REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SAP2101F

Product name(s): ZELORA START

Chemical active substances:

Prothioconazole, 120 g/L
Folpet, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Selectis Produtos para a Agricultura, S.A.

Submission date: December 2023

Updated: April 2024, May 2024

MS Finalisation date: June 2024 (initial Core Assessment)

August 2024 (final Core Assessment)

October 2024 (updated final Core Assessment)

Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Produtos para a Agricultura, S.A. for submission to Poland in the frame of new PPP registration (Acording Art. 33 of Regulation EC No 1107/2009).
April 2024	V1 - Updated version submitted by the Selectis Produtos para a Agricultura, S.A. answering Poland request in the frame of new PPP registration (Acording Art. 33 of Regulation EC No 1107/2009).
May 2024	Updated version based on folpet data provided by the Selectis Produtos para a Agricultura, S.A. answering Poland comments in the frame of SAP50SCF/Folpec registration.
June 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed from the parts updated by the Applicant, and all the text fragments struck through by the applicant as the result of the updates have been removed completely from the document, for better legibility.
August 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.
October 2024	Final Report updated after LoA submission Additional information included by the zRMS in the report are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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7.1 Summary and zRMS Conclusion

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 SAP2101F are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU zone for wheat and barley. A list of all intended uses within the CEU zone is given in Part B, Section 0.

Overall conclusion
The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg for wheat and 0.2 mg/kg for barley for prothioconazole and 0.4 mg/kg for wheat and 2 mg/kg for barley for folpet as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of prothioconazole and folpet residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, ~~the Czech Republic~~ Poland as zRMS agrees with the authorization of the intended uses.

According to available data, no specific mitigation measures should apply.

Data gaps:
~~The applicant should submit a letter of access to the metabolism study for folpet on poultry.~~
None

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as (g/l)**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL[1] min max**	**water L/ha min max**	**kg as/ha[1] min max**		
1	Wheat	CEU (PL)	SAP2101F	F	*Septoria*	SC	120+300[1]	Tractor mounted spray	BBCH 32-61	2	14 days	30+75 – 120+300	150-400	120+300 – 180+450	42	A
2	Barley	CEU (PL)	SAP2101F	F	*Helmintosporium*	SC	120+300[1]	Tractor mounted spray	BBCH 32 30-61	2	14 days	30+75 – 120+300	150-400	120+300 – 180+450	42	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** 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

[1] Prothioconazole + Folpet

Explanation for Column 11 “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

7.1.2 Summary of the evaluation

The preparation SAP2101F is composed of prothioconazole and folpet.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prothioconazole					
ADI	EFSA	2007	0.05 mg/kg bw per d	Rat, 2-year study; dog, 1-year study	100
ARfD	EFSA	2007	0.2 mg/kg bw	Rat, developmental study	100
Prothioconazole-desthio					
ADI	EFSA	2007	0.01 mg/kg bw per d	Rat, carcinogenicity study	100
ARfD	EFSA	2007	0.01 mg/kg bw	Rat, developmental study	100
1,2,4-triazole					
ADI	EC	2021	0.023 mg/kg bw per d	Newly submitted rat 12-month study	300
ARfD	EC	2021	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine					
ADI	EC	2021	0.3 mg/kg bw per d	Rabbit developmental study	100
ARfD	EC	2021	0.3 mg/kg bw	Rabbit developmental study	100
Triazole acetic acid					
ADI	EC	2021	1 mg/kg bw per d	Rat 2-generation and rabbit developmental studies	100
ARfD	EC	2021	1 mg/kg bw	Rat 2-generation and rabbit developmental studies	100
Triazole lactic acid					
ADI	EC	2021	0.3 mg/kg bw per d	Bridging from TA	-
ARfD	EC	2021	0.3 mg/kg bw	Bridging from TA	-
Folpet – Parent compound					
ADI	Dir 07/05	2009	0.1 mg/kg bw/days	1 year dog study supported by the 2 year rat study	100
ARfD	Dir 07/05	2009	0.2 mg/kg bw/day	Teratogenicity study in rabbits	100

7.1.2.1 Summary for Prothioconazole

Table 7.1-3: 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?
1	Wheat	Yes	Yes (13 ~~14~~)	Yes	Yes	Yes	No	No
2	Barley	Yes	Yes (13~~–14~~)	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

For wheat and barley grain, 13 and ~~14~~ 13 trials are available, assessing Prothioconazole residue level in grain; for straw, 1~~4~~5 and 1~~2~~2 trials are available. Regarding TDMs 9 and 8 trials are available in wheat and barley respectively;

Enough data to cover the processing of wheat and barley grain has been provided and is considered enough to cover the proposed uses.
As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.
Regarding TDMs, processing studies on wheat and barley grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).

Considering dietary burden, metabolism data and livestock feeding studies, the requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRL to be exceeded.
Regarding TDMs arising from prothioconazole uses, as concluded by the UK, "further consideration is not required due to the fact that none of the TDMs were identified" in the available livestock metabolism studies conducted with prothioconazole.

Regarding succeeding crops, enough unprotected data is available to cover this point. It is very unlikely that residues will be present in succeeding crops.
Regarding TDMs, in the framework of the confirmatory data, a number of field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SAP2101F. Therefore, other special studies are not needed. Specifically, residues in honey should not be required until the renewal of the active substance take place.

The proposed uses of Prothioconazole in the formulation SAP2101F do not represent unacceptable acute and chronic risks for the consumer. As far as TDMs are concerned, although EFSA considered that for all triazole substances the Consumer Risk Assessment was inconclusive with the data reviewed in the frame of EFSA TDMs peer review in 2018, a "worst-case" assessment was performed for the group of triazole active substances by RMS UK, that concluded that "the outcome of the consumer intake assessment raises no concerns". Additional assessments conducted by the applicant with available data of TDMs also reaches the same conclusion, acceptable chronic and acute risk considering triazole derivative metabolites.

7.1.2.2 Summary for Folpet

Table 7.1-4 Summary for folpet

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?
1	Wheat	Yes	Yes (8)	Yes	Yes	Yes	No	No
2	Barley	Yes	Yes (8)	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

New information regarding the nature of the residue in plants and animals has not been provided. Available information from the DAR and RAR has been considered enough to support the proposed use in cereals.

New residue studies are provided for wheat and barley according with the proposed use. Residues of folpet and phthalimide are quantified in all samples. Data package provided is considered to be enough to cover the proposed use in cereals.

Nature of the residues in rotational crops does not need to be investigated due to its low persistence in soil (<100 days). Residue data in succeeding crops are not required.

One study already assessed in RAR – that has also been summarized here for the sake of completeness – addresses the nature of residues in processed commodities. Processing studies in wheat are not required since the residues are in all trials below 0.1 mg/kg and its impact in diet is below 10% of ADI and ARfD. Regarding barley, new processing studies have been submitted.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Regarding other studies, residues in honey should not be required until the renewal of the active substance take place. Indeed, AIR peer review under new data requirements is still ongoing at the time of this submission. Therefore, currently the old data requirements still apply and residues in honey do not need to be addressed at this stage.

Consumer risk assessment has been assessed, with no chronic risk as well as no acute risk to be expected. TDMI accounts for 59% of ADI and IESTI ranges from 3% of ARfD in wheat to 6% of ARfD in barley.

7.1.2.3 Summary for SAP2101F

Table 7.1-5: Information on SAP2101F (KCA 6.8)

Crop	PHI for SAP2101F proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SAP2101F proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole	Folpet		
Wheat	42 days	Yes	Yes	42 days	-
Barley	42 days	Yes	Yes	42 days	-

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).

Assessment

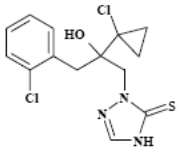
This section has been built considering that the active substance information included in the DAR that was assessed during the first inclusion process is out of data protection in accordance with the Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009.
Moreover, also the information submitted as confirmatory data for the pesticide risk assessment for the triazole derivative metabolites can be considered as data out of protection rights according with the Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009.

7.2 Prothioconazole

General data on prothioconazole are summarized in the table below (last updated 2022/02/22).

Table 7.2-1: 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

Chemical structure	
Molecular formula	C_{14} H_{15} Cl_2 N_3 O S
Molar mass	344.26 g/mol
Chemical group	Group of triazole compounds
Mode of action (if available)	It's mode of action consists of a steroid demethylation in the ergosterol biosynthesis pathway.
Systemic	Yes
Company (ies)	Bayer CropScience*
Rapporteur Member State (RMS)	Poland (The original RMS was UK)
Approval status	Approved Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 2008/44/EC - REGULATION (EU) No 540/2011) Commission Implementing Regulation (EU) 2020/869 Commission Implementing Regulation (EU) 2021/745 Commission Implementing Regulation (EU) 2022/708 Commission Implementing Regulation (EU) 2023/918
Restriction	Restricted to fungicide only.
Review Report	SANCO/3923/07 – final 26/01/2021 (EC, 2021)
Current MRL regulation	Regulation (EU) No ~~2019/552~~ 2024/1318
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA, 2014)
EFSA Journal: Conclusion on the peer review	Yes (Prothioconazole: EFSA, 2007; TDMs (confirmatory data): EFSA, 2018)
EFSA Journal: conclusion on article 12	Yes
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.
Existing data is summarized in table 7.2-2.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration (months)	Reference
Data relied on in EU			
Plant products			
Residue definition: Prothioconazole-desthio			
Wheat green matter	High water content	18 months	EFSA, 2007; United Kingdom, 2004, 2007
Wheat grain	High starch content	18 months	
Wheat straw	No specific category	18 months	

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration (months)				Reference
Residue definition: TDMs (1,2,4-T; TA; TAA; TLA)		1,2,4-T	TA	TAA	TLA	
Apples, tomatoes, mustardleaves, wheat forage,radishes tops/roots, turnipsroots, sugar beet roots,cabbages, lettuces	High water content	6	53	53	48*	EFSA, 2018
Barley, wheat grain	High starch content	12	26	26	48	
Rapeseeds, soya beans	High oil content	12***	26***	53	48	
Peas, dry; Navy beans	High protein content	-	15	25	48	
Oranges	High acid content	-	-	-	48	
Barley, wheat straw	~~Cereal straw~~ No specific category	12	53	40	-**	
Animal products						
Residue definition: Prothioconazole desthio, M14 and M15						
Ruminant	Muscle	1 month				EFSA, 2007b; United Kingdom, 2004, 2007
	Fat	1 month				
	Liver	1 month				
	Kidney	1 month				
Residue definition: TDMs (1,2,4-T; TA; TAA; TLA)		1,2,4-T	TA	TAA	TLA	
Animal product	Milk	18	-	-	-	EFSA, 2018
	Eggs	12	-	-	-	
	Liver	12	-	-	-	
	Muscle	12	-	-	-	
	Fat	12	-	-	-	

*lettuce only
**stability covered by acceptable storage stabilities in 5 different matrices (48 months covered).
***soybean only; not stable in rapeseed.

Conclusion on stability of residues during storage

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, 2007; United Kingdom, 2004, 2007). Since this is active substance data and is currently out of data protection rights, it can be used to support the proposed uses in cereals for SAP2101F.

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, during the Review of the existing MRLs for prothioconazole EFSA concluded that storage stability was demonstrated for prothioconazole and prothioconazole-desthio only, while further metabolites are included in the residue definition for risk assessment. According to them, 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 (EFSA, 2014). Until the renewal of the active substance takes, data approved for the DAR can be considered suitable and sufficient in order to support the uses submitted in this dossier. Therefore, since no information on the hydroxymetabolites is provided in this dossier, this data gap raised by EFSA is considered as not relevant for this application.

Regarding animal matrices, the storage stability of prothioconazole-desthio, M14 and M15 was demonstrated in the framework of the feeding study with lactating cows, which was already submitted in the DAR (United Kingdom, 2004) and further reviewed in its addenda (United Kingdom, 2007). The

storage stability was assured in all matrices for up to 1 month (EFSA, 2014).

For TDMs unprotected data is available in the Peer Review of the pesticide risk assessment of the triazole derivative metabolites (EFSA, 2018). This data was submitted in the framework of confirmatory data requirements that were identified during the inclusion process of prothioconazole (as well as in other azole active substances) and, therefore, according to Regulation (EU) 1107/2009 the data provided as confirmatory data can be considered unprotected.
The available data demonstrates stability from 12 months (1,2,4-T), 26 months (TA and TAA) and 48 months (TLA) for cereal grain and 12 months (1,2,4-T), 53 months (TA), 40 months (TAA) and 48 months (TLA). The stability of TLA in straw is demonstrated based in the stabilities in five different matrices.
For animals, existing data demonstrates the stability of metabolite 1,2,4-T for 12 months for eggs, liver, muscle and fat and 18 months for milk.

No further data is required to cover the proposed uses.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
Studies on the storage stability of prothioconazole and its metabolites in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.
Residues of prothioconazole-desthio are stable for 18 months under deep-freeze storage in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw.

EFSA in EFSA Journal 2014;12(5):3689 concluded that
(…)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.***
As the proposed residue definitions for enforcement and risk assessment are different (see also Section 3.1.1.1), conversion factors (CF) for enforcement to risk assessment of 2 in cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 in cereal straw were derived on the basis of the available metabolism data on wheat, peanut and sugar beet (roots, tops) (EFSA, 2007b, 2009, 2010a, 2010b, 2012; United Kingdom, 2007).

Sufficient stability data are available to support the residue data presented in this dossier.

In EFSA Journal 2014;12(5):3689 it is stated that *in the framework of the reported feeding study, the* ***storage stability of prothioconazole-desthio, M14 and M15*** *was demonstrated in all matrices for* ***up to 1 month*** *when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.*

<u>TDMs</u>
Data gaps related to the uses of prothioconazole that were identified during the peer review of TDMs (EFSA, 2018) are reported below:
"Storage stability data on 1,2,4-T, TA and TAA in high acid content commodities, on 1,2,4-T in high protein content commodities and on TLA in cereal straw and covering the maximum storage time interval of the residue samples of the residue trials in primary and rotational crops."

It should be noted that storage stability has been studied for 4 TDMs in the matrices of wheat and barley grain and for wheat and barley straw, in this last case except for TLA. However, as TLA has been studied in high water, high starch, high acid, high oil and high protein matrices and has proved to be stable up to 48 months, it can be concluded according to OECD guidelines 506 "Stability of Pesticide Residues in Stored Commodities" that TLA is stable in all matrices up to 48 months. In conclusion, the stability is guaranteed for the matrices of relevance in the current dossier.

Regarding stability of TDMs in commodities of animal origin, all samples were analysed within 30 days in the feeding studies (except in two kidney samples: TA for 40 days and TAA for 44 days). Therefore, no further information is required.

Sufficient stability data on storage stability of TDMs are available to support the residue data presented in this dossier.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
No available data at EU level.

Relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch contains at least one freshly fortified sample for concurrent recovery determination. The extracts from fortified and study samples are handled and stored in parallel. If the recoveries in the fortified samples are within the acceptable range of 70%-110%, the stability of the sample extracts is considered as sufficiently proven.

Conclusion on stability of residues in sample extracts
No specific study on the stability of residues in sample extracts was given but, in all studies, recovery experiments were performed concurrently with the analysed samples. The recovery rates for the studies presented in this file were in the 70-110% range for all analytes. Therefore, residues of prothioconazole can be considered stable in the sample extracts.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
No further data are required.

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.

For the inclusion of the active substance, prothioconazole was investigated for foliar application on pulses and oilseeds (peanut) and cereals (wheat) using [U-^{14}C-phenyl]-labelled prothioconazole. The metabolism of prothioconazole-desthio was also investigated for foliar application on cereals (wheat) using [3,5-^{14}C-triazole]-labelled prothioconazole-desthio (United Kingdom, 2004, 2007). Additional studies investigating the metabolism of prothioconazole in root and tuber vegetables (sugar beet), pulses and oilseeds (peanut) and cereals (wheat) using [U-^{14}C-phenyl]-labelled prothioconazole are reported in the literature (EFSA, 2007, 2009). Finally, three additional metabolism studies were conducted on root and tuber vegetables (sugar beet), pulses and oilseeds (peanut) and cereals (wheat) by foliar application using [3,5-^{14}C-triazole]-labelled prothioconazole (FAO, 2008a, 2008b).

From all these studies, only those on cereals are relevant for this submission. Moreover, the studies included in the DAR are considered enough to cover the proposed uses. The characteristics of these studies are summarised in Table 7.2-3 below.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details				Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No (interval in days)	Sampling (DAT)	
Cereals	Wheat	[U-^{14}C-phenyl] prothioconazole	foliar treatment, G (b)	0.22	2 (BBCH 32-65)	Forage: 6 Hay: 26 Grain & straw: 48	EFSA, 2007; United Kingdom, 2004, 2007
		[3,5-^{14}C-triazole] prothioconazole-desthio	foliar treatment, G (summer wheat) (b)	0.25	2 (27 days) (BBCH 31-59)	Forage: 0, 14 Grain & Straw: 48	EFSA, 2007; United Kingdom, 2004, 2007
		[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	EFSA, 2007; United Kingdom, 2004, 2007

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) The plants were frown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated.
(c): 1 day after application, the soil tub was moved to the outside of the greenhouse.

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 the 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 hydroxilation on the chlorphenyl 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 (EFSA, 2014).

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 (EFSA, 2014).

Summary of plant metabolism studies reported in the EU

The residue definition for enforcement, proposed as prothioconazole-desthio in the conclusion of the peer review (EFSA, 2007), was confirmed by the Article 12 MRL review (EFSA, 2014). However, EFSA proposed that this residue definition refers to the 'sum of isomers', since no enantiospecific analytical methods are available (EFSA, 2014). The current residue definition set in Regulation (EC) No 396/2005 is similar and refers to prothioconazole-desthio (sum of isomers).

The residue for risk assessment was defined as the '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)', assuming that all metabolites have a toxicological profile similar to prothioconazole-desthio (EFSA, 2007). EFSA highlighted that the above residue definitions do not take into consideration the triazole derivative metabolites (TDMs), which are present in the crops from the use of prothioconazole and which are common metabolites of other triazole fungicides. Recently, the definitions of the residue of all triazole active substances were revised to include the triazole derved metabolites (TDMs) in the definition of the residue for risk assessment (EC, 2021), including also prothioconazole. This was after the Conclusion on TDMs was published by EFSA in 2018. Metabolism data on plants performed specifically with TDMs is not required and available data made with prothioconazole should cover this point from the TDMs perspective.

Summary of new plant metabolism studies
No new studies are submitted by the applicant.

Conclusion on metabolism in primary crops
Enough unprotected data has been provided to support the proposed uses in cereals.
The definition of the residue for risk assessment has recently been revised to include the TDMs.
Moreover, a "worst-case" consumer dietary intake assessment for the complete group of triazole active substances was conducted by EFSA (EFSA, 2018). The conclusion was that no chronic or acute intake concerns were identified (EFSA, 2018). The RMS concluded that "the outcome of the consumer intake assessment raises no concerns". UK also stated that the confirmatory data requirements were satisfactorily addressed and, pending the outcome of some data gaps, that the approval of several substances including prothioconazole may continue. Therefore, this lack of data, until the re-approval of the prothioconazole based products takes place, does not raise any risk concern to consumers.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.

In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007).
Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.
In EFSA Journal 2018;16(7):5376 it is stated that *Primary crops metabolism data are reported for a total of 16 approved triazole compounds, and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops.(…) Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*

<u>The residue definitions</u>
Taking into account conclusions EFSA regarding residue definitions presented in EFSA Journal 2020;18(2):5999, EFSA Journal 2014;12(5):3689 and EFSA Journal 2018;16(7):5376, based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as '**prothioconazole-desthio (sum of isomers)**' for **enforcement** and, as follows, for **the risk assessment**:
1) 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)
2) Triazole alanine (TA) and triazole lactic acid (TLA)
3) Triazole acetic acid (TAA)
4) 1,2,4-triazole (1,2,4-T).

These residue definitions are applicable to primary crops, rotational crops and processed products and for both foliar and seed treatments.
Since all compounds included in the residue definitions are a mixture of enantiomers and since there are no enantiospecific analytical methods, the residue definitions are expressed as "sum of isomers".
Although the residue definition for risk assessment includes consideration of all metabolites containing a common moiety, it is not possible to develop a common moiety method to meet the residue definition for risk assessment. For this reason, all the analytes have to be determined separately. 6 analytes, representing the major portion of the TRR (Total Radioactive Residue) for prothioconazole in the plant metabolism studies, should be determined in residue trials. These are: prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazoledesthio and alpha-hydroxy-prothioconazole-desthio (including all their acid-hydrolysable conjugates).

No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} field values of prothioconazole and prothioconazole-desthio range between 4.4 – 9.3 days (median: 5.5 days) and 54 – 240 days (median: 140 days), respectively. The DT_{90} field value of prothioconazole-desthio is therefore higher than the trigger value of 100 days (EFSA, 2007b). Further investigation of the nature of the residues in rotational crops is included below.

Available data

No new data submitted in the framework of this application.

A confined rotational crop study investigating the nature of residues following different plant-back intervals is available from the DAR (United Kingdom, 2004, 2007). This study is out of data protection rights and can be used to support the requested uses on cereals for product SAP2101F. The characteristics of this study are summarised in Table 7.2-4 below.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Swiss chard	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	80, 188, 348	-	United Kingdom, 2004, 2007
Root and tuber vegetables	Turnip	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	Root tops: 94, 201, 349	-	
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		

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

Summary of plant metabolism studies reported in the EU

The metabolism of prothioconazole in rotational crops – Swiss chard, turnips, spring wheat - has been evaluated (EFSA, 2007, 2014; United Kingdom, 2004, 2007).

Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites. 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 (EFSA, 2014).

Rotational crop studies with prothioconazole radiolabeled on the triazole ring were not assessed in the framework of the peer review. This information was not considered necessary for the first inclusion of the active substance and should not be considered required until the next renewal process confirms its need. However, such studies were reported and assessed by the JMPR in 2008. A slight piece of information and reference to these studies is reported here as additional information not needed for the approval of the product. The studies 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 (FAO, 2008a, 2008b).

During the assessment of the confirmatory data of TDMs (UK, 2018) it was stated that the metabolism studies conducted to determine the nature of residues in succeeding crops after the use of triazole active substances are outlined in the annex II dossiers of the individual parent triazole active substances. The rotational crop metabolism studies for the triazole active substances demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and/or triazole lactic acid (TLA) were often found to represent a

significant portion of the total radioactive residue in the rotational crops; in addition, 1,2,4-triazole (T) was detected but usually at much lower levels.

Summary of new plant metabolism studies
No new studies are submitted by the applicant.

Conclusion on metabolism in rotational crops
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 (EFSA, 2014).
It is considered that the nature of prothioconazole residues in rotational crops is sufficiently addressed by data out of data protection rights and that the derived residue definitions for enforcement and risk assessment are applicable.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*
The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).
The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.
It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

Triazole Derivate Metabolites, addendum – confirmatory data (UK, 2018)
"For the rotational crops, metabolism data are available on leafy crops, root crops and cereal grain and straw for a total of 12[1] approved triazole active substances and one non approved triazole active substance (flusilazole).
The rotational crop metabolism studies for the triazole active substances demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and/or triazole lactic acid (TLA) were often found to represent a significant portion of the total radioactive residue in the rotational crops; in addition 1,2,4-triazole (T) was detected but usually at much lower levels. Therefore, a number of field rotational crop trials have been conducted to investigate the magnitude of triazole derivative metabolite (TDM) residues in rotational crops after the use of triazole active substances".

No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data
As residues were not expected to exceed the trigger value of 0.1 mg/kg of prothioconazole and metabolites, studies investigating the nature of the residue in processed commodities were not required for the DAR submission (United Kingdom, 2004, 2007). Pending the renewal of the active substance for the Art. 43, no studies are needed for the present submission either. The nature of residues in processed commodities is sufficiently addressed.

However, information available in the literature is displayed below (table 7.2-5) as supplementary information (there is no need to refer to it or be used in the risk assessment).

[1] Epoxiconazole, penconazole, tebuconazole, fenbuconazole, flutriafol, paclobutrazole, metconazole, fluquiconazole, difenoconazole, tetraconazole, propiconazole, ipconazole.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Prothioconazole (89.1%), JAU6476-desthio (2.8%)	FAO, 2008a, 2008b
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Prothioconazole (86.2%), JAU6476-desthio (7.4%)	FAO, 2008a, 2008b
Sterilisation (20 minutes, 120°C, pH 6)	Prothioconazole (79.0%), JAU6476-desthio (10.6%)	FAO, 2008a, 2008b

The effect of processing on the nature of prothioconazole residues was not investigated in the framework of the peer review of Directive 91/414/EEC considering the low residues in the crop (United Kingdom, 2004). Nevertheless, standard hydrolysis studies have been assessed by the JMPR in 2008 (FAO, 2008a, 2008b) and it was concluded that prothioconazole is stable under processing conditions representative of pasteurisation and boiling but slightly degraded (≤ 11%) to prothioconazole-desthio under sterilisation (EFSA, 2014).

Additionally, the Article 12 MRL review refers to a study where the effect of processing on the nature of prothioconazole-desthio was investigated (Germany, 2014). Results indicated that prothioconazole-desthio is stable under standard hydrolysis conditions. The levels of prothioconazole-desthio in the samples after hydrolysis ranged from 99.4 to 99.9 % of the AR (EFSA, 2014).

The Article 12 MRL review concluded that other compounds, which are included in the risk assessment residue definition and contains the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, due to their similar structure to the parent compound and/or prothioconazole-desthio, are expected to remain stable under hydrolysis. The residue definitions in raw and processed crops are therefore concluded to be the same (EFSA, 2015).

For TDMs unprotected data is available in the confirmatory data of the triazole derivative metabolites (EFSA, 2018). This data was submitted in the framework of confirmatory data requirements that were identified during the inclusion process of prothioconazole (as well as for all other azole active substances) and, therefore, according to Regulation (EU) 1107/2009 the data provided as confirmatory data can be considered out of data protection rights. One study on the nature of the residues of TA, TAA, TLA and 1,2,4-T was submitted and assessed within this process. Results showed that the test compounds triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole were stable under three sets of hydrolytic conditions representative of the main food processing procedures (pasteurization, baking, brewing, boiling and sterilization). No significant amounts of hydrolysis products of these triazole derived metabolites could be detected after the high temperature hydrolysis mimicking industrial and domestic food processing (UK, 2018).

Conclusion on nature of residues in processed commodities

Considering that all the metabolites included in the residue definition for risk assessment in primary crops, including TDMs, all are expected to remain stable under hydrolysis. It can be concluded that the relevant residue for enforcement and risk assessment in processed commodities is expected to be the same as for primary crops.

Pending the renewal of the active substance for the Art. 43, no further studies investigating the nature of the residue in processed commodities are needed for the present submission. The nature of residues in processed commodities is sufficiently addressed.

zRMS comments:

The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review.

In EFSA Journal 2014;12(5):3689 it is stated that *The effect of processing on the nature of prothioconazole residues was not investigated in the framework of the peer review. Nevertheless, studies were assessed by the JMPR (FAO,*

2008a, 2008b), 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). From these studies, it was concluded that parent compound prothioconazole is stable under processing by pasteurisation and baking/brewing/boiling. However, under sterilisation, prothioconazole slightly degrades (≤ 11%) to prothioconazole-desthio.

The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018).

No further data are required.

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	Root and tuber vegetables (Sugar beet) Pulses and oilseeds (Peanut) Cereals (Wheat)
Rotational crops covered	Leafy vegetables (Swiss chard) Root and tuber vegetables (Turnip) Cereals (Spring wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. and TDM metabolites 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~~; Reg. (EU) 2024/1318; EFSA, 2014)
Plant residue definition for risk assessment	1. 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, 2014). 2. Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound (EFSA, 2018). 3. TA and TLA, since these compounds share the same toxicity (EFSA, 2018). 4. TAA (EFSA, 2018). 5. 1,2,4-triazole (EFSA, 2018).
Conversion factor from enforcement to RA	CF=2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables. CF=3 for cereal straw. (EFSA, 2014)

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

Available data

The nature of prothioconazole residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2004, 2007). Reported metabolism studies include two studies in lactating goats using respectively [U-^{14}C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-^{14}C-phenyl]-labelled prothioconazole.

Besides the data assessed during the inclusion process, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-^{14}C-triazole]-labelled prothioconazole (EFSA, 2014). Information about these studies is included as supporting information but is not required to support the present submission as information provided during the inclusion process is deemed to be enough until the renewal of the active substance takes place.

All these studies are summarised in Table 7.2-7 below.

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 animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data: prothioconazole								
Lactating ruminants	Goat	[U-^{14}C-phenyl] prothioconazole	1	10 (250 mg a.s./kg feed)	3	Milk	twice daily	United Kingdom, 2004, 2007; FAO, 2008a, 2008b
						Urine and faeces	daily and at sacrifice	
						Tissues	at sacrifice	
		[U-^{14}C-phenyl] prothioconazole-desthio	1	10 (195 mg a.s./kg feed)	3	Milk	twice daily	
						Urine and faeces	daily and at sacrifice	
						Tissues	at sacrifice	
		[3, 5-^{14}C-triazole] prothioconazole	1	10	3	Milk	twice daily	FAO, 2008a, 2008b
						Urine and faeces	daily and at sacrifice	
						Tissues	at sacrifice	
Laying poultry	Hens	[U-^{14}C-phenyl] prothioconazole	6	10	3	Eggs	Once dayly	United Kingdom, 2004, 2007; FAO, 2008a, 2008b
						Excreta	At regular intervals	
						Tissues	At sacrifice (5h after last administration)	
		[3, 5-^{14}C-triazole] prothioconazole	6	10	3	Eggs	Once dayly	FAO, 2008a, 2008b
						Excreta	At regular intervals	
						Tissues	At sacrifice (5h after last administration)	
EU data: Triazole derivative metabolites								
Laying poultry	Hens	[triazole-UL-^{14}C]triazole alanine	6	0,81 mg/kg bw/day	14	Eggs and escreta	Daily	UK, 2018
						Tissues	At sacrifice (6h after last administration)	
Lactating ruminants	Goat	[triazole-UL-^{14}C]triazole alanine	1	15.24 mg/kg DM/day	7	Milk	Twice daily	UK, 2018
						Plasma, urine and faeces	Throughout the dosing period and immediately prior to sacrifice.	
						Tissues	At sacrifice (6h after last administration)	

Summary of animal metabolism studies reported in the EU

It is noted that in poultry no study was performed with prothioconazole-desthio and that the fate of the triazole moiety in livestock was only investigated for prothioconazole. However, the available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Additional studies addressing these requirements are therefore not expected to provide different results. It is also noted that no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants. Nevertheless, EFSA assumed that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary (EFSA, 2014).

Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices. It is noted that although only the glucuronide conjugates of prothioconazole-desthio were detected in milk, the actual residue levels are expected at a trace level at the calculated dietary burden (< 0.01 mg/kg) and EFSA considers that analysing the conjugates of prothioconazole-desthio would have a negligible impact on the residue levels enforced in milk. In case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices (EFSA, 2014).

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore defined in all commodities of animal origin as the 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, 2014).

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 (EFSA, 2014).

For TDMs unprotected data is available in the confirmatory data of the triazole derivative metabolites (EFSA, 2018; UK 2018). This data was submitted in the framework of confirmatory data requirements that were identified during the inclusion process of prothioconazole (as well as for all other azole active substances) and, therefore, according to Regulation (EU) 1107/2009 the data provided as confirmatory data can be considered unprotected.

Two metabolism studies in livestock were provided. The first one was performed in poultry. Laying hens were orally dosed once a day for 14 consecutive days (24 h intervals) with 0.81 mg [triazole-UL-14C]triazole alanine per kg body weight per day (11.20 mg a.s./kg dry feed/day). On the other side, one metabolism study was performed with a single lactating goat that received seven daily doses of triazole labelled [triazole-UL-14C]triazole alanine (radiochemical purity >99 %; specific activity 19.03 Ci mol-1) at a rate of 15.24 mg a.s. /kg DM/day.

Since TA is a major component in feed items, the potential transfer of this compound in poultry andruminant matrices was investigated in these metabolism studies. TA remains the major compound of the total residues in all poultry matrices (84–97.2% TRR) and in ruminant tissues (56–76% TRR) while TA and 1,2,4-T accounted for 8% 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-T present in feed items to the animal matrices was not further investigated. Although there are indications from the ruminant metabolism study conducted with the14C-TA, that there is no accumulation of TAA and TLA (4.2% and<1% of the total administered dose in urine, respectively), these metabolites were however detected in the ruminant matrices from the feeding study conducted with TA (EFSA, 2018).

Conclusion on metabolism in livestock

The nature of residues in livestock is sufficiently addressed by available and unprotected data. No new studies have been submitted by the applicant.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2014;12(5):3689 it is stated that *Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as* ***prothioconazole-desthio (sum of isomers)*** *for all the livestock matrices. This compound is fat soluble.*

(…) For risk assessment, the residue was defined in all commodities of animal origin as the ***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).***

According to the EFSA Journal 2018;16(7):5376: *Ruminant and poultry metabolism studies labelled on the triazole ring are available.*

(…) Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions:

- *Residue definition for enforcement: triazole parent compound only*
- *Residue definition for risk assessment:*
  1. *Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound;*
  2. *TA and TLA, since these compounds share the same toxicity;*
  3. *TAA;*
  4. *1,2,4-triazole.*

No further data are required.

