FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **SNS-F-11**

Product names: **DISFERA 90 EC/LIPOSTAR 90 EC**

Chemical active substance:

Difenoconazole 90 g/l

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 01/2024

MS Finalisation date: 07/2024; 10/2024; 11/2024

Version history

When	What
01/2024	Initial submission.
07/2024	Assessment
10/2024	The Final Registration Report
11/2024	The final RR after the second round of commenting

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Storage stability

Difenoconazole

Residues of difenoconazole in tomato fruit, potato tubers, cottonseed, cottonseed oil, cottonseed meal, wheat forage, wheat straw and wheat grain will be stable for at least 24 months, in lettuce head, soybeans, whole bananas, eggs, milk, poultry breast and beef liver for at least 12 months and at least 10 months in blood, fat, milk and tissues from dairy cattle when stored at <-18°C. CGA 205375 was shown to be stable in animal commodities for at least 10 months stored at <-18°C.

New residue trials submitted in the framework of this application (winter wheat) are valid with regard to storage stability data.

The storage stability data of difenoconazole and TDMs in oilseed rape and honey are not required, as the samples were tested within 30 days of sampling.

Metabolism in plants and animals

EU endpoints:

Plant residue definition for monitoring Difenoconazole Reg. (EU) 2019/552

Plant residue definition for risk assessment separate residue definitions (Difenoconazole,

SANCO/830/08 – rev. 3, 13 December 2013, 18 May 2020:

1) Difenoconazole

2) TA and TLA, since these compounds share the same toxicity;

3) TAA

4) 1,2,4-T

Animal residue definition for monitoring: difenoconazole Reg. (EU) 2019/552

Animal residue definition for risk assessment

1) Difenoconazole

2) TA and TLA, since these compounds share the same toxicity;

3) TAA

4) 1,2,4-T

Magnitude of residues in plants

Spring and winter oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans

Proposed GAP (Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds):

1 application, BBCH 32-39, 90 g as/ha

or

1 application, BBCH 60-65, 103.5 g as/ha

Proposed GAP (Soyabeans)

1 application, BBCH 60-65, 103.5 g as/ha

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Trials are acceptable.

Trials GAP: 1x 108 g, BBCH 65, PHI not relevant (commercial harvest)

Seeds:

E: Difenoconazole: 8x <0.01

RA: Difenoconazole: 8x <0.01

1,2,4-T: 8x <0.01

TA: 0.87, 0.40, 0.67, 0.48, 3.80, 0.16, 0.30, 0.73

TAA: 0.01, 3x<0.01, 0.01, 3x<0.01

TLA: 0.04, 0.02, 0.03, 0.02, 0,17, <0.01, 2x 0.02

Sufficient number of trials are available. Extrapolation from oilseed rape to linseed (common flax), poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans is possible (SANTE/2019/12752 Rev01). The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for proposed uses (Reg. (EU) 2019/552).

Oilseeds	mg/kg
Linseeds	0.2
Poppy seeds	0.05*
Sunflower seeds	0.05*
Rapeseeds/canola seeds	0.5
Soyabeans	0.1
Mustard seeds	0.2
Gold of pleasure seeds	0.05*

*- LOQ

Winter wheat, Winter triticale

Proposed GAP:

2 applications, interval: 14, BBCH 33-55, 90 g as/ha

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Trials are acceptable.

Trials GAP:

Trials GAP: 2x 150 g as/ha, BBCH 33-55, PHI 62d

E: Difenoconazole: 8x < 0.0025 mg/kg

RA: Difenoconazole: 8x < 0.0025 mg/kg

1,2,4-T: 8x < 0.004 mg/kg

TA: 8x < 0.0025 mg/kg

TAA: 8x < 0.004 mg/kg

TLA: 8x < 0.004 mg/kg

Sufficient number of trials are available. Extrapolation from wheat to triticale is possible. The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for proposed uses (0.1 mg/kg, Reg. (EU) 2019/552).

Magnitude of residues in livestock

Information provided by the applicant are sufficient. There is no risk for animal MRL to be exceeded

Additional studies are not required.

Magnitude of residues in processed commodities

Processing studies for difenoconazole are not required.

Processing studies data for TDMs were submitted and evaluated at EU level as confirmatory data for triazole derivative metabolites (Triazole Derivative Metabolites Addendum – Confirmatory Data, 2018). Additional studies are not required.

Magnitude of residues in representative succeeding crops

Waiting periods before planting following succeeding crops: not required.

Other / special studies

Oilseed rape is a melliferous crop foraged by bees. A study to determine the residues in honey and bee products is required.

Therefore, a studies determining the residue levels of difenoconazole and triazole derivative metabolites in honey was performed in accordance with SANTE/11956/2016 rev. 9. The study was conducted using Phacelia tanacetifolia as a crop with high melliferous capacity under semi-field conditions and at four different locations in Poland and Germany.

Residue studies in honey in the Northern Zone in Poland and Germany showed that the level of difenoconazole and triazole derivative metabolites was below LOQ (0.01 mg/kg). The studies showed no negative impact on the life processes and health of the bee family.

The currently established MRL for difenoconazole in honey and other apiculture products is 0.05 mg/kg. The use of the product SNS-F-11 in the cultivation of winter rapeseed during flowering in accordance with the proposed GAP does not pose a risk of exceeding the currently established MRL in honey and other apiculture products.

Consumer risk assessment

The proposed uses of difenoconazole in the formulation SNS-F-11 do not represent unacceptable acute and chronic risks for the consumer.

The accepted calculations were made on the basis of the program EFSA PRIMo revision 3.1.

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 SNS-F-11 are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for oilseed rape, winter wheat, winter triticale and minor uses. A list of all intended uses within the Central 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 0.5 mg/kg (oilseed rape), 0.1 mg/kg (wheat, triticale, soyabeans), 0.2 mg/kg (linseed, mustard seeds), 0.05 mg/kg (poppy seeds, gold of pleasure seeds, sunflower seeds), for difenoconazole as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of difenoconazole residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended

use(s).

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

Data gaps

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**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**g as/hL min max**	**water L/ha min max**	**g as/ha min max**		
1	Winter oilseed rape 401060	N-EU	SNS-F-11	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32-39 or BBCH 60-65	1	-	30 - 45 g as/hL 34.5 – 51.75 g as/hL	200-300	90 g as/ha 103.5 g as/ha	Not relevant – commercial harvest	A
2	Winter wheat 0500090	N-EU	SNS-F-11	F	*Zymoseptoria tritici* *Blumeria graminis tritici/ Blumeria graminis* *Puccinia triticina/ Puccinia recondite* *Pyrenophora tritici-repentis* *Parastagonospora nodorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 33-55	2	14	30 - 45 g as/hL	200-300	90 g as/ha	Not relevant – commercial harvest	A
3	Winter triticale 0500090	N-EU	SNS-F-11	F	*Zymoseptoria tritici* *Blumeria graminis tritici/ Blumeria graminis* *Puccinia triticina/ Puccinia recondite*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 33-55	2	14	30 - 45 g as/hL	200-300	90 g as/ha	Not relevant – commercial harvest	A

					Parastagonospora nodorum										
Minor uses (Article 51)															
4	Spring oilseed rape 401060	N-EU	SNS-F-11	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32-39 or BBCH 60-65	1	-	30 - 45 g as/hL 34.5 – 51.75 g as/hL	200-300	90 g as/ha 103.5 g as/ha	Not relevant – commercial harvest	A
5	Linseed (common flax) 401010	N-EU	SNS-F-11	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32-39 or BBCH 60-65	1	-	30 - 45 g as/hL 34.5 – 51.75 g as/hL	200-300	90 g as/ha 103.5 g as/ha	Not relevant – commercial harvest	A
6	Poppy seeds 401030	N-EU	SNS-F-11	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32-39 or BBCH 60-65	1	-	30 - 45 g as/hL 34.5 – 51.75 g as/hL	200-300	90 g as/ha 103.5 g as/ha	Not relevant – commercial harvest	A
7	Mustard seeds 401080	N-EU	SNS-F-11	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32-39 or BBCH 60-65	1	-	30 - 45 g as/hL 34.5 – 51.75 g as/hL	200-300	90 g as/ha 103.5 g as/ha	Not relevant – commercial harvest	A
8	Gold of pleasure seeds 401130	N-EU	SNS-F-11	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32-39 or BBCH 60-65	1	-	30 - 45 g as/hL 34.5 – 51.75 g as/hL	200-300	90 g as/ha 103.5 g as/ha	Not relevant – commercial harvest	A
9	Sunflower seeds 401050	N-EU	SNS-F-11	F	*Alternaria spp.* *Leptosphaeria lindquistii* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32-39 or BBCH 60-65	1	-	34.5 – 51.75 g as/hL	200-300	103.5 g as/ha	Not relevant – commercial harvest	A
10	Soyabeans 401070	N-EU	SNS-F-11	F	*Cercospora sojina* *Cercospora Kikuchi* *Sclerotinia sclerotiorum*	EC	90 g/l difenoconazole	Foliar spraying	BBCH 32 - 65	1	-	34.5 – 51.75 g as/hL	200-300	103.5 g as/ha	Not relevant – commercial harvest	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

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 SNS-F-11 is composed of difenoconazole.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of difenoconazole

Reference value	Source	Year	Value	Study relied upon	Safety factor
Difenoconazole					
ADI	SANCO/830/08 – rev. 3	2013	0.01 mg/kg bw per day	2-year, rat	100
ARfD	SANCO/830/08 – rev. 3	2013	0.16 mg/kg bw	Rat, developmental	100
1,2,4-Triazole					
ADI	SANCO/830/08 – rev. 3	2020	0.023 mg/kg bw per day	Rat 12-month study	300
ARfD	SANCO/830/08 – rev. 3	2020	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine					
ADI	SANCO/830/08 – rev. 3	2020	0.3 mg/kg bw per day	Rabbit developmental study	100
ARfD	SANCO/830/08 – rev. 3	2020	0.3 mg/kg bw	Rabbit developmental study	100
Triazole acetic acid					
ADI	SANCO/830/08 – rev. 3	2020	1.0 mg/kg bw per day	Rat 2-generation and rabbit developmental studies	100
ARfD	SANCO/830/08 – rev. 3	2020	1.0 mg/kg bw	Rat 2-generation and rabbit developmental studies	100
Triazole lactic acid					
ADI	SANCO/830/08 – rev. 3	2020	0.3 mg/kg bw per day	Bridging from TA	
ARfD	SANCO/830/08 – rev. 3	2020	0.3 mg/kg bw	Bridging from TA	

7.1.2.1 Summary for difenoconazole

Table 7.1-3: Summary for difenoconazole

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	Oilseed rape	Yes	Yes (8 trials)	Yes	Yes	Yes	No	No

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?
2	Winter wheat	Yes	Yes (8 trials)	Yes	Yes	Yes		
3	Winter triticale	Yes	Yes	Yes	Yes	Yes		
4	Spring oilseed rape	Yes	Yes	Yes	Yes	Yes		
5	Linseed (common flax)	Yes	Yes	Yes	Yes	Yes		
6	Poppy seeds	Yes	Yes	Yes	Yes	Yes		
7	Mustard seeds	Yes	Yes	Yes	Yes	Yes		
8	Gold of pleasure seeds	Yes	Yes	Yes	Yes	Yes		
9	Sunflower seeds	Yes	Yes	Yes	Yes	Yes		
10	Soyabeans	Yes	Yes	Yes	Yes	Yes		

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

7.1.2.2 Summary for SNS-F-11

Table 7.1-4: Information on SNS-F-11 (KCA 6.8)

Crop	PHI for SNS-F-11 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SNS-F-11 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Difenoconazole		
Oilseed rape	NR (commercial harvest)	NR (commercial harvest)	-	
Winter wheat	NR (commercial harvest)	NR (commercial harvest)	-	
Winter triticale	NR (commercial harvest)	NR (commercial harvest)	-	
Spring oilseed rape	NR (commercial harvest)	NR (commercial harvest)	-	
Linseed (common flax)	NR (commercial harvest)	NR (commercial harvest)	-	
Poppy seeds	NR (commercial harvest)	NR (commercial harvest)	-	
Mustard seeds	NR (commercial harvest)	NR (commercial harvest)	-	
Gold of pleasure seeds	NR (commercial harvest)	NR (commercial harvest)	-	
Sunflower seeds	NR (commercial harvest)	NR (commercial harvest)	-	
Soyabeans	NR (commercial harvest)	NR (commercial harvest)	-	

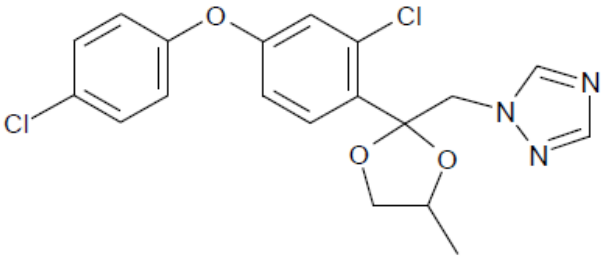
NR: not relevant

Assessment

7.2 Difenoconazole

General data on difenoconazole are summarized in the table below (last updated 01/2024)

Table 7.2-1: General information on difenoconazole

Active substance (ISO Common Name)	difenoconazole
IUPAC	3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1- ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether
Chemical structure	
Molecular formula	$C_{19}H_{17}Cl_2N_3O_3$
Molar mass	406.3 g/mol
Chemical group	Triazole
Mode of action (if available)	It acts by interference with ergosterol biosynthesis in target fungi by inhibition of the C-14-methylation of sterols, which leads to morphological and functional changes of the fungal cell membrane.
Systemic	Yes
Company (ies)	Syngenta Limited
Rapporteur Member State (RMS)	Sweden
Approval status	Approved Date of (25/05/2011) and reference to decision (COMMISSION DIRECTIVE 540/2011 - REGULATION (EU) No 1100/2011)
Restriction	Only uses as fungicide may be authorised.
Review Report	SANCO/830/08– rev. 3 13/12/2013 18/05/2020
Current MRL regulation	Regulation (EU) 2019/552
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	Yes: EFSA, 2011- see list of references
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	Not applicable

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.

