 65.1% to 82.7% of the TRR. In peanut hay, following both labels, prothioconazole-desthio constituted the major component of the total radioactive residues (up to 28.2% TRR, 30.4 mg eq/kg), whilst metabolite M27 was also recovered as a significant metabolite in hay after phenyl label application only (14.1% TRR, 15.09 mg eq/kg). The hydroxylated derivative metabolites of prothioconazole-desthio (M14, M15) accounted together for 9.6% of the TRR (up to 10.31 mg eq/kg). Parent compound and all other identified metabolites were recovered at levels below 10% of the TRR. In nutmeat, after phenyl label application, M27 was the predominant compound of the total residues, accounting for up to 12.2% of the TRR (0.04 mg/eq/kg). M24 was also identified and accounted for up to 9% of the TRR (0.03 mg eq/kg). Neither parent compound nor prothioconazole-desthio were detected and the major part of the radioactivity was incorporated into the fatty acids matrix (up to 47.8% TRR, 0.14 mg eq/kg). For the triazole labelling form, the major compounds identified in nutmeat were triazole lactic acid and triazole alanine (24.5% and 47.8% TRR, respectively) whilst other compounds amongst which the parent compound and prothioconazole-desthio were identified at a level below 10% of the TRR.

In sugar beets, for the phenyl and triazole labellings, TRR levels were higher in leaves (4.3 - 5.2 mg eq/kg) than in roots (0.12 - 0.13 mg eq/kg). Following phenyl labelled prothioconazole application, prothioconazole–desthio accounted for 28% and 58% of the TRR in leaves and roots, respectively. Metabolite M24 was also recovered in leaves at 10% TRR (0.45 mg eq/kg). Regarding the triazole labelling moiety, besides prothioconazole-desthio that was identified in leaves (19% TRR, 0.99 mg eq/kg) and in roots (25% TRR, 0.03 mg eq/kg) and the metabolite M24 detected in leaves (10% TRR, 0.51 mg eq/kg), triazole alanine was found to be the predominant compound of the total residues in roots (29% TRR, 0.04 mg eq/kg). Prothioconazole was seen to be extensively degraded in both leaves and roots and accounted for less than 10% of the TRR.

Based on the available metabolism studies, prothioconazole is extensively metabolised and the metabolic pathway is similar in all crops investigated. The main metabolic pathway consisted in the formation of prothioconazole-desthio: the sulphur group of the triazolinethione ring of parent prothioconazole is firstly *oxidized to the corresponding sulfonic acid with subsequent elimination of the sulfonic acid moiety. This metabolite subsequently undergoes different pathways either by hydroxylation on the chlorophenyl ring, forming various hydroxyl-desthio isomers (M14, M15, M17), dihydroxy-olefins (M27) and hydroxy-dienyl-cysteine (M24) isomers followed by a glucosidation step or by cleavage of the triazole moiety of prothioconazole-desthio resulting in the formation of 'triazole derivative metabolites' (TDMs), mainly triazole alanine, triazole lactic acid and triazole acetic acid.*

These compounds are common metabolites to all triazole fungicides. Finally, a dimerisation of the parent molecule was observed resulting from the combined oxidation of the sulphur atom followed by hydroxylation of the chlorophenyl ring.

Apart from the triazole derivative metabolites (TDMs), all the identified metabolites are structurally closely related to prothioconazole-desthio, being formed by hydroxylation on the phenyl ring. During the peer review, it was assumed as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites."

"EFSA also emphasises that the above residue definitions do not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available."

Conclusion on metabolism in primary crops

The metabolism of prothioconazole in plants following foliar application is sufficiently addressed to support the proposed uses of the product A23282A.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-9: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G[(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy vegetables	Swiss chard	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	80, 188, 348	MR-159/00	United Kingdom, 2004, 2007 EFSA, 2014
		[3,5-^{14}C-triazole] prothioconazole	Bare soil application, F	4x 0.204 (14 days interval)	30, 125, 366	RAC samples (each time interval)	2000623	UK/Poland, 2020, EFSA, 2014

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G(a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
Root and tuber vegetables	Turnip	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	Roots, tops: 94, 201, 349	MR-159/00	United Kingdom, 2004, 2007 EFSA, 2014
		[3,5-^{14}C-triazole] prothioconazole	Bare soil application, F	4x 0.204 (14 days interval)	30, 125, 366	RAC samples (each time interval)	2000623	UK/Poland, 2020, EFSA, 2014
Cereals	Spring wheat	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	Green material: 73, 178, 327 Hay: 111, 231, 377 Grain, straw: 145, 269, 412	MR-159/00	United Kingdom, 2004, 2007 EFSA, 2014
		[3,5-^{14}C-triazole] prothioconazole	Bare soil application, F	4x 0.204 (14 days interval)	30, 125, 366	RAC samples (each time interval)	2000623	UK/Poland, 2020, EFSA, 2014

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of metabolism studies in rotational crops reported in the EU

Reference: EFSA, 2014

"In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (≤ 0.007 mg eq/kg) and no further metabolites' identification was attempted. In wheat green material, hay and straw, TRR ranged from 0.021 mg eq/kg (green material, DAT 28) to 0.450 mg eq/kg (straw, DAT 28). In turnip roots, tops and Swiss chard, the highest residue levels ranged from 0.043 mg eq/kg (turnip root, DAT 28) to 0.053 mg eq/kg (Swiss chard, DAT 146). No significant decline of the residue levels was observed for any crop part throughout the first, second and third rotation.

In the edible parts of the crops at harvest 61 to 87% of the total residues were extracted and the level of identification ranged between 34.4% TRR (Swiss chard, DAT 269) to 77.2% TRR (turnip leaves, DAT 28). The major compounds of the total residues were identified as prothioconazole-desthio, its hydroxylated derivative metabolites, either free or conjugated (M14, M15, M16, M17), M27, free and conjugated and M02. Residue levels of the main metabolites recovered in wheat were in general higher in straw than in hay. In straw, they reached the following levels: prothioconazole-desthio (0.066 mg eq/kg) (DAT 28), M02 (0.063 mg eq/kg) (DAT 269), glucoside of M27 (0.056 mg eq/kg) (DAT 269) and glucosides of the hydroxylated metabolites of prothioconazole-desthio (0.097 mg eq/kg) (DAT 28). In Swiss chard, levels of prothioconazole-desthio reached 0.014 mg eq/kg at 28 DAT, while levels of M27 glucosides were below 0.01 mg eq/kg at all sowing intervals. In turnip roots and leaves, the residue levels of the identified major metabolites were always below 0.01 mg eq/kg.

Consequently, the metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

[…] rotational crop studies with prothioconazole radiolabelled on the triazole ring […]indicated a cleavage of the triazole linkage with the formation of the major metabolites found in all rotational crop matrices as triazole alanine, triazole lactic acid and triazole acetic acid. Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites."

Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Prothioconazole

Table 7.3-10: Nature of the residues in processed commodities: Prothioconazole

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
Pasteurisation (20 minutes, 90°C, pH 4)	Prothioconazole-desthio (99.4%)	MR-106/00	UK/Poland, 2020
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Prothioconazole-desthio (99.9%)		
Sterilisation (20 minutes, 120°C, pH 6)	Prothioconazole-desthio (99.8%)		

TDMs

Table 7.3-11: Nature of the residues in processed commodities: TDMs

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
Pasteurisation (20 minutes, 90°C, pH 4)	Triazole alanine (100%) Triazole acetic acid (98.9%) Triazole lactic acid (98.3%) 1,2,4-Triazole (99.5%)	MEF-10/545 Weber E., 2010	United Kingdom, 2018, EFSA, 2018a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Triazole alanine (96.5%) Triazole acetic acid (98.6%) Triazole lactic acid (98.9%) 1,2,4-Triazole (99.5%)		
Sterilisation (20 minutes, 120°C, pH 6)	Triazole alanine (94.5%) Triazole acetic acid (>95%) Triazole lactic acid (98.9%) 1,2,4-Triazole (99.5%)		

Summary of high temperature studies reported in the EU

Prothioconazole

Reference: UK/Poland, 2020

"The results of the hydrolysis study indicate that for prothioconazole-desthio, the nature of the residue in the processed commodity is expected to be identical to that in the raw agricultural commodity following pasteurisation, baking, brewing and boiling, and sterilisation."

Reference: EFSA, 2014

"It was concluded that prothioconazole-desthio remains stable under these hydrolytic conditions; the levels of prothioconazole-desthio in the samples after hydrolysis ranged from 99.4 to 99.9% of the applied radioactivity."

TDMs

The effect of processing on the nature of TDMs was investigated in the framework of the peer review of confirmatory data for triazole metabolites (United Kingdom, 2018 and EFSA, 2018a). Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6).

Reference: EFSA, 2018a

"The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation."

Conclusion on nature of residues in processed commodities

The nature of residues of prothioconazole-desthio and the TDMs in processed products has been investigated. Prothioconazole-desthio and TDMs are hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.3-12: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root crops (Sugar beet) Pulses and oilseeds (Peanut) Cereals (Wheat)
Rotational crops covered	Swiss chard, turnip and wheat for - 28, 146 and 269 days after treatment at the dose of 1x 580 g a.s./ha of prothioconazole (phenyl label) - 30, 125 and 366 days after treatment at the dose of 4x 204 g a.s./ha of prothioconazole (triazole label)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Prothioconazole-desthio and TDMs are stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole-desthio (sum of isomers) (Regulation (EU) 2019/552)
Plant residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2007, 2014) (1) Prothioconazole-desthio (sum of isomers) (2) TA and TLA; (3) TAA; (4) 1,2,4-triazole (UK/Poland, 2020)
Conversion factor from enforcement to RA	2 (cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables) 3 (cereal straw) (EFSA, 2014) 3 (cereal straw) (UK/Poland, 2020)

7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Prothioconazole

Table 7.3-13: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	[U-^{14}C-phenyl] prothioconazole	1	10 (250 mg a.s./kg feed)	3 (53 h)	Milk	twice daily	MR-092/01	United Kingdom, 2004, 2007 EFSA, 2014
						Urine and faeces	daily		
						Tissues	at sacrifice		
	Goat	[U-^{14}C-phenyl] prothioconazole-desthio	1	10 (195 mg a.s./kg feed)	3 (53 h)	Milk	twice daily	MR-091/01 MEF-06/469	United Kingdom, 2004, 2007, UK/Poland, 2020, EFSA, 2014
						Urine and faeces	daily		
						Tissues	at sacrifice		
	Goat	[3,5-^{14}C-triazole] prothioconazole	1	10	3 (53 h)	Milk	twice daily	MR-448/02	UK/Poland, 2020, EFSA, 2014
						Urine and faeces	daily		
						Tissues	at sacrifice		
	Goat	[3,5-^{14}C-triazole] prothioconazole-desthio	1	10	5 (101 h)	Milk	twice daily	MEF-11/011	UK/Poland, 2020
						Urine and faeces	daily		
						Tissues	at sacrifice		

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
Laying poultry	Hens	[U-^{14}C-phenyl] prothioconazole	6	10	3 (53 h)	Eggs	once daily	MR-309/01	United Kingdom, 2004, 2007 EFSA, 2014
						Excreta	at regular intervals		
						Tissues	at sacrifice		
	Hens	[3,5-^{14}C-triazole] prothioconazole	6	10	3 (53 h)	Eggs	once daily	MEF-005/03	UK/Poland, 2020, EFSA, 2014
						Excreta	at regular intervals		
						Tissues	at sacrifice		

<u>TDMs</u>

Table 7.3-14: Summary of animal metabolism studies: Triazole Alanine

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	[triazole-UL-^{14}C] triazole alanine	1	0.70	7	Milk	Twice Daily	MEF-09/699	United Kingdom, 2018 EFSA, 2018a
						Urine and faeces	Daily		
						Tissues	At sacrifice		
	Cow (rumen fluid at 39°C)	[triazole-UL-^{14}C] triazole alanine	n/a	20 ug	4 (96 h)	Incubation mixtures	0, 4, 8, 24, 72 and 96 hours	PM-09-103	United Kingdom, 2018 EFSA, 2018a
Laying Poultry	Hens	[triazole-UL-^{14}C] triazole alanine	6	0.81	14	Eggs	once daily	MEF-09/839	United Kingdom, 2018 EFSA, 2018a
						Excreta	Once daily		
						Tissues	at sacrifice		

Summary of animal metabolism studies reported in the EU

Prothioconazole

Reference: UK/Poland, 2020

"As there are no significant changes to the proposed metabolic pathway in ruminants, and no new rat metabolism studies have been assessed, the following conclusions on the need for metabolism studies in pigs remain unchanged from the 2014 Article 12 MRL Review (EFSA Journal 2014;12(5):3689):

Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3% AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs."

Reference: EFSA, 2014

"Laying hens were dosed with 10 mg/kg bw per d of phenyl and triazole labelled prothioconazole, respectively. The major part of the total administered dose (AR) was recovered in excreta (66% and 78% AR for the triazole and phenyl labellings, respectively) and only trace amounts of radioactivity were detected both in eggs (0.01% AR) and tissues (about 0.9% AR).

The total radioactive residues accounted for 4.0 - 3.5 mg eq/kg in liver, 0.036 – 0.05 mg eq/kg in eggs, 0.45 - 0.29 mg eq/kg in subcutaneous fat and 0.089 - 0.12 mg eq/kg in muscle, respectively for the phenyl and triazole labellings. The extractability of the total radioactive residues ranged from 77% TRR in eggs to 98% TRR in fat.

Prothioconazole was the major compound of the total residues in liver (25% - 31% TRR, 1.0 - 1.1 mg/kg) and in fat (30% - 16% TRR, 0.14 - 0.046 mg/kg) for the phenyl and triazole labels, respectively. Prothioconazole-desthio (29% - 27% TRR, 0.13 - 0.08 mg eq/kg) and M0135 (20% - 29% TRR, 0.083 - 0.088 mg eq/kg) in fat as well as M0636 in liver (12% - 15% TRR, 0.48 - 0.53 mg eq/kg) were the only metabolites exceeding 10% of the TRR in these commodities. In muscle, the major compounds were M4537 (28% TRR, 0.035 mg eq/kg) and 1,2,4-triazole (19% TRR, 0.023 mg eq/kg) specific to the triazole labelling, and M06 (16% - 10% TRR, 0.014 - 0.012 mg eq/kg) and parent prothioconazole (11% - 2.5% TRR, 0.01 - 0.003 mg eq/kg) for phenyl and triazole labelling, respectively. Prothioconazole-desthio accounted for only 7% - 2.1% TRR (0.006 - 0.003 mg eq/kg). In eggs, the major compounds of the total residues were M06 (24% - 16% TRR, 0.012 - 0.014 mg eq/kg) and prothioconazole-desthio (20% - 6.2% TRR, 0.007 - 0.003 mg eq/kg) for phenyl and triazole label, respectively. For the triazole labelling moiety, the metabolites M45 (15.6% TRR, 0.008 mg eq/kg) and 1,2,4-triazole (11% TRR, 0.006 mg eq/kg) were also identified. Prothioconazole accounted for only 3.6% - 3.4% TRR (0.001 - 0.002 mg eq/kg), for phenyl and triazole label, respectively. All other metabolites identified were either glucuronic acid or sulphate conjugates of the hydroxylated prothioconazole and accounted for less than 10% TRR."

TDMs

Reference: United Kingdom, 2018

"When triazole alanine is fed to livestock and rats the other three triazole derivative metabolites were conclusively identified. In the goat metabolism study with triazole alanine, a significant portion of the radioactivity applied was cleaved to 1,2,4 triazole. Compared to goats, this cleavage is less pronounced in hens where in general only little metabolism was observed. In order to explain the findings, a cow rumen fluid experiment was performed. The experiment confirmed the theory that the cleavage step occurred mainly in the rumen.

Based on these data, further data on the metabolism of T, TAA and TLA in poultry and ruminants is not deemed necessary.

The relevant residues in products of animal origin are T, TA, TAA and TLA."

Reference: EFSA, 2018a

"Since TA is a major component in feed items, the potential transfer of this compound in poultry and ruminant matrices was further investigated in a metabolism study conducted with ^{14}C-TA. TA remains the major compound of the total residues in all poultry matrices (84 to 97.2% TRR) and in ruminant tissues (56 to 76% TRR) whilst TA and 1,2,4-triazole accounted for 8% TRR and 86% TRR respectively in milk. TLA and TAA were detected in very low levels in all matrices (<1% TRR). The potential transfer of TAA, TLA and 1,2,4-triazole present in feed items to the animal matrices was not further investigated."

Conclusion on metabolism in livestock

The metabolism of prothioconazole and prothioconazole-desthio as well as TDMs in livestock is sufficiently addressed to support the proposed uses of the product A23282A.

7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.3-15: Summary on the nature of residues in commodities of animal origin

Endpoints	
Animals covered	Lactating goats, laying hens
Time needed to reach a plateau concentration	1-3 days in milk Not reached within test period of 53 hours in eggs
Animal residue definition for monitoring	Prothioconazole-desthio (sum of isomers) (Regulation (EU) 2019/552)
Animal residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2007, 2014) (1) The sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy and prothioconazole-desthio-4-hydroxy expressed as prothioconazole-desthio (2) TA and TLA; (3) TAA; (4) 1,2,4-triazole (UK/Poland, 2020)
Conversion factor	2 (liver) (EFSA, 2014) 4 (kidney) (UK/Poland, 2020)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 Summary of European data and new data supporting the intended uses

Prothioconazole - No new data are submitted in the framework of this application.

Table 7.3-16: Summary of EU reported and new data supporting the intended uses of A23282A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Wheat (extrapolation to triticale, rye, durum wheat and spelt)	**Zonal cGAP** (Art. 12; EFSA, 2014)	**N-EU**	**3 x 200 g a.s./ha, BBCH 29-69, min. interval between applications 14d, PHI 35d**	N/A				
	Intended cGAP	**N-EU**	**1 x 150 g a.s./ha, BBCH 30-69**					
	EU data (UK/Poland, 2020)	N-EU	GAP on which EU a.s. assessment is based: 2 x 187.5 g a.s./ha, BBCH 25-69, min. interval between applications 14d E: Grain: 24 x <0.01, 0.02 $RA_{PTZ\text{-}desthio\ (sum\ of\ isomers)}$: Grain: 24 x <0.01, 0.02 Straw: 0.02, 0.03, 0.038, 0.04, 3 x 0.05, 4 x 0.06, 0.08, 0.09, 0.19, 0.20, 0.28, 0.29, 0.61, 0.79, 0.92					
	Overall supporting data for intended cGAP (formulation A23282A) **KCA2 6.3.1**	N-EU	E/RA: Grain: 24 x <0.01, 0.02 RA: Straw: 0.02, 0.03, 0.038, 0.04, 3 x 0.05, 4 x 0.06, 0.08, 0.09, 0.19, 0.20, 0.28, 0.29, 0.61, 0.79, 0.92	Grain: 0.01 Straw: 0.06	Grain: 0.02 Straw: 0.92	Grain: 0.020	Wheat:0.1 Rye:0.05	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Barley (extrapolation to oats)	**Zonal cGAP** (Art. 12; EFSA, 2014)	**N-EU**	**2 x 200 g a.s./ha, BBCH 30-69, min. interval between applications 14d, PHI 35d**	N/A				
	Intended cGAP	**N-EU**	**1 x 150 g a.s./ha, BBCH 30-59**					
	EU data (UK/Poland, 2020)	N-EU	GAP on which EU a.s. assessment is based: 2 x 150 g a.s./ha, BBCH 25-61, min. interval between applications 14d E: Grain: 17 x <0.01, 0.01, 0.02 $RA_{PTZ\text{-}desthio\ (sum\ of\ isomers)}$: Grain: 17 x <0.01, 0.01, 0.02 Straw: 0.02, <0.05, 2 x 0.05, 0.08, 0.087, 0.09, 3 x 0.11, 0.14, 0.15, 0.21, 0.29, 0.36, 0.54, 0.56, 0.75, 0.81					
	Overall supporting data for intended cGAP (formulation A23282A) **KCA2 6.3.2**	N-EU	E/RA: Grain: 17 x <0.01, 0.01, 0.02 RA: Straw: 0.02, <0.05, 2 x 0.05, 0.08, 0.087, 0.09, 3 x 0.11, 0.14, 0.15, 0.21, 0.29, 0.36, 0.54, 0.56, 0.75, 0.81	Grain: 0.01 Straw: 0.11	Grain: 0.02 Straw: 0.81	Grain: 0.020	Barley:0.2 Oats:0.05	Yes

(a) E: Prothioconazole-desthio (sum of isomers)
RA: (1) Prothioconazole-desthio (sum of isomers); (2) TA and TLA; (3) TAA; (4) 1,2,4-triazole (UK/Poland, 2020). No residue values for the TDMs are reported in this table. Use pattern in this submission is less critical than the critical GAP used to generate the TDM data previously submitted by the TDMG and can be considered covered by the assessment published in November 2015 and February 2018 as the RMS's draft addendum (United Kingdom, 2015 and 2018: Addendum – Confirmatory Data, addressing sections B.5, B.6, B.7). Although residue trials on wheat and barley analysing for TDMs have been submitted in dRAR (UK/Poland, 2020), it was shown that TDM residues found in these trials were much lower than presented in TDM Confirmatory Data Addendum. Therefore, it is not considered necessary to include these data here.
(b) Source of EU MRL: Reg. (EU) 2019/552

7.3.3.2 Conclusion on the magnitude of residues in plants

A23282A is used as a foliar treatment on field grown cereals (wheat, triticale, rye, spelt, durum wheat, barley and oat).

Wheat

Wheat is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for wheat can be extrapolated to rye, triticale, spelt and durum wheat (SANTE/2019/12752).

The intended cGAP is 1 x 150 g a.s./ha, BBCH 30-69, field.

The intended cGAP is less critical than the zonal cGAP (3 x 200 g a.s./ha, BBCH 29-69, min. interval between applications 14d, PHI 35d) and also less critical than the representative cGAP for the active substance renewal (2 x 187.5 g a.s./ha, BBCH 25-69, min. interval between applications 14d).

Twenty five northern European trials are available in the dRAR (UK/Poland, 2020) to support the intended cGAP use with product A23282A (EC formulation) on wheat. These trials were conducted either with emulsifiable concentrate (EC) formulations or suspension concentrate (SC) formulations, which have been shown to produce comparable results (SANTE/2019/12752). The GAP of these trials was more critical than the intended GAP, thus covering the intended use. In these trials residues of prothioconazole-desthio in wheat grain taken at harvest were in the range of <0.01 – 0.02 mg/kg. Residues of prothioconazole-desthio in wheat straw taken at harvest were in the range of 0.02 – 0.92 mg/kg. All prothioconazole-desthio residues in grain are within the current MRL of 0.1 mg/kg in wheat, triticale, spelt and durum wheat, and within the current MRL of 0.05 mg/kg in rye.

Therefore, sufficient trials are available to support the proposed uses on wheat, triticale, rye, spelt and durum wheat, and to conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

Barley

Barley is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for barley can be extrapolated to oats (SANTE/2019/12752).

The intended cGAP is 1 x 150 g a.s./ha, BBCH 30-59, field.

The intended cGAP is less critical than the zonal cGAP (2 x 200 g a.s./ha, BBCH 30-69, min. interval between applications 14d, PHI 35d) and also less critical than the representative cGAP for the active substance renewal (2 x 150 g a.s./ha, BBCH 25-61, min. interval between applications 14d).

Nineteen northern European trials are available in the dRAR (UK/Poland, 2020) to support the intended cGAP use with product A23282A (EC formulation) on barley. These trials were conducted either with emulsifiable concentrate (EC) formulations or suspension concentrate (SC) formulations, which have been shown to produce comparable results (SANTE/2019/12752). The GAP of these trials was more critical than the intended GAP, thus covering the intended use. In these trials residues of prothioconazole-desthio in barley grain taken at harvest were in the range of <0.01 – 0.02 mg/kg. Residues of prothioconazole-desthio in barley straw taken at harvest were in the range of 0.02 – 0.81 mg/kg. All prothioconazole-desthio residues in grain are within the current MRL of 0.2 mg/kg in barley and within the current MRL of 0.05 mg/kg in oats.

Therefore, sufficient trials are available to support the proposed uses on barley and oats, and to conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The use of A23282A may result in residues of prothioconazole-desthio and TDMs in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations and feeding studies undertaken are provided below.