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	1 or 2 days in milk
	53 h
Animal residue definition for monitoring	Prothioconazole-desthio (sum of isomers) for all livestock matrices (~~Regulation (EU) 2019/552;~~ Reg. (EU) 2024/1318; EFSA, 2014)
Animal residue definition for risk assessment	1. 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, 2014). 2. TA and TLA, since these compounds share the same toxicity (EFSA, 2018). 3. TAA (EFSA, 2018). 4. 1,2,4-triazole (EFSA, 2018).
Conversion factor	CF=2 for liver CF=9 for kidney CF not necessary for milk, ruminant muscle and ruminant fat (EFSA, 2014)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

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

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

A sufficient number of supervised residue trials was submitted in the framework of Directive 91/414/EEC. These trials are in accordance with the representative uses supported by the applicant. In these trials, prothioconazole-desthio residues were determined consistently with the residue definition for monitoring (EFSA, 2007).

As the residue definitions for enforcement and risk assessment are different, conversion factors for enforcement to risk assessment of 2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 for cereal straw were derived on the basis of the available plant metabolism data. The lack of residue trials in compliance with the risk assessment residue definition was identified as a data gap in the review of the existing MRLs according to the Art. 12 (EFSA, 2014). However, as the renewal of the active substance has not taken place yet, data submitted for the DAR (United Kingdom, 2004, 2007) can be considered sufficient.

Wheat:
Wheat is a major crop in NEU region. The 13 trials available for Northern Europe showed no residues at harvest in wheat grains (below the LOQ of 0.01 mg/kg) except for one trial (0.02 mg/kg). Trials consisted of 3 applications at a target rate of 0.2 kg as/ha and were conducted at growth stages ranging from BBCH 69 to 71. Since the proposed GAP for SAP210F on wheat consists in 2 applications performed at a dose rate of 120 g/ha and with a PHI of 42 days, the available trials have been made with a more critical GAP and can be used to support the proposed GAP.

Barley:
Barley is a major crop in NEU region. In barley grains, ~~14~~ 13 trials are available for Northern Europe, all resulting in residues below the LOQ in all cases except for two trials, from which the HR was 0.02 mg/kg. Trials on barley were made with two applications at a dose rate of 200 g/ha made between BBCH58 and BBCH71. Since the proposed GAP for SAP210F on barley consist in 2 applications performed at a dose rate of 120 g/ha and with a PHI of 42 days, the available trials have been made with a more critical GAP and can be used to support the proposed GAP.

A lot of information is available for residues in wheat and barley straw in Northern region, ranging from 0.08 to 1.6 mg/kg at normal harvest time. During these trials, 2-3 applications were carried out at a target rate of 0.2 kg as/ha and BBCHs ranged from 58 to 71.

Triazole derivative metabolites:
A total 8 trials in NEU are provided where levels of TDMs have been quantified in barley. For wheat, 9 trials in NEU are also provided. Since both crops are major crops in both areas, 8 trials are required for NEU for each crop. Results of these studies are shown in table 7.2-10.

Table 7.2--9: Summary of EU reported and new data supporting the intended uses of SAP2101F and conformity to existing MRL – Prothioconazole and its metabolites

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) 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) (rounded)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain	United Kingdom, 2004, 2007	N-EU (11)	GAP on which EU a.s. assessment is based: 3 x 0.2 kg as/ha, BBCH 69, PHI 35-64d E: 11x <0.01 RA: 11x <0.02 (CF: 2.0) RA: no data on prothioconazole-hydroxy-desthio	N/A				
	EFSA, 2014	N-EU** (2)	E: <0.01; 0.02 RA: <0.02; 0.04 (CF: 2.0) RA: no data on prothioconazole-hydroxy-desthio					
	Overall supporting data for cGAP	EU (13)	E: 12x <0.01 ; 0.02 RA: 12x <0.02; 0.04 (CF: 2.0) RA: no data on prothioconazole-hydroxy-desthio	E: 0.01 RA: 0.02	E: 0.02 RA: 0.04	E: 0.02 (0.03) RA: 0.04 (0.05)	0.1	Yes
Wheat straw	United Kingdom, 2004, 2007	N-EU (11)	GAP on which EU a.s. assessment is based: 3 x 0.2 kg as/ha, BBCH 67-71, PHI 35d E: 0.08; 0.09; 0.11; 0.14; 0.15; 0.19; 0.20; 0.27; 0.31; 0.66, 0.72 RA: 0.24; 0.27; 0.33; 0.42; 0.45; 0.57; 0.6; 0.81; 0.93; 1.92; 2.16	N/A				
	EFSA, 2014	N-EU** (4)	E: 0.09; 0.42; 0.48; 1.60 RA: 0.27; 1.26; 1.44; 4.8					
	Overall supporting data for cGAP	N-EU (15)	E: 0.08; 2x 0.09; 0.11; 0.14; 0.15; 0.19; 0.20; 0.27; 0.31; 0.42; 0.48; 0.66, 0.72; 1.6 RA: 0.24; 2x 0.27; 0.33; 0.42; 0.45; 0.57; 0.6; 0.81; 0.93; 1.26; 1.44; 1.92; 2.16; 4.8	E: 0.20 RA: ~~0.59~~ 0.60	E: 1.60 RA: 4.80	E: 1.96 (2.0) RA: 5.89 (6.0)	-	N/A

Barley grain	United Kingdom, 2004, 2007	N-EU (10 9)	GAP on which EU a.s. assessment is based: 2 x 0.2 kg as/ha, BBCH 61-63, PHI 35-61d E: 10 9x <0.01; RA: 10 9x <0.02 CF: 2.0) RA: no data on prothioconazole-hydroxy-desthio					
	EFSA, 2014	N-EU** (4)	E: 2x <0.01; 0.01; 0.02 RA: 2x <0.02; 0.02; 0.04 CF: 2.0) RA: no data on prothioconazole-hydroxy-desthio					
	Overall supporting data for cGAP	NEU (14 13)	E: 12 11x <0.01; 0.01; 0.02 RA: 12 11x <0.02; 0.02; 0.04 CF: 2.0) RA: no data on prothioconazole-hydroxy-desthio	E: 0.01 RA: 0.02	E: 0.02 RA: 0.04	E: 0.02 (0.03) RA: 0.04 (0.05)	0.2	Yes
Barley straw	United Kingdom, 2004, 2007	N-EU (10 9)	GAP on which EU a.s. assessment is based: 2 x 0.2 kg as/ha, BBCH 69, PHI 35d E: 0.05; 0.08; 2x 0.10; 2x 0.13; 2x 0.14; 0.30; 0.24 RA: 0.15; 0.24; 2x 0.3; 2x 0.39; 2x 0.42; 0.9; 0.72					
	EFSA, 2014	N-EU (3)	E: 0.11; 0.36; 0.56 RA: 0.33; 1.08; 1.68					
	Overall supporting data for cGAP	N-EU (13 12)	E: 0.05; 0.08; 2x 0.1; 0.11; 2x 0.13; 2x 0.14; 0.24; 0.30; 0.36; 0.56 RA: 0.15; 0.24; 2x 0.3; 0.33; 2x 0.39; 2x 0.42; 0.72; 0.9; 1.08; 1.68	E: 0.13 RA: 0.39	E: 0.56 RA: 1.68	E: 0.76 (0.80) RA: 2.28 (3.00)	-	N/A

* Source of EU MRL: Reg. (EU) 2019/552 2024/1318

** Trials assessed by FR performed at a similar or less critical GAP than the authorised European cGAP and leading to similar or higher residue levels than the ones assessed in the peer-review (EFSA, 2007b; France, 2014).

Table 7.2-10: Summary of EU reported and new data supporting the intended uses of SAP2101F - TDMs

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) 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) *	MRL compliance
Barley grain	EGL-20-45487 EGL-20-42539 IF21-05704459	NEU	GAP: 2 applications at 195 g/ha PHI 35-64 days 1,2,4-T: 8x<0.01 TA: 0.32, 0.12, 0.83, 0.08, 2x0.16, 0.23,0.13 TAA: 0.26, 0.05, 0.24, 0.03, 0.08, 2x0.09, 0.07 TLA: 2x0.03, 5x<0.01, 0.02	1,2,4-T: 0.01 TA: 0.16 TAA: ~~0.08~~ 0.09 TLA: 0.01	1,2,4-T: 0.01 TA: 0.83 TAA: 0.26 TLA: 0.03	N/A	N/A	N/A
Barley straw	EGL-20-45487 EGL-20-42539 IF21-05704459	NEU	GAP: 2 applications at 195 g/ha PHI 35-64 days 1,2,4-T: 8x<0.01 TA: 0.32, 2x<0.01, 0.13, 0.02, 2x0.03.0.01 TAA: 0.15, <0.01, 0.19, 0.01, 3x0.03, 0.05 TLA: 0.15, 0.02, 0.29, 0.01, 3x0.02, 0.1	1,2,4-T: 0.01 TA: ~~0.02~~ 0.03 TAA: 0.03 TLA: 0.02	1,2,4-T: 0.01 TA: 0.32 TAA: 0.19 TLA: 0.29	N/A	N/A	N/A
Wheat grain	EGL-20-42538 IF21-05705310	NEU	GAP: 2 applications at 195 g/ha PHI 37-49 days 1,2,4-T: 9x<0.01 TA: 0.28, 0.47, 0.54, 0.61, 1.10, 0.45, 0.52, 0.50, 0.27 TAA: 0.057, 0.06, 0.15, 0.29, 0.38, 0.09, 0.38, 0.12, 0.07 TLA: 9x<0.01	1,2,4-T: 0.01 TA: 0.5 TAA: 0.12 TLA: 0.01	1,2,4-T: 0.01 TA: 1.1 TAA: 0.38 TLA: 0.01	N/A	N/A	N/A
Wheat straw	EGL-20-42538 IF21-05705310	NEU	GAP: 2 applications at 195 g/ha PHI 37-49 days 1,2,4-T: 9x<0.01 TA: 0.02, 0.04, 0.1, 0.05, , 0.08, 0.094, 0.22, 0.02, <0.01 TAA: 0.08, 0.088, 2x0.13, 0.1, 0.05, 0.33, 0.03, 0.02 TLA: 0.02, 0.07, 0.03, 2x0.1, 2x0.02, 0.13, 0.05	1,2,4-T: 0.01 TA: 0.05 TAA: 0.08 TLA: 0.05	1,2,4-T: 0.01 TA: 0.22 TAA: 0.33 TLA: 0.13	N/A	N/A	N/A

7.2.3.2 Conclusion on the magnitude of residues in plants

A total of 13 NEU wheat trials (grain) and ~~14~~ 15 NEU trials (straw) carried out at a comparable GAP to the proposed one are available to support the intended uses on wheat.

A total of ~~14~~ 13 NEU barley trials (grain) and ~~13~~ 12 NEU trials (straw) carried out at a comparable GAP to the proposed one are available to support the intended uses on barley.

Results are shown in table 7.2-9.

According to the available data, the intended uses on wheat and barley are considered acceptable in Northern Europe. The data submitted demonstrates that no exceedance of the MRL will occur.

Since no data is available where all the hydroxy metabolites are quantified to comply with the risk assessment definition of the residue (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), the levels of residues for risk assessment have been calculated using conversion factors. The conversion factors used are those stablished during the inclusion process of the active substance prothioconazole (UK, 2004; EFSA, 2007). The use of conversion factors was considered acceptable during the inclusion process, therefore, it should still be considered valid until the next renewal of the active substance.

Regarding TDMs, 8 NEU residue trials are provided in barley while 9 NEU trials on wheat.
In this case, only STMR and HR are calculated since MRLs are not established for TDMs. However, the available residue values will be used in the risk assessments to be performed.

Results are shown in table 7.2-10.

zRMS comments:
Residue Definitions (EFSA 2020; Reg (EU) 2024/1318):
Monitoring (Mo): Prothioconazole-desthio (sum of isomers)
Risk Assessment (RA):
1) 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, 2014)
2) TDMs (EFSA, 2018), with separate assessment of:
- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

The critical EU GAP for cereals is more critical than proposed GAP.

Wheat
Wheat is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Sufficient trials on wheat conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-destio in the DAR (2007).
According to the EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of Prothioconazole for foliar treatments in cereals, 11 trials in Northern Europe showed no residues at harvest in wheat grains (below the LOQ of 0.01 mg/kg).
Grains : 11 x < 0.01 mg/kg
Straw: 0.08, 0.09, 0.11, 0.14, 0.15, 0.19, 020, 0.27, 0.31, 0.66, 0.72 mg/kg.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.
The trials are supported by valid storage stability data and validated analytical methods.

Barley
Barley is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.
Sufficient trials on barley conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-destio in the DAR (2007).

According to the EFSA Scientific Report (2007) 106, 1-98, the results for barley are:
Grains: 9 x < 0.01 mg/kg,
Straw: 0.05, 0.08, 2 x 0.10, 2x 0.13, 2 x 0.14, 0.30 mg/kg.

Storage periods of residue samples covered by available storage stability studies.
Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

TDMs
Triazole derivative metabolites (TDMs) are common metabolites of all triazole fungicides and have to be considered in the consumer risk assessment. The data on TDMs provided in the present application are from the "Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom" (UK, 2018). As confirmatory data, they are out of data protection. Results for TDMs presented by UK (2018) were considered for livestock and consumer exposure.
Additionally Applicant submitted 3 residues studies for barley and 3 residues studies for wheat conducted to determine the magnitude of residues of the prothioconazole metabolites: 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley and wheat after two foliar application with Prothioconazole 300 EC. More details are presented in Appendix 2. Thes studies are acceptable.

No additional studies are required.

The proposed uses on wheat and barley are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Prothioconazole is authorised, at European level for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated by EFSA, in its Review of the existing MRLs for prothioconazole, for different groups of livestock using the, at that time, agreed European methodology (EC, 1996) (EFSA, 2014). In this document, EFSA establishes residue levels to be included in feeding commodities for prothioconazole, residues coming from all existing authorizations in EU. Later, during the MRL modification for prothioconazole in sunflower seeds (EFSA, 2015), the dietary burden calculated under Article 12 MRL review was updated. However, since residues in sunflower showed to not have impact on the dietary burdens calculated in the framework of the Article 12 review, modification of the MRLs proposed for animal commodities under the MRL review was not deemed necessary within that process (EFSA, 2015).

In the present submission, calculations have been performed using the latest Excel calculator model available (EC, 2017), according to the old data requirements (Regulation (EU) Nº 544/2011). Input values are based on EFSA's review according to the Art. 12 (EFSA, 2014) and posterior MRL modifications (EFSA, 2015). These values entail a worse situation compared to results obtained from residue trials STMR and HR calculations (see Table 7.2-11). As no value was provided by EFSA for triticale straw, it has been extrapolated from wheat straw residue trials. Residues from the intended uses are not more critical to the ones already assessed during the art.12 review, they do not increase the dietary burden. The calculation is included below for completeness.

Table 7.2-101: 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
Risk assessment residue definition: 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)				
Head cabbage	0.02	Median residue x CF (EFSA, 2014)	0.12	Highest residue x CF (EFSA, 2014)
Maize silage	0.01	Median residue (EFSA, 2014)	0.01	Highest residue (EFSA, 2014)
Maize grain	0.01	Median residue (EFSA, 2014)	0.01	Median residue (EFSA, 2014)
Barley, oats, rye, triticale and wheat grain	0.02	Median residue x CF (EFSA, 2014)	0.02	Median residue x CF (EFSA, 2014)
Wheat bran	0.16	Median residue x CF x 8 (EFSA, 2014)	0.16	Median residue x CF x 8 (EFSA, 2014)
Barley and oats straw	1.25	Median residue x CF (EFSA, 2014)	7.50	Highest residue x CF (EFSA, 2014)
Wheat straw	2.24	Median residue x CF (EFSA, 2014)	7.20	Highest residue x CF (EFSA, 2014)
Triticale straw	2.16	Median residue x CF (UK, 2007)	7.20	Highest residue x CF (UK, 2007)
Rye straw	0.60	Median residue x CF (EFSA, 2014)	4.80	Highest residue x CF (EFSA, 2014)
Peas and beans (dry)	0.02	Median residue x CF (EFSA, 2014)	0.02	Median residue x CF (EFSA, 2014)
Potatoes	0.01	Median residue (EFSA, 2014)	0.01	Highest residue (EFSA, 2014)
Turnips and swedes	0.06	Median residue x CF (EFSA, 2014)	0.10	Highest residue x CF (EFSA, 2014)
Rape seed meal	0.12	Median residue x CF x 2 (EFSA, 2014)	0.12	Median residue x CF x 2 (EFSA, 2014)
Linseed meal	0.12	Median residue x CF x 2 (EFSA, 2014)	0.12	Median residue x CF x 2 (EFSA, 2014)
Sunflower seed meal	0.04	STMR x CF x PF (EFSA, 2015)	0.04	STMR x CF x PF (EFSA, 2015)

Results of the calculations are reported in Table 7.2-12. 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 (EFSA, 2014).

Table 7.2-112: Results of the dietary burden calculation

Animal species (Relevant groups)	Most critical diet	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 Max burden mg/kg DM
Risk assessment residue definition: 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) (tentative)							
Cattle (all diets)	Dairy cattle	0.042	0.122	Barley Straw	3.33	Y	4.8
Cattle (dairy only)	Dairy cattle	0.042	0.122	Barley Straw	3.17	Y	2.4

Animal species (Relevant groups)	Most critical diet	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 Max burden mg/kg DM
Sheep (all diets)	Lamb	0.063	0.235	Barley Straw	5.72	Y	-
Sheep (ewe only)	Ram/Ewe	0.059	0.191	Barley Straw	5.72	Y	-
Swine (all diets)	Swine (breeding)	0.012	0.016	Potato Process waste	0.69	Y	0.77
Poultry (all diets)	Poultry layer	0.026	0.066	Wheat Straw	0.96	Y	0.3
Poultry (layer only)	Poultry layer	0.026	0.066	Wheat Straw	0.96	Y	0.3

Even though, values used in the calculation are the same as used in the Review of the existing MRLs for prothioconazole (EFSA, 2014) and subsequent publications (EFSA, 2015). Since the model of calculation has been recently updated (EC, 2017) different maximum dietary burdens are given in the table above (Table 7.2-12). Dietary burdens for cattle and swine are covered by the assessment made by EFSA (EFSA, 2014, 2015) but dietary burdens calculated for sheep and poultry give a higher value than the one obtained in previous assessments. Therefore, further calculations are included in the section 7.2.4.2 below.

For TDMs, a full dietary burden calculation is included in the confirmatory data of the Triazole Derivative Metabolites (UK, 2018). In this calculation, residues from all the crops that could have residues in feeding commodities coming from all the different azole active substances are considered (UK, 2018). All the residue values used in the assessment (maximum dietary burden calculation) are higher than the ones calculated from the new data available:

Matrix	Value used in the assessment	1,2,4-T	TA	TAA	TLA
Cereal straw	HR from point B.7.4 from UK, 2018	0.05	0.65	0.78	1.1
	HR from table 7.2-10 of this document	0.01	0.32	0.33	0.29
Cereal grain	STMR from point B.7.4 from UK, 2018	0.05	0.621	0.79	0.02
	Highest STMR from table 7.2-10 of this document	0.01	0.50	0.12	0.01

Therefore, since the dietary burden calculation included in the confirmatory data of the Triazole Derivative Metabolites (UK, 2018), the calculations included in the confirmatory data are reliable to support the present submission.
The dietary burdens for T, TA, TAA and TLA are shown in tables below (extracted from UK, 2018):
The intake calculations for the maximum dietary burden of livestock demonstrate that residues of T, TA, TAA and TLA are significant in the diets of livestock and they all exceed the trigger value of 0.004 mg/kg bw. The intakes are also above the trigger of 0.1 mg/kg applied on a DM basis.

Feeding studies with triazole alanine and triazole acetic acid are available and since they are out of data protection rights, they can be used to support the present submission. The task force chose triazole alanine and triazole acetic acid because they initially appeared to be present at higher levels in animal feed items (especially cereals) than triazole lactic acid and 1,2,4- triazole. The maximum dietary burden does occur for TA. The next highest dietary burden occurs for TLA and TAA; for cattle and sheep the dietary burden is higher for TLA whereas for swine and poultry the dietary burden is higher for TAA compared to TLA.
On the basis of the metabolism observed in livestock the TDMG considered that further feeding studies are not required. However, as outlined below, adequate data have not been provided to enable an estimate of the residue levels of all four triazole derivative metabolites in products of animal origin. Further consideration is still required (UK, 2018).

zRMS comments:
Information given by the Applicant is acceptable and sufficient.

<u>Prothioconazole</u>

The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017).
The calculated dietary burdens for prothioconazole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

TDMs
Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK (UK, 2018) using results from residue trials and from rotational crops.
It should be noted that the proposed uses are less critical than ones assessed in the EFSA Journal 2018;16(7):537 or in the Review of the existing MRLs for prothioconazole (EFSA, 2020) and therefore the results of dietary burdens for TDMs taking into account the intended uses of SAP2101F are covered by the dietary burdens calculated by the UK (UK, 2018) for the different groups of livestock.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data
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 (EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels of 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d, respectively). The samples were analysed for prothioconazole-desthio, M14 and M15 (EFSA, 2014).

In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. However, as stated by EFSA, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment (EFSA, 2014). While waiting for the active substance renewal, EFSA indicates that the aforementioned CFs can be considered suitable for the determination of risk assessment values.

As mentioned in Section 7.2.1.1, degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is not expected as the storage stability study covered the storage time interval of the samples.

Residue values from the feeding study available in cattle have been used to calculate the MRLs for sheep, taking into account the new dietary burden calculations (Table 7.2-12). Calculations are summarized in Table 7.2-13.

Table 7.2-123: Overview of the values derived from livestock feeding studies (sheep)

Animal commodity	**Residues at the closet feeding level** (mg/kg)		**Estimated value at 1N level**		**MRL proposal** (mg/kg)	**CF**	**STMR** (mg/kg)	**HR** (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)				
Sheep (all diets)								
Closest feeding level[(a)]:	0,15	mg/kg bw	0,6	N Lamb (highest diet)				
Muscle	0,01	0,01	0,01	0,01	**0,01**	n.c.	0,01	0,01
Fat	0,01	0,01	0,01	0,01	**0,01**	n.c.	0,01	0,01

Liver	0,03	0,03	0,01	0,05	**0,05**	n.c.	0,01	0,05
Kidney	0,01	0,01	0,01	0,01	**0,015**	n.c.	0,01	0,01
Sheep (dairy only)								
Closest feeding level[(a)]:	0,15	mg/kg bw	0,8	N Ewe				
Milk[(b)]	0,01	0,01	0,01	0,01	**0,005**	n.c.	0,01	0,01

In order to perform this calculation and since no individual data is included in the DAR (United Kingdom, 2004, 2007) or in the Review of the existing MRLs for prothioconazole (EFSA, 2014), HRs have been used as input data.

According to this calculation, no exceedance of the existing MRLs for sheep origin commodities is expected. Moreover, no exceedance of the MRLs calculated by EFSA is shown (EFSA, 2014).

Finally, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and is required, since based on the metabolism study, according to EFSA's conclusions, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden (EFSA, 2014). Same conclusion can be drawn now, even if the dietary burden calculation is higher if the dose level used in the metabolism study and results obtained are compared to the new calculation.

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

The requested uses modify the theoretical maximum daily intake for sheep and poultry, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

Regarding TDMs, poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues.

The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolism to 1,2,4-T 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.
From the ruminant feeding study conducted with TA, TA remained predominant in all tissues but with a significant metabolism of TA into 1,2,4-T in milk and to a minor extent into 1,2,4-T and TAA in tissues. TLA was identified in fat only but its detection was rather attributed to a contamination as the respective levels were independent from the dosing levels. When ruminants were fed with TAA, this metabolite was only detected at the highest dose level in whole milk and in all tissues whilst TA was identified in liver, muscle and kidney at all the dosing levels.1,2,4-T and TLA compounds were never detected (<0.01 mg/kg) (EFSA, 2018).

Livestock feeding studies are only available with TA and TAA. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-T and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-T 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-T 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 was requested by EFSA. In the meantime, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities (EFSA, 2018).

Considering specific data available for prothioconazole (metabolism study in animals) and specific dietary burden calculations made during the revision of the MRLs of prothioconazole (EFSA, 2014), during the assessment of the confirmatory data of triazole derivative metabolites (UK, 2018), it was estimated the predictable residues of 1,2,4-T for prothioconazole specifically:

Parent triazole pesticide	Maximum dietary burden (mg/kg bw/day) considered				Residue levels of 1,2,4-T (mg/kg)
	Dairy ruminants	Beef ruminants	Poultry	Pigs	
Prothioconazole	0.086	0.21	0.018	0.031	Residues not expected.

Lactating goat and laying hen metabolism studies were evaluated for the approval of the active. In the Review of the existing MRLs for prothioconazole (EFSA, 2014). These studies were conducted at a feeding rate of 10 mg/kg bw/day (representing 116N and 556 N for the maximum dietary burdens of ruminants and poultry outlined in table above). According to the Review of the existing MRLs for prothioconazole the only identified triazole related metabolite was the thiocyanate metabolite found in the goat metabolism studies: 41 % TRR (0.061 mg eq/kg) in milk, 30 % TRR (0.035 mg eq/kg) in muscle, 12 % TRR (0.022 mg eq/kg) in fat, 9 % TRR (0.41 mg eq/kg) in kidney and 2 % TRR (0.13 mg eq/kg) in liver. In poultry, the metabolite 1,2,4-T is found at levels >0.01 mg/kg in liver (0.037 mg/kg)and muscle (0.023 mg/kg). However, comparing the exaggerated dose rate used in the study (10 mg/kg bw/day) and the maximum dietary burden calculated for poultry (0.018 mg/kg bw/day), no residues of any TDM are expected to be found in animal commodities. At the maximum dietary burden of meat ruminants or poultry, this metabolite is expected to occur at a trace level in all matrices.

Since the proposed uses in SAP2101F are not more critical than the ones assessed in the Addendum of Confirmatory data of Triazole Derivative Metabolites (UK, 2018) or in the Review of the existing MRLs for prothioconazole (EFSA, 2014), same conclusion regarding the expected residues of 1,2,4-T can be taken in the present assessment, and no residues of any TDM are expected to be present in animal matrices due to the application of SAP2101F according to the proposed uses.

Conclusion on feeding studies
The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRL to be exceeded.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
The livestock feeding studies was investigated during the peer review of prothioconazole. The intended uses do not modify the theoretical maximum daily intake for animals for prothioconazole and for TDMs (for TDMs are covered by UK calculation made in the framework of the confirmatory data on TDM (UK, 2018 and EFSA, 2018)). The residues in animal commodities will not exceed MRLs (Reg. (EU) 2024/1318).
No further data are required to support the intended uses of SAP2101F.

Remark:
It should be noted that EFSA recommended providing a ruminant feeding study to estimate the potential exposure to all the prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.
Additionally, regarding TDMs EFSA identified livestock exposure assessment as a data gap.

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

Residues of prothioconaloze-desthio and the hydroxy metabolites are not expected to exceed the trigger value of 0.1 mg/kg. Thus, pending the renewal of the active substance, no studies investigating the magnitude of the residue in processed commodities are needed for the present submission.

No studies investigating the magnitude of residues in processed commodities are available. According to EFSA, as such studies are not expected to affect the outcome of the risk assessment, they are not required unless further data is needed in the future (EFSA, 2014).

For TDMs unprotected data is available in the confirmatory data of the triazole derivative metabolites (EFSA, 2018). This data was submitted in the framework of confirmatory data requirements that were identified during the inclusion process of prothioconazole (as well as for all other azole active substances)

and, therefore, according to Regulation (EU) 1107/2009 the data provided as confirmatory data can be considered out of data protection rights.
Taking into account the residue levels found in the residue trials (refer to table 7.2-10) processing data is only required for TA and TAA since residue levels of TLA and 1,2,4-T are below the trigger of 0.1 mg/kg established in Regulation (EU) No 544/2011 and until the next renewal of the active substance prothioconazole takes place.

7.2.5.1 Available data for all crops under consideration

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

However, unprotected data is available to cover the magnitude of residues of TDMs in processed commodities after the treatment with prothioconazole. Available data is summarized in table 7.2-14.
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. However, since residues in grain of these metabolites from the field trials are below the trigger value of 0.1 mg/kg, processing data for these two metabolites is not required for the present submission.

Table 7.2-134: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
TA					
Wheat, aspirated grain fractions	1 trial	0.2	-		UK, 2018
Wheat, bran	1 trial	3.7	-		
Wheat, flour	1 trial	0.3	-		
Wheat, germ	1 trial	4.9	-		
Wheat, middlings	1 trial	0.66	-		
Wheat, shorts	1 trial	1.7	-		
Barley, brewer's malt	2 trial	0.78	-		
Barley, brewer's grain	2 trial	<0.04	-		
Barley, brewer's yeast	2 trial	0.19	-		
Barley, beer	2 trial	0.14	-		
TAA					
Wheat, aspirated grain fractions	1 trial	0.39	-		UK, 2018
Wheat, bran	1 trial	2.1	-		
Wheat, flour	1 trial	0.89	-		
Wheat, germ	1 trial	1.3	-		
Wheat, middlings	1 trial	0.8	-		
Wheat, shorts	1 trial	1.2	-		
Barley, brewer's malt	2 trial	1.1	-		
Barley, brewer's grain	2 trial	<0.04	-		
Barley, brewer's yeast	2 trial	0.23	-		
Barley, beer	2 trial	0.21	-		

* 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.

7.2.5.2 Conclusion on processing studies

Enough data to cover the processing of wheat and barley grain has been provided and is considered enough to cover the proposed uses.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.

Regarding TDMs, processing studies on wheat and barley grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).

Overview of the available processing studies - TDMs

Processed commodity	Processing factors				Comments	Reference
	T	TA	TAA	TLA		
EU confirmatory data (B.7.5.2, UK, 2018)						
Wheat, aspirated grain fractions	NC	0.20	0.39	NA		UK, 2018
Wheat, Bran	NC	**3.7**	**2.1**	NA		
Wheat, Flour	NC	0.30	0.89	NA		
Wheat, Germ	NC	**4.9**	1.3	NC		
Wheat, Middlings	NC	0.66	0.80	NC		
Wheat, Shorts	NC	**1.7**	1.2	NC		
Barley, Brewer's malt	NC, NC	0.78, 0.77	1.0, 1.1	>1.1, >1.5		
Barley, Brewer's grain	NC, NC	<0.04, <0.03	<0.05, <0.04	NC, NC		
Barley, Brewer's yeast	NC, NC	0.24, 0.14	0.23, 0.23	NC, NC		
Barley, Beer	NC, NC	0.15, 0.13	0.29, 0.13	NC, NC		

NA not analysed
NC Not calculated 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.

Calculated processing factors show concentration of:
- TA and TAA in wheat bran,
- TA in wheat germ and shorts,
- TAA and TLA in barley, brewer's malt.

However only one trial was used to derive the processing factor, so these processing factors are considered tentative.
No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.
Therefore, further assessment on the residue levels in rotational crops may be needed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

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

Conclusion on rotational crops studies
Based on the confined rotational crop study, considering that the proposed seasonal application rate of prothioconazole is 0.36 kg a.s./ha and since prothioconazole was applied to 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. Therefore, no risk mitigation measures (plant back restrictions) need to be proposed (EFSA, 2014).

For TDMs unprotected data is available in the confirmatory data of the triazole derivative metabolites (EFSA, 2018). This data was submitted in the framework of confirmatory data requirements that were identified during the inclusion process of prothioconazole (as well as for all other azole active substances) and, therefore, according to Regulation (EU) 1107/2009 the data provided as confirmatory data can be considered out of data protection rights.
A total of 4 field rotational studies made with prothioconazole are available in the Addendum of Confirmatory data for the triazole derivative metabolites.
Supervised field trials to investigate the residues in rotational crops after application of prothioconazole were conducted at four test sites located in Germany, the Netherlands, southern France and Spain. The critical GAP to be investigated was defined as a maximum seasonal application rate of 630 g as/ha (which is higher than the seasonal dose rate proposed for SAP2101F).

A summary of the results obtained in the available, unprotected rotational studies performed with prothioconazole is included in Table 7.2-15.