Table 7.2-2: 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			
Plant products			
Tomato	High water content	24 months	DAR, 2006
Lettuce	High water content	12 months	DAR, 2006
Banana	High water content	12 months	DAR, 2006
Wheat forage	High water content	12 months	DAR, 2006
Wheat grain	High starch content	24 months	DAR, 2006
Potato	High starch content	24 months	DAR, 2006
Cotton	High oil content	24 months	DAR, 2006
Animal Products			
Poultry	Breast	12 months	DAR, 2006
Ruminant	Liver	12 months	DAR, 2006
Dairy cattle	Milk	12 months	DAR, 2006
Eggs	Eggs	12 months	DAR, 2006

Stability of triazole derivatives metabolites

Matrix	Characteristics of the matrix	1,2,4-T	TA	TAA	TLA	Reference
Data relied on in EU						
Plant products						
Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, cabbages, lettuces	High water content	6	53	53	48 (lettuce only)	EFSA, 2018
Barley, wheat	High starch content	12	26	26	48	EFSA, 2018
Rapeseed, soya beans	High oil content	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	26	48	EFSA, 2018
Peas, dry; Navy beans	High protein content	No data	15	25	48	EFSA, 2018

Matrix	Characteristics of the matrix	1,2,4-T	TA	TAA	TLA	Reference
Oranges	High acid content	No data	No data	No data	48	EFSA, 2018
Barley, wheat	Cereal straw	12	53	40	No data	EFSA, 2018
Animal Products						
	Milk	18	No data	No data	No data	EFSA, 2018
	Eggs	12	No data	No data	No data	EFSA, 2018
	Liver	12	No data	No data	No data	EFSA, 2018
	Muscle	12	No data	No data	No data	EFSA, 2018
	Fat	12	No data	No data	No data	EFSA, 2018

Conclusion on stability of residues during storage

The storage stability of difenoconazole has been investigated in wheat, wheat forage, tomato, potato, lettuce, banana, cotton, animal tissues (cattle, poultry), milk and eggs (DAR, 2006).
Residues of difenoconazole in tomato fruit, potato tubers, cottonseed, cottonseed oil, cottonseed meal, wheat forage, wheat straw and wheat grain will be stable for at least 24 months, in lettuce head, soybeans, whole bananas, eggs, milk, poultry breast and beef liver for at least 12 months and at least 10 months in blood, fat, milk and tissues from dairy cattle when stored at <-18°C. CGA 205375 was shown to be stable in animal commodities for at least 10 months stored at <-18°C.

New residue trials submitted in the framework of this application (winter wheat) are valid with regard to storage stability data.
The storage stability data of difenoconazole and TDMs in oilseed rape and honey are not required, as the samples were tested within 30 days of sampling.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

New data on the stability of difenoconazole in final extracts of oilseed rape and honey are presented in this application.

Stability of final extracts (oilseed rape):

Analyte Difenoconazole (m/z 406→251)	Fortification level (mg/kg)	Days of storage *	Mean recovery Injection (n = 5) after Storage (%)	Rel. Std. Dev. (n = 5) (%)	References
Oilseed rape (whole plant)	0.10	9	97	4.8	Report S23-103661
Oilseed rape (seed)	0.10	9	72	2.5	Report S23-103661

* from the day of completion of sample work-up to the day of preparation of calibration standards

Stability of final extracts (honey)

Analyte	Fortification level (mg/kg)	Days of storage *	Mean recovery Injection (n = 5) after Storage (%)	Rel. Std. Dev. (n = 5) (%)	References
Difenoconazole (m/z 406→251)	0.10	14	106	2.6	Report S23-103664

* from the day of completion of sample work-up to the day of preparation of calibration standards

Conclusion on stability of residues in sample extracts

The mean recovery value of the stored oilseed rape extracts was in the range of 70 % - 120 % with a relative standard deviation below 20 % when analysed against freshly prepared calibration standards. Therefore, extracts are considered to be stable when stored at 1 °C to 10 °C for 9 days (oilseed rape extracts) and for 14 days (honey extracts) in the dark.
Internal isotopically labelled standards were used for quantification of TDMs and were added directly at the end of the sample extraction procedure. The internal standards are considered to show the same degradation behaviour as the analytes itself so that the stability of the analyte(s) in sample extracts was not investigated.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grapes	[phenyl-^{14}C] Difenoconazole [triazole-^{14}C] difenoconazole	foliar treatment, F	247 g a.i./ha	5	20 DALA		DAR, 2006 EFSA, 2011
	Tomatoes	[phenyl-^{14}C] Difenoconazole [triazole-^{14}C] difenoconazole	foliar treatment, F	123 to 247 g a.i./ha	3 - 6	7 DALA 34 DALA 40 DALA		DAR, 2006 EFSA, 2011
Root and tuber vegetables	Potatoes	[phenyl-^{14}C] Difenoconazole [triazole-^{14}C] difenoconazole	foliar treatment, F	123.5 g a.i./ha	6	11 DALA		DAR, 2006 EFSA, 2011
Pulses and oilseeds	Oilseed rape	[phenyl-^{14}C] Difenoconazole [triazole-^{14}C]	foliar treatment,	125 g a.i./ha	2	39 DALA		DAR, 2006 EFSA, 2011

		difenoconazole	F					
Cereals	Wheat	[phenyl-^{14}C] Difenoconazole [triazole-^{14}C] difenoconazole	Seed treatment	6 g a.i./100 kg seed	1	At harvest		DAR, 2006 EFSA, 2011
	Wheat	[phenyl-^{14}C] Difenoconazole [triazole-^{14}C] difenoconazole	foliar treatment, F	247 g a.i./ha	4	29 DALA		DAR, 2006 EFSA, 2011

Summary of plant metabolism studies reported in the EU

Metabolism in plant was investigated in four plant groups: fruit crops (tomato, grape), cereals (wheat), tuber/root crops (potato) and on oilseeds/pulses crops (oilseed rape), using ^{14}C-difenoconazole labelled in the phenyl or the triazole ring and foliar applications with a total of 2 to 6 treatments. Samples were collected for analysis at interim intervals and 6 to 40 days after the final application. In addition, metabolism was also considered in cereals following seed application.
The metabolism was seen to be similar in all four crop types. The parent difenoconazole remained the major component of the residues in the majority of the plant parts (mostly >40 % TRR), with the exception of the cereal grains, potato tubers and rape seeds, where it accounted for less than 10 – 15 % of the TRR. In these crops, and for the triazole labelling, TRRs are mainly composed of the triazole derivative metabolites (TDM): triazole alanine (56 % and 79 % TRR in rape seeds and potato tubers) and triazole acetic acid (20 % TRR in cereal grain). In addition, triazole alanine was detected up to 42 % TRR in tomato fruits and 1,2,4-triazole up to 12 % in grape. TDM were also the major components of the residues in cereal grains following seed treatment and the major metabolites in the succeeding crop studies. Metabolites CGA 205374 (ketone), CGA 205375 (alcohol) and CGA 189138 (benzoic acid) were also identified in low proportions (below 5 % TRR). Based on the different structures identified, the following metabolic pathway in plants was proposed. As a first step, the metabolism involves hydrolysis of the dioxolane ring to form the ketone metabolite which is then reduced to the corresponding alcohol. Further oxidation of the difenoconazole-alcohol metabolite results in the cleavage of the alkyl bridge to form the difenoconazole-benzoic acid metabolite and the 1,2,4-triazole which is further metabolised to triazole alanine and triazole acetic acid (DAR, 2006).

Conclusion on metabolism in primary crops

Based on these data, the residue for monitoring was defined as the parent compound difenoconazole. For risk assessment, considering that TDM are toxicologically relevant metabolites present in significant proportions in primary and rotational crops. The residue definition for risk assessment for plant commodities (primary, rotational crops and processed commodities) is: 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-T (SANCO/830/08 – rev.3, 18 May 2020).

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.
Crops under consideration can be grown in rotation with other crops and thus possible occurrence of difenoconazole residues in rotational/succeeding crops from the use on primary crops has to be assessed. Difenoconazole slowly degrades in the soil with a maximum DT90 value observed in field studies of 879 days (EFSA, 2011a) which is significantly above the trigger value of 100 days. According to European

guidelines on rotational crops (European Commission, 1997c), further investigation of residues in rotational crops is required.

Summary of plant metabolism studies reported in the EU

Residues in rotational crops were investigated in three studies conducted outdoors. Two radiolabelled forms of difenoconazole, [phenyl-^{14}C] and [triazole-^{14}C] difenoconazole, were used.
In five available studies, total radioactive residues in rotational crops (wheat, sugar beet, maize, lettuce, turnips and mustard) planted 62 to 488 days after one application of difenoconazole applied to bare ground at a rates of 32.4, 125 and 750 g a.i./ha ranged from <0.0001 to 0.34 mg difenoconazole equivalents/kg. Following application equivalent to twice the maximum recommended rate for carrots in Northern and Southern Europe (3 x 125 g a.i./ha), residues of difenoconazole were below the LOD (<0.02 and <0.05 mg/kg). Although the PHI was not within 25% of the critical GAP in Northern and Southern Europe (14 vs. 30), the exaggerated application rate of 750 g a.i./ha represents a worst-case for residues of difenoconazole in rotational crops and in commercial practice residues of difenoconazole will not be expected in succeeding crops. The uptake of radioactive residues in succeeding crops following [triazole-^{14}C] difenoconazole application at 125 g a.i./ha to bare soil was higher than observed in the corresponding [phenyl-^{14}C] difenoconazole study. The TRR levels in lettuce, sugar beet (tops and roots), immature wheat, and immature maize were equal to or less than 0.072 mg/kg. Residues in wheat grain and maize grain at harvest were 0.341 and 0.211 mg/kg, respectively.
The magnitude of these residues was due to the selective transport of triazole derivatives (CGA-131013, CGA-142856 and CGA-205369) from the soil. Based on these findings it is concluded that the application of difenoconazole to seeds of cereals will lead to negligible residues in succeeding crops. The metabolite CGA-205369 (triazole lactic acid) was neither detected in wheat grain nor in the plant metabolism studies.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

The effect of processing on the nature of difenoconazole was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 min at 90°C, pH 4; 60 min at 100°C, pH 5; 20 min at 120°C, pH 6). The peer review concluded that the compound is hydrolytically stable under the representative processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable (EFSA, 2011a). No studies investigating the effect of processing on the magnitude of the residues in the commodities under assessment were submitted in the present application.

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

Table 7.2-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Foliar treatment: Cereals (spring wheat) Root vegetables (potato) Fruits (tomato, grapes)

	Pulses/oilseeds (oilseed rape) Seed treatment: Cereals (spring wheat)
Rotational crops covered	Leafy vegetables (lettuce, spinach), root vegetables (carrot, sugarbeet, turnip), cereals (spring and winter wheat, maize), oilseeds (mustard)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, in part. No residues of parent difenoconazole were found. Residues mainly composed of TDM metabolites: triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA).
Processed commodities	Difenoconazole stable under standard hydrolysis conditions representative of pasteurisation/baking/sterilisation (more than 96% TRR consisted of parent difenoconazole).
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Difenoconazole (Regulation n°2019/552)
Plant residue definition for risk assessment	1) Triazole parent compound and any other relevant metabolite exclusively link to the parent compound; 2) TA and TLA, since this compounds share the same toxicity; 3) TAA; 4) 1,2,4-triazole (SANCO/830/08 – rev.3, 18 May 2020).
Conversion factor from enforcement to RA	None

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

Available data

No new data submitted in the framework of this application.

Table 7.2-5: 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	Goat	Phenyl-^{14}C Triazole-^{14}C	2	5 mg/kg feed/day	10	Milk	daily	DAR, 2006; EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying ruminants	Goat	Phenyl-^{14}C Triazole-^{14}C	4	100 mg/kg feed/day	3	Milk	twice daily	DAR, 2006; EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	

Lactating ruminants	Goat	Phenyl-^{14}C	2	100 mg/kg feed/day	4	Milk	twice daily	DAR, 2006; EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Phenyl-^{14}C Triazole-^{14}C	10	5 mg/kg feed/day	3	Eggs	daily	DAR, 2006; EFSA, 2011
						Excreta	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Phenyl-^{14}C Triazole-^{14}C	20	68 mg/kg feed/day	3	Eggs	daily	DAR, 2006; EFSA, 2011
						Excreta	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Triazole-^{14}C	5	121 mg/kg feed/day	4	Eggs	daily	DAR, 2006; EFSA, 2011
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Metabolism studies were carried out using [phenyl-^{14}C] and [triazole-^{14}C] difenoconazole in lactating goats and laying hens. The test compound was administered orally in the diet at a concentrations of 5 and 100 mg/kg to the lactating goats and 5, 68 and 121mg/kg to the laying hens.
Difenoconazole was rapidly metabolised, with the majority of the applied radioactivity (up to 96.8% in laying hens and >88% in the lactating goats) excreted in the urine and faeces. Maximum radioactive residue levels were present in the liver and kidney, at 9.790 and 2.731mg difenoconazole equivalents/kg, respectively, in lactating goats and up to 4.660 and 2.247mg difenoconazole equivalents/kg, respectively, in laying hens.
Maximum residues of parent difenoconazole were detected in the liver and fat of the lactating goats and laying hens, at concentrations up to 0.891mg/kg (9.1% of the TRR) and 1.912 mg/kg (18.4% of the TRR), respectively. In other edible tissues, residues of parent difenoconazole were _0.107 mg/kg (2.2% of the TRR). In milk, residues of parent difenoconazole were up to 0.028 mg/kg (8.8% of the TRR) and up to 0.236 mg/kg (5.3% of the TRR) in egg yolk.
CGA-205375 was the major metabolite in the goats and hens, occurring at levels up to 7.127 mg/kg (72.8% TRR) in liver, 1.180 mg/kg (43.2% TRR) in kidney, 0.949 mg/kg (91.7% TRR) in fat, 0.423 mg/kg (91.4% TRR) in muscle and up to 0.130 mg/kg (34.4% TRR) in milk, egg white and egg yolk. 1,2,4-triazole CGA-71019 was transported preferentially to eggs and milk, occurring at levels of 0.182 mg/kg (67.7% TRR) and 0.043 mg/kg (32.3% TRR) in egg white and yolk, respectively and levels up to 0.022 mg/kg (5.8% TRR) in milk. Ring hydroxylated difenoconazole, CGA-205374 and CGA-205375 were observed in the goats at levels up to 0.235 mg/kg (3.9% TRR) in liver and 0.021 mg/kg (15.2% TRR) in milk.
The primary metabolic processes in each animal involves hydrolysis of the dioxolane ring to form the ketone CGA-205374, with subsequent reduction of CGA-205374 to give the corresponding alcohol CGA-205375 as a major metabolite. Oxidation of CGA-205374 resulted in cleavage of the alkyl bridge, leading to the formation of the acid CGA-186138 and 1,2,4-triazole CGA-71019. A second pathway involves hydroxylation of difenoconazole to form the hydroxylated CGA-205374 and CGA-205375. Sulphate ester, glycine and glucuronide conjugation were observed as secondary metabolism processes in the lactating goats. Hydroxy acetic acid difenoconazole and amino acid (glutamic acid/threonine) conjugates of

CGA-189138 were also observed as urine specific metabolites. Similar pathways of metabolism were observed in lactating goats and laying hens and consequently a study in pig is not required.