Prothioconazole

The median and maximum dietary burden for livestock was calculated under evaluation of confirmatory data following the Article 12 MRL review using the agreed Animal Model (OECD methodology), and considering livestock intake of all feed products containing prothioconazole residues resulting from all authorized uses of prothioconazole in Europe (EFSA, 2020).

Table 7.3-17: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure (evaluation of confirmatory data) and the uses under consideration) - Prothioconazole

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition in EFSA, 2020: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) Risk assessment residue definition in dRAR (UK/Poland, 2020): (1) Prothioconazole-desthio (sum of isomers); (2) TA and TLA; (3) TAA; (4) 1,2,4-triazole				
Rape seed meal	0.16	STMR x PF (2)[(a)] (EFSA, 2020)	0.16	STMR x PF(2)[(a)] (EFSA, 2020)
Sunflower seed meal	0.04	STMR x CF (2) x PF (2)[(a)] (EFSA, 2015a,b)	0.04	STMR x CF (2) x PF (2)[(a)] (EFSA, 2015a,b)[(a)]
Head cabbage	0.02	STMR x CF (EFSA, 2014)	0.12	HR x CF (EFSA, 2014)
Maize silage	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Maize grain	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)
Maize, milled by-products[(b)] Maize, hominy meal[(b)] Maize gluten feed/ gluten meal[(b)] Distiller`s grain[(b)]	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)
Barley grain	0.07	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)	0.07	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)
Brewer`s grain	0.23	STMR barley grain (FAO, 2009b) x CF (2) (EFSA, 2014) x PF (3.3)[(a)]	0.23	STMR barley grain (FAO, 2009b) x CF (2) (EFSA, 2014) x PF (3.3)[(a)]
Oat grain	0.02	STMR (FAO, 2009a) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2009a) x CF (2) (EFSA, 2014)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat grain	0.04	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)	0.04	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)
Wheat gluten meal[(b)]	0.04	STMR wheat grain (FAO, 2009b) x CF (2) x PF (1.8)[(a)]	0.04	STMR wheat grain (FAO, 2009b) x CF (2) x PF (1.8)[(a)]
Wheat milled by-products[(b)]	0.28	STMR wheat grain (FAO, 2009b) x CF (2) x PF (7)[(a)]	0.28	STMR wheat grain (FAO, 2009b) x CF (2) x PF (7)[(a)]
Rye grain	0.02	STMR (FAO, 2009a) x CF (2)	0.02	STMR (FAO, 2009a) x CF (2)
Barley straw	1.96	STMR (FAO, 2009b) x CF (3) (EFSA, 2014)	7.50	HR[(d)] x CF (3) (EFSA, 2014)
Oats straw	1.26	STMR[(d)] x CF (3) (EFSA, 2014)	7.50	HR[(d)] x CF (3) (EFSA, 2014)
Wheat straw	2.69	STMR (EFSA, 2020)	5.52	HR[(d)] (EFSA, 2014) x CF (2.3)
Rye straw	2.25	STMR[(d)] x CF (3) (EFSA, 2014)	5.52	HR[(d)] (EFSA, 2014) x CF (2.3)
Cotton seed	0.10	STMR (FAO, 2018) x CF (2)	0.10	STMR (FAO, 2018) x CF (2)
Cotton seed meal	0.14	STMR (FAO, 2018) x CF (2) x PF (1.3)[(a)]	0.14	STMR (FAO, 2018) x CF (2) x PF (1.3)[(a)]
Beans (dry)	0.02	STMR x CF (2) (EFSA, 2014)	0.02	STMR x CF (2) (EFSA, 2014)
Peas, lupins (dry)	0.10	STMR (FAO, 2009b) x CF (2)	0.10	STMR (FAO, 2009b) x CF (2)
Lupin seed meal	0.11	STMR (FAO, 2009b) x CF (2) x PF (1.1)[(a)]	0.11	STMR (FAO, 2009b) x CF (2) x PF (1.1)[(a)]
Potatoes	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Potato process waste[(b)] Potato dried pulp[(b)]	0.01	STMR potato (EFSA, 2014) x PF (1)[(c)]	0.01	HR potato (EFSA, 2014) x PF (1)[(c)]
Turnips, swedes, carrot culls	0.08	STMR (EFSA, 2020)	0.10	HR (EFSA, 2020)
Peanut meal	0.04	STMR (FAO, 2009b) x CF (2) x PF (2)	0.04	STMR (FAO, 2009b) x CF (2) x PF (2)
Linseed meal	0.12	STMR x CF (2) x PF (2)[(a)] (EFSA, 2015a,b)	0.12	STMR x CF (2) x PF (2)[(a)] (EFSA, 2015a,b)
Soybean seed	0.10	STMR (FAO, 2014) x CF (2)	0.10	STMR (FAO, 2014) x CF (2)
Soybean seed meal	0.13	STMR (FAO, 2014) x CF (2) x PF (1.3)[(a)]	0.13	STMR (FAO, 2014) x CF (2) x PF (1.3)[(a)]
Soybean hulls[(b)]	1.30	STMR soybean (FAO, 2014) x CF (2) x PF (13)[(a)]	1.30	STMR soybean (FAO, 2014) x CF (2) x PF (13)[(a)]

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement to risk

assessment residue definition.
(a): For rape seed meal/sunflower seed meal, brewer's grain, wheat gluten meal, wheat milled by-products, cotton seed meal, lupin seed meal, soybean meal, lupin seed meal, and soybean hulls in the absence of processing factors supported by data, default processing factors of 2, 3.3, 1.8, 7, 1.3, 1.1, 1.3 and 13 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.
(b): New commodities (OECD methodology), not considered in original MRL review.
(c): Default processing factors were not applied because prothioconazole and its metabolites were below LOQ both in maize and potatoes, indicating no-residue situation. Thus, concentration of residues in these commodities is therefore not expected.
(d): The STMR and HR values derived by the JMPR (FAO, 2009a,b) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review.

The results of the calculations made in EFSA, 2020 are reported in the table below. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.10 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 7.3-18: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet [(a)]	Most critical commodity [(b)]	Trigger exceeded (Yes/No) 0.10 mg/kg DM	JMPR 2017 (FAO, 2018) Max burden mg/kg DM
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.036	0.109	1.15	3.10	Dairy cattle	Barley straw	Y	18.42 (AUT dairy cattle)
Cattle (dairy only)	0.036	0.109	0.84	2.85	Dairy cattle	Barley straw	Y	21.60 (AUT beef cattle)
Sheep (all diets)	0.075	0.236	1.77	5.55	Lamb	Barley straw	Y	Not calculated
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/ewe	Barley straw	Y	Not calculated
Swine (all diets)	0.015	0.018	0.49	0.64	Swine (finishing)	Swede roots	Y	Not calculated
Poultry (all diets)	0.035	0.059	0.52	0.86	Poultry layer	Wheat straw	Y	3.05 (EU poultry layer)
Poultry (layer only)	0.035	0.059	0.52	0.86	Poultry layer	Wheat straw	Y	Not calculated

bw: body weight; DM: dry matter.
(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

<u>TDMs</u>

References: UK, 2018; EFSA, 2018a

The maximum and median dietary burdens for the TDMs were agreed in the Addendum for the TDM Confirmatory Data (UK, 2018). The residue levels across all of the triazole active ingredients included in the review were considered.

EFSA (2018a) concluded: '*The livestock dietary burden calculation has been performed respectively for each TDM compound and triggered livestock feeding studies for 1,2,4-triazole, TA, TAA and TLA, see chapter B.7.4 of the addendum (United Kingdom, 2015 and 2018).*

…..Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-triazole and TLA residues. The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolisation to 1,2,4-triazole in whole eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in eggs, fat and liver with residues of TA in liver only at all dosing levels.

Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-triazole and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-triazole, assuming that the absorption and excretion behaviour of TA and 1,2,4-triazole are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-triazole and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-triazole residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-triazole is therefore not required as no further metabolism of this compound in animal matrices is expected. In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap).'

The TLA dosed poultry and ruminant feeding study, is being addressed within the TDMG and will be evaluated with other new TDMG data as part of a centralised EU process. As per an agreement with EU Commission, any newly generated TDMG data will be part of a centralised EU review process. All new ancillary TDM data are addressed via the TDMG, and as agreed by the European Commission, evaluated by the Austrian Authority AGES in parallel to the AIR evaluation of Paclobutrazol.

Table 7.3-19 and Table 7.3.20 show the maximum and median dietary burden inputs used in the calculation of the worst case dietary burdens in section B.7.4 of the Addendum for the TDM Confirmatory Data (UK, 2018). These worst case residue values can be considered to cover the prothioconazole intended uses for evaluation as they are obtained from triazole GAPs more critical than those presented in this submission. The input values for the raw agricultural commodities have been presented for simplicity, it is logical to expect that the inputs for processed commodities would also result in lower residues than the worst case dietary burden calculations (UK, 2018; EFSA, 2018a).

Table 7.3-19: Input values for the maximum dietary burden calculation for all TDMs

Crop	Source of Data	HR or STMR-P	Residue			
			T	TA	TAA	TLA
Forages						
Alfalfa forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43
Alfalfa hay	Wheat or barley plant	HR × 2.5	0.15	1.31	1.085	3.58
Alfalfa meal	Wheat or barley plant	HR × 2.5	0.15	1.31	1.085	3.58
Alfalfa silage	Wheat or barley plant	HR × 1.1	0.066	0.576	0.477	1.57
Beet, mangel fodder	HR of beet leaves or root	HR	0.12	0.239	0.05	0.14
Beet tops	Sugar beet leaves	HR	0.12	0.239	0.05	0.14
Cabbage heads	Brassica data	HR	0.113	0.5	0.01	0.01
Clover forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43
Clover hay	Wheat or barley plant	HR × 3	0.18	1.57	1.3	4.29
Clover silage	Wheat or barley plant	HR × 1	0.06	5.24	0.434	1.43

Crop	Source of Data	HR or STMR-P	Residue			
			T	TA	TAA	TLA
Grass forage	Wheat or barley plant	HR	0.06	5.24	0.434	1.43
Grass hay	Wheat or barley plant	HR × 3.5	0.21	1.83	1.5	5
Grass silage	Wheat or barley plant	HR × 1.6	0.096	0.838	0.694	2.3
Kale	Brassica data	HR	0.113	0.5	0.01	0.01
Rape forage	Oilseed rape plant	HR	0.023	0.913	0.034	0.04
Cereal straws/stover	Cereal data	HR	0.05	0.65	0.78	1.1
Turnip leaves	Sugar beet leaves	HR	0.12	0.218	0.02	0.14
Root and tubers						
Carrot	Root vegetable data	HR	0.06	0.239	0.05	0.13
Potato	Root vegetable data	HR	0.06	0.239	0.05	0.13
Swede	Root vegetable data	HR	0.06	0.239	0.05	0.13
Turnip	Root vegetable data	HR	0.06	0.239	0.05	0.13
Cereal grains/crop seeds						
All cereal grains	Cereal data	STMR	0.05	0.621	0.79	0.02
Pulses	Cereal data	STMR	0.05	0.17	0.05	0.01
By products						
Apple pomace	Citrus or apple data	STMR-P	0.25	0.167	0.25	0.1
Beet, sugar dried pulp	Sugar beet root data	STMR × 18	0.9	3.3	0.9	0.38
Beet, sugar ensiled pulp	Sugar beet root data	STMR × 3	0.15	0.55	0.15	0.06
Beet, sugar molas-ses	Sugar beet root data	STMR × 28	1.4	5.1	1.4	0.59
Brewer’s grain	Cereal grain data	STMR × 3.3	0.165	2	2.6	0.073
Canola	Oilseed rape data	STMR-P	0.1	1.45	0.24	0.13
Citrus pomace	Citrus or apple data	STMR-P	0.5	0.167	0.5	0.1
Corn, field milled by-products	Cereal grain data	STMR × 1	0.05	0.621	0.79	0.02
Corn, field hominy meal	Cereal grain data	STMR × 6	0.3	3.73	4.74	0.13
Corn, field gluten feed	Cereal grain data	STMR × 2.5	0.125	1.55	1.98	0.06
Corn field, gluten meal	Cereal grain data	STMR × 1	0.05	0.621	0.79	0.02
Cotton meal	Oilseed data	STMR × PF	0.065	1.45	0.24	0.13
Distiller’s grain	Cereal grain data	STMR × 3.3	0.165	2	2.6	0.073
Flaxseed/linseed meal	Oilseed rape data	STMR × PF	0.1	1.45	0.24	0.13
Lupin, seed meal	Pulse data	STMR × 1.1	0.055	0.187	0.055	0.01

Crop	Source of Data	HR or STMR-P	Residue			
			T	TA	TAA	TLA
Potato, process waste	Root vegetable data	STMR × 20	1	3.68	1	0.42
Potato, dried pulp	Root vegetable data	STMR × 38	1.9	6.99	1.9	0.8
Rape, meal	Oillseed rape data	STMR × PF	0.1	1.45	0.24	0.13
Safflower, meal	Oillseed rape data	STMR × PF	0.1	1.45	0.24	0.13
Soybean, meal	Oillseed rape data	STMR × PF	0.1	1.45	0.24	0.13
Soybean, hulls	Oillseed rape data	STMR × 13	0.65	13.5	1.56	0.85
Sugarcane, molas-ses	Sugar plant data	STMR × 32	1.6	5.89	1.6	0.85
Sunflower, meal	Oillseed rape data	STMR × PF	0.1	1.45	0.24	0.13
Wheat, gluten meal	Cereal data	STMR × 1.8	0.09	1.11	1.42	0.04
Wheat, milled by-products	Cereal data	STMR × 7	0.035	4.35	5.53	0.15

Table 7.3-20: Input values for the median dietary burden calculation for all TDMs

Crop	Source of Data	HR or STMR-P	Residue			
			T	TA	TAA	TLA
Forages						
Alfalfa forage	Wheat or barley plant	STMR	0.05	0.16	0.1	0.4
Alfalfa hay	Wheat or barley plant	HR × 2.5	0.3	0.4	0.25	1
Alfalfa meal	Wheat or barley plant	HR × 2.5	0.3	0.4	0.25	1
Alfalfa silage	Wheat or barley plant	HR × 1.1	0.06	0.18	0.11	0.44
Beet, mangel fodder	HR of beet leaves or root	STMR	0.05	0.18	0.05	0.05
Beet tops	Sugar beet leaves	STMR	0.03	0.04	0.01	0.05
Cabbage heads	Brassica data	STMR	0.04	0.17	0.01	0.01
Clover forage	Wheat or barley plant	STMR	0.05	0.16	0.1	0.4
Clover hay	Wheat or barley plant	STMR × 3	0.15	0.48	0.3	1.2
Clover silage	Wheat or barley plant	STMR × 1	0.05	0.16	0.1	0.4
Grass forage	Wheat or barley plant	STMR	0.05	0.16	0.1	0.4
Grass hay	Wheat or barley plant	STMR × 3.5	0.18	0.56	0.35	1.4
Grass silage	Wheat or barley plant	STMR × 1.6	0.08	0.26	0.16	0.64
Kale	Brassica data	STMR	0.04	0.17	0.01	0.01
Rape forage	Oilseed rape plant	STMR	0.01	0.1	0.01	0.04
Cereal straws/stover	Cereal data	STMR	0.05	0.12	0.24	0.37
Turnip leaves	Sugar beet leaves	STMR	0.03	0.04	0.01	0.05
Root and tubers						
Carrot	Root vegetable data	STMR	0.05	0.18	0.05	0.02

Crop	Source of Data	HR or STMR-P	Residue			
			T	TA	TAA	TLA
Potato	Root vegetable data	STMR	0.05	0.18	0.05	0.02
Swede	Root vegetable data	STMR	0.05	0.18	0.05	0.02
Turnip	Root vegetable data	STMR	0.05	0.18	0.05	0.02
Cereal grains/crop seeds						
All cereal grains	Cereal data	STMR	0.05	0.62	0.79	0.022
Pulses	Cereal data	STMR	0.05	0.62	0.79	0.022
By products						
Apple pomace	Citrus or apple data	STMR-P	0.3	0.17	0.13	0.1
Beet, sugar dried pulp	Sugar beet root data	STMR × 18	0.9	3.3	0.9	0.38
Beet, sugar ensiled pulp	Sugar beet root data	STMR x 3	0.15	0.55	0.15	0.06
Beet, sugar molasses	Sugar beet root data	STMR x 28	1.4	5.1	1.4	0.59
Brewer’s grain	Cereal grain data	STMR x 3.3	0.17	2.0	2.6	0.073
Canola	Oilseed rape data	STMR x PF	0.1	1.45	0.24	0.13
Citrus pomace	Citrus or apple data	STMR-P	0.5	0.17	0.13	0.1
Corn, field milled by-products	Cereal grain data	STMR x 1	0.05	0.62	0.79	0.02
Corn, field hominy meal	Cereal grain data	STMR x 6	0.3	3.7	4.74	0.13
Corn, field gluten feed	Cereal grain data	STMR x 2.5	0.13	1.6	1.98	0.06
Corn field, gluten meal	Cereal grain data	STMR-x1	0.05	0.62	0.79	0.02
Cotton meal	Oilseed data	STMR x PF	0.07	1.45	0.24	0.13
Distiller’s grain	Cereal grain data	STMR x 3.3	0.17	2.0	2.6	0.073
Flaxseed/linseed meal	Oilseed rape data	STMR x PF	0.1	1.45	0.24	0.13
Lupin, seed meal	Pulse data	STMR x 1.1	0.06	0.19	0.06	0.01
Potato, process waste	Root vegetable data	STMR x 20	1	3.7	1	0.42
Potato, dried pulp	Root vegetable data	STMR x 38	1.9	6.99	1.9	0.80
Rape, meal	Oillseed rape data	STMR x PF	0.1	1.45	0.24	0.13
Safflower, meal	Oillseed rape data	STMR x PF	0.1	1.45	0.24	0.13
Soybean, meal	Oillseed rape data	STMR - PF	0.07	1.45	0.24	0.13
Soybean, hulls	Oillseed rape data	STMR x 13	0.7	13.5	1.56	0.85
Sugarcane, molasses	Sugar plant data	STMR x 32	1.6	5.89	1.6	0.67
Sunflower, meal	Oillseed rape data	STMR x PF	0.1	1.45	0.24	0.13
Wheat, gluten meal	Cereal data	STMR x 1.8	0.09	1.11	1.42	0.04
Wheat, milled by-products	Cereal data	STMR x 7	0.35	4.35	5.53	0.15

The results of the TDM worst case animal dietary burden calculations as presented in B.7.4 of the Addendum for the TDM Confirmatory Data (UK, 2018) are provided in Table 7.3-21 to Table 7.3-24 below.

Table 7.3-21: Median and maximum dietary burdens for 1,2,4-T

Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**		**Trigger exceeded (Yes/No)**
	mg/kg bw per day		mg/kg DM					0.004 mg/kg bw
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.104	0.109	3.60	3.75	Dairy cattle	Potato	process waste	Yes
Cattle (dairy only)	0.104	0.109	2.70	2.83	Dairy cattle	Potato	process waste	Yes
Sheep (all diets)	0.118	0.121	3.54	3.63	Ram/Ewe	Potato	process waste	Yes
Sheep (ewe only)	0.118	0.121	3.54	3.63	Ram/Ewe	Potato	process waste	Yes
Swine (all diets)	0.045	0.047	1.93	2.04	Swine (breeding)	Potato	process waste	Yes
Poultry (all diets)	0.037	0.038	0.53	0.54	Poultry broiler	Potato	dried pulp	Yes
Poultry (layer only)	0.029	0.032	0.43	0.46	Poultry layer	Potato	dried pulp	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Table 7.3-22: Median and maximum dietary burdens for TA

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004 mg/kg bw
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.376	0.405	12.96	13.62	Dairy cattle	Potato	process waste	Yes
Cattle (dairy only)	0.376	0.405	9.77	10.53	Dairy cattle	Potato	process waste	Yes
Sheep (all diets)	0.425	0.454	12.76	13.63	Ram/Ewe	Potato	process waste	Yes
Sheep (ewe only)	0.425	0.454	12.76	13.63	Ram/Ewe	Potato	process waste	Yes
Swine (all diets)	0.163	0.178	7.08	7.71	Swine (breeding)	Potato	process waste	Yes
Poultry (all diets)	0.158	0.165	2.24	2.34	Poultry broiler	Potato	dried pulp	Yes
Poultry (layer only)	0.131	0.149	1.91	2.18	Poultry layer	Potato	dried pulp	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Table 7.3-23: Median and maximum dietary burdens for TAA

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004 mg/kg bw
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.116	0.140	3.87	4.29	Dairy cattle	Potato	process waste	Yes
Cattle (dairy only)	0.116	0.140	3.01	3.63	Dairy cattle	Potato	process waste	Yes
Sheep (all diets)	0.153	0.170	3.80	4.37	Lamb	Wheat	milled bypdts	Yes
Sheep (ewe only)	0.127	0.146	3.80	4.37	Ram/Ewe	Potato	process waste	Yes
Swine (all diets)	0.108	0.109	3.60	3.76	Swine (finishing)	Wheat	milled bypdts	Yes
Poultry (all diets)	0.138	0.140	1.98	2.05	Poultry broiler	Wheat	milled bypdts	Yes
Poultry (layer only)	0.135	0.140	1.98	2.05	Poultry layer	Wheat	milled bypdts	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Table 7.3-24: Median and maximum dietary burdens for TLA

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004 mg/kg bw
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.078	0.177	2.22	4.61	Dairy cattle	Grass	forage (fresh)	Yes
Cattle (dairy only)	0.078	0.177	2.03	4.61	Dairy cattle	Grass	forage (fresh)	Yes
Sheep (all diets)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)	Yes
Sheep (ewe only)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)	Yes
Swine (all diets)	0.026	0.055	1.11	2.37	Swine (breeding)	Grass	forage (fresh)	Yes
Poultry (all diets)	0.021	0.052	0.31	0.76	Poultry layer	Clover	hay	Yes
Poultry (layer only)	0.021	0.052	0.31	0.76	Poultry layer	Clover	hay	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Prothioconazole

The uses of A23282A are adequately covered by the animal dietary burden calculations previously presented in the Article 12 confirmatory data Reasoned Opinion (EFSA, 2020). Feeding studies have been evaluated in the course of the peer review of the active substance (EFSA, 2007) or in the MRL review (EFSA 2014). The MRLs in animal commidities were not calculated in EFSA 2020, because the existing EU MRLs for livestock commodities reflect CXLs, which are derived on the basis of significantly higher livestock dietary burdens as calculated by the JMPR in 2017 for cattle and poultry (FAO, 2018). In the dRAR (UK/Poland, 2020), the previously evaluated feeding studies were considered and the MRLs were calculated based on these studies. The dietary burden was slightly lower than calculated in the EFSA 2020 Reasoned Opinion. It was concluded that no changes are needed to the MRLs proposed in the previous assessments. The STMR, HR and MRL values calculated in the dRAR are given in the table below, along with the currently applicable MRLs. Based on the conclusions made in EFSA 2020 and in the dRAR, the proposed EU MRLs for prothioconazole in livestock products remain valid for the proposed uses.

Table 7.3-25: Summary of the outcome of livestock feeding studies

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	EU MRL, Reg. (EU) 2019/552 (mg/kg)	CF for RA
	Enforcement residue definition: Prothioconazole -desthio				
Poultry muscle	Not calculated[(c)]	Not calculated[(c)]	Not calculated[(c)]	0.01*	Not calculated[(c)]
Poultry fat	Not calculated[(c)]	Not calculated[(c)]	Not calculated[(c)]	0.01*	Not calculated[(c)]
Poultry liver and kidney	Not calculated[(c)]	Not calculated[(c)]	Not calculated[(c)]	0.1	Not calculated[(c)]
Eggs	Not calculated[(c)]	Not calculated[(c)]	Not calculated[(c)]	0.01*	Not calculated[(c)]
Pig muscle	<0.01	<0.01	0.01*	0.01	n/a
Pig fat	<0.01	<0.01	0.01*	0.02	n/a
Pig liver	<0.01	<0.01	0.01*	0.5	2
Pig kidney	<0.01	<0.01	0.01*	0.5	4
Ruminant muscle	<0.01	<0.01	0.01*	0.01	n/a
Ruminant fat	<0.01	<0.01	0.01*	0.02	n/a
Ruminant liver	<0.01	0.021	0.03	0.5	2
Ruminant kidney	<0.01	<0.01	0.01*	0.5	4
Ruminant milk	<0.01	<0.01	0.01*	0.01*	n/a
Sheep/goat muscle	<0.01	<0.01	0.01*	0.01	n/a
Sheep/goat fat	<0.01	<0.01	0.01*	0.02	n/a
Sheep/goat liver	<0.01	0.045	0.05	0.5	2
Sheep/goat kidney	<0.01	0.01	0.015	0.5	4
Sheep/goat milk	<0.01	<0.01	0.01*	0.01*	n/a

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues) according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(c): Residues in poultry commodities were all below the LOD or LOQ (<0.01 mg/) at 3.2N feeding level (compared to the dietary burden from EFSA 2020).