Table 7.2-15: Overview of the available field rotational studies

Commodity	No of trials	STMR (mg/kg)				HR (mg/kg)			
		1,2,4-T	TA	TAA	TLA	1,2,4-T	TA	TAA	TLA
Carrot or turnip leaf – bare soil*	4	0.01	0.032	0.01	0.57	0.01	0.176	0.01	0.132
Carrot or turnip leaf – normal rotation**	7	0.01	0.01	0.01	0.019	0.01	0.039	0.01	0.046
Carrot or turnip root– bare soil*	4	0.01	0.076	0.01	0.021	0.01	0.195	0.01	0.131
Carrot or turnip root – normal rotation**	7	0.01	0.023	0.01	0.01	0.01	0.041	0.01	0.01
Lettuce – bare soil*	4	0.01	0.047	0.022	0.079	0.01	0.091	0.03	0.01
Lettuce – normal rotation**	8	0.01	0.011	0.023	0.02	0.01	0.012	0.036	0.048
Barley plant – bare soil*	4	0.01	0.068	0.01	0.078	0.01	0.082	0.01	0.165
Barley plant – normal rotation**	8	0.01	0.037	0.01	0.032	0.01	0.057	0.01	0.208
Barley straw – bare soil*	4	0.01	0.053	0.063	0.113	0.01	0.129	0.288	0.192
Barley straw – normal rotation**	8	0.01	0.011	0.019	0.042	0.01	0.023	0.057	0.068
Barley grain – bare soil*	4	0.01	0.412	0.144	0.02	0.01	0.455	0.293	0.037
Barley grain – normal rotation**	8	0.01	0.075	0.067	0.01	0.01	0.184	0.132	0.031

*Bare soil corresponds to a plant back interval of 20-35 days. Application to bare soil at 630 g/ha of prothioconazole.
**Normal rotation corresponds to a plant back interval of 60-200 days. Seeds of wheat are treated at a 15 g a.s./dt. Once sown, 3 applications are made to wheat plants at a rate of 200 g a.s./ha each and at growth stages of BBCH 32, BBCH 39 and BBCH 65-69. At harvest the wheat straw was ploughed in (so as to simulate a worst case scenario in terms of residues) and the plots were left bare until the rotational crops were sown or planted.

According to the assessment performed by EFSA (EFSA, 2018) these trials where not supported by acceptable storage stability data because the samples where stored frozen longer than the periods demonstrated in the stability data available (Refer to section 7.2.1). However, it is stated in the Addendum of the Confirmatory data of Triazole Derivative Metabolites that the maximum length of freezer storage was 589 days in the study 09-2500, 550 days in the study 09-2501, 420 days in the study 09-2502 and 835 days in the study 09-2503. These periods are covered by available stability data except for the metabolite 1,2,4-T (all matrices) and for cereal grain samples of study 09-2502.
According to the confined rotational study, no residues of 1,2,4-T are found in rotational crops. Therefore, even if the stability is not covered for this metabolite, field rotational data would not be required.
Regarding grain, there is enough data even if some samples are not considered valid.

Therefore, enough unprotected data is available to cover this point.

zRMS comments:
Information and explanation on the storage stability of TDMs given by the Applicant is acceptable and sufficient.
No residues are expected in rotational crops for the intended uses of SAP2101F, so additional field rotational crop studies are not considered required.

Regarding TDMs, rotational crop studies were considered by the UK in the assessment of confirmatory data on TDMs (the UK, 2018).

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 SAP2101F. Therefore, other special studies are not needed.

Specifically, residues in honey should not be required until the renewal of the active substance take place. Indeed, AIR peer review under new data requirements is still ongoing at the time of this submission. Therefore, currently the old data requirements still apply and residues in honey do not need to be addressed at this stage.

zRMS comments:
Information given by the Applicant is acceptable.

The intended uses of SAP2101F in cereals are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018. Other special studies including data on prothioconazole residues in pollen and bee products for human consumption are not considered necessary.
In our opinion, no further data is necessary to support the uses of SAP2101F.

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).

7.2.8.1 Input values for the consumer risk assessment

The IEDI calculation was performed taking into account all the crops to which prothioconazole may be applied. Consumer risk assessment was performed using EFSA PRIMo-rev.3.1 model.

In force MRLs have been used as input values for chronic risk assessment calculation, taking into account the corresponding CFs for each commodity. MRLs have been used except for the commodities displayed in Table 7.2-16 below. These values are the ones used by EFSA in the evaluation of confirmatory data following the Article 12 MRL Review and modification of the existing MRLs for prothioconazole in celeriacs and rapeseeds (EFSA, 2020). Finally, the input values related to the intended uses are based on the residue trials submitted in this application, for both chronic and acute risk assessments.

As stated in the Art. 12 reasoned opinion (EFSA, 2014) since residue definitions for enforcement and risk assessment are different, conversion factors for enforcement to risk assessment of 2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables were used when no other data was available.

Table 7.2-146: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: 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)				
Wheat	0.02	STMR-RAC	0.02	STMR-RAC
Barley	0.02	STMR-RAC	0.02	STMR-RAC
Oat	0.02	STMR-RAC	0.02	STMR-RAC
Rye	0.02	STMR-RAC	0.02	STMR-RAC
Celeriac	0.08	STMR (EFSA, 2020)	0.1	HR (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)	0.1	HR (EFSA, 2020)
Rape seed	0.08	STMR (EFSA, 2020)	0.08	STMR (EFSA, 2020)
Cranberries	0.025	STMR[(a)] (FAO, 2014)	0.9	HR[(a)] (FAO, 2014)
Potatoes	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Sweet corn	0.018	STMR[(a)] (FAO, 2014)	0.018	HR[(a)] (FAO, 2014)
Onions, shallots	0.02	STMR (EFSA, 2014, 2015a) x CF(2)	0.04	HR (EFSA, 2014, 2015a) x CF(2)
Flowering brassica	0.02	STMR x CF (2) (EFSA, 2014)	0.04	HR x CF (2) (EFSA, 2014)
Brussels sprouts	0.06	STMR x CF (2) (EFSA, 2014)	0.14	HR x CF (2) (EFSA, 2014)
Head cabbage	0.02	STMR x CF (2) (EFSA, 2014)	0.12	HR x CF (2) (EFSA, 2014)
Leeks	0.02	STMR x CF (2) (EFSA, 2014)	0.08	HR x CF (2) (EFSA, 2014)
Beans	0.02	STMR x CF (2) (EFSA, 2014)	0.02	STMR x CF (2) (EFSA, 2014)
Lentils, peas, lupins	0.1	STMR[(a)] (FAO, 2009b) x CF (2)	0.1	STMR[(a)] (FAO, 2009b) x CF (2)
Linseeds, poppy seeds, mustard seeds	0.06	STMR x CF (2) (EFSA, 2014)	0.06	STMR x CF (2) (EFSA, 2014)
Gold of pleasure seeds	0.02	STMR x CF (2) (EFSA, 2014)	0.02	STMR x CF (2) (EFSA, 2014)
Peanuts	0.02	STMR (FAO, 2009b) x CF (2)	0.02	STMR (FAO, 2009b) x CF (2)
Sunflower seeds	0.02	STMR (EFSA, 2015b) x CF (2)	0.02	STMR (EFSA, 2015b) x CF (2)
Cotton seeds	0.1	STMR (FAO, 2018) x CF (2)	0.1	STMR (FAO, 2018) x CF (2)
Soybean	0.1	STMR (FAO, 2014) x CF (2)	0.1	STMR (FAO, 2014) x CF (2)
Maize grain	0.02	STMR (FAO, 2014) x CF (2)	0.02	STMR (FAO, 2014) x CF (2)
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, edible offal of swine, bovine, sheep, goat, equine, other farmed animals	0.025	STMR[(b)] (FAO, 2009b)	0.15	HR[(b)] (FAO, 2009b)
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)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Liver, kidney, edible offal of poultry	0.071	STMR[(b)] (FAO, 2018)	0.071	HR[(b)] (FAO, 2018)
Milk	0.005	STMR (EFSA, 2014)	0.005	HR (EFSA, 2014)
Eggs	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residuedefinition.
(a): Values refer to the residues of prothioconazole-desthio; data according to Eu risk assessment residue definition notavailable.
(b): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxyand their conjugates expressed as prothioconazole-desthio

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-157: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	N/A
IEDI (% ADI) according to EFSA PRIMo	15% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Highest IESTI Unprocessed: 19% Bovine Liver Highest IESTI Processed: 5% Wheat / milling (flour)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of Prothioconazole in the formulation ~~SAP250F~~ SAP2101F do not represent unacceptable acute and chronic risks for the consumer.

Since triazole derivative metabolites may be generated by several pesticides belonging to the group of triazole fungicides, the new definition of the residue established by EFSA (EFSA, 2018) and the Commission (EC, 2021) indicates that a separate risk assessment should be performed for TDMs.
In this regard, the conclusions of EFSA following the peer review of the initial risk assessment for the TDMs metabolites have been recently published (EFSA, 2018). As stated by them, confirmatory data submitted was not sufficient in order to finalise the consumer risk assessment for several active substances, including prothioconazole. Therefore, the consumer risk assessment is inconclusive at the moment of this submission.
Despite the identified data gaps, a "worst-case" consumer dietary intake assessment for the complete group of triazole active substances was conducted by the RMS using the EFSA PRIMo rev.3 and by EFSA using the EFSA PRIMo rev.2A since PRIMo rev.3 was not applicable in the framework of confirmatory data assessed (EFSA, 2018). The chronic and acute dietary intakes were carried out using the highest input residue values for risk assessment (STMR values and the 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. Residue data presented in table 7.2-10 represent lower residue levels of 1,2,4-T, TA, TAA and TLA than the ones used in the assessment performed under the confirmatory data on the triazole derivative metabolites. Therefore, the conclusions drawn by EFSA (EFSA, 2018) are still valid to support the uses targeted in the current dossier.

Using the EFSA PRIMo rev.3, the highest IEDI accounted was 93% of the ADI (NL toddler) for the metabolite 1,2,4-T. The highest IESTI accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-T. Using the EFSA PRIMo rev.2A, the highest IEDI accounted for 60% of the ADI (FR toddler) for 1,2,4-T. The

highest acute intake was estimated to be 40% of the ARfD (milk) for 1,2,4-T. Considering the mentioned results, no chronic or acute intake concerns were identified neither for the PRIMo rev.3 nor the PRIMo rev.2A calculations (EFSA, 2018).

Regarding the evaluation exposed above, the RMS concluded that "the outcome of the consumer intake assessment raises no concerns". UK also stated that the confirmatory data requirements were satisfactorily addressed and, pending the outcome of some data gaps, that the approval of several substances including prothioconazole may continue.

Nonetheless, and according to Evaluator request, other PRIMo 3.1 additional evaluations have been performed using available unprotected data for prothioconazole TDMs, together with new data TMDs values. When both values are available, the most critical one has been selected .

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat				
1,2,4 T	0.01	STMR (EFSA, 2018)	0.01	~~HR~~ STMR (EFSA, 2018)
TA	0.5	STMR (EFSA, 2018)	~~1.1~~ 0.5	~~HR~~ STMR (EFSA, 2018)
TAA	0.189	STMR (EFSA, 2018)	~~0.38~~ 0.189	~~HR~~ STMR (EFSA, 2018
TLA	0.01	STMR (EFSA, 2018)	0.01	~~HR~~ STMR (EFSA, 2018
Barley				
1,2,4 T	0.01	STMR (EFSA, 2018)	0.01	~~HR~~ STMR (EFSA, 2018)
TA	0.208	STMR (EFSA, 2018)	~~0.83~~ 0.208	~~HR~~ STMR (EFSA, 2018)
TAA	0.107	STMR (EFSA, 2018)	~~0.32~~ 0.107	~~HR~~ STMR (EFSA, 2018)
TLA	0.01	STMR (EFSA, 2018)	~~0.03~~ 0.01	~~HR~~ STMR (EFSA, 2018)
Rest of commodities with available data				
1,2,4 T	STMR	EFSA, 2018	-	-
TA	STMR	EFSA, 2018	-	-
TAA	STMR	EFSA, 2018	-	-
TLA	STMR	EFSA, 2018	-	-

Evaluator comment:
Calculations presented by the Applicant are acceptable.
Prothioconazole
The calculation of the IEDI using EFSA model (version 3.1) and STMR values and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 15% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is milk: Cattle with 3% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-desthio.

An acute consumer risk assessment was performed based on the highest residue values (HR) and STMR values of crops and animal commodities. The highest International Estimated Short-Term Intake (IESTI) is at 19% and 16% of the ARfD for the consumption of Bovine: Liver by children and Swine: Other products by adults respectively.

If only commodities proposed in the framework of this application are considered for acute exposure, the highest International Estimated Short-Term Intake (IESTI) will be at 3% and 1% of the ARfD for the consumption of wheat and barley respectively.

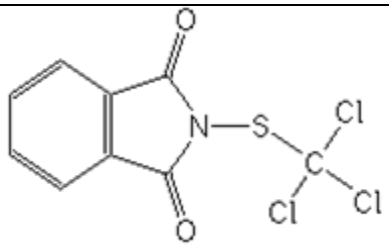
TDMs
The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) were taken into account.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.
The intended uses of SAP2101F are accepted.

7.3 Folpet

General data on folpet are summarized in the table below (last updated 02/05/2022).

Table 7.3-1 General information on folpet

Active substance (ISO Common Name)	Folpet
IUPAC	N-(trichloromethylthio)phthalimide
Chemical structure	
Molecular formula	$C_9H_4Cl_3NO_2S$
Molar mass	296.6 g/mol
Chemical group	Phthalimides fungicides such as captan or captafol
Mode of action (if available)	It inhibits many oxidative enzymes, carboxylases and enzymes involved with phosphate metabolism and citrate synthesis
Systemic	~~No~~ Yes
Company (ies)	Makhteshim Agan International (MKA)*
Rapporteur Member State (RMS)	Austria (former RMS: Italy)
Approval status	Approved 01/10/2007 (2007/5/EC)[2]
Restriction	Use restricted as fungicide.
Review Report	SANCO/10032/2006 – rev. 5 11/07/2008
Current MRL regulation	Reg. (EU) 2023/1042
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2009)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2014)
Current MRL applications on intended uses	No

7.3.1 Stability of Residues (KCA 6.1

7.3.1.1 Stability of residues during storage of samples

Available data

The stability of residues for Folpet was already addressed during the EU Review process.

New stability studies have been submitted by the applicant in the framework of this application. Due to some difficulties found during the development of the method of analysis, the stability studies could not be started in its due time and are still ongoing at the time of submission of this dossier. The studies will be provided once finished and results summarized in **Table 7.3-2** below will be updated. Interim reports for 1 year storage in wheat and barley grain and straw are provided; this on year time interval covers the storage that has taken place in residue trials, proving stability of residues up to one year. The study will be continued to prove stability for longer intervals, as well as for additional folpet metabolites, not relevant for this

[2] OJ L 35, 8.2.2007, p. 11–17

dossier. So this interim is equivalent to a final report, as far as the current dossier is considered. The detailed as-sessment of these studies is presented in Appendix 2.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU (only Folpet)			
Plant products			
Grapes	High acid content	>12 months	Italy, 2005
Grapes juice	High acid content	1 month	Italy, 2005
Cereal (grain and straw)	Dry commodities	>12 months	Italy, 2005
Tomato (whole fruit)	High water content	3 months	Italy, 2005
Tomato (pure and paste)	High acid content	1 month	Italy, 2005
New data (Folpet and phthalimide)			
Plant products			
Wheat (grain)	High starch content	340 days (interim) 18 months (ongoing)	Gordo, J. 2024. Report nº EST06/22.
Barley (grain)	High starch content	340 days (interim) 19 months (ongoing)	Gordo, J. 2024. Report nº EST06/22.
Wheat (straw)	Other commodities	362 days (interim) 18 months (ongoing)	Joos, S. 2024. Report nº S22-07592
Barley (straw)	Other commodities	362 days (interim) 19 months (ongoing)	Joos, S. 2024. Report nº S22-07592
Wheat (whole plant)	High water content	362 days (interim) 20 months (ongoing)	Joos, S. 2024. Report nº S22-07592
Barley (whole plant)	High water content	362 days (interim) 19 months (ongoing)	Joos, S. 2024. Report nº S22-07592
Beer	High water content	6 months	Joos, S. 2024. Report nº S22-07592

Conclusion on stability of residues during storage

The stability of residues for the active substance folpet was already addressed during the EU Review process. It has been proved that folpet is stable on cereal grain and straw for more than one year. In the magnitude studies, wheat and barley grain and straw underwent a maxi-mum storage interval of 340 days and are thus partially covered by the available stability data. Furthermore, new data are provided to cover the stability of both folpet and phthalimide in cereal matrices (whole plant, grain and straw) and processed products (beer). The study was ongoing at the moment of the initial submission and the report covering 12 months interval for cereal matrices and 6 months interval for beer is provided here. No further data is required.

zRMS comments:
Cereal grain is considered as a high starch content commodity, whole plant of cereals is high water content commodity and straw is other commodity according to the OECD 506.
The stability of residues for the active substance folpet were reviewed at the EU level.

According to the EFSA Scientific Report (2009) 297, 54-80 – "Conclusion on the peer review of folpet":
Storage stability data were presented for grapes, grain and straw, whole tomato, tomato pure and paste, grape juice. Folpet is stable in grapes, grain and straw for periods longer than 1 year.
No data are available for phthalimide.

In summary, according to the unprotected data, the active substance folpet was shown to be stable under frozen storage for 12 months in cereal grains and straw, but storage stability data of phthalimide are not available.

Two new studies on storage stability data of folpet and phthalimide (Gordo, J. 2024, Report nº EST06/22 and Joos, S. 2024, Report nº S22-07592) are provided. The studies are ongoing at the moment of initial zRMS assessment. On May 2024 interim reports have been provided by Applicant. Residues of folpet and phthalimide are stable at –18°C when stored for up to 11-12 months in high starch content commodities (wheat and barley grain) and in high

water content commodities (whole plant of cereals), in other commodities (straw) and for 6 months in beer.
Since the maximum storage period of cereals samples in the magnitude studies was 350 days, it appears that the new storage stability data cover this time.

For folpet and phthalimide in beer, the maximum storage intervals from sampling until extraction were 140 days and new storage stability data cover this time.

These data are sufficient to support the residue trials on cereals.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

In some trial studies, timing between sample extraction and analysis overpassed 24 hours. However, in all studies, recovery experiments were performed concurrently with the analysed samples. The recovery rates for the studies presented in this dossier were acceptable, meaning that residues were stable in the sample extracts.

Available data
No further data is required.

Conclusion on stability of residues in sample extracts
Extracts of residue samples of folpet in cereals were shown to be stable for at least 7 days for wheat and 12 days for barley.

zRMS comments:
Procedural recoveries obtained during residue analysis demonstrate the stability of residues of folpet in sample extracts. No additional study is required.

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
Studies on metabolism of folpet in plants were already addressed during the EU Review process and were considered acceptable. Uptake, translocation and metabolism of folpet were evaluated in in DAR on folpet (Italy, 2005), Volume 3, B7. Information on crops tested, application and sampling details are given in **Table 7.3-3** below.
No new data submitted in the framework of this application.

Table 7.3-3 Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate [kg a.s./ha]	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grapes	U-phenyl	Foliar treatment, F	1.5	3	23	-	Italy, 2005
	Avocados		Foliar treatment, F	3.36	3	21, 97	-	
	Tomatoes	Carbonyl	Soil treatment, G	0.1 mg/ plants	1	1, 4, 7, 11	-	EFSA, 2009
Root and tuber vegetables	Potatoes	U-phenyl	Foliar treatment	2	5	1 (after 1st, 2nd and 3rd application) 3, 5 D (after last application)	-	Italy, 2005
Cereals	Winter wheat	U-phenyl	Foliar treatment	1.6	2	1, at BBCH 83, at harvest	-	Italy, 2005

Summary of plant metabolism studies reported in the EU

The metabolism of folpet in plants was investigated on winter wheat, grapes and avocadoes under similar modes of application. The metabolism of folpet was similar in the investigated crops. In addition, studies on tomatoes and potatoes were also submitted giving information on the nature of residues translocated from roots to foliar parts and from leaves to tubers.

In wheat samples taken at normal harvest, the highest residue levels were identified in both grain and straw (23 and 15 mg eq/kg, respectively). Folpet (35.8 % TRR) and its metabolites phthalimide[3] (31.6 % TRR) and phthalic acid (11.2 % TRR) were the major compounds in grain. The situation was similar in straw.

Metabolism studies in grapes and avocados showed that folpet residues easily go through fruit peel. In these crops, parent compound was further degraded, accounting for only 0.5 to 12.8 % of the TRR in mature fruits. The main identified metabolites were phthalic acid (81.9 % TRR in avocado) and its conjugate (41.4 % TRR in grape), both resulting from phthalimide hydrolysis. Phthalimide only accounted for 0.86 to 3.9 % of the TRR in fruits. Other metabolites were found in very small amounts.

Metabolism studies in tomatoes and potatoes gave information on the nature of residues translocated from roots to foliar parts and from leaves to tubers. Residues were rapidly absorbed from the nutrient solution by tomato roots and translocated to tops. However, translocation from foliar parts to roots is limited. In these conditions, phthalic acid and phthalamic acid[4] were the most important components of the residues. About 63 to 80 % of the TRR were due to these compounds in tomatoes and potatoes. Very low levels of parent compound (<0.1 % TRR) indicate that folpet does not translocate from fruits to tubers nor from roots to tops. Phthalimide accounted for 0.5 % of the TRR in potato tubers and up to 5.9 % TRR in tomatoes. Unknown metabolites were also present at 2.9 to 14.1 % of the TRR. These were tentatively identified as phthalamic acid derivative.

The metabolism of folpet is similar in the investigated crops. The parent compound is first degraded to phthalimide through release of the trichloromethylthioside chain. The thiophosgene produced through this cleavage is assumed to be rapidly transformed into CO_2 and incorporated in natural plant components, as demonstrated with metabolism studies on captan. Phthalimide is further hydrolysed to phthalamic acid, phthalic acid and related conjugates (EFSA, 2009). Phthalic acid and phthalamic acid are of no particular concern. Furthermore, phthalic acid and phthalamic acid can naturally occur in the environment and they cannot be considered as specific to folpet. Therefore, both phthalic acid and phthalimic acid should not be taken into account in the residue definition.

The toxicological relevance of phthalimide has been extensively discussed during the peer-review under Council Directive 91/414/EEC and additional toxicological data were assessed following the inclusion of

[3] 1H-isoindole-1,3(2H)-dione,
[4] 2-carbamoylbenzoic acid

Folpet (Italy, 2008). Based on these studies, it was agreed by experts that phthalimide is less toxic than folpet. However, a complete toxicological assessment of this metabolite was not available and no toxicological endpoints could be derived. In the absence of such data, the toxicological endpoints of folpet were used for phthalimide.

Summary of new plant metabolism studies
No additional metabolism studies are required for this dossier as the monograph data covers uses on cereals.

Conclusion on metabolism in primary crops
Folpet is extensively degraded in all crops, especially in fruits and potatoes. EFSA (2009) concludes that the residue for enforcement and risk assessment purpose in all plant commodities can be defined as folpet and phthalimide. Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products and the capabilities of enforcement analytical methods, the residue definitions for risk assessment and enforcement as proposed in the framework of the peer review (EFSA, 2009) were: sum of folpet and phtalimide, expressed as folpet.

zRMS comments:
The metabolism of folpet in primary crops following foliar application in crops belonging to the groups of fruit crops (grapes, avocados, tomatoes), root crops (potatoes) and cereals/grass (wheat) has been investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2009, 2014).
Folpet was extensively metabolised in all tested crops, especially in fruits and potatoes, to phthalimide, phthalamic acid and phthalic acid (EFSA, 2021).

Residue definitions:
The residue definitions for risk assessment and enforcement as proposed in the framework of the peer review (EFSA, 2009) were sum of folpet and phthalimide, expressed as folpet.
The residue definition for enforcement in plant commodities set in Regulation (EC) No 396/2005 (Reg. (EU) 2023/1042) is identical with the above mentioned residue definition.

For the intended uses on barley and wheat the metabolic behaviour in primary crops is sufficiently addressed.
No additional study is required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data
EFSA Journal 2021;19(5):6578
The crops under consideration may be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, the DT90 values for folpet, phthalimide and the soil metabolites phthalic acid and phthalamic acid are expected to range between 1 and 94 days (under laboratory conditions) which are below the trigger value of 100 days.
Additionally, the half-lives of folpet and phthalimide are < 3 days under field conditions (EFSA, 2009, 2014). According to the European guidelines on rotational crops (OECD, 2018), further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.
No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops
No data on the nature of residues in rotational crops is required for the intended use.

zRMS comments:
Data presented by Applicant in point 7.3.2.2 are sufficient. No additional study is required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Residue levels of 0.01 mg/kg or higher may occur in barley and wheat grains which may be processed. Therefore, data on the nature of the residue in processed commodities is discussed below.

Available data
One new hydrolysis study available from RAR has been evaluated and accepted by EFSA in the frame of folpet renewal and is presented here. This study is summarized in **Table 7.3-4** below. The detailed results of this study are presented in Appendix 2 for the sake of completeness, as they have been already evaluated at EU level, under the framework of folpet renewal.

Table 7.3-4 Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) [%]	Reference
EU data		
Pasteurisation (20 min, 90°C, pH 4)	Phthalimide (97.8 %) Phthalamic acid (0.4%) Phthalic acid (1.0 %) Unidentified 3 (0.5%)	EFSA, 2023 M Fitzmaurice and E Mackenzie, 2007, report No OZ/07/007*
Baking, boiling, brewing (60 min, 100°C, pH 5)	Phthalimide (56.1 %) Phthalamic acid (2.8%) Phthalic acid (40.7 %)	
Sterilisation (20 min, 120°C, pH 6)	Phthalimide (6.0 %) Phthalamic acid (32.8%) Phthalic acid (44.9 %) 2-Cyanobenzoic acid (11%) Unidentified 1 (4.5%)	

* Selectis Produtos para a Agricultura, S.A. has LoA from ASCENZA AGRO

Conclusion on nature of residues in processed commodities
Based on the available data it can be concluded that folpet is rapidly hydrolyzed into phthalimide, phthalamic acid and phthalic acid under standard hydrolysis conditions.

zRMS comments:
EFSA (2014) concluded that *In the framework of the peer review, only studies conducted at room temperature were available to investigate the effect of processing on the nature of folpet. Although these studies indicate the transformation of folpet into phthalimide and phtalic acid, they were not deemed sufficient to conclude on the nature of the residue in processed commodities (EFSA, 2009). In the framework of an MRL application, studies 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) were provided and evaluated (EFSA, 2011a). The results of the studies indicated that folpet is completely degraded during processing; phthalimide is formed predominantly under conditions of pasteurisation (92 % TRR) while levels of phthalic acid increase under conditions simulating boiling/brewing/baking (42.2 % TRR) and sterilisation (91.4 % TRR). After processing, the main residues are therefore composed of metabolites already identified in the plant metabolism study where phthalimide was found to be the only metabolite of toxicological relevance (see also section 3.1.1.1). Consequently, as for the primary crops, the relevant residue for enforcement and risk assessment in processed commodities is defined as the sum of folpet and phthalimide, expressed as folpet.*

The hydrolysis studies demonstrate that folpet is completely degraded during processing; phthalimide is formed predominantly under conditions of pasteurisation, while levels of phthalic acid increase under conditions simulating boiling/brewing/baking and sterilisation. Considering that phthalamide was the only compound of toxicological relevance, the relevant residue for enforcement and risk assessment is processed commodities was also defined as the sum of folpet and phthalimide, expressed as folpet.

Residue definition:
The residue definition for processed products as proposed in the framework of the peer review (EFSA, 2009) is sum of folpet and phthalimide, expressed as folpet.

One study on the nature of residues in processed commodities is provided. The results showed that folpet is rapidly hydrolyzed into phthalimide, phthalamic acid and phthalic acid under standard hydrolysis conditions. This study also provided for the renewal process of folpet has been assessed in RAR and accepted by EFSA in folpet peer review (2023).

AIR peer review is still ongoing at the time of this submission. Therefore, currently the old endpoints still apply and the results of M Fitzmaurice and E Mackenzie study (2007, report No OZ/07/007) and the possibly new residue definition for processed commodities do not need to be discussed at this stage.
No additional data are required.

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

Table 7.3-5 Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits and fruiting vegetable (grapes, avocados, tomatoes), root and tuber vegetables (potatoes) and cereals (winter wheat)
Rotational crops covered	Not relevant
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant
Processed commodities	Folpet is rapidly hydrolyzed into phthalimide, phthalamic acid and phthalic acid under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Sum of folpet and phthalimide expressed as folpet (Reg. (EU) ~~2018/832~~ 2023/1042)
Plant residue definition for risk assessment	Sum of folpet and phthalimide, expressed as folpet (EFSA, 2009, 2014)
Conversion factor from enforcement to RA	-

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

Available data

Studies on metabolism of folpet in livestock have been evaluated during the EU Review process and were considered acceptable. Metabolism studies in lactating goats have been assessed in the framework of the EU pesticides peer review and the EFSA MRL review (EFSA, 2009, 2014). The studies were performed for the parent only but were considered acceptable since folpet was extensively metabolised during the study to generate thiophosgene and phthalimide. Thiophosgene is further converted to thiazolidine and incorporated into natural products such as amino acids, sugars and fats whereas phthalimide is metabolised to phthalamic acid and phthalic acid. The latter one may dehydrate to phthalic anhydride, but this reaction is expected to be reversible and phthalic acid is likely to be formed again via hydrolysis in aqueous solutions. As a similar metabolic pathway was found in ruminants can be extrapolated to pigs (EFSA, 2014). A more recent study in poultry was submitted in the framework of the renewal (Austria, 2018).

Studies are summarised in **Table 7.3.-6** below. Further data on the metabolism of folpet in livestock is therefore not required.

Table 7.2-6 Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate [mg/kg bw/d]	Duration [days]	Commodity	Time of sampling	
EU data								
Lactating ruminants	Lactating goat	Benzene ring [U-phenyl-^{14}C]folpet	1	14-24 mg/kg diet/day	6	Milk	twice daily	Italy, 2005 (DAR)
						Urine and faeces	daily	
						Tissues	at sacrifice	
		[trichloromethyl-^{14}C]folpet	1	14-24 mg/kg diet/day	6	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
Poultry	Laying hens	[U-phenyl -^{14}C] folpet	10 per groups	0.020 mg/kg bw/d (0.31 mg/kg feed) Or 0.63 mg/kg bw/d (10 mg/kg feed)	7	Eggs	Twice daily	Austria 2018 (RAR)
						Excreta	Twice daily	
						Tissues	at sacrifice	
New data								
No new data provided								

Summary of animal metabolism studies reported in the EU

In ruminants, the substance is extensively metabolised and excreted and was not found in any edible tissue. After oral administration for 6 days at dose rate of 14 mg/kg diet, residues in animal tissues were very low and no sign of accumulation is present. Only in liver and kidneys Total Radioactive Residues were above 0.01 mg eq folpet/kg (0.02 and 0.05 mg/kg respectively). The metabolism was found to be similar to that observed in rats with hydrolysis of the nitrogen-sulphur bond leading to thiophosgen and phthalimide which is further metabolised to phthalamic acid and phthalic acid.

In eggs and tissues, the total residues were less than 1% of the total radioactive residue (TRR). Apart from folpet (3.8% and 51% TRR in the low and high dose group respectively) the following metabolites were identified in the excreta for the low and high dose group respectively: phthalimide (4.9% and 5.4% TRR), phthalic acid (22.1% and 12.6% TRR), phthalamic acid (21.3% and 11.4% TRR) and phthalic anhydride (8.2% and 5.2% TRR). These results suggest a similar metabolic pathway between poultry and ruminants. Therefore, the residue definition derived for ruminants and pigs is also applicable for poultry commodities.

Summary of new animal metabolism studies

No new study provided and no further data required.

Conclusion on metabolism in livestock

Based on the studies in ruminants and poultry, the following residue definition was derived for enforcement and risk assessment in animal commodities except honey: phthalimide expressed as folpet. The residue is not fat soluble (EFSA, 2009, 2014, 2021).

Taking into account both the results of the metabolism study and dietary burden results no residue of folpet or phthalimide above the usual LOQ of method of analysis are expected.

zRMS comments:

The nature of folpet residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (EFSA, 2009). Reported metabolism studies include two studies in lactating goats using U-^{14}C-phenyl and ^{14}C-trichloromethyl labelled folpet.

Residue definitions:
The residue for enforcement and risk assessment in commodities of ruminants and pigs was defined as phthalimide, expressed as folpet (EFSA, 2009).
In the framework of the peer review, the proposed residue was not considered to be fat soluble (EFSA, 2009).

A new metabolism study in poultry was provided and assessed in the framework of renewal of active substance (2018). The results suggest a similar metabolic pathway between poultry and ruminants. The overall picture of the animal metabolism studies, the current animal residue definition for enforcement and risk assessment is confirmed as phthalimide, expressed as folpet.

It should be noted that Selectis is not owner of new metabolism study in poultry and Selectis should submit a new study. However, taking into consideration art. 62 of Reg (EU) 1107/2009 'Member States shall not accept duplication of tests', thus a new study should not be conducted to support the intended uses.

SELECTIS Reply:
ASCENZA are currently under negotiation with Adama Makhteshim Ltd, the data owner, for the co-ownership of the study [redacted] *(KCA 6.2.2/01), according with Article 62 of the Regulation 1107/2009. Article 62 also allows member States to use vertebrate studies for the purpose of the application of a prospective applicant who has not been able to reach agreement on sharing the data with the data owners. Evidence for the ongoing negotiations are shared within this reply.*
Additionally, we would like to inform you that we are in a joint task force with Adama Makhteshim Ltd (data owner of the mentioned study), with the common purpose of the renewal of the active substance Folpet under AIR3 (we are both notifier of Folpet).