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

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

	Endpoints
Animals covered	Ruminant (goat)
	poultry (hen)
Time needed to reach a plateau concentration	48 hours in milk - [^{14}C-phenyl]-difenoconazole 144 hours in milk - [^{14}C-triazole]-difenoconazole 168 hours in egg yolk - [^{14}C-phenyl] and [14C-triazole] 120 hours in eggs white - [^{14}C-triazole]-difenoconazole
Animal residue definition for monitoring	Parent compound Difenoconazole (SANCO/830/08 – rev.3, 18 May 2020).
Animal 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 (SANCO/830/08 – rev.3, 18 May 2020).
Conversion factor	Not concluded
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

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 7.2-7: Summary of EU reported and new data supporting the intended uses of SNS-F-11 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) *	MRL compliance
Winter wheat grain → extrapolated to triticale grain	New trials Study number: 21FRT-32TRZAWDFKN	N-EU	Trials GAP: 2x 150 g as/ha, BBCH 33-55, PHI 62d E: Difenoconazole: 8x < 0.0025 mg/kg RA: Difenoconazole: 8x < 0.0025 mg/kg 1,2,4-T: 8x < 0.004 mg/kg TA: 8x < 0.0025 mg/kg TAA: 8x < 0.004 mg/kg TLA: 8x < 0.004 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	E: Difenoconazole: 8x < 0.0025 mg/kg RA: Difenoconazole: 8x < 0.0025 mg/kg 1,2,4-T: 8x < 0.004 mg/kg TA: 8x < 0.0025 mg/kg TAA: 8x < 0.004 mg/kg TLA: 8x < 0.004 mg/kg	E: 0.0025 RA: 0.004 (<LOQ =0.01)	E: 0.0025 RA: 0.004 (<LOQ =0.01)	0.01	0.1	Yes

Winter wheat straw → extrapolated to triticale straw	New trials Study number: 21FRT-32TRZAWDFKN	N-EU	Trials GAP: 2x 0.150 kg as/ha, BBCH 33-55, PHI 62d <u>Whole plant:</u> E: Difenoconazole: 2x < 0.0025; 0.0073; 0.0045 RA: Difenoconazole: 2x < 0.0025; 0.0073; 0.0045 1,2,4-T: 4x < 0.004 mg/kg TA: 4x < 0.0025 mg/kg TAA: 4x < 0.004 mg/kg TLA: 4x < 0.004 mg/kg <u>Straw:</u> E: Difenoconazole: 0.0616; 0.0326; 0.0349; 0.0658; 0.0570; 0.0374; 0.0344; 0.0825 RA: Difenoconazole: 0.0616; 0.0326; 0.0349; 0.0658; 0.0570; 0.0374; 0.0344; 0.0825 1,2,4-T: 8x < 0.004 mg/kg TA: 8x < 0.0025 mg/kg TAA: 8x < 0.004 mg/kg TLA: 8x < 0.004 mg/kg	N/A
	Overall supporting data for cGAP	N-EU	Trials GAP: 2x 0.150 kg as/ha, BBCH 33-55, PHI 62d <u>Whole plant:</u> E: Difenoconazole: 2x < 0.0025; 0.0073; 0.0045 RA: Difenoconazole: 2x < 0.0025; 0.0073; 0.0045 1,2,4-T: 4x < 0.004 mg/kg TA: 4x < 0.0025 mg/kg TAA: 4x < 0.004 mg/kg TLA: 4x < 0.004 mg/kg <u>Straw:</u> E: Difenoconazole: 0.0616; 0.0326; 0.0349; 0.0658; 0.0570; 0.0374; 0.0344; 0.0825 RA: Difenoconazole: 0.0616; 0.0326; 0.0349; 0.0658; 0.0570; 0.0374; 0.0344; 0.0825 1,2,4-T: 8x < 0.004 mg/kg TA: 8x < 0.0025 mg/kg TAA: 8x < 0.004 mg/kg TLA: 8x < 0.004 mg/kg	

Winter oilseed rape → Spring oilseed rape, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds sunflower seeds soyabeans	New trials Study number: EU-23-1359	N-EU	Trials GAP: 1x 108 g, BBCH 65, PHI not relevant (commercial harvest) <u>Seeds:</u> E: Difenoconazole: 4x <0.01 RA: Difenoconazole: 4x <0.01 1,2,4-T: 4x <0.01 TA: 0.87, 0.40, 0.67, 0.48 TAA: 0.01, 3x<0.01 TLA: 0.04, 0.02, 0.03, 0.02 <u>Forage:</u> E: Difenoconazole: 2x <0.01 RA: Difenoconazole: 2x <0.01 1,2,4-T: 2x <0.01 TA: 0.09, 0.22 TAA: 0.01, <0.01 TLA: 2x<0.01	N/A				
	New trials Study number: S-23-103623	N-EU	Trials GAP: 1x 125 g, BBCH 65, PHI not relevant (commercial harvest) <u>Seeds:</u> E: Difenoconazole: 4x <0.01 RA: Difenoconazole: 4x <0.01 1,2,4-T: 4x <0.01 TA: 3.8, 0.16, 0.30, 0.73 TAA: 0.04, 3x<0.01 TLA: 0,17, <0.01, 2x 0.02 <u>Forage:</u> E: Difenoconazole: 0.03, <0.01 RA: Difenoconazole: 0.03, <0.01 1,2,4-T: 2x <0.01 TA: 0.09, 0.15 TAA: 0.02, 0.01 TLA: 2x<0.01					
	Overall supporting data for cGAP	N-EU	<u>Seeds:</u> E: Difenoconazole: 8x <0.01 RA: Difenoconazole: 8x <0.01	E: <0.01 RA: 1,2,4-T: <0.01 TA, TLA: 0.48	E: <0.01 RA: 1,2,4-T: <0.01 TA, TLA: 3.80	0.01	0.5 oilseed rape	Yes

			1,2,4-T: 8x <0.01 TA: 0.87, 0.40, 0.67, 0.48, 3.80, 0.16, 0.30, 0.73 TAA: 0.01, 3x<0.01, 0.01, 3x<0.01 TLA: 0.04, 0.02, 0.03, 0.02, 0,17, <0.01, 2x 0.02	TAA: 0.02	TAA: 0.17			

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

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter wheat are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to triticale is possible with 8 trials on wheat, which is the case here.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

According to the available data, the intended uses on oilseed rape are considered acceptable, for outdoor uses.
According to appendix D of EU guidelines, extrapolation to spring oilseed rape, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans is possible with 8 trials on oilseed rape, which is the case here.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation – Animal Model 2017

Table 7.2-8: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/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
Difenoconazole-alcohol (CGA 205375)				
Wheat forage	0.004	STMR (Study number: 21FRT-32TRZAWDFKN)	0.007	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat grain	0.0025	STMR (Study number: 21FRT-32TRZAWDFKN)	0.0025	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat straw	0.046	STMR (Study number: 21FRT-32TRZAWDFKN)	0.083	HR (Study number: 21FRT-32TRZAWDFKN)
Rapeseed forage	0.01	STMR (Study number S23-103662; S23-103661)	0.03	HR (Study numbers: EU-23-1359; S-23-103623)
Rapeseed meal (seed)	<0.01	STMR (Study number S23-103662; S23-103661) x 1.4 PF	Not required	
1,2,4-Triazole (1,2,4-T)				
Wheat forage	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat grain	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat straw	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Rapeseed forage	<0.01	STMR (Study number S23-103662; S23-103661)	<0.01	HR (Study number S23-103662; S23-103661)
Rapeseed meal (seed)	<0.01	STMR (Study number S23-103662; S23-103661) x 1.4 PF	Not required	
Triazole alanine (TA)				
Wheat forage	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat grain	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat straw	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Rapeseed forage	0.14	STMR (Study number S23-103662; S23-103661)	0.22	HR (Study number S23-103662; S23-103661)
Rapeseed meal (seed)	0.93	STMR (Study number S23-103662; S23-103661) x 1.4 PF	Not required	
Triazole acetic acid (TAA)				
Wheat forage	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat grain	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat straw	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Rapeseed forage	0.01	STMR (Study number S23-103662; S23-103661)	0.02	HR (Study number S23-103662; S23-103661)
Rapeseed meal (seed)	0.02	STMR (Study number S23-103662; S23-103661) x 1.4 PF	Not required	
Triazole lactic acid (TLA)				
Wheat forage	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat grain	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Wheat straw	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rapeseed forage	<0.01	STMR (Study number S23-103662; S23-103661)	<0.01	HR (Study number S23-103662; S23-103661)
Rapeseed meal (seed)	0,04	STMR (Study number S23-103662; S23-103661)	Not required	

Table 7.2-9: 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)
Difenoconazole-alcohol (CGA 205375)					
Dairy cattle	0.001	0.002	Wheat straw	0.05	No
Dairy cattle	0.001	0.002	Wheat straw	0.05	No
Lamb	0.003	0.003	Rape forage	0.08	No
Ram/Ewe	0.002	0.002	Rape forage	0.07	No
Swine (breeding)	0.001	0.001	Rape forage	0.06	No
Poultry layer	0.002	0.002	Rape forage	0.03	No
Poultry layer	0.002	0.002	Rape forage	0.03	No
1,2,4- Triazole (1,2,4-T)					
Dairy cattle	0.001	0.001	Wheat, milled bypdts	0.04	No
Dairy cattle	0.001	0.001	Wheat, milled bypdts	0.04	No
Lamb	0.002	0.002	Wheat, milled bypdts	0.05	No
Ram/Ewe	0.002	0.002	Wheat, milled bypdts	0.05	No
Swine (breeding)	0.001	0.001	Wheat, milled bypdts	0.05	No
Poultry layer	0.002	0.002	Wheat, milled bypdts	0.03	No
Poultry layer	0.002	0.002	Wheat, milled bypdts	0.03	No
Triazole alanine (TA)					
Dairy cattle	0.008	0.009	Rape meal	0.37	Yes
Dairy cattle	0.008	0.009	Canola meal	0.23	Yes
Lamb	0.018	0.022	Rape meal	0.52	Yes
Ram/Ewe	0.014	0.017	Rape meal	0.52	Yes
Swine (breeding)	0.009	0.010	Canola meal	0.45	Yes
Poultry layer	0.022	0.022	Canola meal	0.30	Yes
Poultry layer	0.014	0.016	Canola meal	0.23	Yes
Triazole acetic acid (TAA)					
Dairy cattle	0.001	0.001	Wheat, milled bypdts	0.04	No
Dairy cattle	0.001	0.001	Wheat, milled bypdts	0.04	No

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)
Lamb	0.002	0.003	Wheat, milled bypdts	0.07	No
Ram/Ewe	0.002	0.002	Wheat, milled bypdts	0.06	No
Swine (breeding)	0.001	0.001	Wheat, milled bypdts	0.06	No
Poultry layer	0.002	0.002	Wheat, milled bypdts	0.03	No
Poultry layer	0.002	0.002	Wheat, milled bypdts	0.03	No
Triazole lactic acid (TLA)					
Dairy cattle	0.001	0.001	Canola meal	0.03	No
Dairy cattle	0.001	0.001	Canola meal	0.02	No
Lamb	0.001	0.001	Rape meal	0.03	No
Ram/Ewe	0.001	0.001	Rape meal	0.03	No
Swine (breeding)	0.001	0.001	Canola meal	0.03	No
Turkey	0.001	0.001	Canola meal	0.02	No
Poultry layer	0.001	0.001	Canola meal	0.01	No

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

With the proposed use of GAP for the SNS-F-11 product, the content of difenoconazole, 1,2,4-triazoles, triazole acetic acid and triazole lactic acid in the RAC feeding material does not pose a risk of exceeding the max dietary burden values in the diet of animals.

Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analyzed for the magnitude of TA, TAA, 1,2,4-T and TLA residues (Triazole Derivative Metabolites Addendum - Confirmatory Data, UK, 2018). The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolization 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 metabolization 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).
Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-T and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-T, assuming that the absorption and excretion behaviour of TA and 1,2,4-T are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-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.
Meanwhile and provisionally, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to1,2,4-T and to TLA for which feeding studies are not available (EFSA, 2018).