TDMs

The uses of A23282A are adequately covered by the animal dietary burden calculations previously presented in the Addendum for the TDM Confirmatory Data (UK, 2018); as a consequence, the proposed EU STMRs and HRs for prothioconazole in livestock products remain valid for the proposed uses. A summary of the values derived from the feeding studies is presented in the Table 7.3-26.

Table 7.3-26: Summary of the outcome of livestock feeding studies with Triazole Alanine (Ruminant: Report No. MR-09/029, Billian P 2009; Poultry: Report No. MR-09/091, Billian P 2010)

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	CF for RA
Risk Assessment Residue Definition: 1,2,4-Triazole				
Poultry muscle	0.01	0.01	n/a	n/a
Poultry fat	0.01	0.01	n/a	n/a
Poultry liver	0.01	0.01	n/a	n/a
Eggs	0.01	0.01	n/a	n/a
Pig muscle	0.06	0.08	n/a	n/a
Pig fat	0.04	0.06	n/a	n/a
Pig liver	0.06	0.08	n/a	n/a
Pig kidney	0.06	0.08	n/a	n/a
Ruminant muscle	0.14	0.19	n/a	n/a
Ruminant fat	0.09	0.15	n/a	n/a
Ruminant liver	0.16	0.21	n/a	n/a
Ruminant kidney	0.15	0.17	n/a	n/a
Ruminant milk	0.15	0.17	n/a	n/a
Risk Assessment Residue Definition: Triazole Alanine				
Poultry muscle	0.07	0.08	n/a	n/a
Poultry fat	0.05	0.05	n/a	n/a
Poultry liver	0.13	0.16	n/a	n/a
Eggs	0.02	0.02	n/a	n/a
Pig muscle	0.14	0.19	n/a	n/a
Pig fat	0.06	0.11	n/a	n/a
Pig liver	0.32	0.43	n/a	n/a
Pig kidney	0.17	0.21	n/a	n/a
Ruminant muscle	0.33	0.46	n/a	n/a
Ruminant fat	0.14	0.25	n/a	n/a
Ruminant liver	0.75	1.08	n/a	n/a
Ruminant kidney	0.33	0.45	n/a	n/a
Ruminant milk	0.02	0.02	n/a	n/a
Risk Assessment Residue Definition: Triazole Acetic Acid				
Poultry muscle	0.01	0.01	n/a	n/a
Poultry fat	0.01	0.01	n/a	n/a
Poultry liver	0.01	0.01	n/a	n/a
Eggs	0.01	0.01	n/a	n/a

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	CF for RA
Pig muscle	0.01	0.01	n/a	n/a
Pig fat	0.01	0.01	n/a	n/a
Pig liver	0.01	0.01	n/a	n/a
Pig kidney	0.02	0.03	n/a	n/a
Ruminant muscle	0.01	0.01	n/a	n/a
Ruminant fat	0.01	0.01	n/a	n/a
Ruminant liver	0.01	0.01	n/a	n/a
Ruminant kidney	0.04	0.05	n/a	n/a
Ruminant milk	0.01	0.01	n/a	n/a
Risk Assessment Residue Definition: Triazole Lactic Acid				
Poultry muscle	0.01	0.01	n/a	n/a
Poultry fat	0.01	0.01	n/a	n/a
Poultry liver	0.01	0.01	n/a	n/a
Eggs	0.01	0.01	n/a	n/a
Pig muscle	0.01	0.01	n/a	n/a
Pig fat	0.04	0.05	n/a	n/a
Pig liver	0.01	0.01	n/a	n/a
Pig kidney	0.01	0.01	n/a	n/a
Ruminant muscle	0.01	0.01	n/a	n/a
Ruminant fat	0.03	0.06	n/a	n/a
Ruminant liver	0.01	0.01	n/a	n/a
Ruminant kidney	0.01	0.01	n/a	n/a
Ruminant milk	0.01	0.01	n/a	n/a

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2016).

(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2016).

Table 7.3-27: Summary of the outcome of livestock feeding studies with Triazole Acetic Acid (Ruminant: Report No. IF-10/01525218, Zietz, E 2010; Poultry: Report No. MR-09/158, Billian P 2010)

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	CF for RA
Risk Assessment Residue Definition: 1,2,4-Triazole				
Poultry muscle	0.01	0.01	n/a	n/a
Poultry fat	0.01	0.01	n/a	n/a
Poultry liver	0.01	0.01	n/a	n/a
Eggs	0.01	0.01	n/a	n/a
Pig muscle	0.01	0.01	n/a	n/a
Pig fat	0.01	0.01	n/a	n/a
Pig liver	0.01	0.01	n/a	n/a
Pig kidney	0.01	0.01	n/a	n/a
Ruminant muscle	0.01	0.01	n/a	n/a

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	CF for RA
Ruminant fat	0.01	0.01	n/a	n/a
Ruminant liver	0.01	0.01	n/a	n/a
Ruminant kidney	0.01	0.01	n/a	n/a
Ruminant milk	0.01	0.01	n/a	n/a
Risk Assessment Residue Definition: Triazole Alanine				
Poultry muscle	0.01	0.01	n/a	n/a
Poultry fat	0.01	0.01	n/a	n/a
Poultry liver	0.03	0.01	n/a	n/a
Eggs	0.01	0.01	n/a	n/a
Pig muscle	0.03	0.04	n/a	n/a
Pig fat	0.01	0.01	n/a	n/a
Pig liver	0.05	0.06	n/a	n/a
Pig kidney	0.03	0.03	n/a	n/a
Ruminant muscle	0.03	0.05	n/a	n/a
Ruminant fat	0.01	0.01	n/a	n/a
Ruminant liver	0.05	0.08	n/a	n/a
Ruminant kidney	0.03	0.03	n/a	n/a
Ruminant milk	0.01	0.01	n/a	n/a
Risk Assessment Residue Definition: Triazole Acetic Acid				
Poultry muscle	0.01	0.01	n/a	n/a
Poultry fat	0.01	0.01	n/a	n/a
Poultry liver	0.02	0.02	n/a	n/a
Eggs	0.01	0.01	n/a	n/a
Pig muscle	0.01	0.01	n/a	n/a
Pig fat	0.01	0.02	n/a	n/a
Pig liver	0.01	0.01	n/a	n/a
Pig kidney	0.07	0.09	n/a	n/a
Ruminant muscle	0.01	0.01	n/a	n/a
Ruminant fat	0.01	0.02	n/a	n/a
Ruminant liver	0.01	0.02	n/a	n/a
Ruminant kidney	0.08	0.12	n/a	n/a
Ruminant milk	0.01	0.01	n/a	n/a
Risk Assessment Residue Definition: Triazole Lactic Acid				
Poultry muscle	0.01	0.01	n/a	n/a
Poultry fat	0.01	0.01	n/a	n/a
Poultry liver	0.01	0.01	n/a	n/a
Eggs	0.01	0.01	n/a	n/a
Pig muscle	0.01	0.01	n/a	n/a
Pig fat	0.01	0.01	n/a	n/a
Pig liver	0.01	0.01	n/a	n/a
Pig kidney	0.01	0.01	n/a	n/a

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	CF for RA
Ruminant muscle	0.01	0.01	n/a	n/a
Ruminant fat	0.01	0.01	n/a	n/a
Ruminant liver	0.01	0.01	n/a	n/a
Ruminant kidney	0.01	0.01	n/a	n/a
Ruminant milk	0.01	0.01	n/a	n/a

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2016).
(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2016).

Available data

<u>Prothioconazole</u>

No new data were submitted in the framework of this application.

<u>TDMs</u>

No new data were submitted in the framework of this application.

Summary of livestock studies reported in the EU

<u>Prothioconazole</u>

Reference: UK/Poland, 2020

During the peer review under Directive 91/414/EEC, the magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows. Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels of 5.1, 29, and 125 mg/kg in the diet (equivalent to 0.16, 0.95 and 3.93 mg/kg bw/day), with samples analysed for prothioconazole-desthio and the metabolites M14 and M15. In milk, residues of all three metabolites were very low (<0.01 mg/kg).
The magnitude of the residues of prothioconazole and the metabolites prothioconazole-desthio and prothioconazole-4-hydroxy were investigated in a feeding study with laying hens. Forty two laying hens (one control group of six hens, and three dose groups, each with three sub-groups of four hens) were dosed orally for 29 consecutive days with prothioconazole at dose rates corresponding to 0 (control), 0.263 (1x dose), 0.788 (3x dose) and 2.591 (10x dose) mg/kg feed/day. The study report indicates these rates are equivalent to 0.020 mg/kg bw/day, 0.059 mg/kg bw/day and 0.191 mg/kg bw/day. Samples were analysed for prothioconazole, prothioconazole-desthio, prothioconazole-4-hydroxy and their acid-hydrolysable conjugates.
For 24 and 29 day egg samples, and for all liver, muscle, and fat samples from the 10x dose group, residues were < LOQ. Therefore, eggs and edible tissues from poultry fed crops containing prothioconazole at levels below 2.591 mg/kg would not be expected to contain significant residues of prothioconazole and the metabolites prothioconazole-desthio and prothioconazole-4-hydroxy.
It is noted that the study was performed with prothioconazole and not prothioconazole-desthio (which is considered to be present in higher levels in animal feed); however, the available metabolism studies indicate similar metabolic patterns for the different compounds and moieties investigated, and indicate that no residues above the LOQ are expected in poultry matrices at the calculated dietary burden. Additional studies addressing these requirements are therefore not considered necessary.

<u>TDMs</u>

References: UK, 2018; EFSA, 2018a

The maximum and median dietary burdens for the TDMs were agreed in the Addendum for the TDM Confirmatory Data (UK, 2018). The residue levels across all of the triazole active ingredients included in the review were considered.

A full overview of 1,2,4-T, TA, TAA and TLA residue values estimated to be in products of animal origin as a result of TA and TAA consumption are presented in Appendix E Table 7.4.5-2 and Table 7.4.5-3 within the Addendum for the TDM Confirmatory Data (UK, 2018). These tables are also presented in the above tables for completeness.
Additional tables 7.4.5-4 to 7.4.5-6 within the Addendum for the TDM Confirmatory Data (UK, 2018) estimate the TDM residue values in products of animal origin derived from livestock feeding studies with T and TLA through use of transfer factors.
TDMs may also arise in products of animal origin as a result of livestock consuming feed containing parent triazole residues. This contribution across all parent triazoles has been evaluated within Appendix E of the Addendum for the TDM Confirmatory Data (UK, 2018).
Taking into consideration residue levels of the TDMs arising in products of animal origin arising from the various sources in animal feed (combination of parent triazoles and each of the TDMs) the total residue levels for each of the four TDMs are outlined in Appendix E table 7.4.5-8 of the Addendum for the TDM Confirmatory Data (UK, 2018). These residue levels have been included in the worst case consumer risk assessments which cover the whole class of triazoles and evaluated by EFSA (EFSA Journal 2018;16(7):5376).

EFSA (2018) concluded: "*The livestock dietary burden calculation has been performed respectively for each TDM compound and triggered livestock feeding studies for 1,2,4-triazole, TA, TAA and TLA, see chapter B.7.4 of the addendum (United Kingdom, 2015 and 2018).*
.....Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-triazole and TLA residues. The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolisation to 1,2,4-triazole in whole eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in eggs, fat and liver with residues of TA in liver only at all dosing levels.
Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-triazole and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-triazole, assuming that the absorption and excretion behaviour of TA and 1,2,4-triazole are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-triazole and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-triazole residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-triazole is therefore not required as no further metabolism of this compound in animal matrices is expected. In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap)."
The TLA dosed poultry and ruminant feeding study, is being addressed within the TDMG and will be evaluated with other new TDMG data as part of a centralised EU process. As per an agreement with EU Commission, any newly generated TDMG data will be part of a centralised EU review process. All new ancillary TDM data are addressed via the TDMG, and as agreed by the European Commission, evaluated by the Austrian Authority AGES in parallel to the AIR evaluation of Paclobutrazol.

Conclusion on feeding studies

<u>Prothioconazole</u>

The requested uses have no impact on the dietary burdens calculated in the EFSA Reasoned Opinion for the evaluation of confirmatory data following the Article 12 review (EFSA, 2020).

<u>TDMs</u>

The requested uses have no impact on the dietary burdens calculated in the Addendum for the TDM Confirmatory Data (UK, 2018).

7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Prothioconazole

As quantifiable residues of prothioconazole are expected in the treated crops, a study investigating the nature of residues in processed commodities is required. As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops and the contribution of wheat and barley to the estimated daily intake is <10% of the ARfD (see also 7.2.8), investigation of the magnitude of residues in processed commodities is not required. Nevertheless, processing studies on barley and wheat have been EU reviewed and are summarised in Table 7.3-28.

TDMs

As quantifiable residues of TDMs are expected in the treated crops, a study investigating the nature of residues in processed commodities is required. As residues of TA, TAA and TLA exceeding 0.1 mg/kg are expected in the treated crops, investigation of the magnitude of residues in processed commodities is required. However, it should be noted that for these three metabolites, the contribution of wheat, triticale, rye, spelt and durum wheat to the TMDI is <10% and the estimated daily intake is <10% of the ARfD (see also 7.2.8).

Processing studies evaluating the effects of processing on the residues of triazole compounds following processing of various commodities were submitted to the UK in August 2014, by the TDMG member companies.

In the majority of cases where the nature of residue for processing has been assessed for parent triazoles, the parent molecule is determined to be hydrolytically stable or if breakdown products are found these are not identified as TDMs. Additionally, a hydrolysis study with TDMs shows all 4 TDMs to be stable on processing. It is therefore a reasonable assumption that processing factors determined for each of the TDMs are independent of the parent triazole molecule used as the treatment method in a magnitude of residue study (United Kingdom, 2018).

Information about the fate of the triazole derived metabolites during cereal processing is available from processing studies conducted with wheat treated with prothioconazole (1 trial), barley treated with prothioconazole (2 trials), wheat treated with metconazole (4 trials) and wheat treated with tetraconazole (3 trials).

7.3.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

Prothioconazole

Table 7.3-28: Overview of the available processing studies for Prothioconazole

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
EU reviewed data						
Risk assessment residue definition in dRAR (UK/Poland, 2020)[(a)]: (1) Prothioconazole-desthio (sum of isomers); (2) TA and TLA; (3) TAA; (4) 1,2,4-triazole						
Barley, pearl barley rub off	2	3.2	2	-	13-3401	UK/Poland, 2020
Barley, processsing fractions into beer	2	-[(b)]	-	-	RA-3669/07 MR-08/025	UK/Poland, 2020

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
Barley, processsing fractions into beer	2	-(c)	-	-	RA-3062/07	UK/Poland, 2020
Wheat, aspirated grain fractions	1	~~218~~	-	Is there really 218 times more residues after processing than before it?	200521	UK/Poland, 2020
Wheat, bran	1	2.4	-	-		
Wheat, flour	1	0.3	-	-		
Wheat, germ	1	2.1	-	-		
Wheat, middlings	1	0.6	-	-		
Wheat, shorts	1	1.1	-	-		

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

(a) Data on TDMs is reported in a separate table.

(b) For prothioconazole-desthio and its hydroxy metabolites, in both trials no processing factors could be derived as all residues were below the LOQ in the RAC and in the processed fractions.

(c) For prothioconazole-desthio in both trials no processing factors could be derived as all residues were below the LOQ in the RAC and in the processed fractions.

TDMs

Table 7.3-29: Overview of the available processing studies for TDMs

Processed commodity	Number of studies	Median PF **	Median CF ***	Comments	Report reference	Source
EU reviewed data						
Triazole Alanine						
Wheat, Aspirated Grain fractions	2	<0.4	n/a	Metconazole and prothioconazole processing studies	Prothioconazole: 200521 Metconazole: BASF DocID 2006/7007147	UK, 2018
Wheat, husk	1	0.75	n/a	Metconazole processing studies	BASF DocID 2006/7007147	
Wheat, coarse bran	4	2.05	n/a	Metconazole, tetraconazole and prothioconazole processing studies	Prothioconazole: 200521 Metconazole: BASF DocID 2006/7007147 Tetraconazole: RA.10.09 and RA.10.43	
Wheat, straight flour		0.6	n/a			
Wheat, fine bran	1	2.35	n/a	Metconazole processing studies	BASF DocID 2006/7007147	

Processed commodity	Number of studies	Median PF **	Median CF ***	Comments	Report reference	Source
Wheat, middlings	2	0.6	n/a	Metconazole and prothioconazole processing studies	Prothioconazole: 200521 Metconazole: BASF DocID 2006/7007147	
Wheat, shorts		1.4	n/a			
Wheat, germ		2.5	n/a			
Wheat, low grade meal	1	0.9	n/a	Metconazole processing studies	BASF DocID 2006/7007147	
Wheat, flour type 550		0.55	n/a			
Wheat, wholemeal flour	3	0.9	n/a	Metconazole and tetraconazole processing studies	Metconazole: BASF DocID 2006/7007147 Tetraconazole: RA.10.09 and RA.10.43	
Wheat, wholemeal bread	1	0.6	n/a	Metconazole processing studies	BASF DocID 2006/7007147	
Barley, brewer's malt	2	0.775	n/a	Prothioconazole processing studies	Report no. RA-3669/07 and P 1747G	UK, 2018
Barley, brewer's grain	2	<0.035	n/a			
Barley, brewer's yeast	2	0.19	n/a			
Barley, beer	2	0.14	n/a			
Triazole Acetic Acid						
Wheat, Aspirated Grain fractions	2	1.0	n/a	Metconazole and prothioconazole processing studies	Prothioconazole: 200521 Metconazole: BASF DocID 2006/7007147	UK, 2018
Wheat, husk	1	1.0	n/a	Metconazole processing studies	BASF DocID 2006/7007147	
Wheat, coarse bran	2	1.3	n/a	Metconazole, tetraconazole and prothioconazole processing studies	Prothioconazole: 200521 Metconazole: BASF DocID 2006/7007147	
Wheat, straight flour		0.95	n/a			
Wheat, fine bran	1	1.15	n/a	Metconazole processing studies	BASF DocID 2006/7007147	
Wheat, middlings	2	0.9	n/a	Metconazole and prothioconazole processing studies	Prothioconazole: 200521 Metconazole: BASF DocID 2006/7007147	
Wheat, shorts		1.2	n/a			
Wheat, germ		1.2	n/a			
Wheat, low grade meal	1	0.95	n/a	Metconazole processing studies	BASF DocID 2006/7007147	
Wheat, flour type 550		0.85	n/a			

Processed commodity	Number of studies	Median PF **	Median CF ***	Comments	Report reference	Source
Wheat, wholemeal flour	3	0.8	n/a	Metconazole and tetraconazole processing studies	Metconazole: BASF DocID 2006/7007147 Tetraconazole: RA.10.09 and RA.10.43	
Wheat, wholemeal bread	1	0.75	n/a	Metconazole processing studies	BASF DocID 2006/7007147	
Barley, brewer's malt	2	1.05	n/a	Prothioconazole processing studies	Report no. RA-3669/07 and P 1747G	UK, 2018
Barley, brewer's grain	2	<0.045	n/a			
Barley, brewer's yeast	2	0.23	n/a			
Barley, beer	2	0.21	n/a			
Triazole Lactic Acid						
Wheat, coarse bran	2	-*	n/a	tetraconazole processing studies	Tetraconazole: RA.10.09 and RA.10.43	UK, 2018
Wheat, straight flour		-*	n/a			
Wheat, middlings	1	-*	n/a	Prothioconazole processing studies	Prothioconazole: 200521	
Wheat, shorts	1	-*	n/a			
Wheat, germ	1	-*	n/a			
Wheat, wholemeal flour	2	-*	n/a	tetraconazole processing studies	Tetraconazole: RA.10.09 and RA.10.43	
Barley, brewer's malt	2	>1.3	n/a	Prothioconazole processing studies	Report no. RA-3669/07 and P 1747G	UK, 2018
Barley, brewer's grain	2	-*	n/a			
Barley, brewer's yeast	2	-*	n/a			
Barley, beer	2	-*	n/a			

* Since the residues were below the limit of quantification both in the raw agricultural commodity and in the processed fraction, no processing factor could be derived.
** The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
*** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

Summary of processing studies reported in the EU

Prothioconazole

Reference: UK/Poland, 2020

"Residues in raw agricultural commodities are <0.1 mg/kg. The TMDI is <10 % of the ADI and the estimated daily intake is <10 % of the ARfD for any European consumer group diet. Therefore, in accordance with Regulation (EU) No 283/2013, processing studies are not required."

Nevertheless, five processing studies (4 on barley, 1 on wheat) were presented in dRAR and are summarised in the Table 7.3-28 above.

TDMs

Reference: United Kingdom, 2018

"For wheat, the data clearly show that the triazole derived metabolite TA does not concentrate in flour

(straight, type 550 or wholemeal) or aspirated grain fractions, but concentrates in bran (fine and coarse) and germ. The results for TA in shorts and meal were more variable and overall residues levels were similar to the raw agricultural commodity. The results for TAA in all commodities were variable but showed a concentration in bran though overall residues levels in all other processed commodities were similar to the raw agricultural commodity. Limited data in flour or bran indicated that T does not concentrate whereas TLA does concentrate in these commodities. In most studies, residues of T were below the LOQ of 0.01 mg/kg in the raw agricultural commodity and all the processed commodities.

In barley, the data show that the triazole derived metabolites TA and TAA do not concentrate in brewer's malt, brewer's grain brewer's yeast or beer. For most commodities TLA was not found but the results showed that this metabolite concentrates in brewer's malt. Residues of 1,2,4-T were below the LOQ of 0.01 mg/kg in the raw agricultural commodity and all the processed commodities."

7.3.5.2 Conclusion on processing studies

<u>Prothioconazole</u>

Processing factors were derived for wheat processed products. For barley processed products, it was only possible to derive a processing factor for pearl barley rub off, because in all other commodities, the residues were less than LOQ. However, processing studies are not required for prothioconazole.

<u>TDMs</u>

Processing factors were derived for wheat and barley processed products.

Overall, UK (2018) concluded *"[...]The hydrolysis studies show that all four TDM are stable on processing. As a consequence the relevant residues in processed commodities are the TDM and no breakdown products need to be considered. No processing factors have been applied to the consumer risk assessments. However, the processing factors determined do need to be considered for the animal dietary burden of livestock."*

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarised hereafter.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data were submitted in the framework of this application for prothioconazole. Data evaluated during the active substance renewal are summarised in Table 7.3-30 below.

Table 7.3-30: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
EU reviewed data						

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
None (bare soil)	0.630	Leafy vegetables	Lettuce	25-34	09-2500 09-2501 09-2502 09-2503	UK/Poland, 2020
		Root and tuber vegetables	Carrot or turnip	25-34		
		Cereals	Winter barley	21-28		
Wheat	0.03 (seed treatment) 3 x 0.200 (foliar, BBCH 65-69)	Leafy vegetables	Lettuce	56-122 298-343		
		Root and tuber vegetables	Carrot or turnip	56-129 296-345		
		Cereals	Winter or spring barley	90-200 277-293		

Summary of field rotational crop studies reported in the EU

References: EFSA, 2014

"Based on the confined rotational crop study, considering that the application rate of prothioconazole within the EU ranges between 0.009 – 0.600 kg a.s./ha and due to the fact that prothioconazole was applied to a bare soil in the metabolism study (interception of prothioconazole by the plants is expected in practice), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops (see also section 3.1.2.2). Therefore, no risk mitigation measures (plant back restrictions) need to be proposed."

References: UK/Poland, 2020

"In the original approval (DAR B7 Addendum 10) it was concluded that rotational crop studies were not necessary. The confined rotational crop studies indicate that prothioconazole residues in food and feed rotational commodities are expected to be covered by the residue levels in primary crops.