Therefore, it is expected from the applicant to submit a letter of access to the metabolism study on poultry.
October 2024: The applicant submitted a letter of access for folpet to the metabolism study on poultry.

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

Table 7.3-7 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	4 days in milk
	3 days in egg white and 7 days in egg yolk
Animal residue definition for monitoring	Phthalimide expressed as folpet (~~SANTE/10884/2021~~ Reg. (EU) 2023/1042)
Animal residue definition for risk assessment	Phthalimide expressed as folpet (EFSA 2009, 2014)
Conversion factor	/
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 7.3.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.3-8 Summary of new data supporting the intended uses of ~~SAP50SCF~~ SAP2101F and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels [mg/kg] 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] Reg. (EU) 2023/1042	MRL compliance
Wheat grain	New trials	N-EU	**Trials GAP: 2 x 0.60 kg a.s. /ha, up to BBCH61, PHI 34-78** 4x<0.03, 0.032, 0.044, 0.060, 0.087					
	Overall supporting data for cGAP	N-EU	4x<0.03, 0.032, 0.044, 0.060, 0.087	0.03	0.09	0.15	0.4	Yes
Wheat straw	New trials	N-EU	**Trials GAP: 2 x 0.60 kg a.s. /ha, up to BBCH61, PHI 34-78** 1.7, 2 x 1.8, 2 x 3.4, 3.9, 5.0, 7.6					
	Overall supporting data for cGAP	N-EU	1.7, 2 x 1.8, 2 x 3.4, 3.9, 5.0, 7.6	3.40	7.60	-		
Barley grain	New trials	N-EU	**Trials GAP: 2 x 0.60 kg a.s. /ha, up to BBCH61, PHI 34-50** <0.03, 0.047, 0.050, 0.072, 0.28, 0.29, 0.34, 0.75.					
	Overall supporting data for cGAP	N-EU	<0.03, 0.047, 0.050, 0.072, 0.28, 0.29, 0.34, 0.75.	0.18	0.75	1.50	2	Yes
Barley straw	New trials	N-EU	**Trials GAP: 2 x 0.60 kg a.s. /ha, up to BBCH61, PHI 34-50** 2 x 1.70, 2.10, 2.70, 3.50, 3.90, 4.50, 8.50					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels [mg/kg] 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] Reg. (EU) 2023/1042	MRL compliance
	Overall supporting data for cGAP	N-EU	2 x 1.70, 2.10, 2.70, 3.50, 3.90, 4.50, 8.50	3.10	8.5	-		

N/A: Not applicable

7.3.3.2 7.3.3.2 Conclusion on the magnitude of residues in plants

Wheat and barley are major crops in CEU countries and though require 8 NEU residue data in each crop, as the product is to be sprayed in the crop after the forming of the edible part. Those data have been provided.
According to the available data, the intended uses on wheat and barley are considered acceptable. The data show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS comments:
The proposed uses for SAP2101F are wheat and barley.

Wheat and barley are the major crops in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANTE/2019/12752).

16 independent trials were conducted in Northern Europe according to the OECD Test No. 509 to gain the residue level of folpet and its two metabolites phthalimide and phthalic acid in wheat (8 trials) and barley (8 trials) specimens (whole plant, grain and straw) following two foliar applications of SAP50SCF, containing folpet as active ingredient (500 g a.s./L, equivalent to 600 g a.s./ha).
Trials GAP for wheat: 2 x 0.60 kg a.s. /ha with 12-21 days between application, up to BBCH 61, PHI 34-78.
Trials GAP for barley: 2 x 0.60 kg a.s. /ha with 12-21 days between application, up to BBCH 61, PHI 34-50.
The presented residue trials cover the intended uses.

The residues of folpet (sum of folpet and phthalimide expressed as folpet) in the wheat grain samples were 4x<0.03, 0.032, 0.044, 0.060, 0.087 mg/kg.

The residues of folpet (sum of folpet and phthalimide expressed as folpet) in the barley grain samples were <0.03, 0.047, 0.050, 0.072, 0.28, 0.29, 0.34, 0.75 mg/kg.

The value of EU MRL for folpet on wheat and barley equals 0.4 mg/kg and 2 mg/kg, respectively (Reg. (EU) 2023/1042). The residues arising from the proposed uses will not exceed the MRLs established for cereals.
The current EU MRLs for folpet are sufficient to support the proposed uses.

Additional studies are not required to support the proposed uses of SAP2101F.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The dietary burden calculation has been performed following the assessment recently performed by EFSA (EFSA, 2021).The input values used have been included below in the 2017 Animal Model, the most critical value between EFSA data and new data evaluated in this dossier has been selected.
Input values used are included in table 7.3-9 and results of the dietary burden calculation are shown in table 7.3-10.

Table 7.3-9 Input values for the dietary burden calculation (considering the uses evaluated by EFSA (2021) and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value [mg/kg]	Comment	Input value [mg/kg]	Comment
Risk assessment residue definition: Sum of folpet and phthalimide, expressed as folpet				
Barley straw	3.10	STMR	8.50	HR
Oat straw	3.10	STMR	8.50	HR
Rye straw	3.40	STMR	9.10	HR (EFSA, 2014)
Triticale straw	3.40	STMR	9.10	HR (EFSA, 2014)
Wheat straw	3.40	STMR	9.10	HR (EFSA, 2014)
Potato culls	0.10	STMR (EFSA, 2014)	0.10	HR (EFSA, 2014)
Barley grain	0.18	STMR	-	-
Oat grain	0.18	STMR	-	-
Rye grain	0.12	STMR (EFSA, 2014)	-	-
Triticale grain	0.12	STMR (EFSA, 2014)	-	-
Wheat grain	0.12	STMR (EFSA, 2014)	-	-
Apple, wet pomace	0.3	STMR (EFSA, 2017)xPF(5) [(a)]	-	-
Brewers' grain	0.003	STMRxPF (0.016)	-	-
Distiller's grain	0.40	STMR (EFSA, 2014)xPF(3.3)[(a)]	-	-
Potato, process waste	2.00	STMR (EFSA, 2014)xPF(20)[(a)]	-	-
Potato, dried pulp	3.80	STMR (EFSA, 2014)XPF(38)[(a)]	-	-
Wheat gluten meal	0.22	STMRxPF(1.8)[(a)]	-	-
Wheat, milled by-products	0.84	STMRxPF(7.0)[(a)]	-	-

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): In the absence of processing factors supported by data for distiller's grain, potato process waste, potato dried pulp, wheat gluten meal and wheat milled by-products, default processing factors (in bracket) were respectively included in the calculation to consider the potential concentration of residues in these commodities.

Table 7.3-10 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)
Risk assessment residue definition: Sum of folpet and phthalimide, expressed as folpet					
Cattle (all diets)	0,239	0,309	Potato, process waste	9,68	Y
Cattle (dairy only)	0,239	0,309	Potato, process waste	8,04	Y
Sheep (all diets)	0,292	0,413	Potato, process waste	12,40	Y
Sheep (ewe only)	0,292	0,413	Potato, process waste	12,40	Y
Swine (all diets)	0,084	0,084	Potato, process waste	3,64	Y
Poultry (all diets)	0,083	0,128	Wheat, straw	1,86	Y
Poultry (layer only)	0,083	0,128	Wheat, straw	1,86	Y

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

zRMS comments:
Wheat and barley are used for livestock feed purposes.
The previous dietary burden calculation (EFSA, 2021) to estimate whether the intended use of folpet would have an impact on the residues expected in food of animal origin has been updated.
The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw/day. Further investigation of folpet residues is therefore required in all commodities of animal origin.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

The calculated dietary burdens for poultry and ruminants exceed the trigger value of 0.10 mg/kg bw/day. Thus, the results of the metabolism studies were used for further considerations.

According to poultry metabolism study, no residues above the LOQ are expected in any tissues or in eggs. Indeed, at the dose of 10 mg/kg feed for folpet tested in the metabolism study in poultry, being the closest one to the maximum dietary burden for poultry, the estimated total residues are far below the LOQ (0.01 mg/kg). Therefore no feeding studies in poultry are required.

According to the metabolism study in ruminants no residues above LOQ are expected in tissues or milk. The rate tested in the metabolism study in lactating ruminants covers the dietary intake for dairy and meat ruminants calculated above. Following an administration of 24 mg trichloromethyl-^{14}C-folpet/ kg diet (equivalent to 0.367 mg/kg bw/day) residues of 0.181 mg folpet eq./kg (milk, plateau concentration), 0.25 mg folpet eq./kg (liver) and 0.16 mg folpet eq./kg (kidney) were found. Following an administration of 13.6 mg benzene-^{14}C-folpet/ kg diet (equivalent to 0.344 mg/kg bw/day) residues of 0.006 mg folpet eq./kg (milk, plateau concentration), 0.022 mg folpet eq./kg (liver) and 0.055 mg folpet eq./kg (kidney) were found. Based on dietary burden results, residue levels are not expected to occur in ruminant matrices at levels above the LOQ of 0.05 mg/kg. Therefore no feeding studies in lactating ruminants are required.

This same conclusion has been reached by EFSA on the frame of Folpet conclusion of peer review (2023): *"The dietary burden calculation, indicates already an exceedance of the dietary burden trigger value for both, ruminants and poultry. Based on the results of the metabolism studies and the preliminary dietary burden calculation, residues are not expected in poultry and ruminant commodities."*

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.164	Ram/Ewe	0.444	Breeding	0.009	Broiler	0.019	Carp	0.208
	Dairy cattle	0.261	Lamb	0.566	Finishing	0.011	Layer	0.097	Trout	0.118
							Turkey	0.016	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes		Yes		Yes		Yes		Yes	
Feeding study submitted	No Feeding study covered by available metabolism studies. No residues above 0.01 mg/kg in milk and any edible tissue are expected. No feeding studies required.		No		No		No Feeding study covered by available metabolism studies. No residues above 0.01 mg/kg in milk and any edible tissue are expected. No feeding studies required.		No The uptake of folpet and phthalimide residues by fish is considered to be negligible due to the low bioconcentration and bioaccumulation potential of folpet and its metabolites and the fast depuration of folpet residues by fish. No study required	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals
Muscle										
Fat										
Meat[b]										
Liver										
Kidney										
Milk[a]										
Eggs										
Method of calculation[c]										

[a]: Estimated HR calculated at 1N level (**estimated mean level for milk**).

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.023	Ram/Ewe	0.051	Breeding	0.009	Broiler	0.019	Carp	
	Dairy cattle	0.035	Lamb	0.065	Finishing	0.011	Layer	0.033	Trout	
							Turkey	0.016		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N
Muscle										
Fat										
Meat[a]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[c]										

[a]: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[b]: When the mean level is set at the LOQ, the STMR is set at the LOQ.
[c]: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

Conclusion on feeding studies
No feeding studies are required. The requested uses do not modify the theoretical maximum daily intake for animals, there is no risk for animal MRL to be exceeded.

zRMS comments:
It should be noted that Selectis is not owner of new metabolism study in poultry and no data are available to demonstrate that values of MRL in poultry commodities would not be exceeded.
A new metabolism study in poultry was provided and assessed in the framework of renewal of active substance (2018) (see zRMS comments in point 7.3.2.5). Ascenza are currently under negotiation with Adama Makhteshim Ltd, the data owner.
Pending the submission of the letter of access to the study it can be concluded that considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.
October 2024: The applicant submitted a letter of access for folpet to the metabolism study on poultry. The above conclusions are still valid.

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

New studies were also submitted by the applicant.

7.3.5.1 Available data for all crops under consideration

A total of 6 residue trials (3 in wheat and 3 in barley) for processing were initially set during 2021 to determine the processing factors for both folpet and phthalimide. However, from these 6 trials only samples from 2 trials on barley could be processed and analysed. The samples of the rest of the trials were lost since samples were thawed during the processing phase.

Actually, for wheat, as the residue are all below 0.1 mg/kg and the ADI and ARfD are below 10%, processing studies are not required to support wheat in the present dossier. In consequence, no additional processing trials have been undertaken.

For barley, new processing studies have been submitted by the applicant in the framework of this application. As the processing factor (PF) in the two processing barley studies does not differ more than 50%, according to OECD guideline OECD 508 “Magnitude of the Pesticide Residues in Processed Commodities”, no additional trials on barley processing are required. These studies are summarized in **Table 7.3-11** below. The detailed results are presented in Appendix 2.

Table 7.3-11 Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
New data					
Sum of folpet and phthalimide, expressed as folpet					
Barley, brewing malt	2	0.028	-	-	KCA 6.5.3/01
Barley, malt sprout	2	0.125	-	-	
Barley, dried brewer’s grain	2	~~0.016~~ 0.022	-	-	
Barley, brewing yeast	2	<0.02	-	-	
Barley, beer	2	<0.03	-	-	

* 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.

7.3.5.2 Conclusion on processing studies

Processing studies are available for the following intended crops: ~~wheat and~~ barley. For wheat, no processing studies are required in the present dossier, due to residue levels and impact on diet, although an unprotected study on processing wheat is available. For barley, robust processing factors were obtained for

processing to beer as given in **Table 7.3-11** above, with PF differing less than 50% in the 2 studies performed. No more data is required.

zRMS comments:
Processing studies are normally necessary if the residue level > 0.1 mg/kg in RAC or if the total theoretical maximum daily intake (TMDI) is higher than 10% of the ADI. For wheat HR value equals 0.087 mg/kg, so processing studies for wheat are not needed.

New two studies on processing barley have been provided. As the processing factor (PF) in the two processing barley studies does not differ more than 50%, according to the OECD guideline OECD 508 "*Magnitude of the Pesticide Residues in Processed Commodities*", no additional trials on barley processing are required. The studies are considered acceptable. More details are in Appendix 2.

No additional data required.

7.3.6 Magnitude of residues in representative succeeding crops

EFSA Journal 2021;19(5):6578
The crops under consideration may be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, the DT90 values for folpet, phthalimide and the soil metabolites phthalic acid and phthalamic acid are expected to range between 1 and 94 days (under laboratory conditions) which are below the trigger value of 100 days.
Additionally, the half-lives of folpet and phthalimide are < 3 days under field conditions (EFSA, 2009, 2014). According to the European guidelines on rotational crops (European Commission, 1997c), further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.
No new data submitted in the framework of this application.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

No data submitted and no further data required.

zRMS comments:
Data presented by Applicant in point 7.3.6 are sufficient.
No additional study is required.

7.3.7 Other / special studies (KCA 6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SAP50SCF. Therefore, other special studies are not needed.
Specifically, residues in honey should not be required until the renewal of the active substance take place. Indeed, AIR peer review under new data requirements is still ongoing at the time of this submission. Therefore, currently the old data requirements still apply and residues in honey do not need to be addressed at this stage.

zRMS comments:
According to SANTE/11956/2016 rev. 9, 14 September 2018 wheat and barley are not considered melliferous crops. Therefore, residues in honey are not expected from the use of SAP2101F under consideration. No additional data 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 Point 7.1.2).

7.3.8.1 Input values for the consumer risk assessment

The consumer risk assessment has been done using MRLs as currently in force in Regulation (EU) No ~~2922/93~~ 2023/1042. The Excel sheet EFSA PRIMo rev 3.1 has been used to do the calculations.

Table 7.3-12 Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value [mg/kg]	Comment	Input value [mg/kg]	Comment
Sum of folpet and phthalimide expressed as folpet				
All commodities	MRL	Regulation (EU) No 2023/1042	MRL	Regulation (EU) No 2023/1042

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-13 Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	59% (based on PT General)
IEDI (% ADI) according to EFSA PRIMo	Not required.
IESTI (% ARfD) according to EFSA PRIMo*	Highest IESTI Unprocessed: Barley 6% Highest IESTI Processed: Barley cooked 4%
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

* include raw and processed commodities if both values are required for PRIMo.
** if national model is available

The proposed uses of folpet the formulation ~~SAP50SCF~~ SAP2101F do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
A consumer risk assessment was performed with revision 3.1 of EFSA Pesticide Residues Intake Model (PRIMo Rev. 3.1). The Reg. (EU) 2023/1042 for folpet is now in force.

The highest Theoretical Maximum Daily Intake (TMDI) is 59% of the ADI for the PT General. The highest contribution (50% of the ADI) is from wine grapes.

The highest International Estimated Short-Term Intake (IESTI) is at 6% and 5% of the ARfD for the consumption of barley by children and by adults respectively and for processed commodities at 4% of the ARfD from the consumption of barley/cooked for children and 0.9% of the ARfD from the consumption of wheat/bread/pizza for adults.

The proposed uses of folpet in the product SAP2101F do not represent unacceptable acute and 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.

The product is a mixture of two active substances and for both of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.4.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of

the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.3.1) and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.4-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)	HQ (based on NESTI according to national model)*
Wheat	Prothioconazole	0,058	N/A
	Folpet	0,029	N/A
	Cumulative risk Wheat (HI)	**0,087**	**N/A**
Barley	Prothioconazole	0,022	N/A
	Folpet	0,055	N/A
	Cumulative risk Barley (HI)	**0,077**	**N/A**

* if national model wanted, otherwise to be deleted

The Hazard Index is <1. Thus combined exposure to all active substances in SAP2101F is not expected to present a consumer risk. No further refinement of the assessment is required.

7.4.2 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

Evaluator comment:
Information and calculations presented by the Applicant are acceptable.
If we include TDMs in the calculations, the Hazard Index will still be below 1.

Until an EU agreed methodology is not available, additional information on combined exposure and RA is not required.

7.5 References

Prothioconazole:

EC (European Commission), 2021. 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 and updated in the Standing Committee on Plants, Animals, Food and Feed on 26 January 20212. Prothioconazole SANCO/3923 /07 - final 26 January 2021

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EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) Nº 396/2005. EFSA Journal 2014;12(5):3689, 72 pp. doi: 10.2903/j.efsa.2014.3689

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United Kingdom, 2007. Final addendum to the additional report and the draft assessment report on the

active substance prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Council Regulation (EC) No 33/2008, compiled by EFSA, May 2007.

United Kingdom, 2018. Triazole Derivate Metabolites, addendum–confirmatory data prepared by the rapporteur Member State, the United Kingdom in the framework of Regulation (EC) No 1107/2009, revised version ofFebruary 2018.

Folpet:

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Austria, 2018. Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) n° 1107/2009, folpet, March 2018.

OECD, 2018. Guidance document on residues in rotational crops. Series on pesticides No 97 and Series on test-ing and assessment No 278.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
KCP 7.2.3/01	Grall, E.	2022	Prothioconazole – Residue Study on Barley in Northern and Southern Europe – 2020 Staphyt report no EGL-20-42539 GLP Unpublished	N	ASCENZA
KCP 7.2.3/02	Grall, E.	2022	Prothioconazole – Residue Study on Barley in Northern Europe – 2020 Staphyt report no EGL-20-45487 GLP Unpublished	N	ASCENZA
KCP 7.2.3/03	Thirkell, C.	2022	Study on the Residue Behaviour of Prothioconazole in Barley after Treatment with Prothioconazole 300 EC at two Sites under Field Conditions Northern Europe, 2021 SGS report no IF21-05704459 GLP Unpublished	N	ASCENZA
KCP 7.2.3/04	Grall, E.	2022	Prothioconazole – Residue Study on Wheat in Northern Europe – 2020 Staphyt report no EGL-20-42538 GLP Unpublished	N	ASCENZA

KCP 7.2.3/05	Thirkell, C.	2022	Study on the Residue Behaviour of Prothioconazole in Wheat after Treatment with Prothioconazole 300 EC at six Sites under Field Conditions in Northern Europe, 2021 SGS report no IF21-05705310 GLP Unpublished	N	ASCENZA
KCP 7.2.3/06	Thirkell, C.	2023	Study on the Residue Behaviour of Prothioconazole in Wheat after Treatment with Prothioconazole 300 EC at two Sites under Field Conditions in Northern Europe, 2022 SGS report no IF22-06125006 GLP Unpublished	N	ASCENZA
KCP 7.3.1/01	J. Gordo	2024	Stability Study of Folpet and Metabolites in Cereals Stored Under Deep Freezing Conditions Laboratorio Residuos de Pesticidas Ascenza Agro SA. Report nº EST06/22 (study ongoing). Interim report for 12 months storage time. GLP Unpublished	N	ASCENZA AGRO
KCP 7.3.1/02	S. Jooss	2024	Storage Stability of Folpet and its Metabolites in Various Matrices under Deep Frozen Conditions Eurofins Agroscience Services. Report Nº: S22-07592 (study ongoing). Interim report for 12 months storage time. GLP Unpublished	N	ASCENZA AGRO

KCP 7.3.3/01 (field phase)	A.S. Lesbazeilles Beauvalon	2022	Magnitude of the residue of folpet in representative winter wheat Raw Agricultural Commodities after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern Europe- 2021 SGS Report n° 21-00160 GLP Unpublished	N	ASCENZA AGRO
KCP 7.3.3/02 (analytical phase)	S. Jooss	2022	Study on the residue behaviour of folpet and its metabolites in wither wheat after two applications of SAP50SCF (Folpet 500 g/l, SC) in Northern Europe – 2021. Eurofins Agroscience Services Report No: S22-03719 GLP Unpublished	N	ASCENZA AGRO
KCP 7.3.3/03 (field phase)	A.S. Lesbazeilles Beauvalon	2022	Magnitude of the residue of folpet in representative barley Raw Agricultural Commodities after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern Europe SGS Report n° 21-00139 GLP Unpublished	N	ASCENZA AGRO
KCP 7.3.3/04 (analytical phase)	S. Jooss	2022	Study on the residue behaviour of folpet and tis metabolites in barley after two applications of SAP50SCF (Folpet 500 g/l, SC) in Northern Europe – 2021 Eurofins Agroscience Services Report No: S22-01157 GLP Unpublished	N	ASCENZA AGRO
KCP 7.3.5/01 (processing phase)	C. Milhan	2022	Magnitude of the residue of folpet in processed fractions of barley after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern and Southern Europe Staphyt Report n° CMN-21-48321 GLP Unpublished	N	ASCENZA AGRO
KCP 7.3.5/02 (analytical phase)	S. Jooss	2022	Study on the residue behaviour of folpet and its metabolites in processed fractions of barley after one application of SAP50SCF (Folpet 500 g/l) in Northern Europe – 2021 Eurofins Agroscience Services Report No: S22-04739 GLP Unpublished	N	ASCENZA AGRO

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Heinemann, O.	2001a	18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices. Bayer AG, Report nº: MR-282/00, Date: 2001-09-13 GLP Unpublished	N	BAY
KCA 6.1.1/09	Saha M	2010	Freezer Storage Stability of the Triazole Metabolites (1,2,4-Triazole, Triazolylacetic Acid, Triazolylalanine) in Plant Samples. Report Number 138032 BASF, US. Study Dates: October 2005 – February 2008	N	TDMG
KCA 6.1.1/03	Murphy I	2008	Stability of 1,2,4-Triazole, Triazolylalanine, and Triazolylaceticacid in Various Crop Matrices and Processed Commodities during Frozen Storage. Report Number RAJAY006 Bayer CropScience, US. Study Dates: May 2003 – November 2007	N	TDMG
KCA 6.1.1/09	Saha M	2010	Freezer Storage Stability of the Triazole Metabolites (1,2,4-Triazole, Triazolylacetic Acid, Triazolylalanine) in Plant Samples. Report Number 138032 BASF, US. Study Dates: October 2005 – February 2008	N	TDMG
KCA 6.1.1/10	Perez R	2015	Freezer Storage Stability of Triazolyl Lactic Acid in Plant Samples. Report Number 366867 BASF, US. Study Dates: May 2009 – July 2015)	N	TDMG
KCA 6.1.1/07	Zini G	1997	Stability of 1,2,4-Triazole in Milk Stored at -20°C in the Dark. Report Number 2176 Isagro Ricerca, Italy. Study Dates: April 1996 – October 1997	N	TDMG
KCA 6.1.1/08	Zini G	1998	Stability of 1,2,4-Triazole in Biological Substrates Stored at -20°C in the Dark. Report Number 2220 Isagro Ricerca, Italy. Study Dates: March 1997 – April 1998	N	TDMG
KCA 6.2.1	*Haas, M.*	2000	Metabolism of JAU6476 in spring wheat after seed dressing. Bayer AG, Report nº: MR-467/99, Date: 2001-05-10 GLP Unpublished	N	BAY
KCA 6.2.1	*Haas, M.*	2001d	Metabolism of [phenyl-UL-^{14}C] JAU6476 in peanuts. Bayer AG, Report nº: MR-193/01, Date: 2001-11-27 GLP Unpublished	N	BAY
KCA 6.2.1	*Haas, M. ; Bornatsch, W.*	2000	Metabolism of JAU6476 in spring wheat (after foliar application), Bayer AG, Leverkusen, Germany, Bayer CropScience AG, Report No.: MR-198/99, Edition Number: M-041657-01-1, Date: 10.07.2000, GLP unpublished	N	BAY
KCA 6.2.1	*Vogeler, K.; Sakamoto, H.; Brauner, A.*	1993	Metabolism of SXX 0665 in summer wheat. Bayer AG, Report nº: PF3906, Date: 1993-08-13 GLP Unpublished	N	BAY
KCA 6.2.2-	[redacted]	2001a	[Phenyl-UL-^{14}C]JAU6476 Absorption, distribution, excretion and metabolism in the lactating goat. [redacted]	Y	BAY

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.2.5			[redacted] GLP unpublished		
KCA 6.2.2-6.2.5	[redacted]	2001b	[Phenyl-UL-^{14}C]JAU6476 Absorption, distribution, excretion and metabolism in the lactating goat. [redacted], [redacted] GLP unpublished	Y	BAY
KCA 6.2.2-6.2.5	[redacted]	2001a	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in laying hens, [redacted], [redacted] GLP unpublished	Y	BAY
KCA 6.2.2-6.2.5	[redacted]	2002a	[Phenyl-UL-^{14}C]JAU6476-desthio Absorption, distribution, excretion and metabolism in the lactating goat. [redacted], [redacted] GLP unpublished	Y	BAY
KCA 6.2.3/01	[redacted]	2010	[Triazole-UL-14C]Triazole Alanine - Metabolism in the lactating goat [redacted] GLP Unpublished	Y	TDMG

KCA 6.2.2/01	[redacted]	2010	[Triazole-UL-14C]Triazole Alanine: Metabolism in the Laying Hen [redacted] GLP Unpublished	Y	TDMG
KCA 6.2.2-6.2.5	*Weber, H.; Weber, E.; Spiegel, K.*	2002b	Validation of the residue analytical method for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio residues in animal matrices using aged radioactive residues. Bayer AG, Report nº: MR-091/01 Part 2, Date: 2002-02-28 GLP unpublished	N	BAY
KCA 6.3	*Heinemann, O., Elke, K.*	2001c	Determination of residues of JAU 6476-desthio on winter wheat following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in France, Spain and Italy. Bayer AG, Report nº: RA-2149/98, Report includes trials nº: R 1998 1314/1, R 1998 1586/1, R 1998 1588/8, R 1998 1589/6, R 1998 1725/2. Date: 2001-11-13 GLP unpublished	N	BAY
KCA 6.3	*Heinemann, O., Elke, K.*	2001l	Determination of residues of JAU 6476-desthio in/on wheat and triticale after spray application of JAU 6476 250 EC in Spain and France. Bayer AG, Report nº: RA-2105/00, Report includes Trials nº: R 2000 0482/6, R 2000 0479/6, R 2000 0478/8, R 2000 0455/9. Date: 2001-12-06 GLP Unpublished	N	BAY
KCA 6.3	*Heinemann, O.*	2001i	Determination of residues of JAU 6476-desthio on spring wheat after spray application of JAU 6476 250 EC in Sweden, Germany, Nothern France and Great Britain. Bayer AG, Report No.: RA-2104/00. Report includes Trial Nos.: R 2000 0454/0; R 2000 0457/5; R 2000 0474/5; R 2000 0475/3; R 2000 0476/1. GLP Unpublished	N	BAY
KCA 6.3	*Heinemann, O., Elke, K.*	2001a	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, France and Great Britain. Bayer AG, Report nº: RA-2140/98, Report includes Trials nº: R 1998 1582/9, R 1998 1581/0, R 1998 11580/2, R 1998 1247/1. Date: 2001-09-24 GLP unpublished	N	BAY
KCA 6.3	*Heinemann, O., Elke, K.*	2001b	Determination of residues of JAU 6476-desthio in/on winter barley after spray application of JAU 6476 250 EC in France, Italy and Portugal. Bayer AG, Report nº: RA-2144/98, Report includes Trials nº: R 1998 1317/6, R 1998 1571/3, R 1998 1572/1. Date 2001-09-24 GLP unpublished	N	BAY
KCA 6.3	*Heinemann, O.*	2001h	Determination of residues of JAU 6476-desthio on spring wheat and winter wheat following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, Northern France, and Great Britain. Bayer AG, Report nº: RA-2003/99, Report includes Trials nº: R 1999 0023/6, R 1999 0025/2, R 1999 0026/0, R 1999 0027/9, R 1999 0266/2. Date: 2001-10-04 GLP	N	BAY

			unpublished		
KCA 6.3	*Heinemann, O.*	2001j	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain. Bayer AG, Report nº: RA-2101/00, Report includes Trial nº: R 2000 0452/4, R 2000 0456/7, R 2000 0462/1, R 2000 0464/8, R 2000 0465/6. Date: 2001-11-21. GLP Unpublished	N	BAY
KCA 6.3	*Heinemann, O.*	2001f	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Southern France. Bayer AG, Report nº: RA-2079/98, Report includes Trials nº: R 1998 1249/8. Date: 2001-09-27. GLP Unpublished	N	BAY
KCA 6.3	*Heinemann, O.*	2001k	Determination of residues of JAU 6476-desthio in/on spring barley after spray application of JAU 6476 250 EC in Spain, Italy and Southern France. Bayer AG, Report nº: RA-2103/00, Report includes Trials nº: R 2000 0473/7, R 2000 0472/9, R 2000 0470/2, R 2000 0453/2. Date: 2001-11-21. GLP Unpublished	N	BAY
KCA 6.5.1	*Gilges, M.*	2001b	Hydrolysis of JAU 6476 under conditions of processing, Bayer AG, Leverkusen, Germany, Bayer CropScience AG, Report No.: MR-166/00, Edition Number: M-035289-01-1, Date: 29.01.2001 GLP unpublished	N	BAY
KCA 6.5.1/01	*Weber, E.*	2010	Nature of residues of triazole alanine, triazole acetic acid, triazole lactic acid, and 1,2,4-triazole in processed commodities – high temperature hydrolysis Report No. Document No.: MEF-10/545 M-386760-02-1 GLP unpublished	N	TDMG
KCA 6.4.1/01		2010	Triazolylalanine: Feeding study laying hens (Gallus gallus domesticus) [redacted] GLP Unpublished	Y	TDMG
KCA 6.4.1/02		2010	Triazolylacetic acid: Feeding study laying hens (Gallus gallus domesticus) [redacted] GLP Unpublished	Y	TDMG
KCA 6.4.2/01		2009	Triazolylalanine: Feeding study with Dairy Cows [redacted] GLP Unpublished	Y	TDMG
KCA 6.4.2/02	[redacted]	2010	Triazole Acetic Acid: Feeding Study with Dairy Cows [redacted]	Y	TDMG

			GLP Unpublished		
KCA 6.5.2	Kraai, M.J	2004	JAU 6476 480 SC - Magnitude of the residue in/on wheat grain, wheat aspirated grain fractions, and wheat processed commodities Report No Document No 200521 M-000665-01-1 GLP Unpublished	N	BAY
KCA 6.5.2	Freitag T.	2008	Determination of the residues of JAU 6476 in/on winter barley and spring barley after spraying of JAU 6476 (250 EC) in the field in Northern France Report No & Document No: RA-3669/07 M-303475-01-1 GLP Unpublished	N	BAY
KCA 6.5.2	Class, T.; Goecer, M.	2009	Determination of 1,2,4-triazole and its conjugates (triazolylalanine, triazole acetic acid, triazole lactic acid) in samples from BCS study no. RA-3669/07 (processed barley) Report No Document No P 1747G M-356425-01-1 GLP Unpublished	N	BAY
KCA 6.6.1	*Haas, M.*	2001c	Confined rotational crop study with JAU6476, Bayer AG, Report nº: MR-159/00, Date: 2001-05-14 GLP unpublished	N	BAY
KCA 6.4.1-6.4.3	[redacted]	2001	JAU 6476-desthio – Dairy cattle feeding study. [redacted]: [redacted] GLP unpublished	Y	BAY