TA residue levels arising from TA in the feed (based of livestock feeding data from Triazole Derivative Metabolites Addendum - Confirmatory Data, UK, 2018, Appendix E)

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)				
Cattle (all diets)								
Closest feeding level[a]:	0,06	mg/kg bw	6,8 N Beef cattle (highest diet)					
Muscle	0,04	0,05	0,01	0,01	**0,008**	n.c.	0,01	0,01
Fat	0,02	0,02	0,00	0,00	**0,003**	n.c.	0,00	0,00
Liver	0,10	0,15	0,01	0,02	**0,03**	n.c.	0,01	0,02
Kidney	0,04	0,04	0,00	0,01	**0,006**	n.c.	0,00	0,01
Cattle (dairy only)								
Closest feeding level[a]:	0,06	mg/kg bw	7,0 N Dairy cattle					
Milk[b]	0,01	0,01	0,01	0,01	**0,01**	n.c.	0,01	0,01
Sheep (all diets)								
Closest feeding level[a]:	0,06	mg/kg bw	2,7 N Lamb (highest diet)					
Muscle	0,04	0,05	0,01	0,02	**0,02**	n.c.	0,01	0,02
Fat	0,02	0,02	0,01	0,01	**0,008**	n.c.	0,01	0,01
Liver	0,10	0,15	0,03	0,05	**0,06**	n.c.	0,03	0,05
Kidney	0,04	0,04	0,01	0,01	**0,015**	n.c.	0,01	0,01
Sheep (dairy only)								
Closest feeding level[a]:	0,06	mg/kg bw	3,5 N Ewe					
Milk[b]	0,01	0,01	0,01	0,01	**0,01**	n.c.	0,01	0,01
Swine								
Closest feeding level[a]:	0,06	mg/kg bw	5,9 N Breeding (highest diet)					
Muscle	0,04	0,05	0,01	0,01	**0,009**	n.c.	0,01	0,01
Fat	0,02	0,02	0,00	0,00	**0,004**	n.c.	0,00	0,00
Liver	0,10	0,15	0,02	0,03	**0,03**	n.c.	0,02	0,03
Kidney	0,04	0,04	0,01	0,01	**0,007**	n.c.	0,01	0,01
Poultry (all diets)								
Closest feeding level[a]:	0,02	mg/kg bw	0,9 N Turkey (highest diet)					
Muscle	0,02	0,02	0,02	0,02	**0,02**			
Fat	0,02	0,02	0,02	0,03	**0,03**			
Liver	0,06	0,06	0,06	0,06	**0,07**			
Poultry (layer only)								
Closest feeding level[a]:	0,02	mg/kg bw	1,3 N Layer					
Eggs[c]	0,01	0,01	0,01	0,01	**0,009**			

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

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.
The level of difenoconazole and TDM in whole plants, grains and straw of winter wheat and the level of difenoconazole and TDM, with the exception of triazole alanine (TA) in oilseed rape, is below 0.1 mg/kg. According to EU MRL guidelines, processing studies are not required, as difenoconazole and triazole derivative metabolites residues in grains, straw and whole plants of winter wheat are <0.1 mg/kg.
However, processing studies data for TDMs were submitted and evaluated at EU level as confirmatory data for triazole derivative metabolites (Triazole Derivative Metabolites Addendum – Confirmatory Data, 2018)
The hydrolysis studies presented at EU level as confirmatory data for TDMs shows that all four TDMs are stable. As a consequence the relevant residues in processed commodities are the TDM and no break-down products need be considered (EFSA, 2018). No processing factors have been applied to the consumer risk assessments. However, the processing factors determined do need to be considered for the dietary burden of livestock (Triazole Derivative Metabolites Addendum – Confirmatory Data, 2018).

Metabolite	Processed commodity	Transfer factor **Mean** (values) / Median PF	References
1,2,4- Triazole	No processing factors are available. Residues are below 0.01 mg/kg		Triazole Derivative Metabolites Addendum – Confirmatory Data, UK, 2018
Triazole alanine	Rape seed meal	1.4	
Triazole acetic acid	Rape seed meal	2	
Triazole lactic acid	Rape seed meal	2	

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.2-10: Summary of available studies in field rotational crops

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

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
None (bare soil)	0.750 kg a.s./ha	Root and tuber vegetables	Carrot	30	DAR, 2006 EFSA, 2011
		Leafy vegetables	Spinach	31	

Conclusion on rotational crops studies

Two field studies on rotational crops were reported at the EU level: for carrots (root and tuber vegetables) and spinach (leafy vegetables). The described studies show a single application of difenoconazole and triazoloalanine (TA) on bare soil at a dose of 0.750 kg a.s./ha. The study analyzed the content of difenoconazole and triazol alanine (CGA131013). Samples were analyzed for difenoconazole and triazol alanine (CGA131013). Parent difenoconazole and triazol alanine residues in carrot and spinach rot were below the LOQ of 0.02 mg/kg and 0.05 mg/kg, respectively. It was concluded that significant levels of parent difenoconazole and triazole alanine (TA) are not expected in rotational crops (DAR, 2006).

Rotational crops study data for TDMs were submitted and evaluated at EU level as confirmatory data for triazole derivative metabolites (Triazole Derivative Metabolites Addendum – Confirmatory Data, UK, 2018).
Three groups of crop (cereals represented by barley, root crops represented by carrot, leafy crops represented by lettuce) were investigated. Supervised field trials to investigate the residues in rotational crops after application of an EC formulation containing 250 g/L of difenoconazole. At each site, the product was applied once to bare soil at the rate of 375 g as/ha of difenoconazole and rotational crops from three crop groups (cereals represented by barley, root crops represented by carrot and leafy crops represented by lettuce) were planted at three plant-back intervals 29-36 days, 60- 61 days and 322-375 days after application to simulate a crop failure, a normal rotation and an annual rotation, respectively. The study samples were analysed for residues of triazole derivative metabolites.

Commodity	Application to	No of Trials	STMR (mg/kg)				HR (mg/kg)			
			T	TA	TAA	TLA	T	TA	TAA	TLA
Barley plant	Bare soil PBI 30-36 days	4	<0.01	0.06	0.03	0.14	<0.01	0.09	0.04	0.20
	Bare soil PBI 60-61 days	4	<0.01	0.06	0.04	0.12	<0.01	0.14	0.09	0.42
	Bare soil PBI 322-375 days	4	<0.01	0.09	0.02	0.13	<0.01	0.12	0.05	0.19
Barley (plant) worst case			<0.01	0.09	0.04	0.14	<0.01	0.14	0.09	0.42
Barley grain	Bare soil PBI 30-36 days	3	<0.01	0.18	0.16	0.01	<0.01	0.54	0.57	0.01
	Bare soil PBI 60-61 days	3	<0.01	0.23	0.22	<0.01	<0.01	0.31	0.33	<0.01
	Bare soil PBI 322-375 days	4	<0.01	0.28	0.27	0.01	<0.01	0.40	0.35	0.02
Barley (grain) worst case			<0.01	0.28	0.27	0.01	<0.01	0.54	0.57	0.02
Barley straw	Bare soil PBI 30-36 days	4	<0.01	0.11	0.13	0.07	<0.01	0.22	0.17	0.24

	Bare soil PBI 60-61 days	3	<0.01	0.05	0.16	0.07	<0.01	0.19	0.24	0.42
	Bare soil PBI 322-375 days	4	<0.01	0.04	0.13	0.07	<0.01	0.08	0.23	0.10
Barley (straw) worst case			<0.01	0.11	0.16	0.07	<0.01	0.22	0.24	0.42
Carrot tops	Bare soil PBI 30-36 days	4	<0.01	<0.01	<0.01	0.09	<0.01	0.01	<0.01	0.29
	Bare soil PBI 60-61 days	4	<0.01	<0.01	<0.01	0.06	<0.01	<0.01	<0.01	0.09
	Bare soil PBI 322-375 days	4	<0.01	<0.01	<0.01	0.06	<0.01	0.01	<0.01	0.07
Carrot (tops) worst case			<0.01	<0.01	<0.01	0.09	<0.01	0.01	<0.01	0.29
Carrot root	Bare soil PBI 30-36 days	4	<0.01	0.06	<0.01	0.01	<0.01	0.07	<0.01	0.03
	Bare soil PBI 60-61 days	4	<0.01	0.05	<0.01	<0.01	<0.01	0.05	<0.01	0.01
	Bare soil PBI 322-375 days	4	<0.01	0.03	<0.01	<0.01	<0.01	0.04	<0.01	0.01
Carrot (root) worst case			<0.01	0.06	<0.01	0.01	<0.01	0.07	<0.01	0.03
Lettuce	Bare soil PBI 30-36 days	4	<0.01	0.01	<0.01	0.03	<0.01	0.02	<0.01	0.05
	Bare soil PBI 60-61 days	4	<0.01	0.01	<0.01	0.03	<0.01	0.02	<0.01	0.08
	Bare soil PBI 322-375 days	4	<0.01	<0.01	<0.01	0.03	<0.01	0.02	<0.01	0.08
Lettuce worst case			<0.01	0.01	<0.01	0.03	<0.01	0.03	<0.01	0.08

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

According to SANTE/11956/2016 rev. 9, of the intended uses, oilseed rape is a melliferous crop. Residues studies in honey are required.
Therefore, a studies determining the residue levels of difenoconazole and triazole derivative metabolites in honey was performed in accordance with SANTE/11956/2016 rev. 9. The study was conducted using *Phacelia tanacetifolia* as a crop with high melliferous capacity under semi-field conditions and at four different locations in Poland and Germany.

Location	Number of trials	Crop	Applications
Poland	2	Phacelia	1x 150 g a.s./ha, BBCH 61-65
Germany	2	Phacelia	2x 125 g a.s./ha, BBCH 55-58 and 63-65

Overview of the values derived from the magnitude of residues in honey study

Type of sample	Study location	Difenoconazole [mg/kg]	1,2,4-T [mg/kg]	TA [mg/kg]	TAA [mg/kg]	TLA [mg/kg]
Honey	Poland (Kłoda)	n.d.	n.d.	0.01	n.d.	n.d.
	Poland (Wikcinek)	n.d.	n.d.	<0.01	n.d.	n.d.
	Germany	n.d.	n.d.	<0.01	n.d.	n.d.

	Germany	n.d.	n.d.	n.d.	n.d.	n.d.

n.d. – not detected, below LOD = 0,003 mg/kg

Details of the study are described in Appendix 2, point A.2.1.7.

Conclusion on the honey study
Residue studies in honey in the Northern Zone in Poland and Germany showed that the level of difenoconazole and triazole derivative metabolites was below LOQ (0.01 mg/kg). The studies showed no negative impact on the life processes and health of the bee family.
The currently established MRL for difenoconazole in honey and other apiculture products is 0.05 mg/kg. The use of the product SNS-F-11 in the cultivation of winter rapeseed during flowering in accordance with the proposed GAP does not pose a risk of exceeding the currently established MRL in honey and other apiculture products.

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

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Difenoconazole				
Wheat	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Triticale	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Oilseed rape	<0.01	STMR (Study number S23-103662; S23-103661)	<0.01	HR (Study number S23-103662; S23-103661)
Linseeds, poppy seeds, sunflower seeds, soybean, mustard seeds, gold of pleasure seeds	<0.01	STMR (Study number S23-103662; S23-103661)	<0.01	HR (Study number S23-103662; S23-103661)
Pome fruit (apple, pear, quinces, medlar, loquats/Japanese medlars, other pome fruits)	0.16	STMR (FAO, 2013)	Acute risk assessment was undertaken only with regard to the crop under consideration	
Grapes (table and wine)	0.52	STMR (FAO, 2013)		
Oranges, lemoms, limes, mandarins, grapefruits, other citrus fruits	0.16	STMR (FAO, 2013)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Apricots	0.17	STMR (EFSA, 2017)		
Peaches	0.15	STMR (European Commission, 2008)		
Strawberries	0.42	STMR (FAO, 2018)		
Blackberries, raspberries	0.04	STMR (EFSA, 2012)		
Blueberries	1	STMR (FAO, 2018)		
Azarole/ Mediteranean medlar	0.16	STMR (FAO, 2013)		
Olives (table and oil)	0.47	STMR (EFSA, 2010)		
Kumquats	0.16	STMR (FAO, 2013)		
Kaki/Japanese persimmons	0.16	STMR (FAO, 2013)		
Prickly pears/cactus fruits	0.034	STMR (FAO, 2018)		
Avocados	0.05	STMR (FAO, 2015)		
Bananas	0.02	STMR (FAO, 2008)		
Papayas	0.01	STMR (EFSA, 2013)		
Beetroots	0.08	STMR (EFSA, 2013)		
Carrots	0.08	STMR (EFSA, 2013)		
Horsredishes, Jerusalem artichokes, parsnips, parsley roots, radishes,salsifies, swedes, turnips, other root and tuber vegetables	0.08	STMR (EFSA, 2013)		
Garlic, onions, shallots	0.01	STMR (EFSA, 2013)		
Spring onions/green onions and Welsh onions	2.8	STMR (FAO, 2013)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tomatoes	0.72	STMR (European Commission, 2008)		
Sweet peppers/bell peppers	0.24	STMR (FAO, 2017		
Aubergines/eggplants	0.18	STMR (EFSA, 2014)		
Okra/lady'sfingers, other solanaceae	0.18	STMR (FAO, 2018)		
Cucumbers, ghrekins, courgettes	0.01	STMR (EFSA, 2012)		
Melons, pumpkins, watermelons, other cucurbits – inedible peel	0.01	STMR (EFSA, 2013)		
Brocoli	0.13	STMR (EFSA, 2011)		
Cauliflowers	0.02	STMR (FAO, 2008)		
Other flowering brassica	0.01	STMR (EFSA, 2018)		
Brussels sprouts	0.07	STMR (EFSA, 2018)		
Head cabbages	0.02	STMR (EFSA, 2017)		
Lamb's lettuce/corn salads	1.45	STMR (EFSA, 2014)		
Lettuces	0.52	STMR (EFSA, 2017)		
Escaroles/broad-leaved endives, Roman rocket/rucola	0.33	STMR (EFSA, 2018)		
Cress and othersprouts andshoots, land cress, red mustard, baby leaf crops(including brassica species), other lettuce and other salad plants	0.52	STMR (EFSA, 2017, 2018)		
Spinaches, purslanes, other spinach and similar	0.33	STMR (EFSA, 2018a)		
Chards/beetleaves	0.52	STMR (EFSA, 2017)		
Witloofs/Belgian endives	1.3	STMR (EFSA, 2018)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Chervil, celery leaves, parsley, basil and eadible flowers	4.65	STMR (EFSA, 2009)		
Chives, sage, rosemary, thyme, laurel/bay leaves, tarragon, other herbs	0.52	STMR (EFSA, 2017)		
Cardons, celeries	1.22	STMR (EFSA, 2017)		
Florence fennels	1.66	STMR (EFSA, 2009)		
Globe artichokes	0.51	STMR (FAO, 2018)		
Leeks	0.13	STMR (EFSA, 2017)		
Rhubarbs	0.7	STMR (EFSA, 2018)		
Beans, lentils, lupins/lupini beans	0.02	STMR (EFSA, 2017)		
Peas	0.028	STMR (FAO, 2018)		
Rice	1.1	STMR (FAO, 2017)		
Barley	0.02	STMR (EFSA, 2017)		
Liquorice, ginger, turmeric/curcuma, horseradish, root species, other species (roots)	0.64	STMR (EFSA, 2017)		
Other plant and animal commodities	MRL Reg. (EU) 2019/552			
1,2,4- Triazole (1,2,4-T)				
Wheat	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Oilseed rape	<0.01	STMR (Study number S23-103662; S23-103661)	<0.01	HR (Study number S23-103662; S23-103661)
Linseeds, poppy seeds, sunflower seeds, soybean, mustard seeds, gold of pleasure seeds	<0.01	STMR (Study number S23-103662; S23-103661)	<0.01	HR (Study number S23-103662; S23-103661)
Triazole alanine (TA) and Triazole lactic acid (TLA)				
Wheat	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Oilseed rape	0.48	STMR (Study number S23-	3.80	HR (Study number S23-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		103662; S23-103661)		103662; S23-103661)
Linseeds, poppy seeds, sunflower seeds, soybean, mustard seeds, gold of pleasure seeds	0.48	STMR (Study number S23-103662; S23-103661)	3.80	HR (Study number S23-103662; S23-103661)
Triazole acetic acid (TAA)				
Wheat	<0.01	STMR (Study number: 21FRT-32TRZAWDFKN)	<0.01	HR (Study number: 21FRT-32TRZAWDFKN)
Oilseed rape	0.02	STMR (Study number S23-103662; S23-103661)	0.17	HR (Study number S23-103662; S23-103661)
Linseeds, poppy seeds, sunflower seeds, soybean, mustard seeds, gold of pleasure seeds	0.02	STMR (Study number S23-103662; S23-103661)	0.17	HR (Study number S23-103662; S23-103661)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