Nevertheless, residue data for prothioconazole in rotational crops are available from field rotational crop trials conducted on barley (cereal), carrot and turnip (root crop), lettuce (leafy crop). Studies were performed in an effort to address the assessment of consumer exposure to triazole derivative metabolites (TDMs) in rotational crops; prothioconazole-desthio was also determined but the hydroxy metabolites of prothioconazole-desthio were not.

… No residues of prothioconazole-desthio (M04) above the LOQ (0.01 mg/kg) were detected in control samples. At all plant-back intervals and for all matrices, no residues of prothioconazole-desthio (M04) were detected above the LOQ (0.01 mg/kg). Considering the proposed maximum application rate of 187.5 g a.s./ha it can be concluded that prothioconazole-desthio (M04) residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops. Therefore, no risk mitigation measures (plant back restrictions) need to be proposed.

… The studies indicate a potential uptake of the TDMs in rotational crops. Noting that these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA has recommended that a separate risk assessment should be performed for TDMs in rotational crops as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available."

Conclusion on rotational crops studies

Prothioconazole

Considering the intended maximum application rate of 150 g a.s./ha it can be concluded that prothioconazole-desthio (M04) residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops. Therefore, no risk mitigation measures (plant back restrictions) need to be proposed.

TDMs

The field crop studies indicate a potential for TA, TAA and TLA to be taken up into rotational crops. Therefore, residue levels of these three metabolites in rotational commodities may exceed 0.01 mg/kg, when applied at the GAPs supported for this submission. The worst case residue values of TA, TAA and TLA observed in rotated crops after use of any of the triazole class of pesticides have been considered in consumer risk assessment conducted as part of the TDM confirmatory data review (UK, 2018)(EFSA, 2018a), see section 7.2.8.

7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A23282A. Therefore, other special studies are not needed. According to SANTE/11956/2016 rev. 9 (14 September 2018) barley, wheat, oat, durum wheat, spelt and rye are considered to not possess melliferous capacity. No studies on honey are required.

7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.3.8.1 Input values for the consumer risk assessment

Prothioconazole

Table 7.3-31: Input values for the consumer risk assessment for Prothioconazole

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition in EFSA, 2020: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) Risk assessment residue definition in dRAR (UK/Poland, 2020): (1) Prothioconazole-desthio (sum of isomers); (2) TA and TLA; (3) TAA; (4) 1,2,4-triazole				
Cranberries	0.025	STMR[(a)] (FAO, 2014)	-	-
Potatoes	0.01	STMR (EFSA, 2014)	-	-
Celeriac	0.08	STMR (EFSA, 2020)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Beetroots, carrots, horseradish, parsnips, parsley roots, salsifies, swedes, turnips	0.08	STMR (EFSA, 2020)	-	-
Sweet corn	0.018	STMR[(a)] (FAO, 2014)	-	-
Onions, shallots	0.02	STMR (EFSA, 2014, 2015a) x CF (2)	-	-
Flowering brassica	0.02	STMR x CF (2) (EFSA, 2014)	-	-
Brussels sprouts	0.06	STMR x CF (2) (EFSA, 2014)	-	-
Head cabbage	0.02	STMR x CF (2) (EFSA, 2014)	-	-
Leeks	0.02	STMR x CF (2) (EFSA, 2014)	-	-
Beans	0.02	STMR x CF (2) (EFSA, 2014)	-	-
Lentils, peas, lupins	0.10	STMR[(a)] (FAO, 2009b) x CF (2)	-	-
Linseeds, poppy seeds, mustard seeds	0.06	STMR x CF (2) (EFSA, 2014)	-	-
Gold of pleasure seeds	0.02	STMR x CF (2) (EFSA, 2014)	-	-
Peanuts	0.02	STMR (FAO, 2009b) x CF (2)	-	-
Sunflower seeds	0.02	STMR (EFSA, 2015b) x CF (2)	-	-
Rape seed	0.08	STMR (EFSA, 2020)		
Cotton seed	0.1	STMR (FAO, 2018) x CF x (2)	-	-
Soybean	0.1	STMR (FAO, 2014) x CF (2)	-	-
Barley grain	0.07	STMR[(a)] (FAO, 2009b) x CF (2)	0.07	STMR[(a)] (FAO, 2009b) x CF (2)
Maize grain	0.02	STMR[(a)] (FAO, 2014) x CF (2)	0.02	STMR[(a)] (FAO, 2014) x CF (2)
Oat grain	0.1	EU MRL (Reg. (EU) 2019/552) x CF (2)	0.02	STMR[(a)] (FAO, 2009a) x CF (2)
Rye grain	0.02	STMR[(a)] (FAO, 2009a) x CF (2)	0.02	STMR[(a)] (FAO, 2009a) x CF (2)
Wheat grain	0.04	STMR[(a)] (FAO, 2009b) x CF (2)	0.04	STMR[(a)] (FAO, 2009b) x CF (2)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Buckwheat and other pseudo-cereals, common millet/proso millet, rice, sorghum	0.01	LOQ (Reg. (EU) 2019/552)	0.01	LOQ (Reg. (EU) 2019/552)
Muscle of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR(b) (FAO, 2018)	0.01	HR(b) (FAO, 2018)
Fat of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR(b) (FAO, 2018)	0.018	HR(b) (FAO, 2018)
Liver of swine, bovine, sheep, goat, equine, other farmed animals	0.05	STMR(b) (FAO, 2009b)	0.23	HR(b) (FAO, 2009b)
Kidney of swine, bovine, sheep, goat, equine, other farmed animals	0.025	STMR(b) (FAO, 2009b)	0.15	HR(b) (FAO, 2009b)
Edible offals and other products of swine, bovine, sheep, goat, equine, other farmed animals	0.5	EU MRL (Reg. (EU) 2019/552)	0.5	EU MRL (Reg. (EU) 2019/552)
Muscle of poultry	0.0016	STMR(b) (FAO, 2018)	0.0016	HR(b) (FAO, 2018)
Fat of poultry	0.008	STMR(b) (FAO, 2018)	0.008	HR(b) (FAO, 2018)
Liver, kidney, edible offal of poultry	0.071	STMR(b) (FAO, 2018)	0.071	HR(b) (FAO, 2018)
Other products of poultry	0.01	LOQ (Reg. (EU) 2019/552)	-	-
Milks	0.005	STMR (EFSA, 2014)	0.005	STMR (EFSA, 2014)
Eggs	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Honey and other apiculture	0.05	LOQ (Reg. (EU) 2019/552)	0.05	LOQ (Reg. (EU) 2019/552)
Amphibians and reptiles	0.01	LOQ (Reg. (EU) 2019/552)	0.01	LOQ (Reg. (EU) 2019/552)
Terrestrial invertebrate animals	0.01	LOQ (Reg. (EU) 2019/552)	0.01	LOQ (Reg. (EU) 2019/552)
Wild terrestrial vertebrate	0.01	EU MRL (Reg. (EU) 2019/552)	0.01	EU MRL (Reg. (EU) 2019/552)
All other crops/commodities	LOQ	Reg. (EU) 2019/552	-	-

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residue definition.
(a): Values refer to the residues of prothioconazole-desthio; data according to EU risk assessment residue definition not available.
(b): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio.

TDMs

Table 7.3-32: Input values for the consumer risk assessment for TDMs

Crop Group	Residue (mg/kg)							
	1,2,4-T		TA		TAA		TLA	
	STMR	HR	STMR	HR	STMR	HR	STMR	HR
Citrus fruit	0.05	0.05	0.32	0.628	0.05	0.1	0.04	0.14
Pome fruit	0.01	0.021	0.039	0.53	0.03	0.06	0.03	0.11
Stone fruit	0.01	0.01	0.32	0.628	0.02	0.034	0.038	0.138
Berries	0.01	0.026	0.06	0.1	0.05	0.1	0.04	0.14
Banana	0.05	0.05	0.05	0.07	0.05	0.05	n.a	n.a
Root & tuber veg	0.01	0.016	0.184	0.239	0.01	0.01	0.021	0.131
Bulb veg	0.01	0.01	0.06	0.260	0.01	0.01	0.01	0.270
Fruiting veg	0.01	0.03	0.21	0.46	0.01	0.01	0.01	0.27
Brassica veg	0.039	0.113	0.17	0.5	0.01	0.01	0.01	0.01
Leafy veg	0.015	0.02	0.047	0.091	0.023	0.036	0.08	0.14
Legume veg	0.01	0.01	0.09	0.34	0.01	0.03	0.01	0.04
Stem veg	0.01	0.1	0.09	0.114	0.02	0.03	0.01	0.03
Pulses	0.05	0.5	0.17	3.7	0.05	0.052	0.01	0.06
Oilseeds	0.05	0.1	1.039	2.826	0.12	0.68	0.065	0.192
Oilfruits	0.05	0.1	1.039	2.826	0.12	0.68	0.065	0.192
Cereals	0.05	0.08	0.621	2.2	0.79	1.73	0.022	0.160
Sugar plants	0.05	0.06	0.05	0.078	0.05	0.05	0.01	0.01
Ruminant meat	0.27	0.31	0.46	0.62	0.04	0.04	0.04	0.04
Ruminant fat	0.18	0.24	0.22	0.34	0.05	0.08	0.07	0.1
Ruminant liver	0.31	0.36	1.01	1.36	0.05	0.08	0.07	0.1
Ruminant kidney	0.32	0.34	0.49	0.58	0.15	0.22	0.09	0.13
Ruminant milk	0.3	0.35	0.04	0.04	0.04	0.04	0.04	0.04
Sheep meat	0.29	0.33	0.51	0.68	0.04	0.04	0.04	0.04
Sheep fat	0.19	0.26	0.23	0.38	0.06	0.08	0.07	0.11
Sheep liver	0.34	0.39	1.13	1.80	0.05	0.05	0.04	0.04
Sheep kidney	0.34	0.37	0.55	0.65	0.18	0.25	0.09	0.13
Sheep milk	0.32	0.37	0.04	0.04	0.04	0.04	0.04	0.04
Swine meat	0.13	0.17	0.21	0.27	0.04	0.04	0.04	0.04
Swine fat	0.1	0.13	0.09	0.14	0.04	0.05	0.04	0.04
Swine liver	0.13	0.17	0.50	0.61	0.04	0.05	0.04	0.04
Swine kidney	0.14	0.2	0.22	0.27	0.11	0.14	0.05	0.08
Poultry meat	0.04	0.04	0.11	0.12	0.04	0.04	0.04	0.04
Poultry fat	0.04	0.04	0.1	0.11	0.04	0.04	0.04	0.04

Crop Group	**Residue (mg/kg)**							
	1,2,4-T		**TA**		**TAA**		**TLA**	
	STMR	**HR**	**STMR**	**HR**	**STMR**	**HR**	**STMR**	**HR**
Poultry liver	0.04	0.04	0.27	0.31	0.05	0.05	0.04	0.04
Poultry eggs	0.04	0.04	0.06	0.06	0.04	0.04	0.04	0.04

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Prothioconazole

Table 7.3-33: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	Not calculated
IEDI (% ADI) according to EFSA PRIMo 3.1	14% (based on NL toddler)
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1*	Bovine: Edible offals: 36% (based on children) Wheat: 6% (based on children) Barley: 4% (based on children) Rye: 1% (based on children) Oat: 0.2% (based on children)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1*	Wheat / milling (flour): 5% (based on children) Barley / beer: 5% (based on adults) Rye / boiled: 0.7% (based on children) Oat / boiled: 0.7% (based on children)

* include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in A23282A do not represent unacceptable acute and chronic risks for the consumer.

TDMs

A risk assessment of residues of TDMs has been conducted by both UK and EFSA in the TDM review for all triazoles (UK, 2018 and EFSA, 2018a). The trials presented here were also considered during this review. The provisional risk assessments using PRIMo rev. 3 for TDMs indicate that there is no risk to consumers (both chronic and acute) from TDM residues.

EFSA (2018a) stated: "*The chronic and acute dietary intakes have been carried out using the highest input residue values for risk assessment (supervised trials median residue (STMR) values and the highest residue (HR) values), derived for each TDM for each crop groups and each product of animal origin. Since in most of the residue trials in primary and rotational crops, higher residue levels of the TDMs in the control samples were observed, these levels were also considered in the dietary intake calculation. Using the EFSA PRIMo rev.3, the international estimated daily intake (IEDI) accounted for 93% of the ADI (NL toddler) for 1,2,4-triazole, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA. No acute intake concern was identified as the calculated IESTI accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-triazole, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 7% of the ARfD (potatoes) for TLA. Using the EFSA PRIMo rev.2A, the international estimated daily intake (IEDI) accounted for 60% of the ADI (FR toddler) for 1,2,4-triazole, 5% of the ADI (WHO Cluster diet B) for TA, 1% of the ADI (WHO Cluster diet B) for TAA and <1% of the ADI (FR toddler) for TLA. The acute intake was estimated to be 40% of the ARfD (milk) for 1,2,4-triazole, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 6.7% of the ARfD (potatoes) for TLA. Since the toxicological reference values for TLA were derived by bridging with the reference values of TA, a combined dietary risk assessment for TA and TLA was performed. No chronic or acute intake concerns* *were identified with up to 6% ADI (WHO Cluster diet B), and 34% and 8% ARfD (watermelons) respectively for children and adults*."

Within both the UK addendum and the EFSA conclusion for review of triazole metabolites, no consumer risk was identified for any of the TDMs when considering supervised field residue trials and succeeding crop trials across the complete group of triazole active substances for all crops; representing a worst case risk assessment.

A summary of the residue input values (STMR and HR) for the TDMs used in the worst case EU PRIMo 3.0 consumer risk assessments can be found in Table 7.3-32 above. Chronic risk assessment outputs for each of the TDMs can be found in the UK addendum Appendix E tables 7.7-6- 7.7-9 (UK, 2018). Acute risk assessment outputs for each of the TDMs can be found in UK addendum Appendix E tables 7.7-14- 7.7-17 (UK, 2018). TLA toxicological endpoints are bridged from TA studies and therefore, a combined risk assessment for these two metabolites is required. Combined chronic and acute risk assessments for TLA and TA are shown in UK addendum Appendix E tables 7.7-20 and 7.7-22, respectively. No consumer risk was identified for this TA + TLA combined risk assessment either.

The TDM residues produced from the representative GAPs for this submission of A23282A are less critical than residue inputs already evaluated as part of the TDM review. Therefore, the Applicant considers worst case TDM risk assessment to cover the uses considered in this submission of A23282A.

It is concluded that the proposed uses of prothioconazole in A23282A do not represent unacceptable acute or chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

7.5 References

Cyprodinil

- EC (European Commission), 2010. Review report for the active substance cyprodinil. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 04 April 2006 in view of the inclusion of active substance in Annex I of Council Directive 91/414/EEC. SANCO/10014/2006 – final rev 1, 09 July 2010.
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- France, 2005b. Final addendum to the draft assessment report on the active substance cyprodinil prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, September 2005.
- France, 2010. Addendum to the draft assessment report on the active substance cyprodinil prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, March 2010.

Prothioconazole

- EC (European Commission), 2007. Review report for the active substance prothioconazole. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2008 in view of the inclusion of prothioconazole in Annex I of Directive 91/414/EEC. SANCO/3923 /07 – final, 10 December 2007.
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- EFSA (European Food Safety Authority), 2015a. Reasoned opinion on the modification of the existing maximum residue level (MRL) for prothioconazole in shallots. EFSA Journal 2015;13(5):4105,

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- EFSA (European Food Safety Authority), 2020. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds. EFSA Journal 2020;18(2):5999, 50 pp. https://doi.org/10.2903/j.efsa.2020.5999
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- UK/Poland, 2020. Draft (renewal) assessment report on the active substance Prothioconazole prepared by the rapporteur Member State United Kingdom/Poland according to the Commission Regulation (EU) No 1107/2009, May 2020.

TDMs

- EFSA (European Food Safety Authority), 2018a. Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, doi: 10.2903/j.efsa.2018.5376
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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	Verte-brate study Y/N	Owner
Cyprodinil					
XXX	XXXX	XXX	XXXX	XX	XXXX
Prothioconazole					
No new data submitted					

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	Verte-brate study Y/N	Owner
Cyprodinil					
XXX	XXXX	XXX	XXXX	XX	XXXX
KCA2 6.5.3	White M T, Saha M	2006	The magnitude of residues of metconazole (BAS 555 F) and its metabolites in wheat processing commodities. Report No. 2006/7007147 GLP, Unpublished	KCA2 6.5.3	White M T, Saha M

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Cyprodinil

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1 – Report No. T003062-07

Comments of zRMS:	The study has been accepted. The study objective was to conduct ten trials in locations that satisfied the requirements for geographic distribution to determine the magnitude of cyprodinil residues in or on tree nuts, i.e., almond and pecan. Cyprodinil, as an active ingredient in Inspire Super® fungicide, was applied in four applications at a rate of 0.5 lb cyprodinil/A per application with a 14 day retreatment interval (RTI). The raw agricultural commodities of almond and pecan were harvested at typical commercial maturity, which approximated a pre-harvest interval (PHI) of 14 days. However, the study also determined the stability of cyprodinil residue in almond hulls and nutmeat under freezer conditions over a period of 10 months. Results generated through the 10 month interval demonstrate that there is no significant difference in the recoveries of cyprodinil in freezer stored samples versus the freshly fortified procedural recovery samples or the designated “0-day” analyses which are to serve as a benchmark for the study results (see the applicant study description below) The average procedural recoveries at fortification levels of 0.01 ppm, 0.10 ppm, and 10 ppm ranged from 71.0-98.2% for cyprodinil in almond hulls. For almond nutmeat and pecan nutmeat, the average procedural recoveries at fortifications levels of 0.01 ppm and 0.10 ppm ranged from 88.4-97.7% and 86.4-106% respectively.

Reference: KCA1 6.1

Report: Cyprodinil – Magnitude of the Residues in or on Almond and Pecan as Representative Commodities of Tree Nuts, Group 14 and Storage Stability of Almonds (Hulls and Nutmeat).

Mazlo J, 2010

Report No. T003062-07

XXXX File No. VV-467356

unpublished

Guideline(s): Yes

	U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances (OPPTS). 1995. Residue Chemistry Test Guidelines, OPPTS 860.1380, Storage Stability Data
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Summary

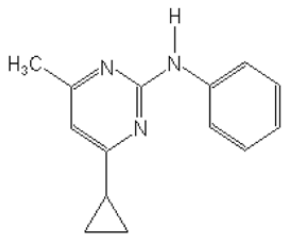
The storage stability of cyprodinil was determined in almond hulls and nutmeat under freezer conditions of approximately -20ºCover a storage period of 10 months.

I. MATERIALS AND METHODS

A. MATERIALS

A1. Test Material

A cyprodinil standard was used to fortify storage stability samples, concurrent recovery samples and to prepare calibration standard solutions. Information pertaining to the cyprodinil standard is given below.

Compound	
Common Name:	Cyprodinil
Code Name:	CGA219417
IUPAC Name:	4-cyclopropyl-6-methyl-N-phenylpyrimidin-2-amine
CAS Number:	121552-61-2
Molecular Formula:	$C_{14}H_{15}N_3$
Molecular Weight:	225.295 g/mol
Source:	XXXX Crop Protection
Standard Reference:	410442
Purity:	99.5% (w/w)
Storage Conditions:	Neat standard was stored <30°C Prepared standards were stored in a refrigerator 3-5°C
Reanalysis Date:	April, 2010
Certificate of Analysis Date	14 May 2007

A2. Test Facilities

The study was conducted at XXXX.

A3. Test Commodities

The test commodities were generated by compositing several untreated samples from previous magnitude of residue studies. Tree nuts is a representative of the high oil content commodity category (OECD 506 – Stability of Pesticide Residues in Stored Commodities).

Test Commodities

Crop	Crop Category	Source
Hulls, almond	High oil	XXXX Prep Group, Greensboro
Nutmeat, almond	No category	XXXX Prep Group, Greensboro

B. STUDY DESIGN

B1. Experimental Conditions

The almond hull and nutmeat samples were fortified with cyprodinil standard at 1.0 ppm concentration level and were stored frozen under conditions identical to those used to store residue samples prior to analysis. Freezer storage temperatures were monitored daily and were typically less than or equal to -20°C.

The stored samples were analysed at storage intervals of approximately 0, 7, and 10 months. Samples were removed from the freezer to warm up prior to extraction in 80:20 (v:v) methanol:water by shaking for 1 hour at room temperature. All smaples were analysed within 1 day of extraction.

B2. Analysis

Residues of cyprodinil were analysed using method AG-631B. Method validation data is summarised in Section 5.

Stock standard solutions were prepared in methanol. Calibration standards for LC-MS/MS were prepared by dilution of the stock standard solution in 0.1% ammonium acetate in water instead of 70:30 (v:v) methanol:water as outlined in the method.

A small amount of concentrated hydrochloric acid was added to the extracts and shaken for an additional 5 minutes prior to centrifugation and filtering. An aliquot of the supernatant was diluted to final volume with 0.1% ammonium acetate in water prior to cyprodinil residues analysis using HPLC with LC-MS/MS. The limit of quantitation (LOQ) was 0.01 ppm.

II. RESULTS AND DISCUSSION

The table below summarises the storage stability for cyprodinil in almond commodities.

Summary of Storage Stability from Almonds with Cyprodinil

Matrix	Mean Storage Stability Results (% of 0 Day) at the Nominal Storage Interval		
	0-day	**7 Months**	**10 Months**
Almond, Nutmeat	100	92	107
[1]Almond, Hulls	100	97	103

Mean storage stability results (% of 0day) = (interval mean concentration/0 day mean concentration) x 100.
[1]The mean concentrations were corrected for control background and procedural recoveries <100%.

The table below summarises the individual results for each storage period and expresses these as a corrected percentage of the nominal. The results generated demonstrate no significant differences in the recoveries of cyprodinil in freezer storage samples versus the freshly fortified procedural recovery samples or the designated 0 day analyses which are to serve as a benchmark for the study results.

The results show that residues of cyprodinil are stable for up to 328 days (or at least 10 months) in almond nutmeat and hulls under freezer conditions of -20°C.

Table A 1: Summary of concurrent recoveries and stability of cyprodinil in almond nutmeat and hulls

Commodity	Storage Interval	Nominal Fortification Level (Procedural Recovery Samples)	Procedural Recovery Residue	[1]Mean Procedural Recovery Residue	Uncorrected Stored Sample Residue	Mean Uncorrected Stored Sample Residue	[2]Mean Corrected Stored Sample Residue	[3]Mean Corrected Stored Sample Recovery
	Days	mg/kg	%	%	mg/kg	mg/kg	mg/kg	(% of nominal)
Almond Nutmeat	0	1.0	113	116	0.971	0.859	0.74	74
			119		0.747			
	208	1.0	117	111	0.861	0.787	0.71	71
			105		0.713			
	328	1.0	127	115	0.956	0.916	0.80	80
			102		0.876			
Almond Hulls	0	1.0	77	76	0.702	0.7045	0.93	93
			74		0.707			
	208	1.0	74	76	0.652	0.677	0.90	90
			77		0.702			
	328	1.0	80	80	0.76	0.7615	0.96	96
			79		0.763			

[1] [Mean Procedural Recovery Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100
[2] [Mean Uncorrected Stored Sample Residue (mg/kg) x 100] / Mean Procedural Recovery (%)
[3] Based on nominal fortification level = [Mean Corrected Stored Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

III. CONCLUSIONS

Freezer storage stability studies are available for almond hulls and nutmeat. These are representative of the commodity categories required to support current EPA Residue Chemistry Test Guidelines, Storage Stability Data, OPPTS 860.1380 requirements (crops containing high levels of oil).

It can be concluded that residues of Cyprodinil can be assumed stable in almond hulls and nutmeat (high oil) when stored at less than or equal to -20°C for at least 10 months.

A 2.1.1.1.1.2 Study 2 – Report No. CER04169/07

Comments of zRMS:	The study has been accepted in the context of its stability purpose. Sixteen canola residue trials were conducted in Canada to determine the magnitude of the residues of fludioxonil and cyprodinil after a single foliar application corresponding to 365.6 g cyprodinil/ha and 243.8 g fludioxonil/ha. The analytical methods (Novartis method AG-631B and XXXX method AG-597B) were modified to make them suitable for LC/MS/MS and to improve the method's ruggedness. Also the complications of extraction from an oily matrix were addressed. The LOQ for fludioxonil was 0.0100 ppm and for cyprodinil was 0.0200 ppm in seed and meal and 0.0100 ppm in oil. Storage stability has previously been demonstrated for cyprodinil in grapes, apples, apple pomace, strawberries, potatoes, peaches, wheat (ears and stalks), and wine for at least 2 years under freezer storage conditions. Freezer storage stability for cyprodinil in canola seed, meal and oil were initiated as part of the study. There was no degradation of cyprodinil in canola seed, meal and oil for up to 9 months (see also Table 22, 23 and 24; p. 209-211 of the original study).