KCA 6.6.2	Freitag T., Ruhl S.;	2011	Determination of the residues of prothioconazole in/on the field rotational crops carrot, lettuce, spring barley and winter barley after either a single application of JAU 6476 EC 250 on bare soil or sowing of spring wheat treated with JAU 6476 FS 100 followed by three spray applications with JAU 6476 EC 250 in the field in Germany Report No 09-2500 Document No: M-426697-01-1 GLP Unpublished	N	BAY
KCA 6.6.2	*Freitag T., Ballmann C.;*	2011	Determination of the residues of prothioconazole in/on the field rotational crops carrot, lettuce, spring barley and winter barley after either a single application of JAU 6476 EC 250 on bare soil or sowing of spring wheat treated with JAU 6476 FS 100 followed by three spray applications with JAU 6476 EC 250 in the field in the Netherlands Report No 09-2501 Document No: M-426699-01-1 GLP Unpublished	N	BAY
KCA 6.6.2	Freitag T. , Ruhl S.	2011	Title: Determination of the residues of prothioconazole in/on the field rotational crops turnip, lettuce, spring barley and winter barley after either a single application of JAU 6476 EC 250 on bare soil or sowing of winter wheat treated with JAU 6476 FS 100 followed by spray application with JAU 6476 EC 250 in the field in southern France Report No 09-2502 Document No: M-426710-01-1 GLP Unpublished	N	BAY
KCA 6.6.2	Freitag T. , Ruhl S.	2011	Determination of the residues of prothioconazole in/on the field rotational crops carrot, lettuce and winter barley after either a single application of JAU 6476 EC 250 on bare soil or sowing of winter wheat treated with JAU 6476 FS 100 followed by three spray applications with JAU 6476 EC 250 in the field in Spain Report No 09-2503 Document No: M-426705-01-1 GLP Unpublished	N	BAY
KCA 6.1	Fuchsbichler, G	1995	Folpet, investigation of the storage stability in white and red grapes. Report n° HVA 12/94 Company file: R-8096 ADAMA Makhteshim Ltd., V20481, R-34718 GLP, unpublished	N	Makhteshim
KCA 6.1	Byast, M.G.	1997	Determination of freezer storage stability for folpet in wheat, grain and straw over a period of 12 months in compliance with good laboratory practice. Oxford Analytical Ltd., Report No.: OA00382. Company file: R-9156 GLP, Unpublished	N	Makhteshim
KCA 6.1	Singer, G.M.	-	Summary of storage stability studies of folpet on various raw agricultural commodities. American Agricultural Services, Inc., company file: R-9142 Not GLP, unpublished	N	Makhteshim
KCA 6.2.1	Crowe, A.	1995	Folpet: distribution and metabolism in winter wheat. Pharmaco LSR Ltd., Report No. 95/MAK204/0049 (company file: R-7823) GLP, unpublished	N	Makhteshim

KCA 6.2.1	O'Connor, J. Mester, T.C	1994	Folpet: nature of residue on grapes. Pharmaco LSR Ltd., Report No 93/WLS019/0962 GLP, unpublished Field report: Nature of the residue study LX1145-05[(14C)-folpet] on grapes in California. Landis International, Inc. report Protocol No.14503B004. (company file: R-6403a). GLP, Unpublished.	N	Makhteshim
KCA 6.2.1	Toia, R.F Collins, E.H	1994	Nature of residue (14C)-folpet (LX1145-05) in avocados applied under field conditions. PREL West Inc., Report No.417W-2. (Company file: R-7302) GLP, Unpublished	N	Makhteshim
KCA 6.2.1	Cheng, H.M.	1980	[Carbonyl-14C] folpet metabolism in tomato plants. Chevron Chemical Company, Report No.721.14 (Company file: R-7036) Not GLP, Unpublished	N	Makhteshim
KCA 6.2.1	Crowe, A.	1999	Folpet: metabolism in potatoes. Huntigdon Life Sciences Ltd., Report No. MAK506/992098 (Company file: R-10347). GLP, Unpublished	N	Makhteshim
KCA 6.2.2	[redacted]	1997a	14C-folpet metabolism in the lactating goat (part A). 14C trichloromethyl folpet: material balance of dosed radioactivity. [redacted] GLP, unpublished	Y	Makhteshim
KCA 6.2.2	[redacted]	2015	Metabolism and disposition of [14C]Folpet in the Laying Hen [redacted] GLP, unpublished	Y	ADM
KCA 6.3.1	Turner, M.G. Byast, M.G.	1996a	Determination of folpet residues in winter wheat (field phase). Oxford Plant Sciences, Report No. OPS/00519/MAK Determination of folpet residues in winter wheat, grain and straw treated with Folpan 80 WDG. Oxford Analytical Ltd., Report No. OA00346/R52862. Determination of folpet residues in decline samples of winter wheat treated with Folpan 80 WDG. Oxford Analytical Ltd., Report No OA00345/R52862. Company file R8580 GLP, unpublished	N	Makhteshim
KCA 6.3.1	Turner, M.G., Byast, M.G.	1996b	Determination of propiconazole, fenpropimorph, prochloraz and folpet residues in winter wheat and winter barley (field phase). Oxford Plant Sciences, Report No. OPS/00514/MAK. Determination of folpet in harvest samples of winter wheat, grain and straw treated with Folpan 80 WDG. Oxford Analytical Ltd., Report No. OA00341/R52855.	N	Makhteshim

			Determination of folpet in decline samples of winter wheat treated with Folpan 80 WDG. Oxofrd Analytical Ltd., Report No. OA00344/R52855. Company file: R-8559 GLP, Unpublished		
KCA6.3.1	Mellet, M.	1993	Determination des résidus de folpel dans des échantillons de céréales après application du produit Folpan SC. Anadiag S.A. unpublished report No RF2095 GLP, unpublished	N	Makhteshim
KCA6.3.1	Mellet, M	1994	Determination des résidus de folpel et de phthalimide dans des échantillons de céréales après application des produits Folpan SC et Folpan WDG. Anadiag S.A. unpublished report No RF4019 GLP, unpublished	N	Makhteshim
KCA6.3.1	Wasser, C.	1996	Folpan SC. Magnitude of the residues in wheat. Anadiag S.A. unpublished report No. R5072 (Company file: R-8676a) GLP, unpublished	N	Makhteshim
KCA6.3.1	Mende, P., Hautavoine, V.	1996b	Residue analysis of folpet and prochloraz in weat and barley treated with Bumper F from residue trials in France. Report n° 96025/F1-RFWC Residue study – field phase. Gaining of samples for the determination of residues of propiconazole and folpet after treatment with Bumper F in cereals under field conditions in France. Biotek Agriculture, Report BKA/618/96/RES Company file : R-9376 GLP, unpublished	N	Makhteshim
KCA 6.3.1	Perney, A.	2002	Determination of folpet and phthalimide residues in winter wheat following treatments with the preparation Folpan 80 WDG under field conditions in France in 2001 Anadiag Reports RA1044 (company file R-13050) GLP, unpublished	N	Makhteshim
KCA 6.5.1	M Fitzmaurice and E Mackenzie,	2007	[14C]-Folpet: Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation Report n° OZ/07/007 GLP Unpublished	N	ASCENZA AGRO
KCA 6.5.3	Perny, A	2002b	Determination of folpet and phthalimide residues in processed fractions (grain, flour, total bran, regrinding and bread) after treatment of winter wheat with the preparation Fopan 80 WDG under field conditions in France in 2001. Anadiag S.A., Report No RA1044 PRO (company file R-13053) GLP, Unpublished	N	Makhteshim

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prothioconazole

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

New data has not been provided.

A 2.1.1.1.2 Storage stability of residues in animal products

New data has not been provided.

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

New data has not been provided.

A 2.1.2.1.2 Nature of residue in rotational crops

New data has not been provided.

A 2.1.2.1.3 Nature of residues in processed commodities

New data has not been provided.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Barley

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applica-tions	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, UK, 2007)	2	200 g/ha	14-21 days	BBCH61	35 days
cGAP EU (Confirmatory data of Art. 12, EFSA, 2020)	2	200 g/ha	14-21 days	BBCH69	35 days
Intended cGAP (2*)	2	180 g/ha	14 days	BBCH61	42 days

* 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

Comments of zRMS:	Trials were conducted at 8 sites: 4 in N-EU and 4 in S-EU to determine the magnitude of residues of the triazole metabolites 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley growing under field conditions after two foliar application with fungicide Prothioconazole 300 EC. Prothioconazole 300 EC was applied two times with nominal content 195 g prothioconazole/ha. Specimens of barley were collected at a nominal sampling timing 0 (S1), 7±1 (S2) and 14±1 (S3) DALA as whole plant, 35 ± 3 DALA (S4) as ears and straw and at normal commercial harvest (BBCH 89) as grain and straw (S5). The barley specimens were analysed for residues of the triazole metabolites following the analytical method 01062/M004. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte. **Results:** <u>Barley grain</u> In untreated specimens of barley grain taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between < 0.010 - 1.05 mg/kg for TA, between < 0.010 - 0.365 mg/kg for TAA and between < 0.010 - 0.0224 mg/kg for TLA. In treated specimens of barley grain taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between 0.0448 - 0.826 mg/kg for TA, between 0.0283 - 0.243 mg/kg for TAA and between < 0.010 - 0.0189 mg/kg for TLA. <u>Barley straw</u> In untreated specimens of barley straw taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between < 0.010 - 0.0798 mg/kg for TA, between < 0.010 - 0.166 mg/kg for TAA and between < 0.010 - 0.0859 mg/kg for TLA. In treated specimens of barley straw taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between < 0.010 - 0.130 mg/kg for TA, between 0.0116 - 0.194 mg/kg for TAA and between 0.0114 - 0.125 mg/kg for TLA. Sufficient stability data are available to support the residue data presented in this study. The study is acceptble.

Reference:	KCP 7.2.3/01
Report	Prothioconazole – Residue Study on Barley in Northern and Southern

	Europe – 2020 Grall, E. 2022 Staphyt report no EGL-20-42539
Guideline(s):	Yes General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). Guidance for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev.4, 11 July 2000). Guidance Documents on Pesticide Residue Analytical Methods (SANCO/825/00 rev.8.1, 16 Nov. 2010). OECD (2007): Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the magnitude of residues of prothioconazole, prothioconazole-desthio (M04) and the prothioconazole OH metabolites (M14, M15, M16, M17 and M18), as well as Triazole Derivative Metabolites (1,2,4-T, TA, TAA, TLA) in raw agricultural commodity (RAC whole plants, grain and straw) of barley after two applications of PROTHIOCONAZOLE 300 EC. Since only residues of TDMs are relevant for the present submission, these are the only results shown in table A2 below.

The crop was subjected to a residue program which simulated the use of PROTHIOCONAZOLE 300 EC as a fungicide in barley in Northern and Southern Europe (Poland, Spain, Italy, Greece, Hungary and Austria) in 2020. Target application rate was 0.65 L/ha and target application time: Application 1 14 ± 2 days before BBCH 61, and application 2 at BBH 61.

Two plots were established in the trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha. Application 1 took place14±2 days before application 2. Application 2 took place at BBCH 61.
Specimens of whole plant were taken at 0, 7±1 and 14±1 DALA. At 35 ±3 DALA, ears and rest of plant were collected and grain and straw were collected at commercial harvest. Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped by freezer truck to the analytical test site for prothioconazole, prothioconazole desthio and prothioconazole OH metabolites. The last delivery was done on 01 September 2020.

Analyses of specimens were performed at SGS INSTITUT FRESENIUS GmbH, Germany.
Homogenized field specimens aliquots were received deep frozen by SGS from Food Safety Laboratory. They were delivered on 29 October 2020, and they were kept deep frozen until analysis.
The method for the analysis of 1,2,4-T, TA, TAA and TLA, was based on the analytical method 01062/M004 (T. Class; "Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-triazole, triazolylalanine, triazole acetic acid and triazole lactic acid by LC/DMS/MS/MS in plant materials", BASF DocID 2012/1294644, 07 December 2011)
Analytes were extracted with a mixture of methanol and water, filtered, concentrated and cleaned up by dispersive SPE cartridge. The analytes were determined by LC-DMS/MS/MS.
Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.
Limit of detection (LOD) was found to be 0.003 mg/kg for all analytes.

Results are shown in table A2 below.

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)							(d)	(e)
EGL-20-42539-PL01 Poland Wielkopolskie 64-610 Prućse	Winter Barley Sandra	1- 17/09/2019 2- 12/05 to 23/05/2020 3- 14/07/2020	186 186	307 293	64 63	29/04/2020 12/05/2020	BBCH49 BBCH61	Whole plant Whole plant Whole plant Ears Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 **<0.01** **<0.01**	0.237 0.258 0.231 0.637 0.024 **0.826** **0.13**	0.08 0.094 0.095 0.225 0.063 **0.243** **0.194**	0.233 0.23 0.156 **0.026** **0.29** 0.019 0.125	0 8 14 36 36 64 64	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Whole plant: 214d Ears: 207d Straw: 208d Grain: 187d
EGL-20-42539-ES02 Spain Andalucia 41400 Ecija	Winter Barley Asteroid	1- 18/11/2019 2- 10/04 to 17/04/2020 3- 08/06/2020	198 187	312 310	63 64	27/03/2020 11/04/2020	BBCH39 BBCH61	Whole plant Whole plant Whole plant Ears Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 **<0.01** **<0.01**	0.054 0.061 0.089 0.155 <0.01 **0.162** **0.013**	0.024 0.025 0.033 0.12 0.02 **0.104** **0.032**	0.053 0.045 0.042 0.022 0.052 **<0.01** **0.062**	0 6 13 36 36 46 46	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Whole plant: 214d Ears: 207d Straw: 208d Grain: 187d
EGL-20-42539-ES03 Spain Extremadura 06250 Bienvenida	Winter Barley Planet	1- 29/11/2019 2- 08/04 to 15/04/2020 3- 20/06/2020	193 201	303 317	64 63	26/03/2020 11/04/2020	BBCH37 BBCH61	Ears Straw Grain Straw	<0.01 <0.01 **<0.01** **<0.01**	0.163 0.025 **0.156** **0.03**	0.077 0.018 **0.161** **0.046**	0.029 0.045 **0.013** **0.112**	33 33 51 51	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Ears: 207d Straw: 208d Grain: 187d
EGL-20-42539-IT04 Italy Veneto 37066 Sommacampagna	Winter Barley Calanque	1- 28/10/2019 2- 30/04 to 10/05/2020 3- 20/06/2020	180 190	283 298	64 64	23/04/2020 07/05/2020	BBCH56 BBCH61	Whole plant Whole plant Whole plant Ears Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 **<0.01** **<0.01**	0.08 0.136 0.15 0.473 0.041 **0.358** **0.051**	0.023 0.031 0.049 0.141 0.034 **0.132** **0.051**	0.059 0.058 0.06 <0.01 0.036 **<0.01** **0.033**	0 7 14 35 35 43 43	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Whole plant: 214d Ears: 207d Straw: 208d Grain: 187d

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
EGL-20-42539-IT05 Italy Piemonte 14100 Asti	Spring Barley Etoile	1- 12/03/2020 2- 03/05 to 18/05/2020 3- 09/07/2020	173 191	273 302	63 63	21/05/2020 05/06/2020	BBCH49 BBCH61	Grain Straw	**<0.01** **<0.01**	**0.083** **0.021**	**0.028** **0.016**	**<0.01** **0.011**	31 31	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Straw: 208d Grain: 187d
EGL-20-42539-GR06 Greece Central Macedonia GR 57100 Koufalia	Winter Barley Planet	1- 15/12/2019 2- 22/04 to 30/04/2020 3- 12/06/2020	191 191	300 300	64 64	08/04/2020 23/04/2020	BBCH49 BBCH61	Ears Straw Grain Straw	<0.01 <0.01 **<0.01** **<0.01**	0.0482 <0.01 **0.071** **<0.01**	0.052 0.017 **0.062** **0.039**	<0.01 0.048 **<0.01** **0.059**	35 35 48 48	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Ears: 207d Straw: 208d Grain: 187d
EGL-20-42539-GR07 Greece Central Macedonia GR 57400 Sindos	Winter Barley Colorado	1- 10/11/2019 2- 20/04 to 30/04/2020 3- 29/05 and 05/06/2020	187 190	295 300	63 63	06/04/2020 22/04/2020	BBCH41 BBCH61	Ears Straw Grain Straw	<0.01 <0.01 **<0.01** **<0.01**	0.046 <0.01 **0.045** **<0.01**	0.036 <0.01 **0.031** **0.012**	<0.01 0.027 **<0.01** **0.02**	35 35 43 43	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Ears: 207d Straw: 208d Grain: 187d
EGL-20-42539-HU08 Hungary Jász-Nagykun-Szolnok 5054 Jászalsószentgy-örgy	Spring Barley Bente	1- 10/03/2020 2- 06/06 to 14/06/2020 3- 11/07/2020	189 196	248 257	76 76	29/05/2020 09/06/2020	BBCH43 BBCH61	Whole plant Whole plant Whole plant Grain Straw	<0.01 <0.01 <0.01 **<0.01** **<0.01**	0.01 0.018 0.034 **0.085** **<0.01**	<0.01 <0.01 <0.01 **0.035** **0.012**	<0.01 <0.01 <0.01 **<0.01** **0.014**	0 8 14 35 35	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Whole plant: 214d Straw: 208d Grain: 187d

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)							(d)	(e)
EGL-20-42539-AT09 Austria Wiener Umland 2471 Rohrau	Spring Barley Elena	1- 12/03/2020 2- 09/06 to 19/06/2020 3- 23/07/2020	198 200	312 316	63 63	28/05/2020 09/06/2020	BBCH37 BBCH61	Whole plant Whole plant Whole plant Ears Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 **<0.01** **<0.01**	<0.01 0.0165 0.029 0.154 <0.01 **0.164** **0.017**	<0.01 <0.01 <0.01 0.057 0.01 **0.078** **0.03**	<0.01 0.012 0.014 0.016 0.031 **<0.01** **0.024**	0 8 14 36 36 44 44	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Whole plant: 214d Ears: 207d Straw: 208d Grain: 187d
EGL-20-42539-PL10 Poland Warmińsko Mazurskie 14-100 Brzydowo	Spring Barley Argento	- 06/04/2020 2- 15/06 to 26/06/2020 3- 10/08/2020	191 181	301 286	63 63	04/06/2020 17/06/2020	BBCH33 BBCH61	Whole plant Whole plant Whole plant Ears Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 **<0.01** **<0.01**	0.33 0.055 0.056 0.144 0.01 **0.155** **0.033**	0.011 0.012 0.012 0.084 0.012 **0.092** **0.046**	0.044 0.04 0.046 0.016 0.044 **0.011** **0.096**	0 6 13 35 35 44 54	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Whole plant: 214d Ears: 207d Straw: 208d Grain: 187d

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) 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

A 2.1.3.1.2 Study 2

Comments of zRMS:	Trials were conducted at 2 sites in N-EU to determine the magnitude of residues of prothioconazole-desthio (M04) and the prothioconazole OH metabolites (M14, M15, M16, M17 and M18), as well as TDMs (1,2,4-T, TA, TAA, TLA) in whole plants, grain and straw of barley after two applications of Prothioconazole 300 EC with nominal content 195 g prothioconazole/ha. First application was 14 ± 2 days before BBCH 61, and the second application at BBH 61. The barley specimens were analysed for residues of the PTZ, PTZ-desthio, hydroxy-metabolites and triazole metabolites following two analytical methods: 00979/M001 and 01062/M004. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte. **Results:** No residue of prothioconazole-desthio was found above LOQ in untreated specimens. The residues of prothioconazole-desthio in barley specimens were <LOD in grain collected at Normal Commercial Harvest, and between 0.155-0.245 mg/kg in straw. <u>TDMs:</u> No residue of 1,2,4-T above LOQ was measured in untreated or treated specimens. Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years. In treated plots: Residue of TA were 0.122 to 0.316 mg/kg in grain and <LOQ to 0.032 mg/kg in straw at commercial harvest. Residue of TAA were 0.050 to 0.260 mg/kg in grain and <LOQ to 0.152 mg/kg in straw at commercial harvest. Residue of TLA were <LOQ in grain and <LOQ to 0.145 mg/kg in straw at commercial harvest. Sufficient stability data are available to support the residue data presented in this study. The study is acceptble.

Reference:	KCP 7.2.3/02
Report	Prothioconazole – Residue Study on Barley in Northern Europe – 2020 Grall, E. 2022 Staphyt report no EGL-20-45487
Guideline(s):	Yes General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). Guidance for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev.4, 11 July 2000). Guidance Documents on Pesticide Residue Analytical Methods (SANCO/825/00 rev.8.1, 16 Nov. 2010). OECD (2007): Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the magnitude of residues of prothioconazole-desthio (M04)

and the prothioconazole OH metabolites (M14, M15, M16, M17 and M18), as well as Triazole Derivative Metabolites (1,2,4-T, TA, TAA, TLA) in raw agricultural commodity (RAC whole plants, grain and straw) of barley after two applications of PROTHIOCONAZOLE 300 EC. The crop was subjected to a residue program which simulated the use of PROTHIOCONAZOLE 300 EC as a fungicide in barley in Northern Europe (Poland and Hungary) in 2020. Target application rate was 0.65 L/ha and target application time: Application 1 14 ± 2 days before BBCH 61, and application 2 at BBH 61.

Two plots were established in the trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha. Application 1 took place14±2 days before application 2 (17 in trial PL01). Application 2 took place at BBCH 61. At 35 ±3 DALA, specimens of ears/grain and straw were collected and grain and straw were collected at commercial harvest. Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped by freezer truck to the analytical test site for prothioconazole-desthio and prothioconazole OH metabolites. The delivery was done on 25 August 2020.

Analyses of specimens were performed at Food Safety Laboratory, Skiernewice, Poland.
The method for the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476-α-hydroxy-desthio (M18) in barley, grain and straw was based on the BAYER CropScience method “Analytical Method 00979/M001 for the determination of residues of JAU-6476- a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxy-desthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS”, Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1. Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes. Limit of detection (LOD) was found to be 0.002 mg/kg for all analytes.

Results are shown in table A3 below.

Table A 3: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)							(d)	(e)
EGL-20-45487-PL01 Poland Wielkopolskie 63-040 Chwalęcin	Spring Barley Soldo	1. 03/04/2020 2. from 05/06 to 12/06/2020 3. 31/07/2020	0.196 0.192	309 302	0.063 0.064	20/05/2020 06/06/2020	31 61	Ears Straw Grain Straw	<0.01 <0.01 **<0.01** **<0.01**	0.2 0.027 **0.32** **0.32**	0.19 0.06 **0.26** **0.15**	**0.03** 0.16 <0.01 **0.15**	37 37 55 55	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Ears: 107d Straw: 104d Grain: 103d
EGL-20-45487-HU02 Hungary Czongrad county 6795 Bordány	Spring Barley Bojos	1- 12/03/2020 2- From 25/05 to 28/05/2020 3- 13/07/2020	0.195 0.194	307 305	0.064 0.064	13/05/2020 36/05/2020	39 61	Ears Straw Grain Straw	<0.01 <0.01 **<0.01** **<0.01**	0.12 <0.01 **0.12** **<0.01**	0.05 <0.01 **0.05** **<0.05**	<0.01 **0.021** **<0.01** <0.01	37 37 41 41	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Ears: 107d Straw: 104d Grain: 103d

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) 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

A 2.1.3.1.3 Study 3

Comments of zRMS:	Trials were conducted at 2 sites in N-EU to determine the magnitude of residues of the prothioconazole metabolites: 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley after two foliar application with Prothioconazole 300 EC. Prothioconazole 300 EC was applied two times with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha. First application was 12 days before BBCH 61, and the second application at BBH 61. The barley specimens were analysed for residues of the triazole metabolites following the analytical method 01062/M004. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte. **Results:** <u>Grain</u> In untreated specimens of barley grain taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T and TLA. Residues ranged between 0.016 - 0.069 mg/kg for TA and between 0.016 - 0.041 mg/kg for TAA. In treated specimens of barley grain taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T and TLA. Residues ranged between 0.13 - 0.23 mg/kg for TA, between 0.066 - 0.089 mg/kg for TAA. <u>Straw</u> In untreated specimens of barley straw taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T and TA. Residues ranged between < 0.010 - 0.013 mg/kg for TAA and between < 0.010 - 0.014 mg/kg for TLA. In treated specimens of barley - straw taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between 0.013 - 0.029 mg/kg for TA, between 0.025 - 0.026 mg/kg for TAA and between 0.017 - 0.018 mg/kg for TLA. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 7.2.3/03
Report	Study on the Residue Behaviour of Prothioconazole in Barley after Treatment with Prothioconazole 300 EC at two Sites under Field Conditions Northern Europe, 2021 Thirkell, C. 2022 SGS report no IF21-05704459
Guideline(s):	Yes European Community Guideline 7029/VI/95 - rev.5, 22/07/97: 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 Guideline for the Testing of Chemicals No. 509: Crop Field Trial, 07 Sep 2009. OECD Principles on Good Laboratory Practice, ENV/MC/CHEM(98)17, 21/01/98. OECD (2016)Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)

	SANTE/2020/12830, Rev.1 (24. February 2021): Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes OECD ENV/JM/MONO(2007) 17 -Guidance Document on Pesticide Residue Analytical Methods
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study IF21-05704459 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of barley (RAC grain/ears and rest of plant/straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole.
The study included two supervised residue trials conducted under field conditions in northern Europe (Germany and northern France) during the 2021 season. Two harvest trials were conducted.
The spraying applications of Prothioconazole 300 EC were performed at 12 days before BBCH 61 and BBCH 61 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha.

Specimens of barley were collected at sampling timing 37-40 DALA (S1) as ears and rest of plant, or grain and straw, and at normal commercial harvest (growth stage BBCH 89) as grain and straw (S2). Where growth stage BBCH 89 was reached at S1 only the normal commercial harvest sampling was conducted.
The analytical method 01062/M004 was used for analysis of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) by LCDMS/MS/MS. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte.
Concurrent recoveries, performed with fortified untreated specimens, were analysed together with the field specimens. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %.
In untreated specimens of barley - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole alanine. Residues ranged between < 0.010 - 0.013 mg/kg for Triazole acetic acid and between < 0.010 - 0.014 mg/kg for Triazole lactic acid.
In untreated specimens of barley - grain taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole lactic acid. Residues ranged between 0.016 - 0.069 mg/kg for Triazole alanine and between 0.016 - 0.041 mg/kg for Triazole acetic acid.
In treated specimens of barley - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.013 - 0.029 mg/kg for Triazole alanine, between 0.025 - 0.026 mg/kg for Triazole acetic acid and between 0.017 - 0.018 mg/kg for Triazole lactic acid.
In treated specimens of barley - grain taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole lactic acid. Residues ranged between 0.13 - 0.23 mg/kg for Triazole alanine, between 0.066 - 0.089 mg/kg for Triazole acetic acid.

Results are shown in table A4 below.

Table A 4: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
21-00228-01 Germany 24857 Fahrdorf	KWS Jessie	a) 12 Apr 2021 b) 23 Jun 2021 c) 30 Jul 2021	203 203	260 260	78.1 78.1	11 Jun 2021 23 Jun 2021	BBCH49 BBCH61	Grain Straw	**<0.01** **<0.01**	**0.23** **0.029**	**0.089** **0.026**	**<0.01** **0.018**	37 37	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain and straw:92d
21-00228-02 Northern France 51110 Aumenancourt-Le-Grand	RGT Planet	a) 16 Mar 2021 b) 08 Jun 2021 c) 26 Jul 2021	185 186	283 287	65.3 64.8	28 May 2021 09 Jun 2021	BBCH43 BBCH61	Ears Rest of plant Grain Straw	<0.01 <0.01 **<0.01** **<0.01**	0.13 0.016 **0.13** **0.013**	0.072 0.014 **0.066** **0.025**	0.014 0.028 **<0.01** **0.017**	40 40 47 47	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain and straw:92d Ears: 100d Rest of plant: 113d

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) 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

A 2.1.3.2 Wheat

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applica-tions	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, UK, 2007)	3	200 g/ha	14-21 days	BBCH69	35 days
cGAP EU (Confirmatory data of Art. 12, EFSA, 2020)	3	200 g/ha	14-21 days	BBCH69	35 days
Intended cGAP (1*)	2	180 g/ha	14 days	BBCH61	42 days

* 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

Comments of zRMS:	One decline trial was conducted in N-EU to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio and Triazole Derivative Metabolites: 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat after two foliar application with Prothioconazole 300 EC. Prothioconazole 300 EC was applied two times with a nominal application rate of 195 g/ha PTZ. First application was 19 days before BBCH 69, and the second application at BBH 69, 48 days before the commercial harvest. The wheat specimens were analysed for residues of the triazole metabolites following the analytical method 01062/M004. The results of the analyses were accepted, since the average recovery data of each analyte in each matrix was found between 70 and 110% and the coefficient of variation (CV) was ≤ 20%. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte. **Results:** No residue of 1,2,4-T was detected in untreated or treated specimens. Some residue of TA, TAA and TLA were detected in the control specimens. <u>Grain</u> In treated specimens of wheat grain at harvest no residues of 1,2,4-T and TLA were found. Residues of TA and TAA were 0.467 mg/kg and 0.0568 mg/kg, respectively. <u>Straw</u> In treated specimens of wheat straw at harvest no residues of 1,2,4-T were found. Residues of TA, TAA and TLA were 0.0352 mg/kg, 0.0767 mg/kg, and 0.0741 mg/kg, respectively. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 7.2.3/04
Report	Prothioconazole – Residue Study on Wheat in Northern Europe – 2020 Grall, E. 2022 Report no: EGL-20-42538
Guideline(s):	Yes General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). Guidance for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev.4, 11 July 2000).

	Guidance Documents on Pesticide Residue Analytical Methods (SANCO/825/00 rev.8.1, 16 Nov. 2010). OECD (2007): Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio, as well as Triazole Derivative Metabolites in raw agricultural commodity (RAC whole plants, grain and straw) of wheat after two applications of PROTHIOCONAZOLE 300 EC. The crop was subjected to a residue program which simulated the use of PROTHIOCONAZOLE 300 EC as a fungicide in wheat in Northern Europe (Poland) in 2020.
Target application rate was 0.65 L/ha and target application time: Application 1 14 ± 2 days before application 2, and application 2 at BBH69.

Two plots were established in the trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha. Application 1 took place 19 days before application 2 (deviation from study plan, application 2 was delayed by rain and waiting for crop stage). Application 2 took place at BBCH 69.
Specimens of whole plant were taken at 0, 7 and 14 DALA. At 35 DALA, ears and rest of plant were collected and grain and straw were collected at commercial harvest.
Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped by freezer truck to the analytical test site for prothioconazole and prothioconazole-desthio metabolites.

Analyses of specimens were performed at SGS INSTITUT FRESENIUS GmbH, Germany. Homogenized field specimens aliquots were received deep frozen by SGS from Food Safety Laboratory. They were delivered on 29 October 2020, and kept deep frozen until analysis. The method for the analysis of 1,2,4-T, TA, TAA and TLA, was based on the analytical method 01062/M004 (T. Class; "Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-triazole, triazolylalanine, triazole acetic acid and triazole lactic acid by LC/DMS/MS/MS in plant materials", BASF DocID 2012/1294644, 07 December 2011) Analytes were extracted with a mixture of methanol and water, filtered, concentrated and cleanedup by dispersive SPE cartridge. The analytes were determined by LC-DMS/MS/MS.
Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.
Limit of detection (LOD) was found to be 0.003 mg/kg for all analytes.

No residue of 1,2,4-T was detected in untreated or treated specimens.
Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years (2020, 2019 and 2018). All TDM residues in control specimens were close to LOQ (maximum 0.0122 mg/kg in whole plant at 0 DALA) and increased slightly in grain at harvest (up to 0.0609 mg/kg for TA in grain).
Residue of Triazole Alanine (TA) were 0.0339 mg/kg in whole plant the day of application and remained present in grain and straw at harvest (0.467 and 0.0352 mg/kg respectively).
Residue of Triazole Acetic Acid (TAA) were 0.0163 mg/kg in whole plant the day of application and remained present in grain and straw at harvest (0.0568 and 0.0767 mg/kg respectively).
Residue of Triazole Lactic Acid (TLA) were 0.0131 mg/kg in whole plant the day of application and remained present in straw at harvest (0.0741 mg/kg, < LOQ in grain).

Results are shown in table A6 below.