Difenoconazole

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	96 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Wheat: 0.09 % (based on results for children) Soybeans: 0.01% (based on results for children) Rapeseeds/canola seeds: 0.01% (based on results for children) Linseeds: 0.01% (based on results for children) Wheat/milling (flour): 0.1% (based on results for children) Wheat/milling (wholemeal)-baking: 0.0% (based on results for children) Soybeans/soya drink: 0.0% (based on results for children) Soyabeans/boiled: 0.0% (based on results for children) Rapeseeds/oils: 0.0% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

1,2,4- Triazole (1,2,4-T)

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	0,4 % (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Wheat: 0.1 % (based on results for children) Sunflower seeds: 0.03% (based on results for children)

	Soybeans: 0.02% (based on results for children) Rapeseeds/canola seeds: 0.01% (based on results for children) Linseeds: 0.01% (based on results for children) Mustard seeds: 0.01% (based on results for children) Wheat/milling (flour): 0.1% (based on results for children) Wheat/milling (wholemeal)-baking: 0.1% (based on results for children) Soybeans/soya drink: 0.0% (based on results for children) Soyabeans/boiled: 0.0% (based on results for children) Rapeseeds/oils: 0.0% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

Triazole alanine (TA) and Triazole lactic acid (TLA)

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	0.6% (based on GEMS/Food G11)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Sunflower seeds: 0.5% (based on results for children) Soybean: 0.4% (based on results for children) Rapeseeds/canola seeds: 0.2% (based on results for children) Linseeds: 0.2% (based on results for children) Mustard seeds: 0.2% (based on results for children) Wheat: 0.05% (based on results for children) Soyabeans/soya drink: 0.7% (based on results for children) Sunflower seeds/oils: 0.4% (based on results for children) Soyabeans/boiled: 0.2% (based on results for children) Rapeseeds/oils: 0.1% (based on results for children) Wheat/milling (flour): 0.0% (based on results for children) Wheat/milling (whole meal)-baking: 0.0% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

Triazole acetic acid (TAA)

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	0.0% (based on GEMS/Food G10)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Wheat: 0.01% (based on results for children) Sunflower seeds: 0.01% (based on results for children) Soyabeans: 0.00% (based on results for children) Rapeseeds/canola seeds: 0.00% (based on results for children) Linseeds: 0.00% (based on results for children) Mustard seeds: 0.00% (based on results for children) Wheat/milling (flour): 0.00% (based on results for children) Soyabeans/soya drink: 0.00% (based on results for children) Wheat/milling (whole meal)-baking: 0.00% (based on results for children) Sunflower seeds/oils: 0.00% (based on results for children)

	Soyabeans/boiled: 0.00% (based on results for children) Rapeseeds/oils: 0.00% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

The proposed uses of difenoconazole in the formulation SNS-F-11 do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.3.1 Acute consumer risk assessment from combined exposure

Not relevant. The product contains only one active substance.

7.3.2 Chronic consumer risk assessment from combined exposure

Not relevant. The product contains only one active substance.

7.4 References

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EFSA (European Food Safety Authority), 2017. Modification of the existing maximum residue levels for difenoconazole in various crops; EFSA Journal 2017;15(7):4893.

EFSA (European Food Safety Authority), 2010. Modification of the existing MRLs for difenoconazole in swedes and turnips; EFSA Journal 2010; 8(2):1510.

EFSA (European Food Safety Authority), 2018. Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted; EFSA Journal 2018;16(7):5376.

Sweden, 2006. DAR for difenoconazole. Volume 3, B.7; Residue data.

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole; EFSA Journal 2011;9(1):1967.

EFSA (European Food Safety Authority), 2017. Modification of the existing maximum residue levels for difenoconazole in various crops; EFSA Journal 2017;15(7):4893.

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. (KCA 6.3)	Figurski R.	2021	Magnitude of residue of difenoconazole (CAS 119446-68-3) in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of a formulated product Valor 250 EC – four harvest trials and four decline curve trials in Northern Europe – Poland (2021) Study code: 21FRT-32TRZAWDFKN Field phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Wójcik M.	2022	Valor 250 EC: Determination of the residues of difenoconazole in winter wheat. Study code: C-08-21 Analytical phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Kurek-Molenda M.	2023	Determination of the residues of difenoconazole and triazole derivative metabolites in/on outdoor winter oilseed rape after one application of SNS-F-11 in Poland in 2023. Study code: EU-23-1359 Field phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Schernikau N., Kissmann H.	2024	Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of SNS-F-11 in four trials in Poland 2023. Study code: S23-103662 Analytical phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Lines J.	2023	Study to generate samples of winter oilseed rape following one application of Tores 250 EC for subsequent residue analysis. 4 sites in Northern Europe 2023. Study code: S23-103623	N	Synthos Agro Sp. z o.o.

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
			Field phase, GLP Unpublished		
KCP 7.2.3. (KCA 6.3)	Schernikau N.	2024	Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of Tores 250 EC in four trials in Northern Europe 2023. Study code: S23-103661 Analytical phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 7.2.7 (KCA 6.3)	Kurek-Molenda M.	2023	Honey residue study with difenoconazole on Phacelia after application of Tores 250 EC Poland 2023. Study code: EU-23-1667 Field phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 7.2.7 (KCA 6.3)	Portail B.	2024	Study to generate samples of honey after two application of TORES 250 EC in *Phacelia tanacetifolia* for subsequent residue analysis at two sites in Germany in 2023. Study code: S23-103847 Field phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 7.2.7 (KCA 6.3)	Schernikau N.	2023	Determination of the residues of difenoconazole and triazoles derivative metabolites in honey following application of Tores 250 EC in four trials in Northern Europe 2023. Study code: S23-103664 Analytical phase, GLP Unpublished	N	Synthos Agro Sp. z o.o.

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
KCP 7.2.1 (KCA. 6.1)	Beidler WT.	1991a	Stability of CGA-169374 residues in potatoes under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90070. GLP, Published. Syngenta File No CGA 169374/0453	N	Syngenta
KCP 7.2.1 (KCA. 6.1)	Beidler WT.	1991b	Stability of CGA-169374 residues in potatoes under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90069. GLP, Published. Syngenta File No CGA 169374/0452	N	Syngenta
KCP 7.2.1 (KCA. 6.1)	Beidler WT.	1992	Stability of CGA-169374 residues in lettuce, soybeans and wheat forage under freezer storage conditions for one year. Syngenta Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-91024. GLP, Published. Syngenta File No CGA 169374/0617	N	Syngenta
KCP 7.2.1 (KCA. 6.1)	Kühne-Thu H.	1994	Residue stability of CGA-169374 (difenoconazole) in banana (whole fruit) under freezer storage conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 125/93. GLP, Published. Syngenta File No CGA 169374/0934	N	Syngenta
KCP 7.2.1 (KCA. 6.1)	Hayworth CG.	1998	Stability of CGA-169374 fortified into wheat and cotton substrates under freezer conditions. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection Inc., Greensboro, United States Report No ABR-98061. GLP, Published. Syngenta File No CGA 169374/1644	N	Syngenta

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 7.2.1 (KCA. 6.1)	Wurz REM.	1993a	Storage stability study of CGA-169374 in dairy and poultry tissues, eggs and milk under freezer storage conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-93012. GLP, Published. Syngenta File No CGA 169374/0795	N	Syngenta
KCP 7.2.1 (KCA. 6.1)	[redacted]	2000	Residue of difenoconazole (CGA 169374) and its metabolite CGA 205375 in milk, blood, and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of difenoconazole at three dose levels. [redacted] Report No 202/99. GLP, Published. Syngenta File No CGA 169374/2039	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Madrid SO. Huber MK	1987a	The distribution and characterization of phenyl-14C vs. triazole 14C-CGA 169374 on spray treated tomatoes – a side by side comparison study in greenhouse. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-87025. Not GLP, Published. Syngenta File No CGA 169374/0043	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Madrid SO. Huber MK	1987b	The distribution and characterization of phenyl-14C vs. triazole 14C-CGA 169374 on their metabolites in field grown tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-87033. Not GLP, Published. Syngenta File No CGA 169374/0044	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Velagaleti PR.	1990a	Metabolism of triazole-14C-CGA 169374 in spray-treated tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0600. GLP, Published. Syngenta File No CGA 169374/0355	N	Syngenta
KCP 7.2.2	Schweitzer MG.	1990a	Metabolism of phenyl-14C-CGA 169374 in spray-treated tomatoes.	N	Syngenta

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 6.2.1)			Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0700. GLP, Published. Syngenta File No CGA 169374/0356		
KCP 7.2.2 (KCA 6.2.1)	Hubbard L.	1991a	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from seed treatment application under field conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90009. GLP, Published. Syngenta File No CGA 169374/0415	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Hubbard L.	1991b	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from seed treatment application under greenhouse conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90010. GLP, Published. Syngenta File No CGA 169374/0416	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Hubbard L.	1991c	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from foliar spray application under greenhouse environment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90011. GLP, Published. Syngenta File No CGA 169374/0417	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Schweitzer MG.	1990b	Metabolism of phenyl-14C-CGA 169374 in spray-treated potatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0400. GLP, Published. Syngenta File No CGA 169374/0357	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Velagaleti PR.	1990b	Metabolism of triazole-14C-CGA 169374 in spray-treated potatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0500.	N	Syngenta

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**
			GLP, Published. Syngenta File No CGA 169374/0489		
KCP 7.2.2 (KCA 6.2.1)	Capps T.	1992	Uptake and metabolism of 14C-CGA 169374 by grapes from foliar spray treatment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-92003. GLP, Published. Syngenta File No CGA 169374/0537	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Naumann Ch.	1993a	Metabolism of [Phenyl-14C] CGA-169374 in field grown spring rape. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 11/93. GLP, Published. Syngenta File No CGA 169374/0809	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Naumann Ch.	1993b	Metabolism of [Triazole-14C] CGA-169374 in field grown spring rape. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 12/93. GLP, Published. Syngenta File No CGA 169374/0810	N	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	[redacted]	1998	Metabolism of triazole and phenyl-14C-CGA 169374 in lactating goats doesed daily for ten consecutive days. [redacted] Report No ABR-88087. Not GLP, Published. Syngenta File No CGA 169374/0234	N	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	[redacted]	1990a	[^{14}C]CGA-169374 phenyl and triazole label distribution, elimination and metabolism in goats. [redacted] Report No ABR-89100. GLP, Published. Syngenta File No CGA 169374/1232	N	Syngenta
KCP 7.2.2.	[redacted]	1996	Metabolism of phenyl-14C CGA 169374 in lactating goats.	N	Syngenta

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 6.2.2 – 6.2.5)			[redacted]. Report No ABR-89051 GLP, Published. Syngenta File No CGA 169374/0364		
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	[redacted]	1989	Metabolism of triazole and phenyl-14C-CGA 169374 in lying hens dosed daily for fourteen consecutive days. [redacted] Report No ABR-89051. GLP, Published. Syngenta File No CGA 169374/0270	N	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	[redacted]	1990b	[^{14}C]CGA-169374 phenyl and triazole label distribution, elimination and metabolism in goats. [redacted] Report No ABR-89101. GLP, Published. Syngenta File No CGA 169374/0364	N	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	[redacted]	2004	[Triazole-14C] CGA-169374-nature of the residue in laying hens. [redacted]. Report No 786-02 GLP, Published. Syngenta File No CGA 169374/2441	N	Syngenta
KCP 7.2.2 (KCA 6.5.1)	Muir GT.	2003	Difenoconazole: Aqueous hydrolysis at 90, 100 and 120°C. Syngenta Crop Protection AG, Basel, Switzerland. Syngenta – Jealott´s Hill International, Bracknell, Berkshire, UK. Report No RJ3360B GLP, Published. Syngenta File No CGA 169374/2312	N	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Walser M.	1994a	Outdoor confined accumulation study on rotational crops after bare ground soil application of [14C-phenyl]-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland. Report No 8/94.	N	Syngenta

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
			GLP, Published. Syngenta File No CGA 169374/0924		
KCP 7.2.6. (KCA 6.6.2)	Walser M.	1994b	Outdoor confined accumulation study on rotational crops after bare ground soil application of [14C-triazole]-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland. Report No 4/94. GLP, Published. Syngenta File No CGA 169374/2395	N	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Close C.	1995	14C-CGA-169374: Uptake and distribution of residues in confined rotational crops. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-95057. GLP, Published. Syngenta File No CGA 169374/1118	N	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Heyer R.	1995a	CGA-169374 (metabolite CGA 131013), 250 EC, A-7402 G, rotational crop: carrot, soil, Germany. Novartis Crop Protection AG, Basel, Switzerland. RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany. Report No 488002. GLP, Published. Syngenta File No CGA 169374/1215	N	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Heyer R.	1995b	CGA-169374 (metabolite CGA 131013), 250 EC, A-7402 G, rotational crop: spinach, soil, Germany. Novartis Crop Protection AG, Basel, Switzerland. RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany. Report No 488001. GLP, Published. Syngenta File No CGA 169374/1216	N	Syngenta

The following tables are to be completed by MS.

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 Difenoconazole

A 2.1.1 Stability of residues

Not required.