Reference:	KCA1 6.1
Report:	Fludioxonil/Cyprodinil WG (A9219B) - Residue Levels on Canola Seed and Processed Fractions, Meal and Refined Oil, from Trials Conducted with SWITCH® 62.5 WG in Canada During 2007 (MRID 47644301) Final Report Amendment 1. Sagen K, 2009 Report No. CER 04169/07 XXXX File No. A9219B_50006 (VV-117239) unpublished
Guideline(s):	Yes Canadian OECD GLP regulations Codex "Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis", ALINORM 87/24A (1987) PMRA Regulatory Directive DIR98-02 "Residue Chemistry Guidelines". PMRA Regulatory Directive DIR98-01
Deviations:	Yes, Deviations were made to the analytical methods for canola seed and meal samples. The deviations are detailed in the analytical section.
GLP:	Yes
Acceptability:	Yes

Executive Summary

Samples of canola seed, meal and oil for cyprodinil were stored under freezer conditions of -20°C and were shown to be stable for at least 9 months.

Storage stability was set up for cyprodinil in canola seed, meal and oil. Sampling periods consisted of 0 days, 3 month, 6 month and 9 months. The storage stability results generated demonstrate no significant differences in the recoveries of cyprodinil in freezer storage samples versus the freshly fortified procedural recovery samples or the designated 0 day analyses which are to serve as a benchmark for the study results.

I. MATERIALS AND METHODS

A. MATERIALS

A1. Test Materials

A cyprodinil standard was used to fortify storage stability samples, concurrent recovery samples and to prepare calibration standard solutions. Information pertaining to the cyprodinil standard is given below.

Test Material	CGA219417
Lot No.	410442
Purity	99.5%

A2. Test Commodities

Canola seed is a representative of the high oil content commodity category (OECD 506 – Stability of Pesticide Residues in Stored Commodities).

A3. Test Facility

The Performing Laboratory was located at: ALS Laboratory Group 9936-67 Avenue, Edmonton, Alberta, T6E 0PS, Canada.

B. STUDY DESIGN

B1.Test Procedures

The canola commodity samples were fortified with cyprodinil standard at 0.2 ppm for seed and meal samples or 0.1 ppm for oil samples. These were then stored frozen under conditions identical to those used to store residue samples prior to analysis. Freezer storage temperatures were monitored daily and were between -41ºC to -15ºC.

For cyprodinil, the stored samples were analysed at storage intervals of approximately 0, 3, 6, and 9 months.

Cyprodinil samples were removed from the freezer to warm up prior to extraction in 80:20 (v:v) methanol:water.

B2. Analysis

Residues of cyprodinil were analysed with Novartis method AG-631B with the following modifications for canola seed and meal samples:

1. The extracts were centrifuged at 5000 rpm instead of being filtered
2. Diethylene glycol diethyl ether was not added.
3. Extracts were brought to 10mL final volume instead of 2mL final volume.

Cyprodinil (CGA 219417) was analysed for canola refined oil samples using XXXX method AG-597B with the following modifications made to them:

1. 10g sample was extracted instead of 25g sample.
2. Hexane, florisil and phyenyl column clean-ups were not performed.

This method addressed the complications of extraction from an oily matrix and produced suitable recoveries at the LOQ. Method validation data is summarised in Section 5.

II. RESULTS AND DISCUSSION

The table below summarises the storage stability for cyprodinil in canola commodities.

Stability of cyprodinil residues in canola commodities following storage at -20ºC

Average Recovery for Aged samples- Cyprodinil

Matrix	**Interval (Months)**				**Overall Average**
	0	**3**	**6**	**9**	
Seed	74	89	80	101	86
Meal	99	107	97	78	95
Oil	102	100	106	105	103

The table below summarises the individual results for each storage period and expresses these as a corrected percentage of the nominal. The results generated demonstrate no significant differences in the recoveries of cyprodinil in freezer storage samples versus the freshly fortified procedural recovery samples or the designated 0 day analyses which are to serve as a benchmark for the study results.

The results show that residues of cyprodinil are stable for up to at least 9 months in tested canola commodities under freezer conditions of -20°C.

Table A 2: Summary of concurrent recoveries and stability of cyprodinil in canola commodities

Commodity	**Storage Interval**	**Nominal Fortification Level (Procedural Recovery Samples)**	**[1]Average Recovery for Aged Samples**	**Uncorrected Stored Sample Residue**	**Mean of Uncorrected Stored Sample Residue**	**[2]Mean Corrected Stored Sample Residue**	**[3]Mean Corrected Stored Sample Recovery**
	Months	**mg/kg**	**%**	**mg/kg**	**mg/kg**	**mg/kg**	**(% of nominal)**
Canola Seed	0	0.2	74	0.142	0.147	0.199	99
				0.152			
	3	0.2	89	0.163	0.174	0.195	97
				0.177			
				0.202			
				0.152			
	6	0.2	80	0.181	0.172	0.215	108
				0.189			
				0.160			
				0.158			
	9	0.2	101	0.183	0.187	0.185	92
				0.162			
				0.200			
				0.202			
Canola Meal	0	0.2	99	0.189	0.198	0.199	100
				0.206			
	3	0.2	107	0.204	0.212	0.198	99
				0.221			
				0.193			
				0.231			
	6	0.2	97	0.213	0.200	0.206	103
				0.200			
				0.220			
				0.168			
	9	0.2	78	0.209	0.172	0.220	110
				0.166			

Commodity	Storage Interval	Nominal Fortification Level (Procedural Recovery Samples)	[1]Average Recovery for Aged Samples	Uncorrected Stored Sample Residue	Mean of Uncorrected Stored Sample Residue	[2]Mean Corrected Stored Sample Residue	[3]Mean Corrected Stored Sample Recovery
				0.148			
				0.164			
Canola Oil	0	0.1	102	0.109	0.102	0.100	100
				0.0947			
	3	0.1	100	0.0857	0.098	0.098	98
				0.107			
				0.106			
				0.0929			
	6	0.1	106	0.0902	0.101	0.095	95
				0.101			
				0.113			
				0.0984			
	9	0.1	105	0.107	0.105	0.100	100
				0.102			
				0.109			
				0.101			

[1] [Mean Procedural Recovery Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100
[2] [Mean Uncorrected Stored Sample Residue (mg/kg) x 100] / Mean Procedural Recovery (%)
[3] Based on nominal fortification level = [Mean Corrected Stored Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

III. CONCLUSIONS

Freezer storage stability studies were performed for Canola seed, meal and oil. These are representative of the commodity categories required to support current OECD 506 – Stability of Pesticide Residues in Stored Commodities requirements (crops containing high levels of oil).

It can be concluded that residues of cyprodinil are stable in canola seed, meal and oil when stored at less than or equal to -20ºC for at least 9 months.

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies are submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new studies are submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies are submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies are submitted.

A 2.1.2.2 Nature of residues in livestock

Comments of zRMS:	The residue hydrolysis method and validation has been accepted. The objective of this study is to develop a method for the quantitative analysis of the residues of CGA-304075 in edible tissues and milk i.e exactly a method to extract and quantify the residues of CGA-304075 [4-(4-cyclopropyl-6-methyl-pyrimidin-2-ylamino) phenol)], the major metabolite of CGA-219417 in cattle, and set hydrolysis conditions to cleave conjugates of CGA-304075 in edible tissues and milk from a goat dosed with 14C- CGA-219417. The radiolabeled equivalent of the test substance used in this study is [pyrimidinyl-2-14C]-CGA-219417. LC-MS/MS was applied for analytical determination. The liver, kidney and milk samples were chosen to use in this study for method development. The optimized conditions for the hydrolysis method were determined to be a reflux for 1 hour using 0.5N hydrochloric acid. The hydrolysis method was used to extract the ^{14}C and cleave the conjugates of CGA-304075 in one step. This reflux method resulted in an increase in the level of CGA-304075 released over the neutral solvent extraction. The results indicate that this quantitative residue hydrolysis method, reflux using 0.5 N HCL, can be used to extract CGA-304075 and hydrolyze conjugates of CGA-304075 from tissues and milk. zRMS additional remark: This is vertebrate study (Approximately six hours after the last dose the test animal was sacrificed; page 16).

Reference:	KCA1 6.2.3
Report	[^{14}C] Pyrimidinyl-Cyprodinil (CGA219417): Method development for analysis of CGA-304075 (metabolite of cyprodinil) and related metabolites from a lactating goat Anderson W, 2006 Report No. T019338-04 XXXX File No. VV-501913
Guideline(s):	Yes Residue Chemistry Test Guidelines, OPPTS 860.1300. Nature of the Residue - Plants, Livestock. United States Environmental Protection Agency, August 1996
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No This is vertebrate study

Executive Summary

VV- 894530

A study was conducted during 2004-2005 in which radio-labelled cyprodinil was dosed to a goat to generate milk and tissue samples containing incurred residues of cyprodinil and its animal metabolites for use in method development work.

^{14}C-Cyprodinil, labelled in the 2-position of the pyrimidinyl ring, was dosed in gelatin capsules and administered to a single goat. Four doses were given, on consecutive days, each containing approximately 150 mg of test substance, equivalent to 100 mg/kg in the diet (~ 4 mg/kg bw/day). The goat was sacrificed 6 hours after the fourth dose and selected tissue samples taken for use in the method validation.

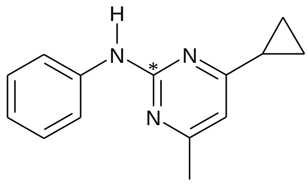
Total radioactive residues in the tissues were determined by combustion analysis, before characterisation of the radioactive residues in these tissues was performed. The results were broadly similar to those of the full metabolism studies summarised above, but rather lower levels of CGA304075 (free and conjugated) were found.

It was demonstrated that, to provide a reliable analytical method for residues of CGA304075 in animal tissues, extraction by reflux in hydrochloric acid (0.5 M) is required. This work formed the basis of method GRM010.01A and is also summarised in part B, Section 5.3.2.3 of this submission.

I. MATERIALS AND METHODS

A. MATERIALS

A1. Test Materials

Structure/Label	**Pyrimidinyl-2-^{14}C Cyprodinil**
	 (* = ^{14}C position)
Batch Number	CL-LVII-16
Radiochemical Purity	99.3%

A2. Test Organism

A goat (*Capra hircus*), of variety Alpine was used.

A3. Test Facilities

The biological phase and analytical phase 1 (TRR determination and profiling of extracts) of this work were performed at XXXX.

Analytical phase 2 (identification and quantification of metabolites) was performed at XXXX.

B. STUDY DESIGN AND METHODS

B1. Experimental Conditions

The goat was housed in a metabolism cage designed for the separate collection of urine and faeces. Treatment room lights were on a 12 hour on/off cycle each 24 hour period. During the 5 day acclimation and 4 day dosing period, room temperatures ranged from 24-31°C and humidity from 28-96%. The health of the goat was checked by a veterinarian; overall, the test animal remained in good health throughout the acclimation and dosing period.

Twice a day the goat was offered a measured ration of grain and hay. The daily diet was given in two equal portions of 400 g grain and 500 g hay in the morning and in the afternoon. Commercial bottled drinking water was provided *ad libitum*.

Four gelatin capsules, each containing approximately 150 mg of [pyrimidinyl-2-^{14}C] cyprodinil, were prepared and one capsule per day was administered with a balling gun. The animal was dosed over a period of 4 consecutive days in the morning, after feeding and collection of milk, urine and faeces.

B2. Sampling

Urine and faeces were collected from the test animal at 24-hour intervals in the morning before dosing. Milk was collected twice a day in the morning and afternoon. A whole blood sample was collected from the test animal just prior to sacrifice.

Approximately 6 hours following the last dose, the test animal was stunned with a captive bolt shot and immediately exsanguinated by severing the major neck vessels. Veterinary examination indicated that the animal was healthy at the time of sacrifice; there were no abnormal findings.

After sacrifice, samples were collected in the following order: leg muscle, omental fat, perirenal fat, kidney, liver, bile, gastrointestinal tract and tenderloin. The two muscle samples were combined, as were the two fat samples.

B3. Extraction and Fractionation of Residues

<u>Analytical Phase 1</u>

The total radioactive residues (TRR) in each tissue (including milk) sample were initially determined by direct combustion/LSC.

Solid and semi-solid samples were homogenized by milling with dry ice. Liquid samples were mixed by hand. Triplicate aliquots (solid samples) were combusted and the released CO_2 trapped in Carbon 14 Cocktail. Combustion values were corrected for oxidizer efficiency. Radioassays were obtained by scintillation counting. Weighed aliquots of fat samples were warmed prior to radioassay. Volumetric aliquots of liquid samples were transferred directly to scintillation vials for radioassay. All samples were counted for a 5 minute interval or until a 2-sigma error of <0.5 was achieved. Background values were determined using a scintillation cocktail blank.

<u>Analytical Phase 2</u>

Liver, kidney and milk were extracted by neutral solvent extraction using acetonitrile (milk) or acetonitrile/water (80:20 v/v) for liver and kidney. These extracts were examined by HPLC co-chromatography against standards.

The urine was used to develop hydrolytic conditions for the cleavage of CGA304075 conjugates. Differing concentrations of HCl were investigated under reflux conditions. High concentrations of HCl (> 1N) caused degradation of metabolites to polar compounds. 0.5N HCl was selected because it gave maximum extraction efficiency without degradation of the sample components. This hydrolytic extraction procedure also gave greater extraction efficiency than the neutral solvent.

II. RESULTS AND DISCUSSION

A. TOTAL RADIOACTIVE RESIDUES (TRRs)

Total radioactive residues in the kidney (3.197 mg/kg), liver (3.802 mg/kg) and milk (from afternoon of day 4) (0.425 mg/kg) were comparable to those found in previous studies, as shown in the table below.

Table A 3: Comparison of extraction efficiencies of CGA304075 from animal tissues

Study (Nominal Dose rate)	Tissue	Total radioactive Residue		Extractable Residue (%)	CGA304075 (%)	Gluc-CGA304075* (%)
		(mg/kg)	(% of dose)			
5/94 (5 mg/kg)	Liver	0.277		80.5	2.7	nd
	Kidney	0.216		88.1	17.7	nd
	Milk	0.048		83.5	nd	27.3
17/96 (100 mg/kg)	Liver	2.488	0.3	67.9	27.6	2.7
	Kidney	2.895	0.1	95.5	39.1	4.6
	Milk	0.708	0.5	96.1	nd	55.2
T019338-04 (100 mg/kg)	Liver	3.802	0.5	73.0	3.4	
	Kidney	3.197	0.1	95.3	<0.1	
	Milk	0.425	<0.1	90.3	<0.1	

* - Glucuronide conjugate of CGA304075
nd - not detected

The TRR values determined from the summation of the radioactivity present in the extracts and the debris after initial extraction were in good agreement with those derived from earlier studies.

B. EXTRACTION OF RESIDUES

The urine contained much higher radioactive residues than the tissues and milk, 3.8 - 11.6 of the applied dose and was used to develop hydrolysis conditions to cleave conjugates of CGA304075. Different concentrations of HCl under reflux conditions were investigated. Results are shown in the table below.

Table A 4: Comparison of hydrolysis efficiencies of CGA304075 from goat urine

Extraction Conditions	CGA304075 Extracted (% TRR)
Day 4 urine (Neutral extraction)	0.2
Day 4 urine (Acid reflux, 6N HCl, 1 hr)	<0.1
Day 4 urine (Acid reflux, 3N HCl, 1 hr)	<0.1
Day 4 urine (Acid reflux, 1N HCl, 1 hr)	0.3
Day 4 urine (Acid reflux, 0.5N HCl, 1 hr)	0.3
Day 4 urine (Acid reflux, 0.25N HCl, 1 hr)	0.3

High concentrations of HCl (6N, 3N and 1N) degraded many of the metabolites to polar compounds. Reflux of urine samples with 0.25N HCl and 0.5N HCl followed by HPLC analysis gave highest recovery of free CGA304075 and the use of 0.5N HCl was selected as giving efficient hydrolysis and recovery without degradation of other components in the sample matrix. The chosen 0.5N HCL reflux extraction also produced higher extraction efficiency than neutral solvent (acetonitrile/water, 80:20, v/v) as shown in the table below.

Table A 5: Comparison of extraction efficiencies of CGA304075 from goat tissues

Matrix	Solvent Extraction		Acid Reflux (0.5N HCl)	
	% Extractable	CGA304075 (mg/kg)	% Extractable	CGA304075 (mg/kg)
Liver	73.0	0.129	93.2	0.373
Milk	90.3	Not detected	97.7	0.059

C. CHARACTERISATION AND IDENTIFICATION OF RESIDUES

Free CGA304075 was highest in the liver, 3.4% TRR (0.129 mg/kg), with less than 0.1% detected in the kidney and milk. In previous metabolism studies (MR 5/94 and 17/96) the glucuronic acid conjugate of CGA304075 was seen in the liver, kidney and milk. In the current study, in the liver, kidney and milk, a number of polar compounds were detected in the region of the CGA304075 glucuronic acid conjugate, which made quantification of the glucuronic acid conjugate difficult. The analysis results are shown in the table below. CGA304075 increased in the liver from 3.4% TRR (0.129 mg/kg) by neutral extraction to 9.8% TRR (0.373 mg/kg). CGA304075 in milk increased from <0.1% TRR (<0.001 mg/kg) by neutral extraction to 14% TRR (0.059 mg/kg).

Table A 6: Distribution of CGA304075 in liver and milk (extraction by acid reflux)

Matrix	TRR (mg/kg)	TRR (% of Dose)	Extractable (%)	CGA304075
Liver	3.802	0.5	93.2% (3.545 mg/kg)	9.8% (0.373 mg/kg)
Milk	0.425	<0.1	97.7% (0.415 mg/kg)	14.0% (0.059 mg/kg)

III. CONCLUSIONS

This study, intended only to produce tissue samples containing incurred radioactive residues of CGA304075 for method-development purposes, gave tissue concentrations of CGA304075 and its conjugates lower than the metabolism studies in lactating goats.

Despite this quantitative difference, the overall distribution of residues was sufficiently consistent with the metabolism studies, and tissues for method development were successfully generated.

Extraction of tissues and milk by acid reflux gives greater extraction efficiency than extraction with solvents. Reflux using 0.5N HCl was selected to give efficient hydrolysis and recovery of residues of free and conjugated CGA304075 without degradation of other components in the sample matrix.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat, extrapolation to triticale, rye, spelt and durum wheat

Table A 7: Comparison of intended and critical EU GAPs - Wheat

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2013)	2	750 g a.s./ha	21 days	BBCH 30-65	42
Intended cGAP (N-EU) (AT1-AT8, BE1-BE8, CZ1-CZ8, DE1-DE4, HU1-HU8, IE1-IE8, LU1-LU8, NL1-NL8, PL1-PL8, RO1-RO8, SK1-SK8, SI1-SI8*)	1	450 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 8: Comparison of intended and critical EU GAPs - Triticale

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2013)	2	750 g a.s./ha	21 days	BBCH 30-65	42
Intended cGAP (N-EU) (AT29-AT30, BE29-BE30, CZ29-CZ30, DE29, IE29-IE30, LU29-LU30, NL29-NL30, PL29-PL30, PL36, SI27-SI28*)	1	450 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 9: Comparison of intended and critical EU GAPs - Rye

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2013)	1	750 g a.s./ha	-	BBCH 30-32	42
Intended cGAP (N-EU) (AT25-AT26, BE25-BE26, CZ25-CZ26, DE25, IE25-IE26, LU25-LU26, NL25-NL26, PL25-PL26, PL37, PL31-PL33, SI23-SI24*)	1	450 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 10: Comparison of intended and critical EU GAPs - Spelt

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2013)	2	750 g a.s./ha	21 days	BBCH 30-65	42
Intended cGAP (N-EU) (AT31-AT34, IE31-IE34, PL38-PL43, RO23-RO26, SK23-SK26, SI29-SI32*)	1	450 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 11: Comparison of intended and critical EU GAPs – Durum wheat

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2013)	2	750 g a.s./ha	21 days	BBCH 30-65	42
Intended cGAP (N-EU) (AT9-AT12, BE9-BE12, HU9-HU12, IE9-IE12, LU9-LU12, NL9-NL12, PL9-PL12, PL34-PL35, RO9-RO12, SK9-SK12, SI9-SI12*)	1	450 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.1.1 Study 1 – Report No. IF21-05733624

Comments of zRMS:	The study has been accepted. 8 residue trials on wheat were conducted in NEU during 2021. 4 trials were conducted as decline trials and 4 trials as harvest trials. Cyprodinil and prothioconazole were applied to wheat as A23282A. 1 application was made at a nominal rate of 450 g cyprodinil/ha and 150 g prothioconazole/ha. The application was done at 38-49 DBH i.e. at BBCH 69. In 4 decline trials samples were collected at 0 days after application (DAA), 7 DAA, 13-15 DAA, 27-29 DAA, 38-42 DAA (NCH) with untreated wheat being collected 0 DBA and 38-42 DAA (NCH). In 4 harvest trials samples were collected at 41-49 DAA (Normal Commercial Harvest). The validated method (REM 141.10; see Section 5 - KCP 5.1.2.5 for validation) has additionally been fully verified (5 recoveries at the LOQ and a higher level, selectivity and linearity) for matrix groups (high water content and dry commodities) as part of this study. Final determination was performed by high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (LC- MS/MS) with positive electro spray ionisation (ESI+) in multiple reaction monitoring mode (MRM). The obtained procedural recoveries and RSDs were within the required range for the required number of fortification levels. This study complied with SANTE/2020/12830 rev.1 and the method was considered suitable for its purpose.