Table A 6: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
Trial number EGL-20-42538 PL01 Poland Warmińsko Mazurskie 14-100 Brzydowo	Winter Wheat Julius	1- 20/09/2019 2- 13/06 to 23/06/2020 3- 10/08/2020	190 190	298 298	63.7 63.7	04/06/2020 23/06/2020	BBCH49 BBCH69	Whole plant Whole plant Whole plant Ears Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 **<0.01** **<0.01**	0.034 0.16 0.19 0.39 <0.01 **0.467** **0.035**	0.016 0.017 0.019 0.058 0.017 **0.057** **0.077**	0.013 0.029 0.027 <0.01 0.037 **<0.01** **0.074**	0 7 14 35 35 48 48	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain:116 Straw: 132 Whole plant: 164 Ears: 132

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) 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

A 2.1.3.2.2 Study 2

Comments of zRMS:	Six supervised residue trials (4H and 2 D) were conducted under field conditions in northern Europe to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in RAC specimens of wheat (whole plant, ears, rest of plant, grain and straw) after two applications of Prothioconazole 300 E. The spraying applications of Prothioconazole 300 EC were performed at 11 – 17 days before BBCH 69 and BBCH 69 with a nominal application rate of 195 g/ha. For the analysis of 1,2,4-T, TA, TAA and TLA the analytical method 01062/M004 was used, which determined the analytes by LC-DMS/MS/MS. **Results:** <u>Straw</u> In untreated specimens of wheat straw at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between < 0.010 - 0.12 mg/kg for TA, between < 0.010 - 0.081 mg/kg for TAA and between < 0.010 - 0.12 mg/kg for TLA. In treated specimens of wheat straw at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between <0.010– 0.22 mg/kg for TA, between 0.024 - 0.33 mg/kg for TAA and were 0.017 – 0.13 mg/kg for TLA. <u>Grain</u> In untreated specimens of wheat grain taken at normal commercial harvest (BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T, between 0.020 – 0.48 mg/kg for TA, between 0.010 - 0.38 mg/kg for TAA and were <0.010 mg/kg for TLA. In treated specimens of wheat grain taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between 0.27 – 1.1 mg/kg for TA, between 0.068 - 0.38 mg/kg for TAA and were <0.010 mg/kg for TLA. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 7.2.3/05
Report	Study on the Residue Behaviour of Prothioconazole in Wheat after Treatment with Prothioconazole 300 EC at six Sites under Field Conditions in Northern Europe, 2021 Thirkell C. 2022 Report no: IF21-05705310
Guideline(s):	Yes European Community Guideline 7029/VI/95 - rev.5, 22/07/97: 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 Guideline for the Testing of Chemicals No. 509: Crop Field Trial, 07 Sep 2009. OECD Principles on Good Laboratory Practice, ENV/MC/CHEM(98)17, 21/01/98. OECD (2016)Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) SANTE/2020/12830, Rev.1 (24. February 2021): Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

	OECD ENV/JM/MONO(2007) 17 -Guidance Document on Pesticide Residue Analytical Methods
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study IF21-05705310 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of wheat (whole plant, ears, rest of plant, grain and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole. The study included six supervised residue trials conducted under field conditions in northern Europe (Germany, Poland and Hungary) during the 2021 season. Four trials were conducted as harvest trials and two trials were conducted as decline trials.
The spraying applications of Prothioconazole 300 EC were performed at 11 – 17 days before BBCH 69 and BBCH 69 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha.

Decline trials were sampled five times at 0 DALA (S1), 6 DALA (S2) and 13-14 DALA (S3) as whole plant, 33-35 DALA (S4) as ears and rest of plant, and BBCH 89 (normal commercial harvest (NCH) (S5) as grain and straw. Harvest trials were sampled once at NCH (BBCH 89) (S1). As an exception grain and straw specimens were sampled from BBCH 85 or greater, in the case of growth stages below BBCH 85 ears and rest of plant were sampled.

Results are shown in table A7 below.

Table A 7: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TAA	TLA	TA		
	(a)	(b)				(c)							(d)	(e)
24980 Wallsbüll Germany F21-05705310 21-00226-01	Winter Wheat GC 0654 TRZAW RGT Reform	1. 25 Oct 2020 2. 15 - 17 June 2021 3. 05 Aug 2021	201 196	258 252	77.9 77.8	31 May 2021 17 Jun 2021	BBCH43 BBCH69	Whole plant Whole plant Whole plant Ears Rest of plant Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.11 0.11 0.097 0.3 0.083 0.29 0.13	0.11 0.11 0.095 <0.01 0.16 <0.01 0.031	0.15 0.022 0.02 0.49 0.012 0.54 0.1	0 6 13 33 33 49 49	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain:156 Straw: 151 Whole plant: 188 Ears: 150 Rest of plant: 150
88-320 Ostrowo Poland F21-05705310 21-00226-03	Winter Wheat GC 0654 TRZAW Tonnage	1. 30 Sep 2020 2. 08 - 20 June 2021 3. 28 Jul 2021	190 189	298 296	63.8 63.9	02 Jun 2021 16 Jun 2021	BBCH49 BBCH69	Whole plant Whole plant Whole plant Ears Rest of plant Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.066 0.098 0.15 0.43 0.058 0.38 0.095	0.074 0.11 0.15 0.013 0.08 <0.01 0.1	0.13 0.24 0.46 1.2 0.055 1.1 0.05	0 6 14 35 35 42 42	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain:156 Straw: 151 Whole plant: 188 Ears: 150 Rest of plant: 150
16775 Teschendorf Germany IF21-05705310 21-00226-04	Winter Wheat GC 0654 TRZAW Jack (IB)	1. 19 Oct 2020 2. 10 - 15 Jun 2021 3. 19 - 25 Jul 2021	183 192	287 300	63.8 64.0	03 Jun 2021 14 Jun 2021	BBCH49 BBCH69	Grain Straw	<0.01 <0.01	0.087 0.048	<0.01 0.017	0.45 0.079	38 38	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain:156 Straw: 151

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TAA	TLA	TA		
	(a)	(b)				(c)							(d)	(e)

16835 Wulkow Germany IF21-05705310 21-00226-05	Winter Wheat GC 0654 TRZAW RGT Reform	1. 20 Oct 2020 2. 10 - 15 Jun 2021 3. 19 - 25 Jul 2021	196 200	307 313	63.8 63.9	03 Jun 2021 15 Jun 2021	BBCH49 BBCH69	Grain Straw	<0.01 <0.01	0.38 0.33	<0.01 0.13	0.52 0.22	37 37	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain:156 Straw: 151
89-430 Kamień Krajeński Poland IF21-05705310 21-00226-06	Winter Wheat GC 0654 TRZAW Tybalt	1. 31 Mar 2021 2. 20 Jun - 02 Jul 2021 3. 09 Aug 2021	190 190	298 297	63.8 64.0	15 Jun 2021 02 Jul 2021	BBCH45 BBCH69	Grain Straw	<0.01 <0.01	0.12 0.027	<0.01 0.024	0.5 0.021	38 38	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain:156 Straw: 151
H-4461 Nyírtelek - Ferenctanya Hungary IF21-05705310 21-00226-07	Winter Wheat GC 0654 TRZAW GK Csillag	1. 12 Nov 2020 2. 28 May - 10 Jun 2021 3. 12 - 17 Jul 2021	188 187	293 293	64.2 63.8	21 May 2021 04 Jun 2021	BBCH47 BBCH69	Grain Straw	<0.01 <0.01	0.068 0.024	<0.01 0.049	0.27 <0.01	38 38	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Storage interval: Grain:156 Straw: 151

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) 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

A 2.1.3.2.3 Study 3

Comments of zRMS:	Two residue trials were conducted under field conditions in northern Europe to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in RAC specimens of wheat (whole plant, grain and straw) after two applications of Prothioconazole 300 E. The spraying applications of Prothioconazole 300 EC were performed at 13vdays before BBCH 69 and BBCH 69 with a nominal application rate of 195 g/ha. For the analysis of 1,2,4-T, TA, TAA and TLA the analytical method 01062/M004 was used, which determined the analytes by LC-DMS/MS/MS. **Results:** <u>Straw</u> In untreated specimens of wheat straw at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between < 0.010 - 0.020 mg/kg for TA, between < 0.010 - 0.043 mg/kg for TAA and between < 0.010 - 0.045 mg/kg for TLA. In treated specimens of wheat straw at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T. Residues ranged between 0.020– 0.094 mg/kg for TA, between 0.013 - 0.088 mg/kg for TAA and were 0.02 – 0.10 mg/kg for TLA. <u>Grain</u> In untreated specimens of wheat grain taken at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T and for TLA, between < 0.010 – 0.099 mg/kg for TA, between < 0.010 - 0.057 mg/kg for TAA. In treated specimens of wheat grain at BBCH 89 no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-T and for TLA. Residues ranged between 0.28– 0.61 mg/kg for TA, between 0.057 - 0.15 mg/kg for TAA. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 7.2.3/06
Report	Study on the Residue Behaviour of Prothioconazole in Wheat after Treatment with Prothioconazole 300 EC at two Sites under Field Conditions in Northern Europe, 2022 Thirkell, C. Report no: IF22-06125006
Guideline(s):	Yes European Community Guideline 7029/VI/95 - rev.5, 22/07/97: 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 Guideline for the Testing of Chemicals No. 509: Crop Field Trial, 07 Sep 2009. OECD Principles on Good Laboratory Practice, ENV/MC/CHEM(98)17, 21/01/98. OECD (2016)Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) SANTE/2020/12830, Rev.1 (24. February 2021): Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes OECD ENV/JM/MONO(2007) 17 -Guidance Document on Pesticide Residue Analytical Methods

Deviations:	No
GLP:	Yes
Acceptability:	No

The objective of the study IF22-06125006 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of wheat (whole plant, ears, rest of plant, grain and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole.
The study included two supervised residue trials conducted under field conditions in northern Europe (France and Denmark) during the 2022 season. One trial was conducted as a harvest trial and one trial was conducted as a decline trial.
The spraying applications of Prothioconazole 300 EC were performed at 13 days before BBCH 69 and BBCH 69 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha.

CONCLUSIONS:
For the analysis of 1,2,4-T, TA, TAA and TLA the analytical method 01062/M004 was used, which determined the analytes by LC-DMS/MS/MS and was validated in study IF-05707367 already evaluated.

1,2,4-T, TA, TAA and TLA were extracted with a mixture of methanol and water. An aliquot was filtered, concentrated and cleaned-up by dispersive C18-SPE step. The analytes were determined by LC-DMS/MS/MS, using two different HPLC stationary phases and a LCMS/MS instrument equipped with SelexION ion mobility technology which is based on planar differential spectrometry (DMS). Residues were quantified using stable isotopically labelled internal standards to compensate matrix effects.

Results are shown in table A8 below.

Table A 8: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TAA	TLA	TA		
(a)		(b)				(c)							(d)	(e)
F22-06125006 22-00143-01 51110 Auménancourt France (NEU) 2022	Winter Wheat Chevignon	1. 28 Sep 2021 2. 17-30 May 2022 3. 4 Jul 2022	190 189	293 291	64.8 64.9	17 May 2022 30 May 2022	BBCH61 BBCH69	Whole plant Whole plant Whole plant Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01	0.011 0.013 0.015 0.057 0.013	0.015 0.020 0.019 <0.01 0.020	0.071 0.130 0.130 0.280 0.020	0 8 14 35 35	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Max. storage interval: Whole plant: 165 days Grain: 93 days Straw: 93 days
F22-06125006 22-00143-02 6200 Aabenraa Denmarck (NEU) 2022	Spring Wheat Killburn	1. 28 Mar 2022 2. 25-28 Jun 2022 3. 9 Ago 2022	193 197	297 303	65.0 65.0	15 Jun 2022 28 Jun 2022	BBCH47 BBCH69	Grain Straw	<0.01 <0.01	0.150 0.088	<0.01 0.10	0.610 0.094	42 42	Method of analysis validated under: IF21-05707367 LOQ: 0.01 mg/kg Max. storage interval Grain: 129 days Straw: 129 days

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

A 2.1.4.1.1 Livestock feeding study 1

New data has not been provided.

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

New data has not been provided.

A 2.1.5.2 Processing studies on a core set of representative processes

New data has not been provided.

A 2.1.6 Magnitude of residues in representative succeeding crops

New data has not been provided.

A 2.1.7 Other/Special Studies

New data has not been provided.

A 2.2 Folpet

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

Comments of zRMS:	The study was evaluated by zRMS-PL in dRR of SAP50SCF (June 2024). zRMS-PL conclusions: *The study is ongoing. The current interim report reflects the results for folpet and phthalimide obtained after 340 days of storage.* *The results of Gordo study demonstrate the stability of residues of folpet and phthalimide upon deep frozen storage at – 18 °C for up to 340 days months in wheat and barley grain.* *The performance of the analytical method was demonstrated by recovery tests injected concurrently with the samples. The results achieved fulfill with the criteria set on SANTE/2020/12830.* The results of the interim report are acceptable.

Reference:	KCP 7.3.1/01
Report	Stability Study of Folpet and Metabolites in Cereals Stored Under Deep Freezing Conditions. Gordo, J. 2024. Laboratorio Residuos de Pesticidas Ascenza Agro SA. Report nº EST06/22 (study ongoing)
Guideline(s):	Yes. - OECD Series on Principles of GLP and Compliance Monitoring: Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17). - Decreto-Lei nº 99/2000 of 30 May 2000 (Portuguese decree on OECD Principles of GLP).
Deviations:	TBC
GLP:	Yes
Acceptability:	Yes

Materials and methods
The objective of the current study is to evaluate the stability of:
Folpet, Phthalimide and Phthalic acid residues in grains of wheat and barley under freezing storage conditions (≤ -18 ºC) over a period of 18 months for wheat and and 19 months for barley;
This study will be conducted by spiking untreated samples at least ten times the limit of quantification of the method.

The analytical work will be performed using method that was validated under Laboratório de Resíduos de Pesticidas GLP study nº VAL22/21.

Internal samples will be available in order to perform the study. The absence of Folpet and metabolites residues will be checked prior to the quantification of the spiked samples.

Samples will be extracted following analytical method that was validated at Laboratório de Resíduos de Pesticidas under GLP study Nº VAL22/21 which follows the QuEChERS method.

The quantification will be done by a liquid chromatography coupled to tandem mass spectrometry.

The stability study will be as described below:

- Several aliquots from previous processed and homogenous samples will be stored in frozen conditions;
- Analytical portions will be stored at ≤ -18 ºC until analysis;
- Samples will be spiked at ten times the limit of quantification of the analytical method;
- Three replicates of supplemented samples will be analysed at the same day of the fortification procedure (zero time), together with a control sample and a recovery test;
- Analytical portions supplemented will be analysed according to the storage described in the table below, at freezing conditions;
- Supplemented samples will be analysed in triplicate;
- In each instrumental analysis day, at least one spike will be done to run together with supplemented samples and one control sample;
- If necessary, dilutions will be done in order to quantify in the validated calibration range;
- Additional samples will be prepared in order to repeat or extend the storage timing if needed.

The storage stability of samples will be evaluated over the period described in the table below.

The analytical work could be distributed in several ways. The table below describes the experimental work design that will be followed.

Specimen	Series	Day of Supplementation and Storage	Planned Storage Period (months)
Wheat grain	S_0	0	0
	S_{365}	0	365
	S_{489}	0	489
	S_{551}	0	551
Barley grain	S_0	0	0
	S_{365}	0	365
	S_{520}	0	520
	S_{582}	0	582

In each analytical series a tolerance of 5 days will be allowed. As long as it leads to storage periods longer than the target time in each analytical series, bigger tolerances will be allowed without need of a formal deviation.

Results and discussions:

Table A 1: Summary of concurrent recoveries of folpet and phtalamide from wheat and barley grain

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)
Folpet				
Wheat grain	0.1	0	1	78.4

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)
	0.1	340	1	74.7
Barley grain	0.1	0	1	122.9
	0.1	340	1	84.3
Phtalamide				
Wheat grain	0.1	0	1	108.7
	0.1	340	1	88.8
Barley grain	0.1	0	1	125.8
	0.1	340	1	109.5

Table A 2: Stability of folpet and phtalamide residues in wheat and barley grain following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual (mean) recovered residues (mg/kg)	Individual recoveries (%)
Folpet				
Wheat grain	0.100	0	0.120 0.110 0.100 (0.110)	109.2
	0.100	340	0.120 0.110 0.110 (0.110)	111.8
Barley grain	0.100	0	0.074 0.093 0.096 (0.088)	87.8
	0.100	340	0.110 0.100 0.110 (0.110)	106.5
Phtalamide				
Wheat grain	0.100	0	0.088 0.100 0.099 (0.096)	95.5
	0.100	340	0.100 0.110 0.110 (0.110)	107.4
Barley grain	0.100	0	0.087 0.110 0.120 (0.110)	105.6
	0.100	340	0.100 0.100 0.098 (0.100)	100.4

Conclusion

The stability results after storage at or below -18 ºC, for 340 days, is demonstrated for folpet and phtalamide in wheat grain and barley grain.

A 2.1.1.1.1.2 Study 2

Comments of zRMS:	The study was evaluated by zRMS-PL in dRR of SAP50SCF (June 2024). zRMS-PL conclusions: *The results of Jooss study demonstrate the stability of residues of folpet and phthalimide upon deep frozen storage at – 18 °C for up to 12 months in wheat (whole plant), barley (whole plant), wheat (straw), barley (straw) and up to 6 months for beer.* *For all matrices the applicability/suitability of the methods was successfully demonstrated according to SANTE/2020/12830, rev. 2.* The results of the interim report are acceptable.

Reference:	KCP 7.3.1/02
Report	Storage Stability of Folpet and its Metabolites in Various Matrices under Deep Frozen Conditions. Jooss, S. 2024. Eurofins Agroscience Services. Report Nº: S22-07592 (study ongoing).
Guideline(s):	Yes. Guideline 7032/VI/95 rev.5 (Appendix H) of the Commission of the European Communitie OECD Test Guideline No 506.
Deviations:	TBC
GLP:	Yes
Acceptability:	Yes

Materials and methods
The objective of the study is to obtain data about the storage stability of folpet and its metabolites PI, PA and PLA in/on representative cereal matrices and beer at ≤ 18 °C (target) in the dark over a storage period of up to 20 months in accordance with guideline 7032/VI/95 rev.5 (Appendix H) of the Commission of the European Communities and OECD Test Guideline No 506.

Matrix Types, Origin, Preparation and Storage:

- Wheat & Barley whole plant (high water) and Wheat & Barley straw (dry): The sample material will be thoroughly homogenised in a knife mill or a cutter and if necessary with dry ice.
- Beer (high water): Beer will be thawed and homogenized by shaking or stirring before taking aliquots for analysis.

Untreated sample material will be supplied by the Test Facility. Sample material origin will be recorded in the raw data and may be included in the final report. Weighed untreated control samples for preparation of concurrent recoveries will be stored at ≤ -20 °C (target) until fortification and extraction.

Test Method:
Method Reference: S22-01156
Validation Status: Fully validated
Limit of Quantification (LOQ): As validated within S22-01156
Limit of Detection (LOD): Lowest calibration standard (≤ 30 % of the LOQ)

Test Program:

- Fortification: An appropriate amount of homogenised sample material is weighed into an appropriate extraction or storage vessel and fortified at the corresponding 10x LOQ level with the test / reference items.
  For all samples that are intended to be used for assessment of storage stability (storage samples) the analytes will be fortified separately. All freshly prepared fortification samples for

demonstrating the analytical performance of the method (recovery samples) may be prepared by fortifying all analytes jointly.
The spiking procedure should be undertaken in the same way as the spiking of the samples in the validation of the analytical methods.
After fortification, the storage vessels will be sealed with screw caps and placed into the deep freezer.
For day 0 testing a set of three (3) storage samples will be prepared. For each of the other storage intervals (12, 16/17, 18/19 or 20 months for wheat and barley and 6 months for beer) a set of at least two (2) storage samples for analysis is prepared per analyte.
In addition, a number of four (4) complete interval sets for wheat and barley and two (2) complete interval sets for beer will be prepared per analyte and matrix at the beginning of the experimental phase for possible extension of the storage interval or as backup for a failure.
The backup samples may be used in case the analysis of the original storage samples failed and a repetition is required. The backup samples may also be used to cover additional testing intervals.

- Sample Storage and Analysis: The samples have to be kept in the dark at a storage temperature of ≤ 20 °C (target). The temperature has to be recorded during the entire storage period.
  On day 0, three (3) of the storage samples per analyte and matrix will be analysed together with one (1) control sample, while the rest of fortified samples are put into the freezer.
  Furthermore, and in order to demonstrate suitability/applicability three (3) recovery samples at the LOQ are analysed at day 0 for each matrix and analyte.
  For each further testing interval (12, 16/17, 18/19 or 20 months for wheat and barley and 6 months for beer) two (2) storage samples per analyte and matrix will be analysed together with one (1) control sample and two (2) procedural recoveries at the level of 10x LOQ.

Results and discussions:

Table A 3: Summary of concurrent recoveries of folpet and phtalamide from wheat whole plant and straw, barley whole plant and straw and beer.

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Folpet					
Wheat whole plant	0.01	0	3	90.8 96.4 90.8	92.7 ± 3.5
	0.10	362	2	90.8 98.4	94.6
Wheat straw	0.01	0	3	88.4 97.6 93.6	95.6 ± 4.8
	0.10	362	2	95.8 104.0	99.8
Barley whole plant	0.01	0	3	69.2 69.2 72.8	71.0 ± 3.6
	0.10	362	2	84.0 89.6	86.8
Barley straw	0.01	0	3	84.8 83.6 77.6	80.6 ± 5.3
	0.10	362	2	81.2 86.8	84.0
Beer	0.01	0	3	83.4	90.8 ± 16.0

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
				80.5 101.0	
	0.10	120	2	94.0 94.2	94.1
	0.10	181	2	90.3 97.4	93.9
Phtalamide					
Wheat whole plant	0.01	0	3	109.0 112.0 102.0	108.0 ± 4.7
	0.10	361	2	94.3 90.3	92.3
Wheat straw	0.05	0	3	110.0 112.0 106.0	109.0 ± 4.2
	0.50	361	2	101.0 97.6	99.2
Barley whole plant	0.01	0	3	84.4 89.2 89.2	87.6 ± 3.2
	0.10	361	2	92.4 97.2	95.0
Barley straw	0.05	0	3	111.0 115.0 106.0	111.0 ± 5.6
	0.50	361	2	98.5 105.0	102.0
Beer	0.01	0	3	117.0 119.0 118.0	118.0 ± 0.8
	0.10	119	2	83.1 87.2	85.3
	0.10	180	2	97.7 103.0	100.0

Table A 4: Stability of folpet and phtalamide residues in wheat whole plant and straw, barley whole plant and straw and beer following storage at or below -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Mean recovery * (%)
Folpet				
Wheat whole plant	0.10	0	0.104 0.094 0.096	98.0
	0.10	362	82.8 77.2	80.0
Wheat straw	0.10	0	0.127 0.130 0.132	117.0
	0.10	362	0.089 0.084	72.6

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Mean recovery * (%)
Barley whole plant	0.10	0	0.088 0.085 0.082	85.1
	0.10	362	0.081 0.088	84.4
Barley straw	0.20**	0	0.200 0.192 0.174	94.3
	0.10	362	0.104 0.101	103.0
Beer	0.10	0	0.114 0.109 0.108	110.0
	0.10	120	0.085 0.093	88.9
	0.10	181	0.077 0.084	80.5
Phtalamide				
Wheat whole plant	0.10	0	0.126 0.129 0.125	116.0
	0.10	361	0.102 0.102	92.5
Wheat straw	0.5	0	0.424 0.476 0.428	88.5
	0.5	361	0.424 0.378	80.2
Barley whole plant	0.10	0	0.114 0.114 0.116	111.0
	0.10	361	0.090 0.092	91.2
Barley straw	0.5	0	0.516 0.460 0.444	94.7
	0.5	361	0.484 0.464	91.7
Beer	0.10	0	0.084 0.084 0.082	83.4
	0.10	119	0.082 0.080	80.8
	0.10	180	0.079 0.078	78.7

*corrected for for blank residues >30% of LOQ
** spiking error

Conclusion

For folpet and phthalimide in all matrices the average amount of analyte recovered relative to the nominal fortification level was ≥ 70 % at any testing interval investigated.
The study is deemed sufficient for assessing the stability of folpet and phthalimide in homogenates of wheat

(whole plant), barley (whole plant), wheat (straw), barley (straw) and beer upon storage at ≤ -18 °C, for 6 months for beer and 12 months for all other matrices respectively.

A 2.1.1.1.2 Storage stability of residues in animal products

No further study submitted and no data required.

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 further study submitted and no data required.

A 2.1.2.1.3 Nature of residues in processed commodities

Comments of zRMS:	The study has been already evaluated at EU level, under the framework of folpet renewal. Based on the available data it can be concluded that folpet is rapidly hydrolyzed into phthalimide, phthalamic acid and phthalic acid under standard hydrolysis conditions.

Reference:	KCP 7.3.2/01
Report	[^{14}C]-Folpet: Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation, M Fitzmaurice and E Mackenzie, 2007, report No OZ/07/007
Guideline(s):	European Council Directive 91/414/EEC as amended by Commission Directive 96/68/EC Section 6.5, Subsection 6.5.1. Guideline 7035/VI/95 Revision 5, Appendix E
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

A hydrolysis study was performed in order to investigate the fate of folpet ingredient under 3 typical conditions of processing 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, see **Table A 2.1.2.1.3-2**). Buffer solutions containing the radiolabelled folpet at an initial concentration of 0.5 mg/L were incubated in closed high pressure stainless steel vessels placed in an autoclave at the desired temperature. Test solutions were analysed before and after incubation under the above described conditions. Samples were cooled in running water after incubation. Transformation products were identified by co-chromatography by HPLC with certified standards and confirmed by LC-MS/MS.

All samples generated during the study were profiled initially by HPLC on the day of their generation. Processed samples were profiled within 4 hours of their generation. Samples were subsequently stored at < -15°C in the dark.

RESULTS AND DISCUSSION

Analysis of the buffer solutions hydrolysed under pasteurisation conditions indicated that folpet was degraded to phthalimide, which was the major component present. Folpet was detected at 94.3% of applied radioactivity (0.492 mg/L) before processing, in addition to 5.8% phthalimide (0.015 mg/L). Folpet was not detected after pasteurisation. After processing, phthalimide was detected at 98% of applied radioactivity (0.252 mg/L). Phthalamic acid and phthalic acid were also detected in lower amounts, 0.4 % and 1.0% of applied radioactivity (0.001 and 0.003 mg/L). Folpet and 2-cyanobenzoic acid were not detected (<0.001 mg/L) after processing.

Analysis of the buffer solutions hydrolysed under baking, brewing and boiling conditions indicated that phthalimide and phthalic acid were the major components present. Folpet was detected at 90.6% of applied radioactivity (0.443 mg/L) before processing. Phthalimide and a small amount of an unidentified component (RRT 0.69) were also found at levels of 8.5% and 0.9% of applied radioactivity (0.021 and 0.005 mg/L) before processing. After processing, residues of folpet were not detected. Phthalimide was detected at 56.1% of applied radioactivity (0.136 mg/L) and phthalic acid at 40.7% of applied radioactivity (0.112 mg/L). Phthalamic acid was also detected at 2.8% of applied radioactivity (0.008 mg/L).

Analysis of the buffer solutions hydrolysed under sterilisation conditions indicated that phthalic acid and phthalamic acid were the major components present. Folpet was detected at 97.1% of applied radioactivity (0.489 mg/L) before processing. Small amounts of phthalimide and an unidentified component (RRT 0.90) were also found at levels of 2.2% and 0.7% of applied radioactivity (0.006 and 0.003 mg/L) before processing.
Folpet was not detected after sterilisation. Phthalimide levels were slightly higher at 6.0% of applied radioactivity (0.015 mg/L) but the major degradates were phthalamic and phthalic acid at 32.8% and 44.9% of applied radioactivity (0.091 and 0.126 mg/L). 2-cyanobenzoic acid was also detected at 11.0% of applied radioactivity (0.027 mg/L). A second unidentified component (RRT 0.43) was found at levels of 4.5% of applied radioactivity (0.023 mg/L) after processing.

Table A-1 Identification of compounds from high temperature hydrolysis study

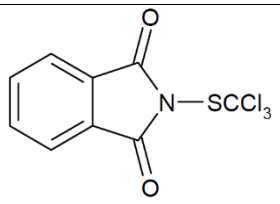
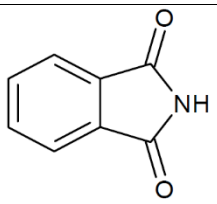
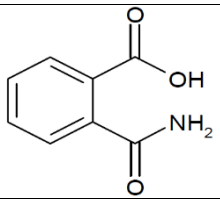
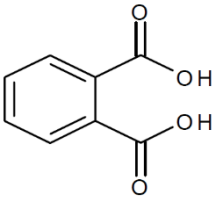
Common name/code ID No.	**Chemical structure**
Folpet	
Phthalimide	
Phthalamic acid	
Phthalic acid	

Table A-2 Standard hydrolysis study of folpet

Component	Test Conditions					
	Pasteurization		Boiling/brewing/baking		Sterilisation	
	Before Processing	After Processing	Before Processing	After Processing	Before Processing	After Processing
Folpet	94.3	-	90.6	-	97.1	-
Phthalimide	5.8	97.8	8.5	56.1	2.2	6.0
Phthalamic acid	-	0.4	-	2.8	-	32.8
Phthalic acid	-	1.0	-	40.7	-	44.9

2-Cyanobenzoic acid	-	-	-	-	-	11.0
Unidentified 1	-	-	-	-	-	4.5
Unidentified 2	-	-	0.9	-	-	-
Unidentified 3	-	0.5	-	-	-	-
Unidentified 4	-	-	-	-	0.7	-

CONCLUSIONS
The results of this study indicate that residues of folpet are likely to be degraded to form phthalimide, phthalamic acid, phthalic acid and 2-cyanobenzoic acid during processing.

A 2.1.2.2 Nature of residues in livestock

No further study submitted and no data required.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

Table A-3 Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI [days]
cGAP EU (DAR, Italy, 2005)	2	750 g a.s./ha	7-28 days	Up to z65	42
cGAP EU (Art. 12, EFSA, 2014)	2	750 g a.s./ha	14 days	BBCH 31-59	42
cGAP EU (EFSA, 2021)	2	750 g a.s./ha	14 days	BBCH 31-59	42
Intended cGAP (1)	2	600 g a.s./ha	14 days	BBCH 30-59	42

* 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

Comments of zRMS:	The study was evaluated by zRMS-PL in dRR of SAP50SCF (June 2024). zRMS-PL conclusions: *Eight field trials (4 DCS and 4 HS) were conducted in Northern Europe according to the OECD Test No. 509 to gain the residue level of folpet and its two metabolites phthalimide and phthalic acid in wheat specimens (whole plant, grain and straw) following two foliar applications of SAP50SCF, containing folpet as active ingredient (500 g a.s./L).* *Analytical phase was performed in independent studies (phase study code is: S22-03719). The study is considered acceptable.*

Reference:	KCP 7.3.3/01
Report	Magnitude of the residue of folpet in representative winter wheat Raw Agricultural Commodities after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern Europe- 2021, A.S. Lesbazeilles Beauvalon, 2021, report n° 21-00160 (field phase)
Guideline(s):	Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market Commission Regulation (EU) No 283/2013 and 284/2013 setting out the data requirements for active substances and plant protection products, in accordance with Regulation (EC) No 1107/2009 General recommendations for the design, preparation and realization of residue trials, 7029/VI/95-rev 5, 22.07.97 and amendments OECD (2009),Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing.

	EU pesticide residue legislation: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 - SANCO/3029/99 rev.4, 11 July 2000 EU pesticide residue legislation: Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes – SANTE/2020/12830 rev.1, 24 February 2021 Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

A study on the magnitude of the residue of folpet and its metabolites in representative winter wheat Raw Agricultural Commodity (RAC) was conducted in Northern Europe, following two foliar application(s) of SAP50SCF, containing folpet as active ingredient (500 g a.s./L).
Eight wheat trials, 4 DCS and 4 HS, were set up in Northern Europe (Northern France, Germany, Hungary and Poland). Each trial consisted of one untreated plot U and one treated plot.
Two foliar applications of SAP50SCF were performed on the treated plot T1 at the target dose rate of 1.2 L/ha formulated product (FP) (equivalent to 600 g a.s./ha). The target spray of water volume was in the range 150 to 400 L/ha, according to Good Agricultural Practices.
The deviations calculated on the amount of formulated product per hectare were all between ±5%.
Foliar applications were performed following the actual schedule specified in study plan: SAP50SCF was applied 13-21 DBA2 and at BBCH 61 on plot T1.
In the decline trials (DCS), RAC specimens (whole plants, grain and straw) for analyses were collected at 0 DBLA and at BBCH 89 (commercial harvest) in the control plot and at 0 DALA, 13-15, 27-29 and 34-78 DALA, commercial harvest, (BBCH 89) in the treated plot T1.
In the harvest trials (HS), RAC specimens (grain and straw) for analyses were collected at BBCH 89 (commercial harvest) in the control plot and treated plot (44-56 DALA).
All RAC specimens from plot U and T1, were deep frozen on the day of collection and stored at the target temperature below -18°C. All specimens remained deep frozen during storage at field test sites and homogenization test site, during shipment and storage at the analytical laboratory. RAC specimens were maintained frozen after collection through the shipment for homogenization.