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

Not required.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Winter wheat

Table A 1: 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)
Intended cGAP	2	150 g a.s./ha	14 days	BBCH 55	62 (commercial harvest)

* 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 is accepted. The trials are independed and valid with regard to storage stability data. Acceptable analytical methods were used. The limit of quantification (LOQ) for difenoconazole was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg

Reference:	K.C.P. 7.3.2
Report	Magnitude of the residues of difenoconazole (CAS 119446-68-3) in winter wheat (Raw Agriculture Commodity – RAC) grown in open field conditions after two applications of a formulated product Valor 250 EC – four harvest trials and four decline trials in Northern Europe – Poland (2021), 21FRT-34TRZAWDFKN, Figurski R., 2021. Analytical phase: Valor 250 EC. Determination of the residues of difenoconazole in winter wheat. C-08-21, Wójcik M., 2022.
Guideline(s):	Yes (OECD Guidelines for the testing of chemicals on Crop Field Trial 509, SANTE/2020/12830, Rev.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Eight residue trials of winter wheat, including four residue decline studies were carried out in Poland in 2021. Product Valor 250 EC (difenoconazole 250 g/l) was applied 2-times at a rate of 150 g of difenoconazole from BBCH 33 to BBCH 55. Application of the Valor 250 EC was carried out at intervals of 14±1 days. The last treatment was at BBCH 55. Winter wheat samples of were harvested 14±1 days after last application (in residue harvest studies) and 0, 14, 28, 45 and 62±2 (commercial harvest) days after last application (in residue decline studies). Samples were collected from inner part of each plot. Samples were taken from untreated plot firstly than from treated plots. After harvesting samples were frozen and stored at the temperature ≤ -18°C for approx. 6 months.

The concentration of difenoconazole and its metabolites in winter wheat samples was chemically determined with a liquid chromatographic method with mass spectrometer detection. The method for each compound was validated in according to EC Guidance Documents SANTE/2020/12830, Rev.1.

Difenoconazole were verified for two transitions 406.10 > 250.95 (quantitation transition) and 406.10 > 337.00 (as confirmatory transition). The range of linearity of the analytical graph of difenoconazole varied from 0.5 to 50 ng/ml (0.0025 – 0.25 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels in winter wheat whole plant samples were 84.0% and 94.5 % (for transition 406.10 > 250.95) and 77.8 % and 94.1 % (406.10 > 337.00); in winter wheat grains were 78.6% and 90.6 % (for transition 406.10 > 250.95) and 80.7 % and 89.5% (406.10 > 337.00); in winter wheat straw were 82.9% and 92.8 % (for transition 406.10 > 250.95) and 78.4 % and 92.4 % (406.10 > 337.00), respectively for LOQ and 10 x LOQ levels. The precision for difenoconazole was between 1.3 % to 6.9 % for winter wheat whole plants, from 1.9% to 9.5% for winter wheat grains and from 1.1% to 5.7% for winter wheat straw. Matrix effect was checked during the validation method. Assessment of matrix effects was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 2.0 ng/mL. The matrix effect was -0.03% (for transition 406.10 > 250.95) and 2.2% (406.10 > 337.00) for winter wheat whole plants; -0.85% (for transition 406.10 > 250.95) and 3.6% (406.10 > 337.00) for winter wheat grains and 7.7% (for transition 406.10 > 250.95) and 12.4% (406.10 > 337.00) for winter wheat straw. The limit of quantification (LOQ) for difenoconazole was 0.01 mg/kg and the limit of detection was 0.0025 mg/kg.

Triazole alanine (TA) were verified for two transitions 157.00 > 70.15 (quantitation transition) and 157.00 > 88.10 (as confirmatory transition). The range of linearity of the analytical graph of triazole alanine varied from 0.5 to 50 ng/ml (0.0025 – 0.25 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels in winter wheat whole plant samples were 98.6 % and 95.8 % (for transition 157.00 > 70.15) and 97.3 % and 95.7 % (for transition 157.00 > 88.10); in winter wheat grains samples were 97.3 % and 94.2 % (for transition 157.00 > 70.15) and 97.5 % and 95.4 % (for transition 157.00 > 88.10); in winter wheat straw samples were 88.8 % and 92.5 % (for transition 157.00 > 70.15) and 86.8 % and 92.6 % (for transition 157.00 > 88.10), respectively for LOQ and 10 x LOQ levels. The precision for triazole alanine was between 1.7 % and 2.9 % for winter wheat whole plants; between 2.5% and 4.7% for winter wheat grain and between 3.5% and 5.2% for winter wheat straw. Matrix effect was checked during the validation method. Assessment of matrix effects was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 2.0 ng/mL. The matrix effect in winter wheat whole plants was -16.7 % (for transition 157.00 > 70.15) and -15.9% (for transition 157.00 > 88.10); for winter wheat grains was -17.5 % (for transition 157.00 > 70.15) and -18.6 % (for transition 157.00 > 88.10); for winter wheat straw was -15.3 % (for transition 157.00 > 70.15) and -16.6 % (for transition 157.00 > 88.10). The limit of quantification (LOQ) for triazole alanine was 0.01 mg/kg and the limit of detection was 0.0025 mg/kg.

1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) were verified for two transitions: quantitation transition and confirmatory transition. The range of linearity of the analytical graph of triazole alanine varied from 1 to 100 ng/ml (0.004 – 0.40 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg.

The mean extraction recovery levels for **1,2,4-T** in winter wheat whole plant samples were 79.4 % and 96.2 % (for transition 70.20 > 70.10) and 84.0 % and 95.0 % (for transition 70.20 > 43.20); in winter wheat grains samples were 78.0 % and 95.0 % (for transition 70.20 > 70.10) and 74.7 % and 88.4 % (for transition 70.20 > 43.20); in winter wheat straw samples were 76.4 % and 92.5 % (for transition 70.20 > 70.10) and 84.5 % and 91.9% (for transition 70.20 > 43.20), respectively for LOQ and 10 x LOQ levels. The precision for 1,2,4-T was between 2.1 % and 4.2 % for winter wheat whole plants; between 1.3 % and 6.9 % for winter wheat grains; between 1.9% and 5.0% for winter wheat straw. Matrix effect was checked during the validation method. Assessment of matrix effects for 1,2,4-T was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 2.5 ng/mL. The matrix effect for 1,2,4-T in winter wheat whole plants was -4.3 % (for transition 70.20 > 70.10) and -1.4 % (for transition 70.20 > 43.20); in winter wheat grains was -12.4 % (for transition 70.20 > 70.10) and -10.8 % (for transition 70.20 > 43.20); in winter wheat straw 0.5% (for transition 70.20 > 70.10) and -3.9 % (for transition 70.20 > 43.20).

The mean extraction recovery levels for **TAA** in winter wheat whole plant samples were 83.2 % and 94.3 % (for transition 128.20 > 70.20) and 81.0% and 90.9 % (for transition 128.20 > 43.10); in winter wheat grains samples were 78.0 % and 95.0 % (for transition 128.20 > 70.20) and 76.0% and 94.3 % (for transition 128.20 > 43.10); in winter wheat straw samples were 84.7 % and 92.4 % (for transition 128.20 > 70.20) and 81.2 % and 88.4 % (for transition 128.20 > 43.10) , respectively for LOQ and 10 x LOQ levels. The precision for TAA was between 2.1 % and 8.2 % in winter wheat whole plant; between 1.3% and 8.2% in winter wheat grains; between 1.4% and 8.9% in winter wheat straw. Matrix effect was checked during the validation method. Assessment of matrix effects for TAA was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 2.5 ng/mL. The matrix effect for TAA in winter wheat whole plant was -6.5 % (for transition 128.20 > 70.20) and -4.0 % (for transition 128.20 > 43.10); in winter wheat grains was -7.5 % (for transition 128.20 > 70.20) and -11.6 % (for transition 128.20 > 43.10); in winter wheat straw was 4.6 % (for transition 128.20 > 70.20) and 5.0 % (for transition 128.20 > 43.10).

The mean extraction recovery levels for **TLA** in winter wheat whole plant samples were 81.7 % and 93.6 % (for transition 158.00 > 70.10) and 74.8 % and 94.3 % (for transition 158.00 > 42.95); in winter wheat grains samples were 79.9 % and 93.8 % (for transition 158.00 > 70.10) and 80.0 % and 92.8 % (for transition 158.00 > 42.95); in winter wheat straw samples were 82.4 % and 92.4 % (for transition 158.00 > 70.10) and 87.1 % and 96.4 % (for transition 158.00 > 42.95), respectively for LOQ and 10 x LOQ levels. The precision for TLA was between 1.8 % and 4.0 % for winter wheat whole plants; between 2.1% and 10.4% for winter wheat grains and between 1.2% and 14.4% for winter wheat straw. Matrix effect was checked during the validation method. Assessment of matrix effects for TLA was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 2.5 ng/mL. The matrix effect for TLA was 7.1 % (for transition 158.00 > 70.10) and 15.7 % (for transition 158.00 > 42.95) for winter wheat whole plant; -3.3% (for transition 158.00 > 70.10) and 6.4 % (for transition 158.00 > 42.95) for winter wheat grains; 8.0% (for transition 158.00 > 70.10) and 13.1 % (for transition 158.00 > 42.95) for winter wheat

The limit of quantification (LOQ) for 1,2,4-T, TAA and TLA was 0.01 mg/kg and the limit of detection was 0.004 mg/kg.

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				Difenoconazole	TA	1,2,4-T	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
21FRT-32TRZAWDFKN-01/Niemienice, Poland/2021	Winter Wheat (Sherpa)	1. 03.11.2020 2. 20.06.2021 – 29.06.2021 3. 16.08.2021	150	200	75	2	BBCH 55	Grains Straw	<LOD 0.0616	<LOD <LOD	<LOD <LOD	<LOD <LOD	<LOD <LOD	62	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg
21FRT-32TRZAWDFKN-02/Żukówka 05-870, Poland/2021	Winter Wheat (Hondia)	1. 10.10.2020 2. 10.06.2021 – 18.06.2021 3. 03.08.2021	150	200	75	2	BBCH 55	Grains Straw	<LOD 0.0326	<LOD <LOD	<LOD <LOD	<LOD <LOD	<LOD <LOD	61	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg
21FRT-32TRZAWDFKN-03/Moraków 99-122, Poland/2021	Winter Wheat (Euforia)	1. 10.11.2020 2. 25.06.2021 – 04.07.2021 3. 03.08.2021	150	200	75	2	BBCH 55	Grains Straw	<LOD 0.0349	<LOD <LOD	<LOD <LOD	<LOD <LOD	<LOD <LOD	62	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg

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				Difenoconazole	TA	1,2,4-T	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
21FRT-32TRZAWDFKN-04/Ludwików 27-350, Poland/2021	Winter Wheat (Hondia)	1. 25.09.2020 2. 05.06.2021 – 17.06.2021 3. 16.08.2021	150	200	75	2	BBCH 55	Grains Straw	<LOD 0.0658	<LOD <LOD	<LOD <LOD	<LOD <LOD	<LOD <LOD	61	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg
21FRT-32TRZAWDFKN-05/Mokra 96-100, Poland/2021	Winter Wheat (Hondia)	1. 19.09.2020 2. 08.06.2021 – 21.06.2021 3. 13.08.2021	150	200	75	2	BBCH 55	Whole plants Whole plants Whole plants Whole plants Grains Straw	0.1131 0.0353 0.0091 <LOD <LOD 0.0570	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	0 DALA 14 DALA 28 DALA 45 DALA 62 DALA	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg
21FRT-32TRZAWDFKN-06/Kolonia Sójki 99-307, Poland/2021	Winter Wheat (Julius)	1. 02.10.2020 2. 12.06.2021 – 25.06.2021 3. 20.08.2021	150	200	75	2	BBCH 55	Whole plants Whole plants Whole plants Whole plants Grains Straw	0.0923 0.0348 0.0129 <LOD <LOD 0.0374	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	0 DALA 14 DALA 28 DALA 45 DALA 62 DALA	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg

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				Difenoconazole	TA	1,2,4-T	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
21FRT-32TRZAWDFKN-07/Sadowiec 09-142, Poland/2021	Winter Wheat (Astoria)	1. 19.10.2020 2. 04.06.2021 – 14.06.2021 3. 14.08.2021	150	200	75	2	BBCH 55	Whole plants Whole plants Whole plants Whole plants Grains Straw	0.0822 0.0361 0.0107 0.0073 <LOD 0.0344	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	0 DALA 14 DALA 28 DALA 45 DALA 62 DALA	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg
21FRT-32TRZAWDFKN-08/Gogole Steczki 06-420, Poland/2021	Winter Wheat (Patras)	1. 08.10.2021 2. 03.06.2021 – 15.06.2021 3. 10.08.2021	150	200	75	2	BBCH 55	Whole plants Whole plants Whole plants Whole plants Grains Straw	0.0919 0.0526 0.0116 0.0045 <LOD 0.0825	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD <LOD	0 DALA 14 DALA 28 DALA 45 DALA 62 DALA	LOD $_{\text{Difenoconazole, TA}}$ = 0.0025 mg/kg LOD $_{\text{1,2,4T, TAA, TLA}}$ = 0.004 mg/kg

(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 Oilseed rape

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)
Intended cGAP	1	108 g a.s./ha	n.a.	BBCH 65	n.a.

* 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 is accepted. The trials are independed and valid with regard to storage stability data. Acceptable analytical methods were used. The limit of quantification (LOQ) for difenoconazole was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg

Reference:	K.C.P. 7.3.2
Report	**Field phase:** Determination of the residues of difenoconazole and triazole derivative metabolites in/on outdoor winter oilseed rape after one application of SNS-F-11 in Poland 2023, EU-23-1359, Kurek-Molenda M., 2023. **Analytical phase:** Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of SNS-F-11 in four trials in Poland, S23-103662, Schernikau N., Kissmann H., 2024
Guideline(s):	Yes (OECD Guidelines for the testing of chemicals on Crop Field Trial 509, SANTE/2020/12830, Rev.2)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four residue trials of oilseed rape, including two residue decline studies were carried out in Poland in 2023. Product SNS-F-11 was applied one-time at a rate of 108 g of difenoconazole at BBCH 65. Oilseed rape samples were harvested at normal commercial harvest 73 days after last application (in residue harvest studies) and 0, 14, 32, 64 and 73 (normal harvest) days after last application (in residue decline studies). Untreated plot was sampled first, whole plots were harvested by combine harvester, except 0.5 m edged of plots. Samples were frozen at a freezer at temperature below -18°C. Samples were analyzed within 30 days after sampling.

The analytical method for each compound was validated in according to EC Guidance Documents SANTE/2020/12830, Rev.2.
Method validation was not performed within this analytical phase because the analytical methods were previously validated in accordance to SANTE/2020/12830, rev. 2 for the determination of Difenoconazole or 1,2,4 triazole, TA, TAA and TLA in oilseed rape (whole plant and seed) in GLP study S23-103661 (presented in a Study 2 for oilseed rape).