Reference:	KCA1 6.3.1
Report	Cyprodinil - Residue Study on Wheat in Germany, Poland, Northern France, Hungary and Denmark in 2021 Gabriel EJ & Link T, 2021 Report No. IF21-05733624 XXXX File No. VV-936833
Guideline(s):	Yes Guidelines for the Generation of Data concerning Residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market (EU) 1607/VI/97 (1999). Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials European Commission Technical Guideline SANTE/2019/12752: On data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (former 7525/VI/95 - rev.10.3) OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment No. 64 and Series on Pesticides No. 32, ENV/JM/MONO(2009)31. OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD – Guideline for the Testing of Chemicals, Test Guideline 509; Crop field trial, 07/09/2009 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post approval Control and Monitoring Purposes - SANTE/2020/12830, Rev.1, 24. Feb 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 12: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Cyprodinil - Residue Study on Wheat in Germany, Poland, Northern France, Hungary and Denmark in 2021			
Active Substance (common name):	Cyprodinil	**Commercial Product (name):**	
Crop/Crop Group:	Wheat	**Producer of commercial product:**	XXXX
Responsible body for reporting (name, address):	XXXX	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Germany, Poland, Northern France, Hungary and Denmark	**Other active substance in the formulation (common name and content):**	Prothioconazole, 75 g/L
Content of active substance (g/kg or g/L):	A23282A: 225 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23282A EC		
Analytical Method:	Cyprodinil (Grain, Straw, Whole Plant) REM 141.10; 0.01 mg/kg		
Recovery data:	Cyprodinil Grain Mean = 87-88% RSD = 5.7-6.8 (n = 12 in 0.01 – 1.0 spiking range) Cyprodinil Straw Mean = 85-94% RSD = 1.8-11.1 (n = 13 in 0.01 – 1.0 spiking range) Cyprodinil Whole Plant Mean = 88-100% RSD = 3.4-13.7 (n = 15 in 0.01 - 20 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analysed**	**(9) Residue found (Uncorrected)**	**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Cyprodinil (mg/kg)**			
IF21-05733624 21-00344-01 Germany (Europe North) (16845)	Winter wheat / Aktivus IG	1. 01 Oct 2020 2. 07 Jun – 10 Jun 2021 3. 19 Jul – 25 Jul 2021	- -	- -	- -	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	0	10 Jun 2021/ -	Field SP (max days): 140
									Grain	< 0.01 mg/kg	41	21 Jul 2021/ -	
									Straw	< 0.01 mg/kg	41	21 Jul 2021/ -	
	Winter wheat / Aktivus IG	1. 01 Oct 2020 2. 07 Jun – 10 Jun 2021 3. 19 Jul – 25 Jul 2021	1. Foliar	-	1. 293 L/ha	1. 437.1 g a.s./ha A23282A (-)	1. 10 Jun 2021 (N/A)	1. BBCH 69	Whole plant	8.4 mg/kg	0	10 Jun 2021/ -	Field SP (max days): 140
									Whole plant	2.7 mg/kg	7	17 Jun 2021/ -	
									Whole plant	0.96 mg/kg	14	24 Jun 2021/ -	
									Whole plant	0.78 mg/kg	27	07 Jul 2021/ -	
									Grain	0.03 mg/kg	41	21 Jul 2021/ -	
									Straw	0.58 mg/kg	41	21 Jul 2021/ -	
IF21-05733624 21-00344-02	Winter wheat / Tonnage	1. 30 Sep 2020	- -	- -	- -	-	-	-	Whole plant	< 0.01 mg/kg	0	29 Jun 2021/ -	Field

Poland (Europe North) (88-320)		2. 15 Jun – 29 Jun 2021 3. 10 Aug 2021				(-)	(-)		Grain	< 0.01 mg/kg	42	10 Aug 2021/ -	SP (max days): 121
									Straw	< 0.01 mg/kg	42	10 Aug 2021/ -	
	Winter wheat / Tonnage	1. 30 Sep 2020 2. 15 Jun – 29 Jun 2021 3. 10 Aug 2021	1. Foliar	-	1. 299 L/ha	1. 445.9 g a.s./ha A23282A (-)	1. 29 Jun 2021 (N/A)	1. BBCH 69	Whole plant	4.2 mg/kg	0	29 Jun 2021/ -	Field SP (max days): 121
									Whole plant	1.6 mg/kg	7	06 Jul 2021/ -	
									Whole plant	0.50 mg/kg	14	13 Jul 2021/ -	
									Whole plant	0.18 mg/kg	28	27 Jul 2021/ -	
									Grain	0.04 mg/kg	42	10 Aug 2021/ -	
									Straw	0.10 mg/kg	42	10 Aug 2021/ -	
IF21-05733624 21-00344-03 France (Europe North) (08300)	Winter wheat / Chevignon	1. 07 Nov 2020 2. 10 Jun – 14 Jun 2021 3. 22 Jul – 25 Jul 2021	- -	- -	- -	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	0	16 Jun 2021/ -	Field SP (max days): 118
									Grain	< 0.01 mg/kg	38	24 Jul 2021/ -	
									Straw	< 0.01 mg/kg	38	24 Jul 2021/ -	
	Winter wheat / Chevignon	1. 07 Nov 2020 2. 10 Jun – 14 Jun 2021 3. 22 Jul – 25 Jul 2021	1. Foliar	-	1. 239 L/ha	1. 427.4 g a.s./ha A23282A (-)	1. 16 Jun 2021 (N/A)	1. BBCH 69	Whole plant	5.4 mg/kg	0	16 Jun 2021/ -	Field SP (max days): 134
									Whole plant	1.0 mg/kg	7	23 Jun 2021/ -	
									Whole plant	0.34 mg/kg	15	01 Jul 2021/ -	
									Whole plant	0.07 mg/kg	29	15 Jul 2021/ -	
									Grain	0.05 mg/kg	38	24 Jul 2021/ -	
									Straw	0.07 mg/kg	38	24 Jul 2021/ -	
IF21-05733624 21-00344-04 Hungary (Europe North) (H-4461)	Winter wheat / GK Csillag	1. 12 Nov 2020 2. 28 May – 10 Jun 2021 3. 12 – 17 Jul 2021	- -	- -	- -	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	0	09 Jun 2021/ -	Field SP (max days): 145
									Grain	< 0.01 mg/kg	38	17 Jul 2021/ -	
									Straw	< 0.01 mg/kg	38	17 Jul 2021/ -	
	Winter wheat / GK Csillag	1. 12 Nov 2020 2. 28 May – 10 Jun 2021 3. 12 – 17 Jul 2021	1. Foliar	-	1. 305 L/ha	1. 454.5 g a.s./ha A23282A (-)	1. 09 Jun 2021 (N/A)	1. BBCH 69	Whole plant	6.9 mg/kg	0	09 Jun 2021/ -	Field SP (max days): 141
									Whole plant	0.94 mg/kg	7	16 Jun 2021/ -	
									Whole plant	0.41 mg/kg	13	22 Jun 2021/ -	
									Whole plant	0.27 mg/kg	27	06 Jul 2021/ -	

									Grain	0.10 mg/kg	38	17 Jul 2021/ -	
									Straw	0.25 mg/kg	38	17 Jul 2021/ -	
IF21-05733624 21-00344-05 Germany (Europe North) (24980)	Winter wheat / RGT Reform	1. 20 Oct 2020 2. 15 Jun – 17 Jun 2021 3. 05 Aug 2021	- -	- -	- -	- (-)	- (-)	-	Grain	< 0.01 mg/kg	49	05 Aug 2021/ -	Field
									Straw	< 0.01 mg/kg	49	05 Aug 2021/ -	SP (max days): 68
	Winter wheat / RGT Reform	1. 20 Oct 2020 2. 15 Jun – 17 Jun 2021 3. 05 Aug 2021	1. Foliar	-	1. 203 L/ha	1. 453.0 g a.s./ha A23282A (-)	1. 17 Jun 2021 (N/A)	1. BBCH 69	Grain	0.04 mg/kg	49	05 Aug 2021/ -	Field
									Straw	0.16 mg/kg	49	05 Aug 2021/ -	SP (max days): 68
IF21-05733624 21-00344-06 Poland (Europe North) (89-430)	Spring Wheat / Tybalt	1. 31 Mar 2021 2. 20 Jun – 02 Jul 2021 3. 10 Aug 2021	- -	- -	- -	- (-)	- (-)	-	Grain	< 0.01 mg/kg	42	10 Aug 2021/ -	Field
									Straw	< 0.01 mg/kg	42	10 Aug 2021/ -	SP (max days): 63
	Spring Wheat / Tybalt	1. 31 Mar 2021 2. 20 Jun – 02 Jul 2021 3. 10 Aug 2021	1. Foliar	-	1. 296 L/ha	1. 440.7 g a.s./ha A23282A (-)	1. 29 Jun 2021 (N/A)	1. BBCH 69	Grain	0.07 mg/kg	42	10 Aug 2021/ -	Field
									Straw	0.35 mg/kg	42	10 Aug 2021/ -	SP (max days): 63
IF21-05733624 21-00344-07 Hungary (Europe North) (H-3397)	Winter wheat / Genius	1. 13 Oct 2020 2. 28 May – 10 Jun 2021 3. 20 – 23 Jul 2021	- -	- -	- -	- (-)	- (-)	-	Grain	< 0.01 mg/kg	41	21 Jul 2021/ -	Field
									Straw	< 0.01 mg/kg	41	21 Jul 2021/ -	SP (max days): 83
	Winter wheat / Genius	1. 13 Oct 2020 2. 28 May – 10 Jun 2021 3. 20 – 23 Jul 2021	1. Foliar	-	1. 291 L/ha	1. 433.7 g a.s./ha A23282A (-)	1. 10 Jun 2021 (N/A)	1. BBCH 69	Grain	0.05 mg/kg	41	21 Jul 2021/ -	Field
									Straw	0.88 mg/kg	41	21 Jul 2021/ -	SP (max days): 83
IF21-05733624 21-00344-08 Denmark (Europe North) (6200)	Winter wheat / Graham	1. 25 Sep 2020 2. 14 – 16 Jun 2021 3. 30 Jul 2021	- -	- -	- -	- (-)	- (-)	-	Grain	< 0.01 mg/kg	44	30 Jul 2021/ -	Field
									Straw	< 0.01 mg/kg	44	30 Jul 2021/ -	SP (max days): 74
	Winter wheat / Graham	1. 25 Sep 2020	1. Foliar	-	1. 215 L/ha	1. 479.0 g a.s./ha	1. 16 Jun 2021	1. BBCH 69	Grain	0.03 mg/kg	44	30 Jul 2021/ -	Field

		2. 14 – 16 Jun 2021 3. 30 Jul 2021				A23282A (-)	(N/A)		Straw	0.23 mg/kg	44	30 Jul 2021/ -	SP (max days): 74

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.2 Barley, extrapolated to oat

Table A 13: Comparison of intended and critical EU GAPs - Barley

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2013)	2	750 g a.s./ha	21 days	BBCH 30-65	42
cGAP SYN A14325E	1-2	450 g a.s./ha	14 days	BBCH 30-61	45
Intended cGAP (N-EU) (AT13-AT24, BE13-BE24, CZ13-CZ24, DE13-DE18, HU13-HU22, IE13-IE24, LU13-LU24, NL13-NL24, PL13-PL24, RO13-RO22, SK13-SK22, SI13-SI22*)	1	450 g a.s./ha	-	BBCH 30-59	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 14: Comparison of intended and critical EU GAPs - Oat

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2013)	2	600 g a.s./ha	-	BBCH up to 55	42
cGAP SYN A14325E	1-2	450 g a.s./ha	14 days	BBCH 30-61	45
Intended cGAP (N-EU) (AT27-AT28, BE27-BE28, CZ27-CZ28, DE27, HU23-24, IE27-IE28, LU27-LU28, NL27-NL28, PL27-PL28, SI25-SI26*)	1	450 g a.s./ha	-	BBCH 30-59	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.2.1 Study 1 – Report No. TK0223253-REG

Comments of zRMS:	The study has been accepted. 4 residue trials on spring barley were conducted in NEU during 2014. Cyprodinil was applied to spring barley as A14325E. 2 applications at BBCH 30 and BBCH 65 – 75 were made at 450 g ai/ha. In 2 trials samples were taken at NCH. In 2 trials samples were taken at 0 DALA, at 19 - 20 DALA and 42 DALA. For residues final determination high performance liquid chromatography coupled to a triple quadrupole mass spectrometry (LC-MS/MS) detector in multiple reaction monitoring mode was used. The obtained procedural recoveries and RSDs were within the required range. The analytical method has been shown to be acceptable for analysis of cyprodinil in cereal grain and straw.

Reference:	KCA1 6.3.2
Report	Cyprodinil- Residue Study on Barley in Denmark, Germany, the United Kingdom and Hungary in 2014 Mahlo C, 2015 Report No. TK0223253-REG XXXX File No. A14325E_10084, VV-412939
Guideline(s):	Yes Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, EU 1999: 1607/VI/97 (rev. 2). European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 rev. 4 (11 Jul 2000). European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 rev. 8.1 (16 Nov 2010). Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. The national requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 15: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Cyprodinil- Residue Study on Barley in Denmark, Germany, the United Kingdom and Hungary in 2014			
Active Substance (common name):	Cyprodinil	**Commercial Product (name):**	
Crop/Crop Group:	Barley	**Producer of commercial product:**	XXXX
Responsible body for reporting (name, address):	XXXX	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Denmark, United Kingdom, Hungary, Germany	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A14325E: 300 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A14325E EC		
Analytical Method:	Cyprodinil (Grain, Straw, Whole Plant) REM 141.10; 0.01 mg/kg		
Recovery data:	Cyprodinil Grain Mean = 93% RSD = N/A (n = 2 in 0.01 - 2 spiking range) Cyprodinil Straw Mean = 95% RSD = N/A (n = 2 in 0.01 - 2 spiking range) Cyprodinil Whole Plant Mean = 93% RSD = 6% (n = 3 in 0.01 - 14 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analysed**	**(9) Residue found (Uncorrected)**	**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Cyprodinil (mg/kg)**			
TK0223253-REG 14-00701-01 Denmark (Europe North) (6300)	Barley / Evergreen	1.04 Apr 2014 2 – 3 -	-	-	-	(-)	- (-)		Grain	< 0.01 mg/kg	36	31 Jul 2014/ -	Field SP (max days): 237
									Straw	< 0.01 mg/kg	36	31 Jul 2014/ -	
	Barley / Evergreen	1.04 Apr 2014 2 – 3 -	1. Foliar 2. Foliar	-	1. 209.26 L/ha 2. 198.15 L/ha	1. 467.3284 g a.s./ha 2. 442.5145 g a.s./ha A14325E (-)	1. 21 May 2014 2. 25 Jun 2014 (N/A, 35)	1. BBCH 29-31 2. BBCH 73-75	Grain	0.3 mg/kg	36	31 Jul 2014/ -	Field SP (max days): 237
									Straw	0.33 mg/kg	36	31 Jul 2014/ -	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Cyprodinil (mg/kg)			
TK0223253-REG 14-00701-02 Germany (Europe North) (16818)	Barley / Salome	1.15 Apr 2014 2 – 3 -	-	-	-	(-)	- (-)		Grain	< 0.01 mg/kg	37	24 Jul 2014/24 Jul 2014	Field SP (max days): 244
									Straw	< 0.01 mg/kg	37	24 Jul 2014/24 Jul 2014	
	Barley / Salome	1.15 Apr 2014 2 – 3 -	1. Foliar 2. Foliar	-	1. 207.44 L/ha 2. 209.67 L/ha	1. 463.2927 g a.s./ha 2. 468.1334 g a.s./ha A14325E (-)	1. 16 May 2014 2. 17 Jun 2014 (N/A, 32)	1. BBCH 26-30 2. BBCH 61-65	Grain	0.79 mg/kg	37	24 Jul 2014/24 Jul 2014	Field SP (max days): 244
									Straw	0.16 mg/kg	37	24 Jul 2014/24 Jul 2014	
TK0223253-REG 14-00701-03 United Kingdom (Europe North) (NN12 8PA)	Barley / Concerto	1.01 Mar 2014 2 – 3 -	-	-	-	(-)	- (-)		Whole Plant	< 0.01 mg/kg	0	02 Jul 2014/ -	Field SP (max days): 266
									Grain	< 0.01 mg/kg	47	18 Aug 2014/ -	
									Straw	< 0.01 mg/kg	47	18 Aug 2014/ -	
	Barley / Concerto	1.01 Mar 2014 2 – 3 -	1. Foliar 2. Foliar	-	1. 210.42 L/ha 2. 197.45 L/ha	1. 469.9131 g a.s./ha 2. 440.9636 g a.s./ha A14325E (-)	1. 23 May 2014 2. 02 Jul 2014 (N/A, 40)	1. BBCH 30-31 2. BBCH 61-65	Whole Plant	8.1 mg/kg	0	02 Jul 2014/ -	Field SP (max days): 266
									Whole Plant	1.04 mg/kg	19	21 Jul 2014/ -	
									Whole Plant	0.88 mg/kg	42	13 Aug 2014/ -	
									Straw	0.5 mg/kg	47	18 Aug 2014/ -	
									Grain	0.72 mg/kg	47	18 Aug 2014/ -	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Cyprodinil (mg/kg)			
									Grain	0.88 mg/kg	49	20 Aug 2014/ -	
									Straw	0.58 mg/kg	49	20 Aug 2014/ -	
									Straw	0.61 mg/kg	55	27 Aug 2014/ -	
									Grain	0.83 mg/kg	55	27 Aug 2014/ -	
TK0223253-REG 14-00701-04 Hungary (Europe North) (H-3397)	Barley / Scarlett	1.06 Mar 2014 2 – 3 -	-	-	-	(-)	- (-)		Whole Plant	< 0.01 mg/kg	0	03 Jun 2014/ -	Field SP (max days): 295
									Grain	< 0.01 mg/kg	44	17 Jul 2014/ -	
									Straw	< 0.01 mg/kg	44	17 Jul 2014/ -	
	Barley / Scarlett	1.06 Mar 2014 2 – 3 -	1. Foliar 2. Foliar	-	1. 261.67 L/ha 2. 252.78 L/ha	1. 468.06595 g a.s./ha 2. 452.4673 g a.s./ha A14325E (-)	1. 06 May 2014 2. 03 Jun 2014 (N/A, 28)	1. BBCH 30 2. BBCH 65-67	Whole Plant	9.7 mg/kg	0	03 Jun 2014/ -	Field SP (max days): 295
									Whole Plant	3.18 mg/kg	20	23 Jun 2014/ -	
									Whole Plant	0.9 mg/kg	42	15 Jul 2014/ -	
									Straw	1.3 mg/kg	44	17 Jul 2014/ -	
									Grain	0.28 mg/kg	44	17 Jul 2014/ -	
									Grain	0.29 mg/kg	48	21 Jul 2014/ -	
									Straw	1.32 mg/kg	48	21 Jul 2014/ -	
									Grain	0.29 mg/kg	53	26 Jul 2014/ -	
									Straw	1.03 mg/kg	53	26 Jul 2014/ -	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.2.2 Study 2 – Report No. TK0178711

Comments of zRMS:	The study has been accepted. 4 residue trials on spring barley were conducted in NEU during 2013. Cyprodinil was applied to spring barley as A14325E. 2 applications at BBCH 24 - 31 and BBCH 61– 69 were made at 450 g ai/ha. In 2 trials samples were taken at 45 DALA-NCH. In 2 decline trials samples were taken at 0 DALA, at 9 – 10, 20-21, 30 DALA and 39-41, 44-46 DALA. For residues final determination high performance liquid chromatography coupled to a triple quadrupole mass spectrometry (LC-MS/MS) detector in multiple reaction monitoring mode was used. The obtained procedural recoveries and RSDs were within the required range. The analytical method has been shown to be acceptable for analysis of cyprodinil in cereal grain and straw.

Reference:	KCA1 6.3.2
Report	Cyprodinil- Residue Study on Barley in the United Kingdom, Germany and Northern France in 2013 Meyer M, 2015. Report No. TK0178711 XXXX File No. A14325E_10078, VV-412163
Guideline(s):	Yes Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, EU 1999: 1607/VI/97 (rev. 2). European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 rev. 4 (11 Jul 2000). European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 rev. 8.1 (16 Nov 2010). Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. The national requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 16: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) : Cyprodinil- Residue Study on Barley in the United Kingdom, Germany and Northern France in 2013			
Active Substance (common name):	Cyprodinil	**Commercial Product (name):**	
Crop/Crop Group:	Barley	**Producer of commercial product:**	XXXX
Responsible body for reporting (name, address):	XXXX	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France, Germany, United Kingdom	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A14325E: 300 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A14325E EC		
Analytical Method:	Cyprodinil (Grain, Straw, Whole Plant) REM 141.10; 0.01 mg/kg		
Recovery data:	Cyprodinil Grain Mean = 96% RSD = N/A (n = 2 in 0.01 - 2 spiking range) Cyprodinil Straw Mean = 91% RSD = N/A (n = 2 in 0.01 - 2 spiking range) Cyprodinil Whole Plant Mean = 99% RSD = N/A (n = 2 in 0.01 - 3.03 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Cyprodinil (mg/kg)			
TK0178711 13-00252-01 United Kingdom (Europe North) (OX15 6EP)	Barley / Flagon	1.19 Oct 2012 2 – 3 -	-	-	-	(-)	- (-)		Whole Plant	< 0.01 mg/kg	0	10 Jun 2013/ -	Field SP (max days): 330
									Grain	< 0.01 mg/kg	46	26 Jul 2013/ -	
									Straw	0.01 mg/kg	46	26 Jul 2013/ -	
	Barley / Flagon	1.19 Oct 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 253.33 L/ha 2. 240.67 L/ha	1. 453.2803 g a.s./ha 2. 430.6163 g a.s./ha A14325E (-)	1. 26 Apr 2013 2. 10 Jun 2013 (N/A, 45)	1. BBCH 30-31 2. BBCH 65-69	Whole Plant	8.99 mg/kg	0	10 Jun 2013/ -	Field SP (max days): 330
									Whole Plant	1.28 mg/kg	10	20 Jun 2013/ -	
									Whole Plant	0.44 mg/kg	21	01 Jul 2013/ -	
									Whole Plant	0.34 mg/kg	30	10 Jul 2013/ -	
									Whole Plant	0.33 mg/kg	39	19 Jul 2013/ -	

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analysed**	**(9) Residue found** (Uncorrected)	**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Cyprodinil (mg/kg)**			
									Grain	0.26 mg/kg	46	26 Jul 2013/ -	
									Straw	0.55 mg/kg	46	26 Jul 2013/ -	
TK0178711 13-00252-02 Germany (Europe North) (51519)	Barley / Highlight	1.28 Oct 2012 2 – 3 -	-	-	-	(-)	- (-)		Grain	< 0.01 mg/kg	45	19 Jul 2013/ -	Field SP (max days): 291
									Straw	< 0.01 mg/kg	45	19 Jul 2013/ -	
	Barley / Highlight	1.28 Oct 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 201.17 L/ha 2. 310.83 L/ha	1. 449.2556 g a.s./ha 2. 463.9303 g a.s./ha A14325E (-)	1. 15 Apr 2013 2. 04 Jun 2013 (N/A, 50)	1. BBCH 30 2. BBCH 65	Grain	0.61 mg/kg	45	19 Jul 2013/ -	Field SP (max days): 291
									Straw	1.51 mg/kg	45	19 Jul 2013/ -	
TK0178711 13-00252-03 France (Europe North) (02190)	Barley / Shandy	1.04 Mar 2013 2 – 3 -	-	-	-	(-)	- (-)		Whole Plant	< 0.01 mg/kg	0	25 Jun 2013/ -	Field SP (max days): 315
									Grain	< 0.01 mg/kg	44	08 Aug 2013/ -	
									Straw	< 0.01 mg/kg	44	08 Aug 2013/ -	
	Barley / Shandy	1.04 Mar 2013 2 – 3 -	1. Foliar 2. Foliar	-	1. 208.12 L/ha 2. 204.2 L/ha	1. 464.7789 g a.s./ha 2. 456.02102 g a.s./ha	1. 27 May 2013 2. 25 Jun 2013 (N/A, 29)	1. BBCH 30 2. BBCH 65	Whole Plant	9.75 mg/kg	0	25 Jun 2013/ -	Field SP (max days): 315
									Whole Plant	2.15 mg/kg	9	04 Jul 2013/ -	
									Whole Plant	0.79 mg/kg	20	15 Jul 2013/ -	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Cyprodinil (mg/kg)			
						A14325E (-)			Whole Plant	1.2 mg/kg	30	25 Jul 2013/ -	
									Whole Plant	0.93 mg/kg	41	05 Aug 2013/ -	
									Straw	0.96 mg/kg	44	08 Aug 2013/ -	
									Grain	0.92 mg/kg	44	08 Aug 2013/ -	
TK0178711 13-00252-04 Germany (Europe North) (49456)	Barley / KWS Thessa	1.09 Apr 2013 2 – 3 -	-	-	-	(-)	- (-)		Straw	< 0.01 mg/kg	45	08 Aug 2013/ -	Field SP (max days): 271
									Grain	< 0.01 mg/kg	45	08 Aug 2013/ -	
	Barley / KWS Thessa	1.09 Apr 2013 2 – 3 -	1. Foliar 2. Foliar	-	1. 198 L/ha 2. 203 L/ha	1. 442.2084 g a.s./ha 2. 453.3499 g a.s./ha A14325E (-)	1. 17 May 2013 2. 24 Jun 2013 (N/A, 38)	1. BBCH 24-30 2. BBCH 65-67	Straw	0.16 mg/kg	45	08 Aug 2013/ -	Field SP (max days): 271
									Grain	0.43 mg/kg	45	08 Aug 2013/ -	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies are submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new studies are submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new studies are submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.6.1 Study 1 – Report No. 37SRX09R03

Comments of zRMS:	The study has been accepted. The crop samples were analysed for residues of cyprodinil by LC-MS/MS using method REM 141.10 (see section 5 - KCP 5.1.2.5 for validation). The analytical method has been shown to be acceptable for the analysis of cyprodinil in barley grain and straw and therefore was considered suitable for the analysis of plant matrices from this study without further validation. The treated plots received to bare soil a single application of cyprodinil at a rate of 1500 g ai/ha. Then in crops planted 30 days after application, cyprodinil residues in wheat whole plant (forage), grain, straw, carrot root, carrot top and lettuce samples were below the LOQ of 0.01 mg/kg, except 2 trials (=0.01, 0.05 mg/kg). In crops planted 60 days after application, cyprodinil residues in all wheat, carrot and lettuce samples were below the LOQ. In winter wheat planted 200 days after application, residues in all wheat samples were below the LOQ. In crops planted 365 days after application, residues in all wheat, carrot and lettuce samples were below the LOQ. The obtained procedural recoveries were within the required range. The analytical method has been shown to be acceptable for this analysis. Cyprodinil residues in all control samples were below the LOQ of the method.