A 2.1.3.1.2 Study 2

Comments of zRMS:	The study was evaluated by zRMS-PL in dRR of SAP50SCF (June 2024). zRMS-PL conclusions: *Method validation was not performed within this study because the analytical methods were previously validated in accordance to SANTE/2020/12830, rev.1 for the determination of folpet, phthalimide and phthalic acid in wheat (green material), wheat (grain) and wheat (straw) (as representatives of dry matrices and matrices with high water content) with an LOQ of 0.01 mg/kg for folpet in all matrices and phthalimide in (wheat green material) and wheat (grain) as well as 0.05 mg/kg for phthalic acid in all matrices and phthalimide in wheat (straw) in GLP study S22-01156.* *With regard to selectivity, accuracy and precision, the analytical methods were applied successfully for each analytical set when analysing the samples of the study. The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830.* *Sufficient stability data are available to support the residue data presented in this study.* *Trials GAP for wheat: 2 x 0.60 kg a.s. /ha with 12-21 days between application, up to BBCH 61, PHI 34-78.* *The following residues were detected in the wheat grain samples:* *E=RA (Sum of folpet and phthalimide expressed as folpet): 4x<0.03, 0.032, 0.044, 0.060, 0.087 mg/kg.* *The study is considered acceptable.*

Reference:	KCP 7.3.3/02
Report:	Study on the Residue behaviour of folpet and its metabolites in winter wheat after two applications of SAP50SCF (Folpet 500 g/l SC) in Northern Europe – 2021. Sandro Jooss, 2022. Report No: S22-03719 (analytical phase)
Guideline(s):	Commission Regulation (EU) No 283/2013 and 284/2013 setting out the data requirements for active substances and plant protection products, in accordance with Regulation (EC) No 1107/2009 SANTE/2020/12830, Rev1 Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes. 24/02/2021 OECD Series on Testing and Assessment, Number 72. OECD ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

The objective of the study was to analyse residues of folpet as well as its two metabolites phthalimide and phthalic acid in wheat specimens with limits of quantification (LOQ) of 0.01 mg/kg for folpet in all matrices and for phthalimide in wheat (whole plant) and wheat (grain) as well as 0.05 mg/kg for phthalimide in wheat (straw) and phthalic acid in all matrices.

Analytical methods:
Extraction of Folpet from Wheat: In brief, samples of wheat (whole plant), wheat (grain) and wheat (straw) were extracted with acetonitrile containing 1% of formic acid and water was added. Isotopically labelled internal standard was added to the raw extract before clean-up. Addition of internal standard amount must be adjusted depending on the residue level obtained within the samples if residues are higher.

Clean-up was carried out by partition into acetonitrile (addition of citrate salts, magnesium sulfate and sodium chloride) followed by dispersive SPE with PSA and magnesium sulfate). Quantification was performed by use of LC MS/MS with an isotopically labelled internal standard.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Extraction of Phthalimide from Wheat: In brief, samples of wheat (whole plant), wheat (grain) and wheat (straw) were extracted with acetonitrile containing 1% of formic acid and water was added. Isotopically labelled internal standard (addition of internal standard must be adjusted to the necessary dilution) was added to the raw extract before clean-up. Clean-up was carried out by partition into acetonitrile (addition of citrate salts, magnesium sulfate and sodium chloride) followed concentration and dilution in water containing 0.1% of acetic acid. Quantification was performed by use of LC MS/MS with an isotopically labelled internal standard.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix, except cereal straw, with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For cereal straw, the LOQ was 0.05 mg/kg and the LOD was 0.015 mg/kg.

Extraction of Phthalic Acid from Wheat: In brief, samples of wheat (whole plant), wheat (grain) and wheat (straw) were extracted with acetonitrile containing 1% of formic acid and if necessary, after addition of water. Isotopically labelled internal standard was added to the raw extract before clean-up. Addition of internal standard amount must be adjusted depending on the residue level obtained within the samples if residues are higher.
Clean-up was carried out by partition into acetonitrile (addition of magnesium sulfate and sodium chloride). Quantification was performed by use of LC MS/MS with an isotopically labelled internal standard.
The limit of quantification (LOQ) of the analytical method was 0.05 mg/kg for each matrix with a limit of detection (LOD) set at 0.015 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Method validation and concurrent recoveries: The analytical methods were previously validated at Eurofins Agroscience Services EAG Laboratories GmbH according to SANTE/2020/12830, rev. 1 for wheat (green material), wheat (grain) and wheat (straw) as representatives for dry matrices and matrices with high water content, respectively. Five (5) fortifications of untreated control samples at the level of LOQ and five (5) fortifications at the level of 10x LOQ were performed per analyte/matrix combination. For each analytical set of sample analysis, the method's applicability in terms of accuracy and repeatability was assessed by concurrent recoveries.
For folpet and phthalimide, blank values of control sample materials used for recovery determinations did not exceed a level that would correspond to 30 % of the LOQ.
For phthalic acid, blank values of reagents and those control sample materials used for recovery determinations in most cases exceeded a level that would correspond to 30 % of the LOQ. Therefore, recoveries for phthalic acid were corrected for both, residues >30% of LOQ detected in control samples and residues >30% of LOQ detected in reagent blanks.
Fortifications for the individual analyte/matrix combinations were performed at levels of 0.01 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.5 mg/kg, 2.0 mg/kg, 4.0 mg/kg, 5.0 mg/kg and/or 14 mg/kg and therefore encompassed the range of target analyte concentrations found in the samples of the study.
The accuracy and precision of the method was considered to be acceptable since the mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1 and OECD ENV/JM/MONO(2007)17.

Residue results are summarized in Table A-4 below:

Table A-4 Summary of the studies 1 & 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Folpet	Phthalimide	Sum of folpet and phthalimide expressed as folpet		
	(a)	(b)				(c)						(d)	(e)
21-00160-01 Poland (Warmińsko-Mazurskie) Janowiec Kościelny 13-111	Winter wheat MONDIA	1. 20/09/20y 2. 23/06 to 06/07/21 3. 27/07/21	548.1 554.40	295.0 298.5	185,8 185,7	08/06/21 23/06/21	55 61	Whole plant Whole plant Whole plant Grain Straw	11 6,4 1,3 0,015 1,6	3,9 2,2 0,58 0,023 1,1	19 11 2,5 <u>0,06</u> 3,9	0 13 27 34 34	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) <u>Maximum storage:</u> Grain: 315 days W.plant: 344 days Straw: 330 days
21-00160-02 Poland (Kujawsko-Pomorskie) Cerekwica 88-400	Winter wheat BATAJA	1. 23/09/20 2. 15/06 to 25/06/21 3. 30/07/21	583.68 728.16	304.0 289.3	192,0 251,7	02/06/21 16/06/21	49 61	Grain Straw	0,004 1,1	0,008 1,1	<u>0,019</u> 3,4	44 44	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) <u>Maximum storage:</u> Grain: 312 days Straw: 320 days

21-00160-03 Hungary (Heves) Maklár H-3397	Winter wheat GENIUS	1. 13/10/20 2. 28/05 to 10/06/21 3. 20/07 to 23/07/21	582.72 569.76	310.0 296.7	188,0 192,0	11/05/21 28/05/21	41 61	Grain Straw	< LOD 0,80	0,005 0,45	0,011 1,7	56 56	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 319 days Straw: 327 days
21-00160-04 Hungary (Szabolcs-Szatmár-Bereg) Nyírtelek H-4461	Winter wheat GK CSILLAG	1. 12/11/20 2. 28/05 to 10/06/21 3. 12/07 to 17/07/21	569.76 550.56	296.7 286.7	192,0 192,0	15/05/21 28/05/21	39 61	Whole plant Whole plant Whole plant Grain Straw	8,9 3,9 2,8 0,004 3,3	3,6 1,5 0,52 0,011 0,84	16 7,0 3,8 0,026 5,0	0 13 27 78 78	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 326 days W.plant: 370 days Straw: 341 days
21-00160-05 Germany (Schleswig-Holstein) Wallsbüll 24980	Winter wheat TALENT	1. 28/10/20 2. 15/06 to 17/06/21 3. 05/08/21	595.20 576.00	206.7 200.0	288,0 288,0	01/06/21 15/06/21	43 61	Grain Straw	0,005 4,4	0,008 1,6	0,020 7,6	51 51	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 306 days Straw: 321 days

21-00160-06 Germany (Brandenburg) Kerzlin 16845	Winter wheat AKTIVUS	1. 01/10/20 2. 07/06 to 10/06/21 3. 19/07 to 25/07/21	576.00 576.00	300.0 300.0	192,0 192,0	17/05/21 07/06/21	39 61	Grain Straw	< LOD 0,76	0,006 0,51	0,013 1,8	44 44	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 321 days Straw: 329 days
21-00160-07 Northern France (Haut de France) Mont Notre Dame 02220	Winter wheat CHEVIGNON	1. 16/10/20 2. 15/06 to 19/06/21 3. 20/07 to 30/07/21	564.48 568.32	245.0 246.7	230,4 230,4	02/06/21 14/06/21	59 61	Whole plant Whole plant Whole plant Grain Straw	8,7 2,2 1,7 0,032 1,6	2,7 0,63 0,26 0,027 0,91	14 3,5 2,3 0,087 3,4	0 15 29 36 36	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 314 days W.plant: 358 days Straw: 322 days
21-00160-08 Northern France (Grand-Est) Bourgogne 51110	Winter wheat NEMO	1. 06/11/20 2. 09/06 to 15/06/21 3. 28/07/21	576.00 579.84	250.0 251.7	230,4 230,4	27/05/21 09/06/21	47 61	Whole plant Whole plant Whole plant Grain Straw	9,4 3,4 2,0 0,004 0,96	1,9 0,73 0,34 0,017 0,44	13 4,8 2,7 0,038 1,8	0 15 28 49 49	Analytical method: S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 314 days W.plant: 358 days Straw: 322 days

A 2.1.3.2 Barley

Table A-5 Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI [days]
cGAP EU (EFSA, 2021)	2	750 g a.s./ha	7-10 days	BBCH 30-59	42
Intended cGAP (1)	2	600 g a.s./ha	14 days	BBCH 30-59	42

* 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

Comments of zRMS:	The study was evaluated by zRMS-PL in dRR of SAP50SCF (June 2024). zRMS-PL conclusions: *Eight field trials (4 DCS and 4 HS) were conducted in Northern Europe according to the OECD Test No. 509 to gain the residue level of folpet and its two metabolites phthalimide and phthalic acid in barley specimens (whole plant, grain and straw) following two foliar applications of SAP50SCF, containing folpet as active ingredient (500 g a.s./L).* *Analytical phase was performed in independent studies (phase study code is: S22- 01157). The study is considered acceptable.*

Reference:	KCP 7.3.3/03
Report	Magnitude of the residue of folpet in representative barley Raw Agricultural Commodities after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern Europe- 2021, A.S. Lesbazeilles Beauvalon, 2021, report n° 21-00139 (field phase)
Guideline(s):	Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market Commission Regulation (EU) No 283/2013 and 284/2013 setting out the data requirements for active substances and plant protection products, in accordance with Regulation (EC) No 1107/2009 General recommendations for the design, preparation and realization of residue trials, 7029/VI/95-rev 5, 22.07.97 and amendments OECD (2009),Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing. EU pesticide residue legislation: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 - SANCO/3029/99 rev.4, 11 July 2000 EU pesticide residue legislation: Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes – SANTE/2020/12830 rev.1, 24 February 2021 Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

A study on the magnitude of the residue of folpet and its metabolites in representative barley Raw Agricultural Commodity (RAC) was conducted in Northern Europe, following one or two foliar application(s) of FOLPET 500 g/L (SAP50SCF) containing folpet as active ingredient (500 g a.s./L).

Eight barley trials, 4 DCS and 4 HS, were set up in Northern Europe (Northern France, Germany, Hungary and Poland). Each trial consisted of one untreated plot U and one treated plot T1 or two treated plots T1/T2 (T2 processing plot) in trials -01 (Poland) and -02 (Northern France),
Two foliar applications of SAP50SCF were performed on the treated plot T1 at the target dose rate of 1.2 L/ha formulated product (FP) (equivalent to 600 g a.s./ha). The target spray of water volume was in the range 150 to 400 litres per hectare, according to Good Agricultural Practices.
The deviations calculated on the amount of formulated product per hectare were all between ±5%.
Foliar applications were performed following the actual schedule specified in study plan: SAP50SCF was applied 12-15 days before application 2 and at BBCH 61 on plot T1.
In the decline trials (DCS), RAC specimens (whole plants, grain and straw) for analyses were collected at 0 DBLA and at BBCH 89 (commercial harvest) in the control plot and at 0 DALA, 14-15, 27-33 and 40-48 DALA for commercial harvest (BBCH 89) in the treated plots.
In the harvest trials (DCS), RAC specimens (grain and straw) for analyses were collected at BBCH 89 (commercial harvest) in the control plot and treated plot (34-50 DALA).
All RAC specimens from plot U and T1, were deep frozen on the day of collection and stored at the target temperature below -18°C. All specimens remained deep frozen during storage at the test sites, during shipment and storage at the analytical laboratory. RAC specimens were maintained frozen after collection through the shipment for homogenization.
For processing trials, one foliar application was performed on the treated plot T2 at the target dose rate of 6.0 L/ha formulated product (FP) (equivalent to 3000 g a.s./ha). The target spray of water volume was in the range 150 to 400 litres per hectare, according to Good Agricultural Practices. The deviations calculated on the amount of formulated product per hectare were all between ±5%. One foliar application was performed at BBCH 61 on the treated plot T2 and samplings were done in plots U/T2, with grain, at BBCH 89, commercial harvest, at 40-41 DALA. Specimens from plot T2, with an additional specimen of grain from plot U, were kept at ambient temperature before shipment at ambient temperature to the processing facility. Temperature was recorded with a data logger.
For the sake of clarity, the residue data on the processing field phases will be included and summarized in the point A.2.1.5." Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)".

A 2.1.3.2.2 Study 2

Comments of zRMS:	The study was evaluated by zRMS-PL in dRR of SAP50SCF (June 2024). zRMS-PL conclusions: *Method validation was not performed within this study because the analytical methods were previously validated in accordance to SANTE/2020/12830, rev.1 for the determination of folpet, phthalimide and phthalic acid in wheat (green material), wheat (grain) and wheat (straw) (as representatives of dry matrices and matrices with high water content) with an LOQ of 0.01 mg/kg for folpet in all matrices and phthalimide in (wheat green material) and wheat (grain) as well as 0.05 mg/kg for phthalic acid in all matrices and phthalimide in wheat (straw) in GLP study S22-01156.* *With regard to selectivity, accuracy and precision, the analytical methods were applied successfully for each analytical set when analysing the samples of the study. The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830.* *Sufficient stability data are available to support the residue data presented in this study.* *Trials GAP for barley: 2 x 0.60 kg a.s. /ha with 12-21 days between application, up to BBCH 61, PHI 34-50.* *The following residues were detected in the barley grain samples:* *E=RA (Sum of folpet and phthalimide expressed as folpet): <0.03, 0.047, 0.050, 0.072, 0.28, 0.29, 0.34, 0.75 mg/kg.* *The study is considered acceptable.*

Reference:	KCP 7.2.3/04
Report:	Study on the residue behaviour of folpet and its metabolites in barley after two applications of SAP50SCF (Folpet 500 g/l, SC) in Northern Europe – 2021. S. Jooss, 2022. Report No: S22-01157 (analytical phase)
Guideline(s):	Commission Regulation (EU) No 283/2013 and 284/2013 setting out the data requirements for active substances and plant protection products, in accordance with Regulation (EC) No 1107/2009 SANTE/2020/12830, Rev1 Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes. 24/02/2021 OECD Series on Testing and Assessment, Number 72. OECD ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

The objective of the study was to analyse residues of folpet as well as its two metabolites phthalimide and phthalic acid in barley specimens with limits of quantification (LOQ) of 0.01 mg/kg for folpet in all matrices and for phthalimide in barley (whole plant) and barley (grain) as well as 0.05 mg/kg for phthalimide in barley (straw) and phthalic acid in all matrices.

Analytical Methods

Extraction of Folpet from Barley: In brief, samples of barley (whole plant), barley (grain) and barley (straw) were extracted with acetonitrile containing 1% of formic acid and water was added. Isotopically labelled internal standard was added to the raw extract before clean-up. Addition of internal standard amount must be adjusted depending on the residue level obtained within the samples if residues are higher.

Clean-up was carried out by partition into acetonitrile (addition of citrate salts, magnesium sulfate and sodium chloride) followed by dispersive SPE with PSA and magnesium sulfate). Quantification was performed by use of LC-MS/MS with an isotopically labelled internal standard.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Extraction of Phthalimide from Barley: In brief, samples of barley (whole plant), barley (grain) and barley (straw) were extracted with acetonitrile containing 1% of formic acid and water was added. Isotopically labelled internal standard (addition of internal standard must be adjusted to the necessary dilution) was added to the raw extract before clean-up. Clean-up was carried out by partition into acetonitrile (addition of citrate salts, magnesium sulfate and sodium chloride) followed by concentration and dilution in water containing 0.1% of acetic acid. Quantification was performed by use of LC-MS/MS with an isotopically labelled internal standard.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix, except cereal straw, with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For cereal straw, the LOQ was 0.05 mg/kg and the LOD was 0.015 mg/kg.

Extraction of Phthalic Acid from Barley: In brief, for phthalic acid, samples of barley (whole plant), barley (grain) and barley (straw) were extracted with acetonitrile containing 1% of formic acid after addition of water. Isotopically labelled internal standard was added to the raw extract before clean-up. Addition of internal standard amount must be adjusted depending on the residue level obtained within the samples if residues are higher.

Clean-up was carried out by partition into acetonitrile (addition of magnesium sulfate and sodium chloride). Quantification was performed by use of LC-MS/MS with an isotopically labelled internal standard.

The limit of quantification (LOQ) of the analytical method was 0.05 mg/kg for each matrix with a limit of detection (LOD) set at 0.015 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Method Validation and Concurrent Recoveries: The analytical methods were previously validated at Eurofins Agroscience Services EAG Laboratories GmbH according to SANTE/2020/12830, rev. 1 for wheat (green material), wheat (grain) and wheat (straw) as representatives for dry matrices and matrices with high water content, respectively. Five (5) fortifications of untreated control samples at the level of LOQ and five (5) fortifications at the level of 10x LOQ were performed per analyte/matrix combination. For each analytical set of sample analysis, the method's applicability in terms of accuracy and repeatability was assessed by concurrent recoveries. At least three (3) fortifications of untreated control samples at the level of LOQ and three (3) fortifications at the level of 10x LOQ were performed for each analyte/matrix combination.
For folpet and phthalimide, blank values of control sample materials used for recovery determinations in several cases exceeded a level that would correspond to 30 % of the LOQ. Recoveries were corrected in this case.
For phthalic acid, blank values of reagents and those control sample materials used for recovery determinations in all cases exceeded a level that would correspond to 30 % of the LOQ. Therefore, recoveries for phthalic acid were corrected for both, residues >30% of LOQ detected in control samples and residues >30% of LOQ detected in reagent blanks.
Fortifications for the individual analyte/matrix combinations were performed at levels of 0.01 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.5 mg/kg, 0.6 mg/kg, 2.0 mg/kg, 5.0 mg/kg and/or 14 mg/kg and therefore encompassed the range of target analyte concentrations found in the samples of the study.
The accuracy and precision of the methods was considered to be acceptable since the mean recoveries at each fortification level for each analyte/matrix combination comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1 and OECD ENV/JM/MONO(2007)17.

Residue results are summarized in Table A-6 below:

Table A-6 Summary of the studies 1 & 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Folpet	Phthalimide	Sum of folpet and phthalimide expressed as folpet		
	(a)	(b)				(c)						(d)	(e)
21-00139-01 Poland(Pomorskie) Angowice 89-620	Spring barley PROPINO	1. 05/04/21 2. 21/06 to 30/06/21 3. 01/08/21	757.64 748.34	203.7 201.2	371,9 371,9	07/06/21 21/06/21	43 61	Whole plant Whole plant Whole plant Grain Straw	13 1,7 1,1 0,18 1,3	3,0 1,5 0,53 0,053 1,3	19 4,8 2,2 <u>0,28</u> 3,9	0 15 30 41 41	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) <u>Maximum storage:</u> Grain: 306 days W.plant: 345 days Straw: 316 days
21-00139-02 Northern France (Grand-Est) Avancon 08300	Spring barley RGT PLANET	1. 02/03/21 2. 16/06 to 20/06/21 3. 24/07 to 25/07/21	757.64 771.28	280.0 285.0	270,6 270,6	02/06/21 14/06/21	51 61	Whole plant Whole plant Whole plant Grain Straw	8,500 1,7 0,37 0,023 1,5	3,472 0,27 0,098 0,024 0,60	15,500 2,2 0,57 <u>0,072</u> 2,7	0 15 33 40 40	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) <u>Maximum storage:</u> Grain: 314 days W.plant: 374 days Straw: 324 days

21-00139-03 Hungary (Heves) Maklár H-3397	Winter barley SU ELLEN	1. 05/10/20 2. 17/05 to 22/05/21 3. 26/06 to 28/06/21	719.20 760.74	290.0 306.7	248,0 248,0	03/05/21 17/05/21	41 61	Grain Straw	0,018 2,7	0,016 0,42	0,050 3,5	42 42	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 340 days Straw: 350 days
21-00139-04 Germany (Schelswig Holstein) Wallsbüll 24980	Winter barley KWS	1. 10/10/20 2. 15/06 to 17/06/21 3. 19/07/21	768.80 775.00	206.7 208.3	371,9 372,1	31/05/21 15/06/21		Grain Straw	0,48 5,6	0,13 1,5	0,75 8,5	34 34	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 319 dasy Straw: 329 days
21-00139-05 Poland (Kujawsko-Pomorskie) Szelejewo 88-410	Winter barley KOSMOS	1. 15/09/20 2. 08/06 to 20/06/21 3. 15/07/21	753.30 729.74	303.7 294.3	248,0 248,0	27/05/21 10/06/21	58 61	Grain Straw	< LOD 0,86	< LOD 0,64	<LOD 2,1	35 35	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 323 days Straw:333 days
21-00139-06 Northern France (Grand-Est) Bourgogne 51110	Spring barley PLANET	1. 28/02/21 2. 09/06 to 15/06/21 3. 28/07/21	713.62 758.88	240.0 255.0	297,3 297,6	28/05/21 10/06/21	43 61	Whole plant Whole plant Whole plant Grain Straw	11 3,6 2,3 0,013 0,86	4,1 0,47 0,36 0,017 0,40	20 4,6 3,0 0,047 1,7	0 14 27 48 48	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) Maximum storage: Grain: 310 days W.plant: 356 days Straw: 320 days

21-00139-07 Germany (Brandenburg) Teschendorf 16775	Winter barley KWS FARO	1. 12/10/20 2. 30/05 to 01/06/21 3. 12/07 to 16/07/21	773.76 753.92	260.0 253.3	297,6 297,6	10/05/21 31/05/21	39 61	Grain Straw	0,20 0,87	0,07 0,41	<u>0,34</u> 1,7	50 50	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) <u>Maximum storage:</u> Grain: 325 days Straw:335 days
21-00139-08 Hungary (Borsod-Abaúj-Zemplén) Monok H-3905	Winter barley ANTONELLA	1. 05/10/20 2. 18/05 to 23/05/21 3. 02/07 to 03/07/21	714.86 719.20	288.3 290.0	248,0 248,0	06/05/21 19/05/21	41 61	Whole plant Whole plant Whole plant Grain Straw	4,5 3,7 2,6 0,19 1,9	3,0 0,96 0,33 0,051 1,3	11 5,6 3,3 <u>0,29</u> 4,5	0 15 28 44 44	S22-01156 LOQ: 0.01 mg/kg folpet (grain and straw), phthalimide (grain) 0.05 mg/kg phthalimide (straw) <u>Maximum storage:</u> Grain: 336 days W.plant: 378 days Straw: 346 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) 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

A 2.1.4 Magnitude of residues in livestock

No further study submitted and no data required.

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

Not relevant.

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Study 1

Comments of zRMS:	The study was evaluated by zRMS-Greece in RR of SAP50SCF (December 2023). The study is considered acceptable.

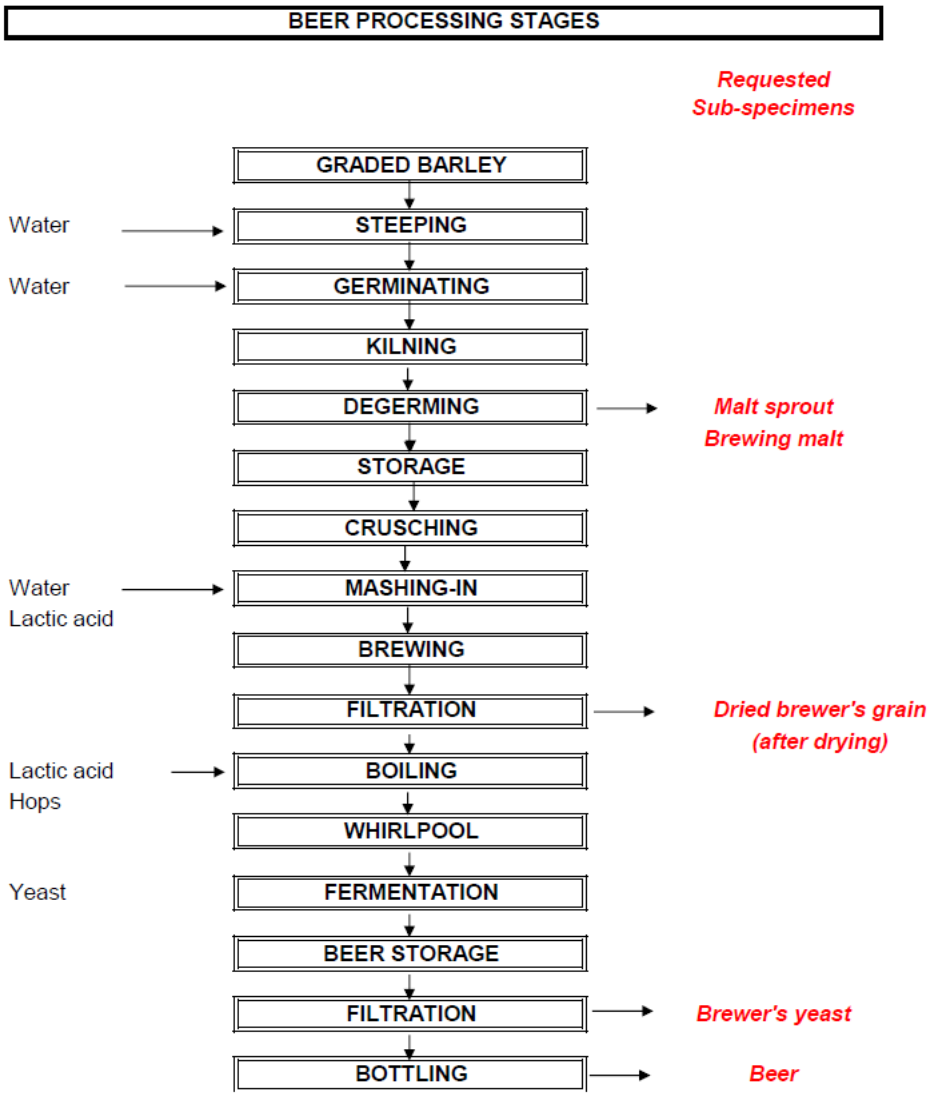
Reference:	KCP 7.3.5/01
Report	Magnitude of the residue of folpet in processed fractions of barley after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern and Southern Europe - 2021, C. MILHAN, 2021, CMN-21-48321 (processing phase)
Guideline(s):	Processing studies (SANCO 7035/VI/95 rev.5, 22 July 1997). OECD Guideline for the Testing of Chemicals: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis (TG 507 published on 16 October 2007). OECD Guideline for the Testing of Chemicals: Magnitude of pesticide residues in Processed Commodities (TG 508 published on 3 October 2008).
Deviations:	No impact.
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

A follow up study was performed on the processing of barley grains to malt sprout, brewing mal, dried brewer's grain, brewer's yeast and bear. In three trials in Poland (21-00139-01; KCP 6.3.1/04), Northern (21-00139-02; KCP 6.3.1/04) and Southern France (21-00157-03; KCP 6.3.1/03), barley crops were sprayed with folpet (500 g/L) with one application of 3000 g a.s./ha (under trials 21-00139-01, 21-00139-02 and 21-200157-03). However, samples from the trial 21-00157-03 were lost because sub-specimens were thawed during storage.

Samples were processed to malt sprout, brewing mal, dried brewer's grain, brewer's yeast and beer shown in **Figure A 2.1.5.2.1-1**. The processing phase was done according to technological procedures in a laboratory scale. All processes were comparable to the processes used for commercial or household productions of the goods produced within this study.

Figure A 2.1.5.2.1-1 Processing flowchart for barley brewing process



CONCLUSION

The following fractions were sampled: grain, homogenized barley grains, brewing malt, homogenized brewing malt, malt sprout, homogenized malt sprout, dried brewers grains, Homogenized dried brewers grain, brewer's yeast and beer. Those samples were analysed for residues in study S22-04739.

A 2.1.5.2.2 Study 2

Comments of zRMS:	The study was evaluated by zRMS-Greece in RR of SAP50SCF (December 2023). The study is considered acceptable.

Reference:	KCP 7.3.5/02
Report	Study on the residue behaviour of folpet and its metabolites in processed fractions of barley after one application of SAP50SCF (Folpet 500 g/l) in Northern Europe – 2021. S. Jooss, 2022. Report No: S22-04739
Guideline(s):	Commission Regulation (EU) No 283/2013 and 284/2013 setting out the data requirements for active substances and plant protection products, in accordance with Regulation (EC) No 1107/2009 SANTE/2020/12830, Rev1 Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes. 24/02/2021

	OECD Series on Testing and Assessment, Number 72. OECD ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

All samples were received at the test facility in frozen condition. After their arrival at the test facility the samples were stored at ≤ -18 °C with no exceedance until homogenisation. Samples of barley grain, brewing malt, malt sprouts and dried brewers grain were received homogenized. Samples of brewer's yeast and beer were used without homogenization.

The water content of the matrices was determined using a Sartorius MA150 moisture analyser and representative specimens as follows:

Matrix (specimen)	Water Content (Weight %)	Matrix	Water Content (Weight %)
Barley Grain (CMN-21-48321-001H)	11.46	Dried Brewers Grain (CMN-21-48321-017H)	1.50*
Brewing Malt (CMN-21-48321-005H)	2.37*	Brewer's Yeast (CMN-21-48321-01H)	92.30*
Malt Sprouts (CMN-21-48321-009H)	2.93*	Beer	92**

*mean of three determinations. **water content taken from a food database

Extraction of Folpet from Processed Fractions of Barley: Samples of barley grain, brewing malt, malt sprouts, dried brewers grain, brewer's yeast and beer extracted with acetonitrile containing 1% of formic acid and water was added. Isotopically labelled internal standard was added to the raw extract before clean-up. Addition of internal standard amount must be adjusted depending on the residue level obtained within the samples if residues are higher.
Clean-up was carried out by partition into acetonitrile (addition of citrate salts, magnesium sulfate and sodium chloride) followed by dispersive SPE with PSA and magnesium sulfate). Quantification was performed by use of LC-MS/MS with an isotopically labelled internal standard.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Extraction of Phthalimide from Processed Fractions of Barley: For phthalimide, samples of barley grain, brewing malt, malt sprouts, dried brewers grain, brewer's yeast and beer were extracted with acetonitrile containing 1% of formic acid and water was added. Isotopically labelled internal standard (addition of internal standard must be adjusted to the necessary dilution) was added to the raw extract before clean-up. Clean-up was carried out by partition into acetonitrile (addition of citrate salts, magnesium sulfate and sodium chloride) followed concentration and dilution in water containing 0.1% of acetic acid. Quantification was performed by use of LC-MS/MS with an isotopically labelled internal standard.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix, except cereal straw, with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For cereal straw, the LOQ was 0.05 mg/kg and the LOD was 0.015 mg/kg.

Extraction of Phthalic Acid from Processed Fractions of Barley: Samples of barley grain, brewing malt, malt sprouts, dried brewers grain, brewer's yeast and beer were extracted with acetonitrile containing 1% of formic acid and if necessary, after addition of water. Isotopically labelled internal standard was added to the raw extract before clean-up. Addition of internal standard amount must be adjusted depending on the residue level obtained within the samples if residues are higher.
Clean-up was carried out by partition into acetonitrile (addition of magnesium sulfate and sodium chloride). Quantification was performed by use of LC-MS/MS with an isotopically labelled internal standard.

The limit of quantification (LOQ) of the analytical method was 0.05 mg/kg for each matrix with a limit of detection (LOD) set at 0.015 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Extraction of Phthalamic Acid from Processed Fractions of Barley: Samples of barley grain, brewing malt, malt sprouts, dried brewers grain, brewer's yeast and beer were extracted with (water containing 0.1% of ammonium carbonate)/methanol (4/1, v/v). Clean-up was carried out by centrifugation and filtration using a syringe filter. Quantification was performed by use of LC-MS/MS with matrix-matched standards.
The limit of quantification (LOQ) of the analytical method was 0.05 mg/kg for each matrix with a limit of detection (LOD) set at 0.015 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

RESULTS AND DISCUSSIONS
Processing factors were calculated by dividing the residue found in the respective sample by the initial residue in the raw agricultural commodity. A summary of the residues found in the processed samples is given in **Table A-7.**

Table A -7 Residue data from barley grain processing study with folpet

RAC	Residues in RAC (unwashed sample, mg/kg)	PHI [days]	Processed commodity	Residue [mg/kg]	PF*	Comments/ Reference
Barley grain	1,8	41	Brewing malt	0,057	0,032	21-00139-01
Barley grain	1,8	40	Brewing malt	0,043	0,024	21-00139-02
Barley grain	1,8	41	Malt sprout	0,29	0,161	21-00139-01
Barley grain	1,8	40	Malt sprout	0,16	0,089	21-00139-02
Barley grain	1,8	41	Dried brewer's grain	0,039	0,022	21-00139-01
Barley grain	1,8	40	Dried brewer's grain	0,037	0,021	21-00139-02
Barley grain	1,8	41	Brewing yeast	<0.03	<0.02	21-00139-01
Barley grain	1,8	40	Brewing yeast	<0.03	<0.02	21-00139-02
Barley grain	1,8	41	Beer	<0.03	<0.02	21-00139-01
Barley grain	1,8	40	Beer	<0.03	<0.02	21-00139-02

* processing factor

CONCLUSION
Residues of active substance were found not to concentrate in consumable fractions after processing. Processing factors varied between 0.02 and 0.161.