Difenoconazole

The analyte difenoconazole was determined in the final extracts by use the LC-MS/MS detection with evaluation of one (1) mass transition. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of target analyte.
The range of linearity of the analytical graph of difenoconazole varied from 0.075 ng/mL to 7.5 ng/ml (0.003 – 0.3 mg/kg). The linear coefficient r^2 was higher than 0.98. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg.
The analytical performance in terms of accuracy and repeatability was assessed for each analytical set by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the concurrent recoveries upon applying the analytical method.
The mean concurrent recoveries and precision in oilseed rape samples (whole plant and seed) are presented below:

Matrix	Fortification Level (mg/kg)	Mean recovery (%)	Overall Rel. Std. Dev. (%)
Difenoconazole (m/z 406/251)			
Oilseed rape (whole plant)	0.010	97	6.1
	0.10	95	
	2.0	107	
Oilseed rape (seed)	0.10	82	5.2
	0.01	84	

The effect of oilseed rape (whole plant and seed) matrix on the detector response of difenoconazole was assessed by comparing peak areas of matrix-matched standards (90 % matrix amount) with solvent standards at the same nominal concentrations. Assessment of matrix effects for difenoconazole was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 0.25 ng/mL, 0.50 ng/mL, 1.0 ng/mL, 2.5 ng/mL, 5.0 ng/mL and 7.5 ng/mL. The matrix effect for whole plant ranged from (-) 1.9 to (-) 8.5 for whole plant and from (-) 18 to (-) 26 for seeds. Matrix effects were $\geq \pm$ 20 % and deemed to be significant for oilseed rape (seed). Therefore, matrix-matched standards were used for quantification throughout the analytical phase.
The limit of quantification (LOQ) for difenoconazole was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg.

Triazole derivative metabolites
The analytes 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid were determined in the final sample extracts by addition of isotopically labelled standards and by use of LC DMS-MS/MS detection.
For **triazole alanine (TA)**, one (1) mass transition was evaluated. For **1,2,4-triazole (1,2,4-T)**, **triazole acetic acid (TAA)** and **triazole lactic acid (TLA)**, one (1) mass transition was evaluated. A confirmatory run was performed on a different stationary phase for validation samples but was not used for quantification of samples.
The range of linearity of the analytical graph of TA, 1,2,4-T, TAA and TLA varied from 0.30 ng/mL to 30 ng/ml (0.003 – 0.3 mg/kg). The linear coefficient r^2 was higher than 0.98. For 1,2,4-Triazole, TA, TAA and TLA calibration standards contained the internal standards at a constant concentration level of 25 ng/mL.
The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg.
The mean concurrent recoveries and precision in oilseed rape samples (whole plant and seed) are presented below:

Mass Transition	Fortification Level (mg/kg)	Mean recovery (%)	Overall Rel. Std. Dev. (%)
1,2,4-Triazole (whole plant)			

m/z 70→43	0.01	96	9.0
	0.1	83	
1,2,4-Triazole (seeds)			
m/z 70→43	0.01	93	2.9
	0.1	92	
Triazole alanine (whole plant)			
m/z 157→70	0.01	91	1.9
	0.1	88	
	0.20	89	
Triazole alanine (seeds)			
m/z 157→70	0.01	97	8.0
	0.1	84	
	0.20	87	
Triazole lactic acid (whole plant)			
m/z 158→70	0.01	87	2.6
	0.1	85	
Triazole lactic acid (seeds)			
m/z 158→70	0.01	98	2.7
	0.1	87	
Triazole acetic acid (whole plant)			
m/z 128→70	0.01	98	2.6
	0.1	95	
Triazole acetic acid (seeds)			
m/z 128→70	0.01	101	1.3
	0.1	101	

Isotopically labelled internal standard was used for quantification of the triazole metabolites 1,2,4-triazole, TA, TAA and TLA so that possible matrix effects on the detector response are automatically compensated when using the response ratio of analyte to internal standard for quantification. Therefore, matrix effects on detection were not determined.

The limit of quantification (LOQ) for TA, 1,2,4-T, TAA and TLA was 0.01 mg/kg and the limit of detection was 0.03 mg/kg.

Table A 4: Summary of the study 1 trials

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: g a.s./ ha	Water (l/ha)	g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Difenoconazole	TA	1,2,4-T	TAA	TLA	PHI (days) (d)	Details on trial (e)
EU-23-1359-01 Osówka (woj. lubelskie)	Winter oilseed rape/ Tom	1) 15 Sep 2022 2) 02-23 May 2023 3) 18 July 2023	108	250	43.2	11 May 2023	BBCH 65	seed	n.d	0.87	n.d.	0.01	0.04	68 (NCH)	NCH – normal commercial harvest, PHI is not relevant
EU-23-1359-02 Lucjanów (woj. mazowieckie)	Winter oilseed rape/ Luciano KWS F1	1) 22 Aug 2022 2) 19 Apr – 13 May 2023 3) 17 July 2023	108	250	43.2	05 May 2023	BBCH 65	seed	n.d	0.40	n.d.	n.d.	0.02	73 (NCH)	NCH – normal commercial harvest, PHI is not relevant
EU-23-1359-03 Wola Kałkowa (woj. łódzkie)	Winter oilseed rape/ Gemini	1) 18 Aug 2022 2) 04 May – 26 May 2023 3) 17 July 2023	108	250	43.2	05 May 2023	BBCH 65	whole plant whole plant whole plant whole plant seed	1.4 0.05 0.02 <0.01 n.d.	0.05 0.05 0.04 0.09 0.67	n.d. n.d. n.d n.d. n.d.	n.d. n.d. n.d <0.01 <0.01	n.d. n.d. <0.01 0.01 0.03	0 DALA 14 DALA 32 DALA 64 DALA 73 (NCH)	NCH – normal commercial harvest, PHI is not relevant
EU-23-1359-04 Murczyn (woj. kujawsko-pomorskie)	Winter oilseed rape/ LG Acapulko F1	1) 26 Aug 2022 2) 02-12 May 2023 3) 21 July 2023	108	250	43.2	12 May 2023	BBCH 65	whole plant whole plant whole plant whole plant seed	1.1 0.13 0.02 n.d n.d.	0.05 0.09 0.13 0.03 0.48	n.d. n.d. n.d n.d. n.d.	n.d. n.d. <0.01 <0.01 <0.01	n.d. n.d. <0.01 <0.01 0.02	0 DALA 14 DALA 32 DALA 64 DALA 73 (NCH)	NCH – normal commercial harvest, PHI is not relevant

n.d – not detected, below LOD
(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:	The study is accepted. The trials are independed and valid with regard to storage stability data. Acceptable analytical methods were used. The limit of quantification (LOQ) for difenoconazole was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg

Reference:	K.C.P. 7.3.2
Report	**Field phase:** Study to generate samples of winter oilseed rape following one application of Tores 250 EC for Subsequent Residue Analysis. 4 sites in Northern Europe 2023, S23-103623, Lines J., 2024. **Analytical phase:** Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of TORES in four trials in Northern Europe, S23-103661, Schernikau N., 2024.
Guideline(s):	Yes (OECD Guidelines for the testing of chemicals on Crop Field Trial 509, SANTE/2020/12830, Rev.2)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four residue trials (2 harvest studies and 2 decline curve residue studies) were conducted on winter oilseed rape during 2023: one in Romania, two in Germany and one on Northern France. One application of Tores 250 EC (250 g/L, difenoconazole) was applied at a target rate of 125 g ai/ha at BBCH 65.
Oilseed rape samples were harvested at normal commercial harvest (in residue harvest studies) and 0, 14±2, 32±3, 64±3 and normal commercial harvest (NCH) days after last application (in residue decline studies). Untreated plot was sampled first. Samples were frozen at a freezer at temperature below -18°C. Samples were analyzed within 30 days after sampling.

The analytical method for each compound was validated in according to EC Guidance Documents SANTE/2020/12830, Rev.2.

Difenoconazole
The analyte difenoconazole was determined in the final extracts by use the LC-MS/MS detection with evaluation of one (1) mass transition. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of target analyte.
The range of linearity of the analytical graph of difenoconazole varied from 0.075 ng/mL to 7.5 ng/ml (0.003 – 0.3 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg.
The mean extraction recovery levels and precision in oilseed rape samples (whole plant and seed) are presented below:

Mass Transition	Fortification Level (mg/kg)	Mean recovery (%)	RSD (%)
Difenoconazole (whole plant)			
m/z 406→251*	0.01	97	2.5
	0.1	90	1.1
m/z 406→188	0.01	98	3.8
	0.1	94	1.4
Difenoconazole (seeds)			

m/z 406→251*	0.01	77	1.8
	0.1	75	3.6
m/z 406→188	0.01	79	1.7
	0.1	74	3.1

*quantification ion

The effect of oilseed rape (whole plant and seed) matrix on the detector response of difenoconazole was assessed by comparing peak areas of matrix-matched standards (90 % matrix amount) with solvent standards at the same nominal concentrations. Assessment of matrix effects for difenoconazole was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 0.25 ng/mL, 0.50 ng/mL, 1.0 ng/mL, 2.5 ng/mL, 5.0 ng/mL and 7.5 ng/mL. The matrix effect for whole plant ranged from (-) 1.1 to (-) 10 and from (-) 22 to (-) 31 for seeds. Matrix effects were ≥ ± 20 % and deemed to be significant for oilseed rape (seed). Therefore, matrix-matched standards were used for quantification throughout the analytical phase.
The limit of quantification (LOQ) for difenoconazole was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg.

Triazole derivative metabolites
The analytes 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid were determined in the final sample extracts by addition of isotopically labelled standards and by use of LC DMS-MS/MS detection.
For **triazole alanine (TA)**, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity for validation samples but was not used for quantification of samples. For **1,2,4-triazole (1,2,4-T)**, **triazole acetic acid (TAA)** and **triazole lactic acid (TLA)**, one (1) mass transition was evaluated. A confirmatory run was performed on a different stationary phase for validation samples but was not used for quantification of samples
The range of linearity of the analytical graph of TA, 1,2,4-T, TAA and TLA varied from 0.30 ng/mL to 30 ng/ml (0.003 – 0.3 mg/kg). The linear coefficient r^2 was higher than 0.99. For 1,2,4-Triazole, TA, TAA and TLA calibration standards contained the internal standards at a constant concentration level of 25 ng/mL.
The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg.
The mean extraction recovery levels and precision in oilseed rape samples (whole plant and seed) are presented below:

Mass Transition	Fortification Level (mg/kg)	Mean recovery (%)	Rel. Std. Dev. (%)
1,2,4-Triazole (whole plant)			
m/z 70→43*	0.01	99	7.7
	0.1	97	2.8
m/z 70→43	0.01	92	13
	0.1	90	7.1
1,2,4-Triazole (seeds)			
m/z 70→43*	0.01	92	6.1
	0.1	85	2.7
m/z 70→43	0.01	86	8.9
	0.1	77	4.3
Triazole alanine (whole plant)			
m/z 157→70*	0.01	85	6.0
	0.1	89	1.6

m/z 157→88	0.01	85	4.2
	0.1	84	3.1
Triazole alanine (seeds)			
m/z 157→70*	0.01	76	26
	0.1	79	5.1
m/z 157→88	0.01	79	19
	0.1	82	6.3
Triazole lactic acid (whole plant)			
m/z 158→70*	0.01	90	6.8
	0.1	96	2.5
m/z 158→70)	0.01	89	13
	0.1	98	2.9
Triazole lactic acid (seeds)			
m/z 158→70*	0.01	81	4.5
	0.1	94	2.6
m/z 158→70)	0.01	90	2.3
	0.1	95	6.1
Triazole acetic acid (whole plant)			
m/z 128→70*	0.01	91	4.6
	0.1	95	3.0
m/z 128→70	0.01	87	14
	0.1	100	4.2
Triazole acetic acid (seeds)			
m/z 128→70*	0.01	80	4.0
	0.1	95	1.6
m/z 128→70	0.01	80	6.2
	0.1	95	3.8

*quantification ion

Isotopically labelled internal standard was used for quantification of the triazole metabolites 1,2,4-triazole, TA, TAA and TLA so that possible matrix effects on the detector response are automatically compensated when using the response ratio of analyte to internal standard for quantification. Therefore, matrix effects on detection were not determined.

The limit of quantification (LOQ) for TA, 1,2,4-T, TAA and TLA was 0.01 mg/kg and the limit of detection was 0.03 mg/kg.

Table A 5: Summary of the study 2 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				Difeno-conazole	TA	1,2,4-T	TAA	TLA		
S23-103623-01 Romania/ Northern Zone 2023	Winter oilseed rape/	1. 10 Oct 2022 2. 17 Apr - 19 May 2023	125	200-300	41,7 -62,5	27 Apr 2023	BBCH 65	seed	n.d	3.8	n.d.	0.04	0.17	78 (NCH)	NCH – normal commercial harvest, PHI is not relevant
S23-103623-02 Germany/ Northern Zone 2023 21784, Gever-sodof, Nieder-sachsen,	Winter oilseed rape/	1. 22 Aug 2022 2. 28 Apr - 25 May 2023	125	200-300	41,7 -62,5	01 May 2023	BBCH 65	seed	n.d	0.16	n.d.	n.d	<0.01	93 (NCH)	NCH – normal commercial harvest, PHI is not relevant
S23-103623-03 North France/ Northern Zone 2023	Winter oilseed rape/	1. 20 Aug 2022 2. 08 Apr - 15 May 2023	125	200-300	41,7 -62,5	26 Apr 2023	BBCH 65	whole plant whole plant whole plant whole plant seed	3.6 0.20 0.01 0.03 n.d.	0.06 0.04 0.09 0.09 0.30	n.d. n.d. n.d n.d. n.d.	n.d. n.d. n.d <0.01 <0.01	n.d. n.d. <0.01 0.02 0.02	0 DALA 14 DALA 32 DALA 64 DALA 77 (NCH)	NCH – normal commercial harvest, PHI is not relevant
S23-103623-04 Germany/ Northern Zone 2023 16356 Blum-berg, Branden-burg	Winter oilseed rape/	1. 28 Aug 2022 2. 24 Apr - 22 May 2023	125	200-300	41,7 -62,5	11 May 2023	BBCH 65	whole plant whole plant whole plant whole plant seed	1.7 0.03 <0.01 <0.01 n.d.	0.04 0.19 0.12 0.15 0.73	n.d. n.d. n.d n.d. n.d.	n.d. n.d. <0.01 <0.01 <0.01	n.d. <0.01. <0.01 0.01 0.02	0 DALA 14 DALA 32 DALA 64 DALA 70 (NCH)	NCH – normal commercial harvest, PHI is not relevant

n.d – not detected, below LOD = 0.003 mg/kg
(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

Not required.