Reference:	KCA1 6.6.2
Report:	Cyprodinil – Residue study on rotational crops in Austria and the United Kingdom in 2009/2010 Chambers J, 2015 Report No. 37SRX09R03

	XXXX File No. A8637C_10060 (VV-696953) unpublished
Guidelines:	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990). Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; (SANCO 7029/V1/95 rev. 5 22/7/1997). Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of active Substances in Annex I of directive 91/414/EEC (Article 5.3 and 8.2), 1996. OECD Test Guideline 504: Residues in Rotational Crops (Limited Field Studies) (8 January 2007). Testing of plant protection products in rotational crops: (SANCO 7524/V1/95 rev. 2 22/7/1997).
Deviations:	~~No~~; Yes. No impact, amended because the sampling or plant-back intervals for a number of specimens on pages 31, 42 and 44 were wrongly assigned. The amended data on these pages are underlined.
GLP:	Yes
Acceptability:	Yes

EXECUTIVE SUMMARY

Two field trials were conducted during 2009, one in Austria and one in the United Kingdom. Cyprodinil was applied as A8637C, a water dispersible granule (WG) formulation containing 500 g cyprodinil per kg at a rate of 1500 g a.s./ha to bare soil drilled with ryegrass. A representative cereal (wheat), leafy vegetable (lettuce) and root vegetable (carrot) were sown into the soil at nominal rotational intervals of 30, 60, 200 (wheat only) and 365 days after application (DAT). The ryegrass was sprayed off with glyphosate approximately two weeks before sowing the rotational crops. The rotational crops were grown under field conditions and harvested at immature and mature growth stages. After harvest of the rotational crops sown 30 and 60 DAT, the plots were cleared, cultivated and re-sown with ryegrass which was then sprayed off prior to sowing the 200 and 365 DAT crops. Due to poor crop development of the wheat in the 2009 trial, a second plot was sprayed in the same way in 2010 in the UK and the wheat sowings at 30 and 60 DAT were repeated.

Commodities of representative food and feed items (immature whole wheat plants, mature wheat straw and grain; immature and mature lettuce; mature carrot tops and roots) were sampled at intervals after sowing and analysed for residues of cyprodinil with a LOQ of 0.01 mg/kg.

At the rotational interval of 30 DAT, cyprodinil residues in all samples were <0.01 mg/kg except for immature lettuce heads and mature carrot tops (0.01 mg/kg) in the Austria trial, and mature carrot roots in the UK trial (0.05 mg/kg). At rotational intervals of 60, 200 and 365 DAT, residues of cyprodinil were <0.01 mg/kg in all samples.

I. MATERIALS AND METHODS

A. MATERIALS

A1. Test Materials

Test Material	A8637C
Description	Water dispersible granule formulation containing cyprodinil

Purity	500 g/kg
Batch number	SMO6K782
Stability of test compound	The test substance is assumed to be stable for the period of use in the study

A2. Test System

Trial site	SRK09-040-37FR, Hopton, UK	SRA09-040-37FR, Rohrau, Austria
Soil	Sandy loam	Silty loam
Leafy vegetable	Lettuce (variety: Cosmic)	Lettuce (variety: Santoro)
Cereal	Spring wheat (variety Tybalt) Winter wheat (variety: Diego)	Spring wheat (variety Midas) Winter wheat (variety: Michael)
Root vegetable	Carrot (variety: Maestro F1)	Carrot (variety: VAC 43 81)

A3. Test Facilities

Field trials	Hopton, UK	Rohrau, Austria
Analytical phase	Battelle UK LTD., Battelle house, Fyfield Business and Research Park, Fyfield, road, Ongar, Essex, CM5 0GZ, UK	

B. STUDY DESIGN AND METHODS

B1. Field Phase

In 2009, plots were treated with cyprodinil formulated as a WG at a rate of 1500 g a.s./ha (actual rates were 1492-1560 g a.s./ha) applied to bare soil which had been sown with ryegrass 2-8 days before treatment. The soil was aged for 33, 63, 212 and 365 days (trial SRK09-040-37FR) or 32, 60, 216 and 383 days (trial SRA09-012-37FR) after which the soil was lightly cultivated before drilling representative crops of carrot, lettuce and spring or winter wheat. Due to poor crop development of the rotational wheat crop at trial SRK09-040-37FR, a second plot was sprayed in the same way in the following year (2010) and aged for 29 and 56 days before drilling wheat. The ryegrass was sprayed off with glyphosate approximately two weeks before the rotational crops were planted. The crops were grown outdoors in accordance with usual agricultural practice.

Test Samples

Samples of lettuce (immature and mature heads), carrot (mature roots and tops) and spring/winter wheat (immature whole plant, mature grain and straw) were taken by hand (separated using a hand thresher for wheat grain and straw) and the samples were stored deep frozen at <-18 °C before analysis. Samples were stored for up to 12 months before analysis.

B2. Analytical Phase

Samples were analysed for cyprodinil using method REM 141.10; the LOQ was 0.01 mg/kg for all commodities. A full method description and validation data are presented in Section 5.

II. RESULTS AND DISCUSSION

Method Validation

Procedural recoveries were determined for each commodity and the individual and mean procedural recoveries for these are summarised in the table below.

Table A 17: Summary of procedural recoveries for cyprodinil in following crops

Commodity	Fortification Level (mg/kg)	Cyprodinil		
		Recovery (%)	**Mean recovery (%)**	**RSD (%)**
Lettuce heads	0.01	71, 78	75	--
Carrot root	0.01	72, 72	72	--
Carrot tops	0.01	80	80	--
Wheat whole plant	0.01	76, 101, 97, 70	81	18
	0.1	69, 72		
Wheat grain	0.01	75, 73	74	2.4
	0.1	72, 76		
Wheat straw	0.01	84	80	6.8
	0.02	73, 79		
	0.1	85		

Residues in following crops

At the rotational interval of 30 (29-33) DAT, cyprodinil residues in mature lettuce heads (sampled at BBCH 49), immature whole wheat plants (sampled at BBCH 31-39), and mature wheat grain and straw (sampled at BBCH 89) were <0.01 mg/kg in both trials. Cyprodinil residues in immature lettuce heads (sampled at BBCH 45) were also <0.01 mg/kg in both trials. Cyprodinil residues in carrot (sampled at BBCH 48-49) were <0.01 mg/kg in the Austria trial and 0.05 mg/kg in the UK trial for roots, and 0.01 mg/kg in the Austria trial and <0.01 mg/kg in the UK trial for tops. At rotational intervals of 60 (56-63), 200 (212-216) and 365 (365-383) DAT, cyprodinil residues in all samples were <0.01 mg/kg.

The results of the rotational crop trials are presented in the table below. The results are not corrected for recoveries.

Table A 18: Residues of cyprodinil in rotational crops grown in soil treated with cyprodinil at 1500 g a.s/ha

Commodity	Trial SRK09-040-37FR, UK		Trial SRA09-012-37FR, Austria	
	Interval: Treatment to Sampling (days)	**Cyprodinil Residues (mg/kg)**	**Interval: Treatment to Sampling (days)**	**Cyprodinil Residues (mg/kg)**
Plant-back interval:	**29/33 days**		**32 days**	
Immature lettuce heads	101	<0.01	67	0.01*
Mature lettuce heads	113	<0.01	75	<0.01
Carrot roots	122	0.05*	127	<0.01*
Carrot tops	122	<0.01	127	0.01*
Immature wheat plants	98	<0.01	70	<0.01
Wheat grain	164	<0.01	122	<0.01
Wheat straw	164	<0.01	122	<0.01
Plant-back interval:	**56/63 days**		**60 days**	
Immature lettuce heads	140	<0.01	107	<0.01
Mature lettuce heads	157	<0.01	119	<0.01

Commodity	**Trial SRK09-040-37FR, UK**		**Trial SRA09-012-37FR, Austria**	
	Interval: Treatment to Sampling (days)	**Cyprodinil Residues (mg/kg)**	**Interval: Treatment to Sampling (days)**	**Cyprodinil Residues (mg/kg)**
Carrot roots	197	<0.01	157	<0.01
Carrot tops	197	<0.01	157	<0.01
Immature wheat plants	116	<0.01	94	<0.01
Immature wheat plants	125	<0.01	--	--
Wheat grain	181	<0.01	162	<0.01
Wheat straw	181	<0.01	162	<0.01
Plant-back interval:	**212 days**		**216 days**	
Immature wheat plants	410	<0.01	--	--
Wheat grain	487	<0.01	454	<0.01
Wheat straw	487	<0.01	454	<0.01
Plant-back interval:	**365 days**		**383 days**	
Immature lettuce heads	442	<0.01	438	<0.01
Mature lettuce heads	455	<0.01	449	<0.01
Carrot roots	491	<0.01	518	<0.01
Carrot tops	491	<0.01	518	<0.01
Immature wheat plants	434	<0.01	462	<0.01
Wheat grain	490	<0.01	526	<0.01
Wheat straw	490	<0.01	526	<0.01

* Mean of three analyses.

III. CONCLUSIONS

At the rotational interval of 30 DAT, cyprodinil residues in all samples were <0.01 mg/kg except for immature lettuce heads and mature carrot tops (0.01 mg/kg) in the Austria trial, and mature carrot roots in the UK trial (0.05 mg/kg). At rotational intervals of 60, 200 and 365 DAT, cyprodinil residues in all samples were <0.01 mg/kg.

A 2.1.6.2 Study 2 – Report No. 37SRX09R04

Comments of zRMS:	The study has been accepted as supplementary because it is SEU study. The crop samples were analysed for residues of cyprodinil by LC-MS/MS method. The analytical method (REM 141.10; see Section 5 - KCP 5.1.2.5 for validation) has been shown to be acceptable for the analysis of cyprodinil in barley grain and straw and therefore was considered suitable for the analysis of plant matrices from this study without further validation. The treated plots received to bare soil a single application of cyprodinil at a rate of 1500 g ai/ha. In crops planted 30 days after application, cyprodinil residues in wheat whole plant (forage), grain, straw, carrot root, carrot top and lettuce samples were below the LOQ of 0.01 mg/kg, except in trial SRF09-002-37FR (southern France), where cyprodinil residue levels were 0.01 mg/kg for the treated whole plant and carrot top samples and in the treated carrot root samples cyprodinil residue level was at 0.02 mg/kg. In crops planted 60 days after application, residues in wheat grain and straw samples were all below the LOQ. Residue levels in wheat whole plant (forage) and carrot top samples were 0.01 mg/kg. Residues in carrot root was 0.03 mg/kg and residues in lettuce ranged from below 0.01 mg/kg to 0.01 mg/kg. In winter wheat planted 200 days after application, residues in all wheat samples were below the LOQ. In crops planted 365 days after application, residues in all wheat, carrot and lettuce samples were below the LOQ. The obtained procedural recoveries were within the required range. The analytical method has been shown to be acceptable for this analysis. Cyprodinil residues in all control samples were below the LOQ of the method.

Reference:	KCA1 6.6.2
Report:	Cyprodinil – Residue study on rotational crops in Italy and Southern France in 2009/2010 The Report is amended Chambers J, 2015 Report No. 37SRX09R04 XXXX File No. A8637C_10059 (VV-696952) unpublished
Guidelines:	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990). Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; (SANCO 7029/V1/95 rev. 5 22/7/1997). Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of active Substances in Annex I of directive 91/414/EEC (Article 5.3 and 8.2), 1996. OECD Test Guideline 504: Residues in Rotational Crops (Limited Field Studies) (8 January 2007). Testing of plant protection products in rotational crops: (SANCO 7524/V1/95 rev. 2 22/7/1997).
Deviations:	~~No~~ Yes; The report was amended because two sampling intervals were wrongly transposed. The amended data on page 47 are underlined.
GLP:	Yes

Acceptability:	Supplementary

EXECUTIVE SUMMARY

Two field trials were conducted during 2009, one in Italy and one in southern France. Cyprodinil was applied as A8637C, a WG formulation containing 500 g cyprodinil per kg at a rate of 1500 g a.s./ha to bare soil drilled with ryegrass. A representative cereal (wheat), leafy vegetable (lettuce) and root vegetable (carrot) were sown into the soil at nominal rotational intervals of 30, 60, 200 (wheat only) and 365 days after application (DAT). The ryegrass was sprayed off with glyphosate approximately two weeks before sowing the rotational crops. The rotational crops were grown under field conditions and harvested at immature and mature growth stages. After harvest of the rotational crops sown 30 and 60 DAT, the plots were cleared, cultivated and re-sown with ryegrass which was then sprayed off prior to sowing the 200 and 365 DAT crops. Due to poor crop development in the 2009 trial, a second plot was sprayed in 2010. Wheat sowings at 30 and 60 DAT and the sowing at 60 DAT in the southern France trial were repeated.

Commodities of representative food and feed items (immature whole wheat plants, mature wheat straw and grain; immature and mature lettuce; mature carrot tops and roots) were sampled at intervals after sowing and analysed for residues of cyprodinil with a LOQ of 0.01 mg/kg.

At the rotational interval of 30 DAT, cyprodinil residues in all samples were <0.01 mg/kg except for immature lettuce heads, immature wheat whole plants, mature carrot tops (0.01 mg/kg) and mature carrot roots (0.02 mg/kg) in the southern France trial. At the rotational interval of 60 DAT, cyprodinil residues in all samples were <0.01 mg/kg except for immature lettuce heads, immature wheat whole plants, carrot tops (0.01 mg/kg) and carrot roots (0.03 mg/kg) in the southern France trial. At rotational intervals of 200 (201-204) and 365 (323-384) DAT, cyprodinil residues in all samples were <0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

A1. Test Materials

Test Material	A8637C
Description	Water dispersible granule formulation containing cyprodinil
Purity	500 g/kg
Batch number	SMO6K782
Stability of test compound	The test substance is assumed to be stable for the period of use in the study

A2. Test System

Trial site	SRI09-368-37FR, Castagnito d'Alba, Italy	SRF09-002-37FR, Nimes, France
Soil	Loamy	Silty clay
Leafy vegetable	Lettuce (varieties: Icaro and Ballerina)	Lettuce (variety: Pitice)
Cereal	Spring wheat (variety Valbona) Winter wheat (varieties: Bologna and Sirtaki)	Spring wheat (varieties Courtot and Arbon) Winter wheat (variety: Isidor)
Root vegetable	Carrot (variety: Nantese di Chioggia)	Carrot (variety: Maestro)

A3. Test Facilities

Field trials	Castagnito d'Alba, Italy	Nimes, southern France
Analytical phase	Battelle UK LTD., Battelle house, Fyfield Business and Research Park, Fyfield, road, Ongar, Essex, CM5 0GZ, UK	

B. STUDY DESIGN AND METHODS

B1. Field Phase

In 2009, plots were treated with cyprodinil formulated as a WG at a rate of 1500 g a.s./ha (actual rates were 1438-1593 g a.s./ha) applied to bare soil which had been sown with ryegrass on the day of treatment or 9 days before treatment. The soil was aged for 30, 60, 204 and 327/384 days (trial SRI09-368-37FR) or 28, 61, 201 and 323/364 days (trial SRF09-002-37FR) after which the soil was lightly cultivated before drilling representative crops of carrot, lettuce and spring or winter wheat. Due to poor crop development of the rotational wheat crop at trial SRI09-368-37FR, a second plot was sprayed in the same way in the following year (2010) and aged for 25 and 55 days before drilling wheat. Due to poor crop development of the rotational wheat and carrot crops at trial SRF09-002-37FR, a second plot was sprayed in the same way in the following year (2010) and aged for 33 and 65 days before drilling wheat and carrot. The ryegrass was sprayed off with glyphosate approximately two weeks before the rotational crops were planted. The crops were grown outdoors in accordance with usual agricultural practice.

Test Samples

Samples of lettuce (immature and mature heads), carrot (mature roots and tops) and spring/winter wheat (immature whole plant, mature grain and straw) were taken by hand (separated using a hand thresher for wheat grain and straw) and the samples were stored deep frozen at <-18 °C before analysis. Samples were stored for up to 12 months before analysis.

B2. Analytical Phase

Samples were analysed for cyprodinil using method REM 141.10; the LOQ was 0.01 mg/kg for all commodities. A full method description and validation data are presented in Section 5.

II. RESULTS AND DISCUSSION

Method Validation

Procedural recoveries were determined for each commodity and the individual and mean recoveries are summarised in the table below.

Table A 19: Summary of procedural recoveries for cyprodinil in following crops

Commodity	Fortification Level (mg/kg)	Cyprodinil		
		Recovery (%)	Mean recovery (%)	RSD (%)
Lettuce heads	0.01	81, 69	76	8.1
	0.10	77		
Carrot root	0.01	71, 75, 70	73	4.9
	0.10	70, 78		
Wheat whole plant	0.01	75, 74, 78, 80, 82, 78	77	4.9
	0.10	73, 72, 82		
Wheat grain	0.01	67, 77, 88, 87, 70	75	12
	0.10	72, 66		
Wheat straw	0.01	89, 86, 84, 90, 89	88	2.9

Residues in following crops

At the rotational interval of 30 (25-33) DAT, cyprodinil residues in mature lettuce heads (sampled at BBCH 49), and mature wheat grain and straw (sampled at BBCH 89) were <0.01 mg/kg in both trials. Cyprodinil residues in immature lettuce heads (sampled at BBCH 45-46), immature wheat whole plants (sampled at BBCH 31-55) and carrot tops (sampled at BBCH 48-49) were 0.01 mg/kg in the southern France trial and <0.01 mg/kg in the Italy trial. Cyprodinil residues in carrot roots (sampled at BBCH 48-49) were 0.02 mg/kg in the southern France trial and <0.01 mg/kg in the Italy trial.

At the rotational interval of 60 (55-65) DAT, cyprodinil residues in mature lettuce heads (sampled at BBCH 49), and mature wheat grain and straw (sampled at BBCH 89) were <0.01 mg/kg in both trials. Cyprodinil residues in immature lettuce heads (sampled at BBCH 45-46), immature wheat whole plants (sampled at BBCH 31-55) and carrot tops (sampled at BBCH 48-49) were 0.01 mg/kg in the southern France trial and <0.01 mg/kg in the Italy trial. Cyprodinil residues in carrot roots (sampled at BBCH 48-49) were 0.03 mg/kg in the southern France trial and <0.01 mg/kg in the Italy trial.

At rotational intervals of 200 (201-204) and 365 (323-384) DAT, cyprodinil residues in all samples were <0.01 mg/kg.

The results of the rotational crop trials are presented in the table below. The results are not corrected for procedural recoveries.

Table A 20: Residues of cyprodinil in rotational crops grown in soil treated with cyprodinil at 1.50 kg a.s/ha

Commodity	Trial SRI09-368-37FR, Italy		Trial SRF09-002-37FR, Southern France	
	Interval: Treatment to Sampling (days)	Cyprodinil Residues (mg/kg)	Interval: Treatment to Sampling (days)	Cyprodinil Residues (mg/kg)
Plant-back interval:	**25/30 days**		**28/33 days**	
Immature lettuce heads	78	<0.01	70	0.01*
Mature lettuce heads	85	<0.01	76	<0.01
Carrot roots	157	<0.01	145	0.02*
Carrot tops	157	<0.01	145	0.01*
Immature wheat plants	86	<0.01	117	0.01*

Commodity	Trial SRI09-368-37FR, Italy		Trial SRF09-002-37FR, Southern France	
	Interval: Treatment to Sampling (days)	**Cyprodinil Residues (mg/kg)**	**Interval: Treatment to Sampling (days)**	**Cyprodinil Residues (mg/kg)**
Immature wheat plants	86	<0.01	--	--
Wheat grain	142	<0.01	182	<0.01
Wheat straw	142	<0.01	182	<0.01
Plant-back interval:	**55/60 days**		**61/65 days**	
Immature lettuce heads	113	<0.01	130	0.01*
Mature lettuce heads	116	<0.01	141	<0.01
Carrot roots	183	<0.01	187	0.03*
Carrot tops	183	<0.01	187	0.01*
Immature wheat plants	99	<0.01	139	0.01*
Wheat grain	163	<0.01	194	<0.01
Wheat straw	163	<0.01	194	<0.01
Plant-back interval:	**204 days**		**201 days**	
Immature wheat plants	386	<0.01	357	<0.01
Wheat grain	453	<0.01	431	<0.01
Wheat straw	453	<0.01	431	<0.01
Plant-back interval:	**327/384 days**		**323/364 days**	
Immature lettuce heads	419	<0.01	406	<0.01
Mature lettuce heads	425	<0.01	418	<0.01
Carrot roots	495	<0.01	489	<0.01
Carrot tops	495	<0.01	489	<0.01
Immature wheat plants	406	<0.01	406	<0.01*
Wheat grain	462	<0.01	452	<0.01
Wheat straw	462	<0.01	452	<0.01

* Mean of three analyses.

III. CONCLUSIONS

At the rotational interval of 30 DAT, cyprodinil residues in all samples were <0.01 mg/kg except for immature lettuce heads, immature wheat whole plants, mature carrot tops (0.01 mg/kg) and mature carrot roots (0.02 mg/kg) in the southern France trial. At the rotational interval of 60 DAT, cyprodinil residues in all samples were <0.01 mg/kg except for immature lettuce heads, immature wheat whole plants, carrot tops (0.01 mg/kg) and carrot roots (0.03 mg/kg) in the southern France trial. At rotational intervals of 200 (201-204) and 365 (323-384) DAT, cyprodinil residues in all samples were <0.01 mg/kg.

A 2.1.6.3 Study 3 – Report No. IF-14/03024493

Comments of zRMS:	The study has been accepted. This study contained four field rotational trials on winter and spring rape conducted in Northern and Southern Europe. The crop samples were analysed for residues of cyprodinil by LC-MS/MS using method REM 141.10 (see Section 5 - KCP 5.1.2.5 for validation). As part of this study the method was validated on rape (seed) at the LOQ (0.01 mg/kg) and 10 x LOQ. The obtained procedural recoveries were within the required range. The analytical method has been shown to be acceptable for this analysis. Cyprodinil residues in all control samples were below the LOQ of the method. The treated plots received to bare soil 1 application of 1125 g Cyprodinil /ha at 29 - 30 days before planting (plot 2), at 59 - 62 days before planting (plot 3) and at 169 - 171 days before planting (plot 4). Rape (seed) samples taken from plot P2, plot P3 and plot P4 showed no residues of cyprodinil at or above the LOQ (0.01 mg/kg) at 30 days, 60 days or 170 days plant back interval.

Reference:	KCA1 6.6.2
Report:	Cyprodinil – Residue study on rotational crops in Germany, United Kingdom, Italy and Spain in 2014 Ziske J, Bodsch J, 2016 Report No. IF-14/03024493 XXXX File No. A9219B_12328 (VV-465458) unpublished
Guidelines:	Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, EU 1999: 1607/VI/97 (rev. 2). European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 rev. 4 (11 Jul 2000). European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010). Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OECD Test Guideline 504: Residues in Rotational Crops (Limited Field Studies). Commission of the European Communities, Rotational Studies, Guidance document on testing of plant protection products in rotational crops; 7524/VI/95 (rev.2, 1997). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. The national requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements. FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990).

Deviations:	No
GLP:	Yes
Acceptability:	Yes

EXECUTIVE SUMMARY

Four field trials were conducted during 2014, one in Germany, one in the United Kingdom, one in Italy and one in Spain. Cyprodinil was applied as A9219B, a WG formulation containing 375 g cyprodinil per kg at a rate of 1125 g a.s./ha to bare soil. Application was made 29-30, 59-62 and 169 – 171 days prior to planting oilseed rape.

Commodities of rape seed after sowing and analysed for residues of cyprodinil at NCH with a LOQ of 0.01 mg/kg.