A 2.1.6 Magnitude of residues in representative succeeding crops

No study submitted and no further data required.

A 2.1.7 Other/Special Studies

No study submitted and no further data required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 IEDI calculations Prothioconazole and TDMs

A.3.1.1 Prothioconazole

EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole-desthio

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	15%	NL toddler	1,54	3%	Milk: Cattle	3%	Maize/corn	2%	Wheat	4%	5%
	14%	GEMS/Food G11	1,38	7%	Soyabeans	1%	Wheat	0,6%	Carrots	2%	2%
	12%	GEMS/Food G10	1,24	7%	Soyabeans	2%	Wheat	0,3%	Potatoes	1%	2%
	11%	GEMS/Food G08	1,06	4%	Soyabeans	2%	Wheat	0,4%	Potatoes	1%	3%
	10%	GEMS/Food G07	1,04	4%	Soyabeans	2%	Wheat	0,4%	Rapeseeds/canola seeds	1%	3%
	10%	GEMS/Food G15	1,02	3%	Soyabeans	2%	Wheat	0,4%	Potatoes	1%	3%
	10%	GEMS/Food G06	1,01	3%	Wheat	2%	Soyabeans	0,6%	Cotton seeds	2%	3%
	8%	NL child	0,83	2%	Wheat	1%	Milk: Cattle	0,8%	Sugar beet roots	3%	3%
	8%	DE child	0,80	2%	Wheat	1%	Apples	1,0%	Milk: Cattle	3%	3%
	8%	FR child 3 15 yr	0,77	2%	Wheat	1%	Milk: Cattle	0,6%	Swine: Other products	2%	4%
	8%	DK child	0,76	2%	Rye	2%	Wheat	1%	Carrots	0,8%	3%
	7%	UK infant	0,67	2%	Milk: Cattle	1%	Carrots	1%	Wheat	0,9%	3%
	7%	FR toddler 2 3 yr	0,66	1%	Milk: Cattle	1%	Wheat	0,6%	Carrots	2%	3%
	6%	IE adult	0,62	0,9%	Wheat	0,6%	Peas	0,4%	Sweet potatoes	2%	1%
	6%	RO general	0,57	2%	Wheat	0,6%	Milk: Cattle	0,4%	Maize/corn	1,0%	3%
	5%	ES child	0,55	2%	Wheat	0,6%	Milk: Cattle	0,5%	Lentils	1%	3%
	5%	UK toddler	0,54	2%	Wheat	1%	Milk: Cattle	0,4%	Carrots	1%	3%
	5%	SE general	0,52	1%	Wheat	0,7%	Carrots	0,6%	Milk: Cattle	0,9%	2%
	5%	PT general	0,47	2%	Wheat	0,6%	Soyabeans	0,5%	Potatoes	0,9%	2%
	4%	DE women 14-50 yr	0,45	0,9%	Wheat	0,6%	Milk: Cattle	0,5%	Sugar beet roots	2%	2%
	4%	DE general	0,45	0,8%	Wheat	0,6%	Milk: Cattle	0,4%	Sugar beet roots	2%	2%
	4%	FI adult	0,43	3%	Coffee beans	0,3%	Rye	0,3%	Carrots	3%	0,1%
	4%	NL general	0,43	0,8%	Wheat	0,4%	Milk: Cattle	0,3%	Sugar beet roots	1%	2%
	4%	IT toddler	0,39	3%	Wheat	0,2%	Other cereals	0,1%	Carrots	0,8%	3%
	4%	FR adult	0,35	0,9%	Wheat	0,3%	Swine: Other products	0,2%	Wine grapes	1%	2%
	3%	FI 3 yr	0,35	0,7%	Carrots	0,5%	Wheat	0,5%	Potatoes	0,9%	0,5%
	3%	FR infant	0,35	0,9%	Carrots	0,8%	Milk: Cattle	0,3%	Wheat	0,6%	1%
	3%	ES adult	0,32	0,9%	Wheat	0,2%	Milk: Cattle	0,2%	Lentils	0,9%	2%
	3%	FI 6 yr	0,28	0,5%	Carrots	0,4%	Wheat	0,4%	Potatoes	0,7%	0,4%
	3%	IT adult	0,27	2%	Wheat	0,1%	Tomatoes	0,1%	Carrots	0,7%	2%
	2%	UK vegetarian	0,25	0,8%	Wheat	0,2%	Carrots	0,2%	Milk: Cattle	0,6%	1%
	2%	LT adult	0,24	0,4%	Rye	0,4%	Wheat	0,3%	Potatoes	0,4%	0,8%
	2%	DK adult	0,23	0,4%	Wheat	0,4%	Carrots	0,3%	Milk: Cattle	0,5%	1,0%
	2%	UK adult	0,21	0,7%	Wheat	0,1%	Milk: Cattle	0,1%	Carrots	0,5%	1%
	2%	PL general	0,16	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%	0,7%

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

A.3.1.2 1,2,4 Triazole

EFSA PRIMo revision 3.1; 2019/03/19

1,2,4-triazole (T)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,023**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**EFSA 2018**	Source of ARfD:	**EFSA 2018**
Year of evaluation:		Year of evaluation:	

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0,8%	NL toddler	0,18	0,3%	Maize/corn	0,2%	Potatoes	0,2%	Wheat		0,3%
	0,5%	GEMS/Food G06	0,11	0,3%	Wheat	0,1%	Potatoes	0,1%	Maize/corn		0,1%
	0,5%	RO general	0,11	0,2%	Wheat	0,2%	Potatoes	0,0%	Maize/corn		0,0%
	0,5%	PT general	0,11	0,2%	Potatoes	0,2%	Wheat	0,0%	Carrots		0,0%
	0,5%	GEMS/Food G15	0,11	0,2%	Wheat	0,2%	Potatoes	0,0%	Barley		0,1%
	0,5%	GEMS/Food G08	0,11	0,2%	Wheat	0,2%	Potatoes	0,0%	Barley		0,1%
	0,4%	GEMS/Food G07	0,10	0,2%	Wheat	0,2%	Potatoes	0,0%	Barley		0,0%
	0,4%	GEMS/Food G11	0,09	0,2%	Potatoes	0,2%	Wheat	0,0%	Barley		0,0%
	0,4%	GEMS/Food G10	0,09	0,2%	Wheat	0,1%	Potatoes	0,0%	Maize/corn		0,1%
	0,4%	NL child	0,09	0,2%	Wheat	0,1%	Potatoes	0,0%	Rapeseeds/canola seeds		0,0%
	0,4%	SE general	0,09	0,2%	Potatoes	0,1%	Wheat	0,0%	Carrots		
	0,4%	DK child	0,08	0,2%	Wheat	0,1%	Potatoes	0,1%	Carrots		0,0%
	0,4%	UK infant	0,08	0,1%	Potatoes	0,1%	Wheat	0,1%	Carrots		0,0%
	0,4%	DE child	0,08	0,2%	Wheat	0,1%	Potatoes	0,0%	Carrots		0,0%
	0,4%	UK toddler	0,08	0,2%	Wheat	0,2%	Potatoes	0,0%	Carrots		0,0%
	0,3%	IT toddler	0,08	0,3%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,0%
	0,3%	FI 3 yr	0,07	0,2%	Potatoes	0,1%	Wheat	0,0%	Carrots		0,0%
	0,3%	FR child 3 15 yr	0,07	0,2%	Wheat	0,1%	Potatoes	0,0%	Carrots		0,0%
	0,3%	ES child	0,07	0,2%	Wheat	0,1%	Potatoes	0,0%	Maize/corn		0,0%
	0,3%	FR toddler 2 3 yr	0,06	0,1%	Wheat	0,1%	Potatoes	0,0%	Carrots		0,0%
	0,3%	FI 6 yr	0,06	0,2%	Potatoes	0,0%	Wheat	0,0%	Carrots		0,0%
	0,2%	NL general	0,05	0,1%	Potatoes	0,1%	Wheat	0,0%	Barley		0,0%
	0,2%	IE adult	0,05	0,1%	Wheat	0,1%	Potatoes	0,0%	Carrots		0,0%
	0,2%	IT adult	0,05	0,2%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,0%
	0,2%	LT adult	0,04	0,1%	Potatoes	0,0%	Wheat	0,0%	Carrots		0,0%
	0,2%	ES adult	0,04	0,1%	Wheat	0,0%	Potatoes	0,0%	Barley		0,0%
	0,2%	PL general	0,04	0,1%	Potatoes	0,0%	Onions	0,0%	Carrots		0,0%
	0,2%	DE general	0,04	0,1%	Wheat	0,1%	Potatoes	0,0%	Barley		0,0%
	0,2%	FR infant	0,04	0,1%	Potatoes	0,0%	Carrots	0,0%	Wheat		0,0%
	0,2%	DE women 14-50 yr	0,04	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,0%
	0,2%	UK vegetarian	0,04	0,1%	Wheat	0,1%	Potatoes	0,0%	Carrots		0,0%
	0,1%	UK adult	0,03	0,1%	Wheat	0,1%	Potatoes	0,0%	Carrots		0,0%
	0,1%	FR adult	0,03	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,0%
	0,1%	DK adult	0,03	0,1%	Potatoes	0,0%	Wheat	0,0%	Carrots		
	0,1%	FI adult	0,02	0,1%	Potatoes	0,0%	Carrots	0,0%	Wheat		0,0%
	0,1%	IE child	0,02	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-triazole (T) is unlikely to present a public health concern.

A.3.1.3 Triazole Alanine

EFSA PRIMo revision 3.1; 2019/03/19

Triazole alanine (TA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,3**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**EFSA 2018**	Source of ARfD:	**EFSA 2018**
Year of evaluation:		Year of evaluation:	

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1%	GEMS/Food G06	3,97	1%	Wheat	0,1%	Maize/corn	0,0%	Potatoes		1%
	1%	NL toddler	3,77	0,7%	Wheat	0,5%	Maize/corn	0,1%	Rapeseeds/canola seeds		0,7%
	1%	IT toddler	3,36	1%	Wheat	0,0%	Potatoes	0,0%	Onions		1%
	1,0%	RO general	2,85	0,8%	Wheat	0,1%	Maize/corn	0,0%	Potatoes		0,8%
	0,9%	GEMS/Food G15	2,73	0,8%	Wheat	0,1%	Barley	0,0%	Maize/corn		0,8%
	0,9%	GEMS/Food G07	2,56	0,7%	Wheat	0,1%	Rapeseeds/canola seeds	0,0%	Barley		0,7%
	0,8%	GEMS/Food G08	2,53	0,7%	Wheat	0,1%	Barley	0,0%	Potatoes		0,7%
	0,8%	FR child 3 15 yr	2,44	0,8%	Wheat	0,0%	Maize/corn	0,0%	Potatoes		0,8%
	0,8%	GEMS/Food G10	2,39	0,7%	Wheat	0,0%	Maize/corn	0,0%	Barley		0,7%
	0,8%	NL child	2,34	0,7%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Potatoes		0,7%
	0,8%	ES child	2,33	0,7%	Wheat	0,0%	Maize/corn	0,0%	Potatoes		0,7%
	0,8%	DK child	2,31	0,7%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,7%
	0,7%	DE child	2,23	0,7%	Wheat	0,0%	Potatoes	0,0%	Maize/corn		0,7%
	0,7%	PT general	2,22	0,7%	Wheat	0,0%	Potatoes	0,0%	Maize/corn		0,7%
	0,7%	GEMS/Food G11	2,11	0,6%	Wheat	0,1%	Barley	0,0%	Potatoes		0,7%
	0,7%	IT adult	2,10	0,7%	Wheat	0,0%	Potatoes	0,0%	Onions		0,7%
	0,7%	UK toddler	2,07	0,7%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,7%
	0,6%	SE general	1,74	0,5%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,5%
	0,5%	FR toddler 2 3 yr	1,63	0,5%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,5%
	0,5%	UK infant	1,63	0,4%	Wheat	0,1%	Maize/corn	0,0%	Potatoes		0,4%
	0,4%	ES adult	1,33	0,4%	Wheat	0,0%	Barley	0,0%	Potatoes		0,4%
	0,4%	IE adult	1,26	0,4%	Wheat	0,0%	Potatoes	0,0%	Maize/corn		0,4%
	0,4%	NL general	1,19	0,3%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Barley		0,3%
	0,4%	DE women 14-50 yr	1,17	0,4%	Wheat	0,0%	Barley	0,0%	Potatoes		0,4%
	0,4%	FR adult	1,15	0,4%	Wheat	0,0%	Potatoes	0,0%	Maize/corn		0,4%
	0,4%	DE general	1,10	0,3%	Wheat	0,0%	Barley	0,0%	Potatoes		0,3%
	0,4%	UK vegetarian	1,08	0,3%	Wheat	0,0%	Potatoes	0,0%	Onions		0,3%
	0,3%	UK adult	0,89	0,3%	Wheat	0,0%	Potatoes	0,0%	Onions		0,3%
	0,3%	FI 3 yr	0,79	0,2%	Wheat	0,0%	Potatoes	0,0%	Rapeseeds/canola seeds		0,2%
	0,2%	FI 6 yr	0,64	0,2%	Wheat	0,0%	Potatoes	0,0%	Rapeseeds/canola seeds		0,2%
	0,2%	LT adult	0,62	0,2%	Wheat	0,0%	Potatoes	0,0%	Barley		0,2%
	0,2%	DK adult	0,61	0,2%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,2%
	0,2%	IE child	0,60	0,2%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,2%
	0,2%	FR infant	0,48	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,1%
	0,1%	FI adult	0,21	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		0,1%
	0,0%	PL general	0,10	0,0%	Potatoes	0,0%	Onions	0,0%	Carrots		

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

A.3.1.4 Triazole Acetic Acid

EFSA PRIMo revision 3.1; 2019/03/19

Triazole acetic acid (TAA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EFSA 2018	Source of ARfD:	EFSA 2018
Year of evaluation:		Year of evaluation:	

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0,1%	GEMS/Food G06	1,42	0,1%	Wheat	0,0%	Potatoes	0,0%	Maize/corn		
	0,1%	IT toddler	1,27	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	RO general	1,02	0,1%	Wheat	0,0%	Potatoes	0,0%	Maize/corn		
	0,1%	GEMS/Food G15	1,00	0,1%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,1%	GEMS/Food G08	0,92	0,1%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,1%	GEMS/Food G07	0,92	0,1%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,1%	NL toddler	0,90	0,1%	Wheat	0,0%	Maize/corn	0,0%	Potatoes		
	0,1%	FR child 3 15 yr	0,90	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	DK child	0,88	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	ES child	0,86	0,1%	Wheat	0,0%	Potatoes	0,0%	Maize/corn		
	0,1%	GEMS/Food G10	0,85	0,1%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,1%	DE child	0,83	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	NL child	0,83	0,1%	Wheat	0,0%	Potatoes	0,0%	Rapeseeds/canola seeds		
	0,1%	GEMS/Food G11	0,81	0,1%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,1%	PT general	0,81	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	IT adult	0,79	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	UK toddler	0,78	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	SE general	0,66	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	FR toddler 2 3 yr	0,61	0,1%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	UK infant	0,55	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,1%	ES adult	0,51	0,0%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,0%	IE adult	0,47	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	DE women 14-50 yr	0,44	0,0%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,0%	FR adult	0,43	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	NL general	0,43	0,0%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,0%	DE general	0,43	0,0%	Wheat	0,0%	Barley	0,0%	Potatoes		
	0,0%	UK vegetarian	0,41	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	UK adult	0,34	0,0%	Wheat	0,0%	Potatoes	0,0%	Barley		
	0,0%	FI 3 yr	0,29	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	FI 6 yr	0,24	0,0%	Wheat	0,0%	Potatoes	0,0%	Barley		
	0,0%	LT adult	0,24	0,0%	Wheat	0,0%	Potatoes	0,0%	Barley		
	0,0%	DK adult	0,23	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	IE child	0,23	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	FR infant	0,18	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	FI adult	0,08	0,0%	Wheat	0,0%	Potatoes	0,0%	Carrots		
	0,0%	PL general	0,04	0,0%	Potatoes	0,0%	Onions	0,0%	Carrots		

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

A.3.1.5 Triazole Lactic Acid

EFSA PRIMo revision 3.1; 2019/03/19

Triazole lactic acid (TLA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,3**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**EFSA 2018**	Source of ARfD:	**EFSA 2018**
Year of evaluation:		Year of evaluation:	

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0,1%	NL toddler	0,22	0,1%	Maize/corn	0,0%	Wheat	0,0%	Carrots		0,0%
	0,0%	GEMS/Food G06	0,10	0,0%	Wheat	0,0%	Maize/corn	0,0%	Barley		0,0%
	0,0%	GEMS/Food G15	0,09	0,0%	Wheat	0,0%	Barley	0,0%	Maize/corn		0,0%
	0,0%	GEMS/Food G08	0,08	0,0%	Wheat	0,0%	Barley	0,0%	Maize/corn		0,0%
	0,0%	GEMS/Food G10	0,08	0,0%	Wheat	0,0%	Barley	0,0%	Maize/corn		0,0%
	0,0%	GEMS/Food G07	0,08	0,0%	Wheat	0,0%	Barley	0,0%	Maize/corn		0,0%
	0,0%	RO general	0,08	0,0%	Wheat	0,0%	Maize/corn	0,0%	Carrots		0,0%
	0,0%	GEMS/Food G11	0,07	0,0%	Wheat	0,0%	Barley	0,0%	Carrots		0,0%
	0,0%	IT toddler	0,07	0,0%	Wheat	0,0%	Carrots	0,0%	Maize/corn		0,0%
	0,0%	UK infant	0,06	0,0%	Wheat	0,0%	Maize/corn	0,0%	Carrots		0,0%
	0,0%	FR child 3 15 yr	0,06	0,0%	Wheat	0,0%	Maize/corn	0,0%	Carrots		0,0%
	0,0%	DK child	0,06	0,0%	Wheat	0,0%	Carrots	0,0%	Rapeseeds/canola seeds		0,0%
	0,0%	PT general	0,06	0,0%	Wheat	0,0%	Maize/corn	0,0%	Carrots		0,0%
	0,0%	DE child	0,06	0,0%	Wheat	0,0%	Carrots	0,0%	Maize/corn		0,0%
	0,0%	NL child	0,06	0,0%	Wheat	0,0%	Maize/corn	0,0%	Rapeseeds/canola seeds		0,0%
	0,0%	ES child	0,05	0,0%	Wheat	0,0%	Maize/corn	0,0%	Carrots		0,0%
	0,0%	UK toddler	0,05	0,0%	Wheat	0,0%	Carrots	0,0%	Barley		0,0%
	0,0%	IT adult	0,04	0,0%	Wheat	0,0%	Carrots	0,0%	Maize/corn		0,0%
	0,0%	ES adult	0,04	0,0%	Wheat	0,0%	Barley	0,0%	Maize/corn		0,0%
	0,0%	IE adult	0,04	0,0%	Wheat	0,0%	Linseeds	0,0%	Maize/corn		0,0%
	0,0%	SE general	0,04	0,0%	Wheat	0,0%	Carrots				0,0%
	0,0%	FR toddler 2 3 yr	0,04	0,0%	Wheat	0,0%	Carrots	0,0%	Maize/corn		0,0%
	0,0%	DE general	0,04	0,0%	Wheat	0,0%	Barley	0,0%	Carrots		0,0%
	0,0%	NL general	0,03	0,0%	Wheat	0,0%	Barley	0,0%	Rapeseeds/canola seeds		0,0%
	0,0%	DE women 14-50 yr	0,03	0,0%	Wheat	0,0%	Barley	0,0%	Carrots		0,0%
	0,0%	FR adult	0,03	0,0%	Wheat	0,0%	Carrots	0,0%	Maize/corn		0,0%
	0,0%	FI 3 yr	0,02	0,0%	Wheat	0,0%	Carrots	0,0%	Barley		0,0%
	0,0%	UK vegetarian	0,02	0,0%	Wheat	0,0%	Carrots	0,0%	Barley		0,0%
	0,0%	FR infant	0,02	0,0%	Carrots	0,0%	Wheat	0,0%	Maize/corn		0,0%
	0,0%	UK adult	0,02	0,0%	Wheat	0,0%	Carrots	0,0%	Barley		0,0%
	0,0%	FI 6 yr	0,02	0,0%	Wheat	0,0%	Carrots	0,0%	Barley		0,0%
	0,0%	DK adult	0,02	0,0%	Wheat	0,0%	Carrots				0,0%
	0,0%	LT adult	0,01	0,0%	Wheat	0,0%	Barley	0,0%	Carrots		0,0%
	0,0%	IE child	0,01	0,0%	Wheat	0,0%	Carrots	0,0%	Barley		0,0%
	0,0%	FI adult	0,01	0,0%	Carrots	0,0%	Wheat	0,0%	Barley		0,0%
	0,0%	PL general	0,00	0,0%	Carrots	0,0%	Maize/corn				

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

A 3.2 TDMI calculations Folpet

EFSA PRIMo revision 3.1; 2019/03/19

Folpet

LOQs (mg/kg) range from:	0,03	to:	0,15

Toxicological reference values

ADI (mg/kg bw/day):	0,1	ARfD (mg/kg bw):	0,2
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	59%	PT general	58,92	50%	Wine grapes	4%	Tomatoes	2%	Table grapes	0,6%	2%
	52%	FR adult	51,99	46%	Wine grapes	2%	Tomatoes	0,9%	Wheat	0,6%	0,9%
	48%	RO general	48,43	34%	Wine grapes	10%	Tomatoes	2%	Wheat	1%	2%
	42%	GEMS/Food G07	42,35	30%	Wine grapes	5%	Tomatoes	2%	Table grapes	1%	3%
	35%	GEMS/Food G08	34,64	21%	Wine grapes	6%	Tomatoes	2%	Table grapes	1%	3%
	34%	GEMS/Food G15	34,35	20%	Wine grapes	6%	Tomatoes	2%	Table grapes	1%	3%
	33%	GEMS/Food G11	33,14	20%	Wine grapes	5%	Tomatoes	3%	Table grapes	2%	3%
	33%	IE adult	32,56	25%	Wine grapes	2%	Tomatoes	2%	Table grapes	1%	0,9%
	31%	GEMS/Food G06	31,11	18%	Tomatoes	6%	Table grapes	3%	Wheat	1%	3%
	29%	DE general	28,68	17%	Wine grapes	3%	Tomatoes	3%	HOPS (dried)	1%	2%
	28%	UK adult	28,38	22%	Wine grapes	3%	HOPS (dried)	2%	Tomatoes	0,4%	0,7%
	28%	NL toddler	27,82	9%	Table grapes	5%	Tomatoes	3%	Apples	5%	2%
	27%	DE women 14-50 yr	27,20	17%	Wine grapes	4%	Tomatoes	2%	Table grapes	1%	1%
	25%	DK adult	24,65	19%	Wine grapes	3%	Tomatoes	1%	Table grapes	0,5%	0,4%
	24%	DE child	23,99	8%	Table grapes	5%	Tomatoes	4%	Apples	2%	2%
	23%	UK vegetarian	23,06	16%	Wine grapes	3%	Tomatoes	1%	HOPS (dried)	0,5%	0,9%
	23%	GEMS/Food G10	22,91	8%	Wine grapes	7%	Tomatoes	2%	Table grapes	1%	3%
	19%	FR child 3 15 yr	19,47	7%	Wine grapes	4%	Tomatoes	2%	Table grapes	2%	2%
	19%	NL general	18,82	12%	Wine grapes	2%	Tomatoes	2%	Table grapes	1%	1%
	17%	NL child	17,01	6%	Table grapes	3%	Tomatoes	2%	Apples	2%	2%
	16%	ES adult	15,87	8%	Wine grapes	4%	Tomatoes	1,0%	Barley	0,7%	2%
	13%	FR toddler 2 3 yr	12,52	5%	Wine grapes	2%	Tomatoes	1%	Milk: Cattle	2%	1%
	12%	IT toddler	11,75	7%	Tomatoes	3%	Wheat	0,6%	Table grapes	0,3%	3%
	12%	FI adult	11,68	6%	Wine grapes	3%	Tomatoes	0,7%	Strawberries	0,7%	0,2%
	11%	DK child	10,91	3%	Tomatoes	2%	Wheat	2%	Rye	1%	2%
	10%	UK toddler	10,13	3%	Tomatoes	2%	Wheat	1%	Table grapes	2%	2%
	9%	ES child	9,36	5%	Tomatoes	2%	Wheat	0,6%	Milk: Cattle	1%	2%
	9%	IT adult	9,13	6%	Tomatoes	2%	Wheat	0,8%	Table grapes	0,2%	2%
	9%	FI 3 yr	8,87	3%	Tomatoes	2%	Strawberries	1%	Table grapes	0,6%	0,6%
	8%	UK infant	8,24	2%	Milk: Cattle	2%	Tomatoes	1%	Strawberries	3%	1%
	8%	SE general	7,91	4%	Tomatoes	1%	Wheat	0,8%	Strawberries	1%	1%
	7%	PL general	7,42	4%	Tomatoes	2%	Table grapes	0,6%	Apples	0,3%	
	7%	FI 6 yr	6,69	2%	Tomatoes	1%	Strawberries	1%	Table grapes	0,5%	0,5%
	6%	LT adult	5,59	3%	Tomatoes	0,6%	Apples	0,4%	Wheat	0,6%	0,5%
	4%	FR infant	4,18	0,9%	Strawberries	0,8%	Milk: Cattle	0,8%	Wine grapes	1%	0,3%
	2%	IE child	1,63	0,5%	Wheat	0,3%	Table grapes	0,3%	Tomatoes	0,3%	0,5%

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

A 3.3 IESTI calculations – Prothioconazole and TDMs Raw commodities

A.3.3.1. Prothioconazole

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Bovine: Liver	0,5 / 0,23	1,9
11%	Bovine: Edible offals (other	0,5 / 0,15	1,1
6%	Milk: Cattle	0,01 / 0,01	0,62
6%	Wheat	0,1 / 0,04	0,58
6%	Bovine: Kidney	0,5 / 0,15	0,56
5%	Swine: Edible offals (other	0,5 / 0,15	0,45
3%	Swine: Liver	0,5 / 0,23	0,28
2%	Barley	0,2 / 0,04	0,22
2%	Swine: Kidney	0,5 / 0,15	0,19
2%	Poultry: Liver	0,1 / 0,14	0,16
1%	Eggs: Chicken	0,01 / 0,01	0,12
1%	Swine: Muscle/meat	0,01 / 0,01	0,12
1%	Milk: Goat	0,01 / 0,01	0,12
0,7%	Bovine: Muscle/meat	0,01 / 0,01	0,07
0,7%	Other farmed animals:	0,01 / 0,01	0,07

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Swine: Other products	0,5 / 0,5	1,6
10%	Bovine: Other products	0,5 / 0,5	1,00
9%	Bovine: Liver	0,5 / 0,23	0,92
8%	Poultry: Kidney	0,1 / 0,64	0,82
7%	Poultry: Liver	0,1 / 0,14	0,67
6%	Sheep: Liver	0,5 / 0,23	0,64
5%	Bovine: Edible offals (other	0,5 / 0,15	0,50
4%	Swine: Edible offals (other	0,5 / 0,15	0,39
3%	Wheat	0,1 / 0,04	0,34
3%	Swine: Kidney	0,5 / 0,15	0,33
3%	Swine: Liver	0,5 / 0,23	0,32
3%	Bovine: Kidney	0,5 / 0,15	0,32
2%	Barley	0,2 / 0,04	0,19
2%	Milk: Cattle	0,01 / 0,01	0,19
1%	Sheep: Edible offals (other	0,5 / 0,15	0,10

A.3.3.2 1,2,4 Triazole

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

Show results for all crops

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	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)
0,1%	Wheat	0,01 / 0,01	0,14	0,08%	Wheat	0,01 / 0,01	0,08
0,06%	Barley	0,01 / 0,01	0,06	0,05%	Barley	0,01 / 0,01	0,05
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A.3.3.3 _Triazole Alanine

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0,5 / 0,5	7,2
0,4%	Barley	0,21 / 0,21	1,2

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0,5 / 0,5	4,2
0,3%	Barley	0,21 / 0,21	1,0

A.3.3.3 _Triazole Acetic Acid

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Wheat	0,19 / 0,19	2,7
0,06%	Barley	0,11 / 0,11	0,60

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,2%	Wheat	0,19 / 0,19	1,6
0,05%	Barley	0,11 / 0,11	0,52

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

A.3.3.4. Triazole Lactic Acid

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,06%	Barley	0,01 / 0,03	0,17
0,05%	Wheat	0,01 / 0,01	0,14

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,05%	Barley	0,01 / 0,03	0,15
0,03%	Wheat	0,01 / 0,01	0,08

A 3.4 IESTI calculations – Folpet Raw commodities

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Barley	2 / 2	11
3%	Wheat	0,4 / 0,4	5,8

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Barley	2 / 2	9,7
2%	Wheat	0,4 / 0,4	3,4

A 3.5 IESTI calculations – Prothioconazole and TDMs Processed commodities

A.3.5.1 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
2%	Wheat / milling (wholemeal)-l	0,1 / 0,04	0,22
1%	Barley / cooked	0,2 / 0,04	0,15
0,7%	Barley / milling (flour)	0,2 / 0,04	0,07
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#NUM!	#NUM!	#NUM!	#NUM!

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)
3%	Barley / beer	0,2 / 0,01	0,29
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
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#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

A.3.5.2 1,2,4 Triazole

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)
0,1%	Wheat / milling (flour)	0,01 / 0,01	0,12
0,1%	Wheat / milling (wholemeal)-I	0,01 / 0,01	0,06
0,0%	Barley / cooked	0,01 / 0,01	0,04
0,0%	Barley / milling (flour)	0,01 / 0,01	0,02

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)
0,1%	Barley / beer	0,01 / 0	0,07
0,04%	Wheat / bread/pizza	0,01 / 0,01	0,04
0,04%	Wheat / pasta	0,01 / 0,01	0,04
0,03%	Wheat / bread (wholemeal)	0,01 / 0,01	0,03

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of 1,2,4-triazole (T) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A.3.5.3 Triazole Alanine

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)
2%	Wheat / milling (flour)	0,5 / 0,5	6,0
0,9%	Wheat / milling (wholemeal)-l	0,5 / 0,5	2,8
0,3%	Barley / cooked	0,21 / 0,21	0,75
0,1%	Barley / milling (flour)	0,21 / 0,21	0,38

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)
0,7%	Wheat / bread/pizza	0,5 / 0,5	2,2
0,6%	Wheat / pasta	0,5 / 0,5	1,9
0,6%	Wheat / bread (wholemeal)	0,5 / 0,5	1,7
0,5%	Barley / beer	0,21 / 0,04	1,5

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Triazole alanine (TA) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A.3.5.4 Triazole Acetic Acid

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)
0,2%	Wheat / milling (flour)	0,19 / 0,19	2,3
0,1%	Wheat / milling (wholemeal)-l	0,19 / 0,19	1,0
0,0%	Barley / cooked	0,11 / 0,11	0,39
0,0%	Barley / milling (flour)	0,11 / 0,11	0,19

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)
0,1%	Wheat / bread/pizza	0,19 / 0,19	0,83
0,08%	Barley / beer	0,11 / 0,02	0,77
0,07%	Wheat / pasta	0,19 / 0,19	0,72
0,07%	Wheat / bread (wholemeal)	0,19 / 0,19	0,66

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Triazole acetic acid (TAA) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A.3.5.5 Triazole Lactic Acid

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)
0,0%	Wheat / milling (flour)	0,01 / 0,01	0,12
0,0%	Barley / cooked	0,01 / 0,03	0,11
0,0%	Wheat / milling (wholemeal)-l	0,01 / 0,01	0,06
0,0%	Barley / milling (flour)	0,01 / 0,03	0,05

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)
0,1%	Barley / beer	0,01 / 0,01	0,22
0,01%	Wheat / bread/pizza	0,01 / 0,01	0,04
0,01%	Wheat / pasta	0,01 / 0,01	0,04
0,01%	Wheat / bread (wholemeal)	0,01 / 0,01	0,03

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Triazole lactic acid (TLA) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.6 IESTI calculations – Folpet Processed commodities

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)
4%	Barley / cooked	2 / 2	7,3
2%	Wheat / milling (flour)	0,4 / 0,4	4,8
2%	Barley / milling (flour)	2 / 2	3,6
1%	Wheat / milling (wholemeal)-l	0,4 / 0,4	2,2

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)
0,9%	Wheat / bread/pizza	0,4 / 0,4	1,8
0,8%	Wheat / pasta	0,4 / 0,4	1,5
0,7%	Wheat / bread (wholemeal)	0,4 / 0,4	1,4
0,2%	Barley / beer	2 / 0,01	0,43