I. MATERIALS AND METHODS

A. MATERIALS

A1. Test Materials

Test Material	A9219B
Description	Water dispersible granule formulation containing cyprodinil
Purity	375 g/kg
Batch number	SMO0L138
Stability of test compound	The test substance is assumed to be stable for the period of use in the study

A2. Test System

Trial site	14-00834-01 Vechta, Germany	14-00834-02 Banbury, UK	14-00834-03 Lombardia, Italy	14-00834-04 Andalucia, Spain
Soil	Sandy loam	Clay	Sandy loam	Clay loam
Oil seed rape	Plots C, P2 and P3 – Winter rape (variety Lorenz) Plot P4 – Spring rape (variety Campino)	Plots C, P2 and P3 – Winter rape (variety Excel) Plot P4 – Spring rape (variety Heros)	Plots C, P2 and P3 – Winter rape (variety Excalibur) Plot P4 – Spring rape (variety Marathon)	Plots C, P2 and P3 – Winter rape (variety Visby) Plot P4 – Spring rape (variety Jura)

A3. Test Facilities

Field trials	Vechta, Germany Banbury, UK Lombardia, Italy Andalucia, Spain
Analytical phase	SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, Taunusstein, Germany

B. STUDY DESIGN AND METHODS

B1. Field Phase

In 2014, plots were treated with cyprodinil formulated as a WG at a rate of 1125 g a.s./ha (actual rates were 1081-1163 g a.s./ha) applied to bare soil in a spray solution. The soil was aged for 30, 60, and 170 days after which the soil was lightly cultivated before drilling with winter or spring oil seed rape which was grown in accordance with usual agricultural practice.

Test Samples

Samples were taken by hand (pods were cut and separated either by beating in a paper bag followed by wind sifting in trial 14-00834-01, or threshed and cleaned using a thresher in trials 14-00834-02 and 14-00834-03, or using a minibatt in trial 14-00834-04) and the samples were stored deep frozen at <-18 °C before analysis. Samples were stored for up to 280 days before analysis.

B2. Analytical Phase

Samples were analysed for cyprodinil using method GRM010.02A; the LOQ was 0.01 mg/kg. A full method description and validation data are presented in Section 5.

II. RESULTS AND DISCUSSION

Method Validation

Procedural recoveries were determined for each commodity and the individual and mean recoveries are summarised in the table below.

Table A 21: Summary of procedural recoveries for cyprodinil in following crops

Commodity	Fortification Level (mg/kg)	Cyprodinil		
		Recovery (%)	Mean recovery (%)	RSD (%)
Oilseed rape	0.01	75	75	0.7
	0.10	75		
	1.1	74		

The study report also includes method validation data for GRM010.02A in oilseed rape and this is summarised in the table below.

Table A 22: Summary of method validation for cyprodinil in oil seed rape using GRM010.02A

Matrix	Fortification Level (mg/kg)	Recovery (%)	n	Mean (%)	RSD (%)	Range (%)	Recovery (%)	n	Mean (%)	RSD (%)	Range (%)
		Primary transition m/z 226 → 93					Confirmatory transition m/z 226 → 77				
Rape (seed)	0.01*	81, 79, 78, 75, 75	5	78	3.4	75 - 81	81, 79, 78, 75, 75	5	79	4.1	74 - 82
	0.10	70, 70, 72, 72, 72	5	71	1.8	70 - 72	70, 70, 72, 72, 72	5	71	1.8	69 - 72
	Overall	--	10	74	5.3	70 - 81	--	10	75	6.2	69 - 82

Residues in following crops

Treated and untreated samples of rape (seed) were taken at normal commercial harvest (NCH). All samples (seeds) were analysed. Rape (seed) samples taken from plot P2, plot P3 and plot P4 showed no residues of cyprodinil at or above the LOQ (0.01 mg/kg) at 30 days, 60 days or 170 days plant back interval. No residues of cyprodinil were found at or above the LOQ (0.01 mg/kg) in any of the untreated samples.

III. CONCLUSIONS

Cyprodinil residues in all samples were <0.01 mg/kg at all plant back intervals in all trials.

A 2.1.7 Other/Special Studies

No new studies are submitted.

A 2.2 Prothioconazole

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

No new studies are submitted.

A 2.2.1.1.2 Storage stability of residues in animal products

No new studies are submitted.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

No new studies are submitted.

A 2.2.2.1.2 Nature of residue in rotational crops

No new studies are submitted.

A 2.2.2.1.3 Nature of residues in processed commodities

No new studies are submitted.

A 2.2.2.2 Nature of residues in livestock

No new studies are submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Wheat, extrapolation to triticale, rye, spelt and durum wheat

Table A 23: Comparison of intended and critical EU GAPs - Wheat

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2014)	3	200 g a.s./ha	14 days	BBCH 29-69	35
cGAP EU (dRAR, UK/Poland, 2020)	2	187.5 g a.s./ha	14 days	BBCH 25-69	-
Intended cGAP (N-EU) (AT1-AT8, BE1-BE8, CZ1-CZ8, DE1-DE4, HU1-HU8, IE1-IE8, LU1-LU8, NL1-NL8, PL1-PL8, RO1-RO8, SK1-SK8, SI1-SI8*)	1	150 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 24: Comparison of intended and critical EU GAPs - Triticale

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2014)	3	200 g a.s./ha	14 days	BBCH 29-69	35
cGAP EU (dRAR, UK/Poland, 2020)	2	187.5 g a.s./ha	14 days	BBCH 25-69	-
Intended cGAP (N-EU) (AT29-AT30, BE29-BE30, CZ29-CZ30, DE29, IE29-IE30, LU29-LU30, NL29-NL30, PL29-PL30, PL36, SI27-SI28*)	1	150 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 25: Comparison of intended and critical EU GAPs - Rye

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2014)	3	200 g a.s./ha	14 days	BBCH 29-69	35
cGAP EU (dRAR, UK/Poland, 2020)	2	187.5 g a.s./ha	14 days	BBCH 25-69	-
Intended cGAP (N-EU) (AT25-AT26, BE25-BE26, CZ25-CZ26, DE25, IE25-IE26, LU25-LU26, NL25-NL26, PL25-PL26, PL37, PL31-PL33, SI23-SI24*)	1	150 g a.s./ha	-	BBCH 30-69	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Table A 26: Comparison of intended and critical EU GAPs - Spelt

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2014)	3	200 g a.s./ha	14 days	BBCH 29-69	35
cGAP EU (dRAR, UK/Poland, 2020)	2	187.5 g a.s./ha	14 days	BBCH 25-69	-
Intended cGAP (N-EU) (AT29-AT30, BE29-BE30, CZ29-CZ30, DE29, IE29-IE30, LU29-LU30, NL29-NL30, PL29-PL30, PL36, SI27-SI28*)	1	150 g a.s./ha	-	BBCH 30-69	-

Table A 27: Comparison of intended and critical EU GAPs – Durum wheat

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2014)	3	200 g a.s./ha	14 days	BBCH 29-69	35
cGAP EU (dRAR, UK/Poland, 2020)	2	187.5 g a.s./ha	14 days	BBCH 25-69	-
Intended cGAP (N-EU) (AT9-AT12, BE9-BE12, HU9-HU12, IE9-IE12, LU9-LU12, NL9-NL12, PL9-PL12, PL34-PL35, RO9-RO12, SK9-SK12, SI9-SI12*)	1	150 g a.s./ha	-	BBCH 30-69	-

No new studies are submitted. Acceptable residue trials are available in the dRAR (UK/Poland, 2020) and support the intended cGAP on wheat, triticale, rye, spelt and durum wheat.

A 2.2.3.2 Barley, extrapolation to oat

Table A 28: Comparison of intended and critical EU GAPs - Barley

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2014)	2	200 g a.s./ha	14 days	BBCH 30-69	35
cGAP EU (dRAR, UK/Poland, 2020)	2	150 g a.s./ha	14 days	BBCH 25-61	-

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (N-EU) (AT13-AT24, BE13-BE24, CZ13-CZ24, DE13-DE18, HU13-HU22, IE13-IE24, LU13-LU24, NL13-NL24, PL13-PL24, RO13-RO22, SK13-SK22, SI13-SI22*)	1	150 g a.s./ha	-	BBCH 30-59	-

*	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

**Table A 29:		Comparison of intended and critical EU GAPs - Oat**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP N-EU (Art. 12, EFSA, 2014)	2	200 g a.s./ha	14 days	BBCH 30-69	35
cGAP EU (dRAR, UK/Poland, 2020)	2	150 g a.s./ha	14 days	BBCH 25-61	-
Intended cGAP (N-EU) (AT27-AT28, BE27-BE28, CZ27-CZ28, DE27, HU23-24, IE27-IE28, LU27-LU28, NL27-NL28, PL27-PL28, SI25-SI26*)	1	150 g a.s./ha	-	BBCH 30-59	-

*	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

No new studies are submitted. Acceptable residue trials are available in the dRAR (UK/Poland, 2020) and support the intended cGAP on barley and oat.

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new studies are submitted.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.2.5.1 Distribution of the residue in peel/pulp

No new studies are submitted.

A 2.2.5.2 Processing studies on a core set of representative processes

No new studies are submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies are submitted.

A 2.2.7 Other/Special Studies

No new studies are submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Not calculated

A 3.2 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

CYPRODINIL (F)			
LOQs (mg/kg) range from:	0,02	to:	0,10
Toxicological reference values			
ADI (mg/kg bw/day):	0,03	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
58%	NL toddler	17,32	17%	Apples	7%	Spinaches	7%	Pears	6%	
43%	DE child	13,03	20%	Apples	3%	Table grapes	2%	Spinaches	2%	
29%	NL child	8,83	9%	Apples	3%	Spinaches	2%	Table grapes	3%	
29%	GEMS/Food G11	8,56	8%	Celeries	2%	Apples	2%	Wine grapes	2%	
24%	GEMS/Food G07	7,34	4%	Celeries	3%	Wine grapes	2%	Lettuces	1%	
23%	GEMS/Food G08	6,81	2%	Wine grapes	2%	Barley	2%	Lettuces	1%	
21%	IE adult	6,30	4%	Celeries	3%	Wine grapes	1%	Spinaches	1%	
20%	GEMS/Food G10	6,07	3%	Lettuces	2%	Wheat	2%	Celeries	1%	
20%	GEMS/Food G15	5,97	2%	Celeries	2%	Wine grapes	2%	Barley	1%	
20%	GEMS/Food G06	5,88	3%	Wheat	2%	Table grapes	2%	Tomatoes	1%	
18%	FR child 3 15 yr	5,45	3%	Apples	2%	Wheat	2%	Milk: Cattle	3%	
18%	DK child	5,44	4%	Apples	2%	Rye	2%	Carrots	1%	
18%	FR toddler 2 3 yr	5,30	5%	Apples	2%	Milk: Cattle	2%	Spinaches	3%	
17%	IT adult	5,02	4%	Lettuces	2%	Wheat	2%	Other lettuce and other salad plants	0,1%	
16%	IT toddler	4,89	3%	Lettuces	3%	Wheat	1%	Apples	0,2%	
16%	DE women 14-50 yr	4,85	4%	Apples	2%	Wine grapes	1%	Lettuces	2%	
16%	ES adult	4,82	6%	Lettuces	1%	Barley	1%	Apples	0,7%	
16%	SE general	4,80	4%	Lettuces	2%	Apples	1%	Wheat	2%	
16%	DE general	4,76	4%	Apples	2%	Wine grapes	1%	Barley	2%	
16%	ES child	4,67	4%	Lettuces	2%	Wheat	2%	Apples	2%	
15%	PT general	4,55	6%	Wine grapes	2%	Wheat	2%	Apples	0,5%	
15%	RO general	4,39	4%	Wine grapes	2%	Apples	2%	Wheat	1%	
15%	FR adult	4,37	5%	Wine grapes	2%	Other lettuce and other salad plants	1%	Apples	0,8%	
14%	NL general	4,28	2%	Apples	2%	Spinaches	1%	Wine grapes	1%	
14%	UK infant	4,13	3%	Milk: Cattle	3%	Apples	2%	Carrots	3%	
13%	FR infant	4,02	3%	Spinaches	3%	Apples	2%	Carrots	1%	
13%	UK toddler	3,88	3%	Apples	2%	Wheat	1%	Milk: Cattle	2%	
12%	FI 3 yr	3,48	2%	Apples	1%	Oat	1%	Carrots	0,6%	
10%	UK vegetarian	2,87	2%	Wine grapes	1%	Lettuces	1,0%	Celeries	0,5%	
9%	DK adult	2,76	2%	Wine grapes	2%	Apples	0,9%	Lettuces	0,6%	
9%	FI 6 yr	2,69	0,9%	Strawberries	0,9%	Apples	0,9%	Carrots	0,5%	
8%	FI adult	2,55	2%	Coffee beans	1%	Lettuces	0,9%	Apples	2%	
8%	UK adult	2,37	2%	Wine grapes	1%	Lettuces	0,7%	Wheat	0,5%	
8%	PL general	2,34	3%	Apples	0,7%	Table grapes	0,5%	Tomatoes	0,3%	
7%	LT adult	2,19	3%	Apples	0,7%	Lettuces	0,5%	Rye	0,6%	
3%	IE child	0,79	0,5%	Apples	0,5%	Wheat	0,3%	Carrots	0,4%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of CYPRODINIL (F) is unlikely to present a public health concern.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole

LOQs (mg/kg) range from:	0,01	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
14%	NL toddler	1,38	3%	Milk: Cattle	2%	Wheat	1%	Maize/corn	4%	
10%	GEMS/Food G11	1,01	4%	Soyabeans	1%	Wheat	0,6%	Carrots	2%	
9%	GEMS/Food G10	0,89	3%	Soyabeans	2%	Wheat	0,4%	Barley	1%	
8%	GEMS/Food G08	0,85	2%	Soyabeans	2%	Wheat	0,6%	Barley	1%	
8%	GEMS/Food G07	0,84	2%	Soyabeans	2%	Wheat	0,4%	Rapeseeds/canola seeds	1%	
8%	GEMS/Food G15	0,83	2%	Wheat	2%	Soyabeans	0,5%	Barley	1%	
8%	GEMS/Food G06	0,80	3%	Wheat	1%	Soyabeans	0,4%	Tomatoes	2%	
8%	NL child	0,79	2%	Wheat	1%	Milk: Cattle	0,8%	Sugar beet roots	3%	
8%	DE child	0,79	2%	Wheat	1%	Apples	1,0%	Milk: Cattle	3%	
7%	FR child 3 15 yr	0,74	2%	Wheat	1%	Milk: Cattle	0,6%	Swine: Other products	2%	
7%	UK infant	0,73	2%	Milk: Cattle	1%	Carrots	1%	Wheat	0,9%	
7%	DK child	0,67	2%	Wheat	1%	Rye	1%	Carrots	0,8%	
6%	FR toddler 2 3 yr	0,64	1%	Milk: Cattle	1%	Wheat	0,6%	Carrots	2%	
6%	IE adult	0,61	0,9%	Wheat	0,5%	Sheep: Edible offals (other than liver and ki	0,4%	Sweet potatoes	2%	
5%	UK toddler	0,55	2%	Wheat	1%	Milk: Cattle	0,4%	Carrots	1%	
5%	RO general	0,54	2%	Wheat	0,6%	Milk: Cattle	0,4%	Potatoes	1,0%	
5%	SE general	0,51	1%	Wheat	0,7%	Carrots	0,6%	Milk: Cattle	1,0%	
5%	ES child	0,51	2%	Wheat	0,6%	Milk: Cattle	0,3%	Cocoa beans	1%	
4%	DE general	0,45	0,8%	Wheat	0,6%	Milk: Cattle	0,4%	Sugar beet roots	2%	
4%	DE women 14-50 yr	0,44	0,9%	Wheat	0,6%	Milk: Cattle	0,5%	Sugar beet roots	2%	
4%	PT general	0,42	2%	Wheat	0,5%	Potatoes	0,5%	Potatoes	0,9%	
4%	FI adult	0,42	3%	Coffee beans	0,3%	Carrots	0,1%	Rye	3%	
4%	NL general	0,41	0,8%	Wheat	0,4%	Milk: Cattle	0,3%	Sugar beet roots	1%	
4%	IT toddler	0,39	3%	Wheat	0,2%	Other cereals	0,1%	Carrots	0,8%	
4%	FI 3 yr	0,37	0,7%	Carrots	0,6%	Oat	0,5%	Wheat	0,9%	
4%	FR adult	0,36	0,9%	Wheat	0,3%	Swine: Other products	0,2%	Wine grapes	1%	
3%	FR infant	0,34	0,9%	Carrots	0,8%	Milk: Cattle	0,3%	Wheat	0,6%	
3%	ES adult	0,32	0,9%	Wheat	0,3%	Barley	0,2%	Milk: Cattle	0,9%	
3%	FI 6 yr	0,28	0,5%	Carrots	0,4%	Wheat	0,4%	Potatoes	0,7%	
3%	IT adult	0,26	2%	Wheat	0,1%	Tomatoes	0,1%	Carrots	0,7%	
2%	UK vegetarian	0,24	0,8%	Wheat	0,2%	Carrots	0,2%	Milk: Cattle	0,6%	
2%	LT adult	0,22	0,4%	Wheat	0,3%	Potatoes	0,2%	Rye	0,4%	
2%	DK adult	0,22	0,4%	Wheat	0,4%	Carrots	0,3%	Milk: Cattle	0,5%	
2%	UK adult	0,21	0,7%	Wheat	0,1%	Milk: Cattle	0,1%	Carrots	0,5%	
2%	PL general	0,15	0,3%	Potatoes	0,2%	Carrots	0,2%	Apples	0,5%	
1%	IE child	0,11	0,5%	Wheat	0,2%	Milk: Cattle	0,1%	Carrots	0,1%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prothioconazole is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.3 IESTI calculations - Raw commodities

Cyprodinil

Not required, no ArfD necessary.

Prothioconazole

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Unic

The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
36%	Bovine: Edible offals (other	0,5 / 0,5	3,6	17%	Bovine: Edible offals (other	0,5 / 0,5	1,7
19%	Bovine: Liver	0,5 / 0,23	1,9	16%	Swine: Other products	0,5 / 0,5	1,6
15%	Swine: Edible offals (other	0,5 / 0,5	1,5	13%	Swine: Edible offals (other	0,5 / 0,5	1,3
6%	Milk: Cattle	0,01 / 0,01	0,62	10%	Bovine: Other products	0,5 / 0,5	1,00
6%	Wheat	0,1 / 0,04	0,58	9%	Bovine: Liver	0,5 / 0,23	0,92
6%	Bovine: Kidney	0,5 / 0,15	0,56	6%	Sheep: Liver	0,5 / 0,23	0,64
4%	Barley	0,2 / 0,07	0,39	3%	Sheep: Edible offals (other	0,5 / 0,5	0,34
3%	Swine: Liver	0,5 / 0,23	0,28	3%	Barley	0,2 / 0,07	0,34
2%	Swine: Kidney	0,5 / 0,15	0,19	3%	Wheat	0,1 / 0,04	0,34
2%	Honey and other apiculture	0,05 / 0,05	0,18	3%	Poultry: Liver	0,1 / 0,07	0,33
1%	Maize/corn	0,1 / 0,02	0,13	3%	Swine: Kidney	0,5 / 0,15	0,33
1%	Rye	0,05 / 0,02	0,13	3%	Swine: Liver	0,5 / 0,23	0,32
1%	Rice	0,01 / 0,01	0,13	3%	Bovine: Kidney	0,5 / 0,15	0,32
1%	Eggs: Chicken	0,01 / 0,01	0,12	2%	Milk: Cattle	0,01 / 0,01	0,19
1%	Swine: Muscle/meat	0,01 / 0,01	0,12	1,0%	Rye	0,05 / 0,02	0,10
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

IESTI new **Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new** **Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
40%	Bovine: Liver	0,5 / 0,5	4,0	20%	Bovine: Liver	0,5 / 0,5	2,0
36%	Bovine: Edible offals (other	0,5 / 0,5	3,6	19%	Barley	0,2 / 0,4	1,9
29%	Wheat	0,1 / 0,2	2,9	17%	Wheat	0,1 / 0,2	1,7
22%	Barley	0,2 / 0,4	2,2	17%	Bovine: Edible offals (other than liver	0,5 / 0,5	1,7
19%	Bovine: Kidney	0,5 / 0,5	1,9	16%	Swine: Other products	0,5 / 0,5	1,6
15%	Swine: Edible offals (other	0,5 / 0,5	1,5	14%	Sheep: Liver	0,5 / 0,5	1,4
13%	Maize/corn	0,1 / 0,2	1,3	13%	Swine: Edible offals (other than liver	0,5 / 0,5	1,3
12%	Milk: Cattle	0,01 / 0,01	1,2	11%	Swine: Kidney	0,5 / 0,5	1,1
6%	Swine: Kidney	0,5 / 0,5	0,63	11%	Bovine: Kidney	0,5 / 0,5	1,1
6%	Rye	0,05 / 0,1	0,63	10%	Bovine: Other products	0,5 / 0,5	1,00
6%	Swine: Liver	0,5 / 0,5	0,61	7%	Swine: Liver	0,5 / 0,5	0,71
2%	Milk: Goat	0,01 / 0,01	0,24	5%	Rye	0,05 / 0,1	0,49
2%	Honey and other apiculture	0,05 / 0,05	0,18	5%	Poultry: Liver	0,1 / 0,1	0,47
2%	Poultry: Muscle/meat	0,01 / 0,01	0,17	4%	Maize/corn	0,1 / 0,2	0,43
1%	Other farmed animals:	0,01 / 0,02	0,14	4%	Milk: Cattle	0,01 / 0,01	0,39
Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)							

A 3.4 IESTI calculations - Processed commodities

Cyprodinil

No required, no ArfD necessary.

Prothioconazole

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Wheat / milling (flour)	0,1 / 0,04	0,48
5%	Maize / oil	0,1 / 0,5	0,47
3%	Barley / cooked	0,2 / 0,07	0,25
2%	Wheat / milling (wholemeal)-l	0,1 / 0,04	0,22
1%	Barley / milling (flour)	0,2 / 0,07	0,13
0,7%	Rye / boiled	0,05 / 0,02	0,07
0,7%	Oat / boiled	0,05 / 0,02	0,07
0,7%	Rye / milling (wholemeal)-	0,05 / 0,02	0,07
0,6%	Rice / milling (polishing)	0,01 / 0	0,06
0,6%	Oat / milling (flakes)	0,05 / 0,02	0,06
0,5%	Millet / boiled	0,01 / 0	0,05
0,5%	Buckwheat / bulgur and grits	0,01 / 0,01	0,05
0,4%	Maize / processed (not speci	0,1 / 0,02	0,04
0,4%	Buckwheat / boiled	0,01 / 0,01	0,04
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Barley / beer	0,2 / 0,01	0,50
3%	Maize / oil	0,1 / 0,5	0,25
2%	Wheat / bread/pizza	0,1 / 0,04	0,18
2%	Wheat / pasta	0,1 / 0,04	0,15
1%	Wheat / bread (wholemeal)	0,1 / 0,04	0,14
0,4%	Rice / milling (polishing)	0,01 / 0	0,04
0,3%	Oat / boiled	0,05 / 0,02	0,03
0,2%	Millet / boiled	0,01 / 0	0,02
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
47%	Maize / oil	0,1 / 5	4,7
24%	Wheat / milling (flour)	0,1 / 0,2	2,4
15%	Barley / cooked	0,2 / 0,4	1,5
11%	Wheat / milling (wholemeal)-	0,1 / 0,2	1,1
7%	Barley / milling (flour)	0,2 / 0,4	0,72
4%	Maize / processed (not	0,1 / 0,2	0,43
4%	Rye / boiled	0,05 / 0,1	0,36
4%	Oat / boiled	0,05 / 0,1	0,36
4%	Rye / milling (wholemeal)-	0,05 / 0,1	0,35
3%	Oat / milling (flakes)	0,05 / 0,1	0,30
0,6%	Rice / milling (polishing)	0,01 / 0	0,06
0,5%	Millet / boiled	0,01 / 0	0,05
0,5%	Buckwheat / bulgur and	0,01 / 0,01	0,05
0,4%	Buckwheat / boiled	0,01 / 0,01	0,04
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Barley / beer	0,2 / 0,08	2,9
25%	Maize / oil	0,1 / 5	2,5
9%	Wheat / bread/pizza	0,1 / 0,2	0,88
8%	Wheat / pasta	0,1 / 0,2	0,76
7%	Wheat / bread (wholemeal)	0,1 / 0,2	0,70
2%	Oat / boiled	0,05 / 0,1	0,15
0,4%	Rice / milling (polishing)	0,01 / 0	0,04
0,2%	Millet / boiled	0,01 / 0	0,02
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Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Prothioconazole is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

No additional information included.