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

Not required.

A 2.1.6 Magnitude of residues in representative succeeding crops

Not required.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1

Comments of zRMS:	Study is acceptable

Reference:	KCP 7.2.7
Report	**Field phase:** Honey residue study with difenoconazole on Phacelia after application of TORES 250 EC Poland-2023. Study number EU-23-1667, Kurek-Molenda M., 2023. **Field phase:** Study to generate samples of honey after two application of TORES 250 EC in *Phacelia tanacetifolia* for subsequent residue analysis at two sites in Gemany in 2023. Study number S23-103847, Portail B., 2024. **Analytical phase:** Determination of the residues of difenoconazole and triazoles derivative metabolites in honey following application of Tores 250 EC in four trials in Northern Europe 2023. Study number S23-103664, Schernikau N., 2023.
Guideline(s):	Yes (SANTE/11956/2016 rev. 9 and SANTE/2020/12830, Rev.2)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Four honey residue studies in *Phacelia tanacetifolia* plants were carried out in Northern Europe in 2023.

Location	Number of trials	Crop	Applications
Poland	2	Phacelia	1x 150 g a.s./ha, BBCH 61-65
Germany	2	Phacelia	2x 125 g a.s./ha, BBCH 55-58 and 63-65

Studies in Poland

In Poland studies product TORES 250 EC (difenoconazole 250 g/kg) was applied one-time at a rate of 150 g of difenoconazole during flowering at BBCH 61-65, under semi-field conditions. Trials sites were situated at different locations at a distance of over 200 km. Two tunnels, each of at least 200 m^2 with a mesh covering, were erected over Phacelia plants at least one day prior to the foliar spray application. There was 1 replicate for untreated control group and 1 replicate for the treated group. Application was conducting in the morning without the presence of flying bee.
Honeybee colonies were assessed and selected 2-3 days prior the application.
Honey was sampled mature at comb-closure and water content is < 20%. Samples from control tunnels were taken first. Samples were frozen at a freezer at temperature below -18°C. Samples were analyzed within 30 days after sampling.

Studies in Germany

Two separate field trials were conducted in Germany in 2023 in *Phacelia tanacetifolia*. In each trial, product TORES 250 EC was applied twice at a target rate of 0.5 L product/ha (125 g difenoconazole/ha).

The first applications were performed at BBCH 55-58 and the second applications at BBCH 63-65. For each application, the product was diluted in water immediately prior to application to a total spray volume of 300 L/ha. In all trials, the plot area covered with tunnels was 200 m².
Honeybee colonies (*Apis mellifera* L.) were used as sampling device. One hive was set up per tunnel in the evening one day before the second application. The colony strength across both trials varied from 7371 to 8190 bees at the 1st colony assessment and from 9126 to 12227 bees at the 2nd colony assessment.
Honey was sampled when water content was ≤ 20 %, except in the control sample of trial 02 (water content: 20.4%). The honey samples were frozen shortly after sampling and were stored in frozen conditions (≤ -18°C) at the test sites. Samples were analyzed within 30 days after sampling.

The analytical method for evaluation of difenoconazole and TDMs in honey was validated in according to EC Guidance Documents SANTE/2020/12830, Rev.2.

Difenoconazole
The analyte difenoconazole was determined in the final extracts by use the LC-MS/MS detection with evaluation of one (1) mass transition. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of target analyte.
The range of linearity of the analytical graph of difenoconazole varied from 0.075 ng/mL to 7.5 ng/ml (0.003 – 0.3 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg.
The mean extraction recovery levels and precision in honey samples are presented below:

Mass Transition	Fortification Level (mg/kg)	Mean recovery (%)	RSD (%)
Difenoconazole			
m/z 406→251*	0.01	108	8.3
	0.1	95	6.1
m/z 406→188	0.01	111	6.1
	0.1	104	4.5

*quantification ion

The effect of matrix on the detector response of difenoconazole was assessed by comparing peak areas of matrix-matched standards (90 % matrix amount) with solvent standards at the same nominal concentrations. Assessment of matrix effects for difenoconazole was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 0.25 ng/mL, 0.50 ng/mL, 1.0 ng/mL, 2.5 ng/mL, 5.0 ng/mL and 7.5 ng/mL. The matrix effect for whole plant ranged from (-)17 to (+)14. Matrix effects were < ± 20 % and deemed to be insignificant.
The limit of quantification (LOQ) for difenoconazole was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg.

Triazole derivative metabolites
The analytes 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid were determined in the final sample extracts by addition of isotopically labelled standards and by use of LC DMS-MS/MS detection.
For **triazole alanine (TA)**, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity for validation samples but was not used for quantification of samples. For **1,2,4-triazole (1,2,4-T)**, **triazole acetic acid (TAA)** and **triazole lactic acid (TLA)**, one (1) mass transition was evaluated. A confirmatory run was performed on a different stationary phase for validation samples but was not used for quantification of samples.
The range of linearity of the analytical graph of TA, 1,2,4-T, TAA and TLA varied from 0.30 ng/mL to 30 ng/ml (0.003 – 0.3 mg/kg). The linear coefficient r^2 was higher than 0.99. For 1,2,4-Triazole, TA,

TAA and TLA calibration standards contained the internal standards at a constant concentration level of 25 ng/mL.
The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg.
The mean extraction recovery levels and precision in honey samples are presented below:

Mass Transition	Fortification Level (mg/kg)	Mean recovery (%)	Rel. Std. Dev. (%)
1,2,4-Triazole			
m/z 70→43*	0.01	91	6.3
	0.1	91	4.1
m/z 70→43	0.01	96	12
	0.1	88	5.9
Triazole alanine			
m/z 157→70*	0.01	88	3.4
	0.1	91	3.7
m/z 157→88	0.01	88	8.1
	0.1	90	5.0
Triazole lactic acid			
m/z 158→70*	0.01	83	2.7
	0.1	87	4.9
m/z 158→70)	0.01	94	2.7
	0.1	87	6.8
Triazole acetic acid			
m/z 128→70*	0.01	88	4.0
	0.1	86	3.9
m/z 128→70	0.01	84	13
	0.1	82	8.1

*quantification ion

Isotopically labelled internal standard was used for quantification of the triazole metabolites 1,2,4-triazole, TA, TAA and TLA so that possible matrix effects on the detector response are automatically compensated when using the response ratio of analyte to internal standard for quantification. Therefore, matrix effects on detection were not determined.

The limit of quantification (LOQ) for TA, 1,2,4-T, TAA and TLA was 0.01 mg/kg and the limit of detection was 0.03 mg/kg.

Summary of the study trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Growth stage treat-ment	Portion ana-lyzed	Residues (mg/kg)					Details on trial (d)
			g a.s./ ha	Water (l/ha)	g a.s./hl			Difenocona-zole	TA	1,2,4-T	TAA	TLA	
EU-23-1667-01 /Poland/Kłoda (woj. wielkopolskie)	Phacelia/ Stella	2. 15 Jun -07 Jul 2023	150	300	50	BBCH 61-65	honey	n.d	0.01	n.d.	n.d.	n.d.	
EU-23-1667-02/ Poland/ Wikcinek (woj. mazowieckie)	Phacelia/ Stella	2. 19 Jun -10 Jul 2023	150	300	50	BBCH 61-65	honey	n.d	<0.01	n.d.	n.d.	n.d.	
S23-103847-01/ Germany	Phacelia/ Asta	1. 24 Jun 2023	125	300	41.7	BBCH 55-58 BBCH 63-65	honey	n.d.	< 0.01	n.d.	n.d.	n.d.	
S23-103847-02/ Germany	Phacelia/ Not available	1. 20 May 2023	125	300	41.7	BBCH 55-58 BBCH 63-65	honey	n.d.	n.d.	n.d.	n.d.	n.d.	

n.d – not detected, below LOD = 0.003 mg/kg

(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

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Difenoconazole

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Difenoconazole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,16**
Source of ADI:	**European Comission**	Source of ARfD:	**European Comission**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Input values

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

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

Comments:

Use hyperl

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/EDI calculation (based on average food consumption)	96%	NL toddler	9,61	17%	Apples	8%	Beans (with pods)	8%	Table grapes		0,5%
	75%	DE child	7,52	20%	Apples	7%	Tomatoes	7%	Table grapes		0,4%
	74%	GEMS/Food G06	7,42	26%	Tomatoes	17%	Rice	5%	Table grapes		0,8%
	57%	GEMS/Food G11	5,68	7%	Tomatoes	6%	Celeriacs/turnip rooted celeries	5%	Wine grapes		0,7%
	57%	GEMS/Food G10	5,66	14%	Rice	10%	Tomatoes	3%	Chinese cabbages/pe-tsai		0,7%
	57%	IE adult	5,65	7%	Wine grapes	4%	Other leafy brassica	4%	Sweet potatoes		0,2%
	52%	PT general	5,19	13%	Wine grapes	9%	Rice	6%	Tomatoes		0,4%
	52%	GEMS/Food G07	5,19	8%	Tomatoes	8%	Wine grapes	4%	Rice		0,7%
	50%	NL child	5,03	9%	Apples	5%	Table grapes	4%	Tomatoes		0,5%
	49%	GEMS/Food G08	4,88	8%	Tomatoes	5%	Wine grapes	4%	Potatoes		0,6%
	46%	FR child 3 15 yr	4,62	6%	Tomatoes	5%	Oranges	5%	Rice		0,5%
	46%	GEMS/Food G15	4,60	9%	Tomatoes	5%	Wine grapes	4%	Potatoes		0,6%
	43%	FR toddler 2 3 yr	4,31	8%	Beans (with pods)	7%	Rice	5%	Apples		0,3%
	43%	RO general	4,29	14%	Tomatoes	9%	Wine grapes	4%	Potatoes		0,5%
	40%	SE general	3,98	6%	Tomatoes	4%	Rice	4%	Potatoes		0,3%
	38%	ES child	3,78	7%	Tomatoes	5%	Rice	3%	Oranges		0,4%
	35%	DE women 14-50 yr	3,52	5%	Tomatoes	4%	Wine grapes	4%	Apples		0,2%
	34%	UK infant	3,39	7%	Rice	6%	Peas (without pods)	3%	Potatoes		0,3%
	33%	UK toddler	3,31	6%	Rice	4%	Tomatoes	3%	Potatoes		0,4%
	33%	FR adult	3,26	12%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)		0,2%
	33%	DE general	3,26	5%	Tomatoes	4%	Wine grapes	4%	Apples		0,2%
	31%	DK child	3,12	6%	Rye	4%	Tomatoes	4%	Apples		0,4%
	30%	NL general	3,04	3%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)		0,2%
	30%	ES adult	2,96	6%	Tomatoes	3%	Lettuces	3%	Rice		0,2%
	29%	IT toddler	2,89	10%	Tomatoes	2%	Rice	2%	Lettuces		0,7%
	27%	IT adult	2,70	8%	Tomatoes	2%	Rice	2%	Lettuces		0,4%
	27%	FI 3 yr	2,67	6%	Rice	5%	Potatoes	4%	Tomatoes		0,1%
	24%	UK vegetarian	2,38	4%	Tomatoes	4%	Wine grapes	4%	Rice		0,2%
	22%	UK adult	2,18	6%	Wine grapes	4%	Rice	3%	Tomatoes		0,2%
	21%	FI 6 yr	2,12	5%	Rice	4%	Potatoes	3%	Tomatoes		0,1%
	21%	DK adult	2,07	5%	Wine grapes	4%	Tomatoes	2%	Apples		0,1%
	20%	FR infant	2,03	5%	Beans (with pods)	3%	Apples	2%	Potatoes		0,1%
	20%	PL general	2,01	6%	Tomatoes	3%	Potatoes	3%	Apples		0,0%
	18%	LT adult	1,80	4%	Tomatoes	3%	Potatoes	3%	Apples		0,1%
	17%	FI adult	1,75	4%	Tomatoes	3%	Coffee beans	2%	Wine grapes		0,0%
	8%	IE child	0,80	3%	Rice	0,9%	Beans (without pods)	0,6%	Potatoes		0,1%

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

1,2,4-triazole (1,2,4-T)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,2,4-triazole (1,2,4-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:	SANCO/830/0	Source of ARfD:	SANCO/830/08 – rev. 3 1
Year of evaluation:	2020	Year of evaluation:	2020

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Use hyperlink to

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)	0,4%	GEMS/Food G06	0,09	0,3%	Wheat	0,1%	Soyabeans	0,0%	Sunflower seeds		
	0,3%	GEMS/Food G10	0,08	0,2%	Wheat	0,1%	Soyabeans	0,0%	Rapeseeds/canola seeds		
	0,3%	GEMS/Food G11	0,07	0,2%	Soyabeans	0,2%	Wheat	0,0%	Sunflower seeds		
	0,3%	GEMS/Food G15	0,07	0,2%	Wheat	0,1%	Soyabeans	0,0%	Sunflower seeds		
	0,3%	GEMS/Food G07	0,07	0,2%	Wheat	0,1%	Soyabeans	0,0%	Rapeseeds/canola seeds		
	0,3%	GEMS/Food G08	0,07	0,2%	Wheat	0,1%	Soyabeans	0,0%	Sunflower seeds		
	0,3%	IT toddler	0,07	0,3%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,2%	RO general	0,06	0,2%	Wheat	0,0%	Sunflower seeds				
	0,2%	NL toddler	0,05	0,2%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
	0,2%	NL child	0,05	0,2%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
	0,2%	FR child 3 15 yr	0,05	0,2%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,2%	ES child	0,05	0,2%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,2%	PT general	0,05	0,2%	Wheat	0,0%	Soyabeans	0,0%	Sunflower seeds		
	0,2%	DK child	0,04	0,2%	Wheat	0,0%	Rapeseeds/canola seeds				
	0,2%	DE child	0,04	0,2%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,2%	IT adult	0,04	0,2%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,2%	UK toddler	0,04	0,2%	Wheat		FRUIT AND TREE NUTS				
	0,1%	FR toddler 2 3 yr	0,03	0,1%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,1%	SE general	0,03	0,1%	Wheat		FRUIT AND TREE NUTS				
	0,1%	IE adult	0,03	0,1%	Wheat	0,0%	Sunflower seeds	0,0%	Linseeds		
	0,1%	UK infant	0,03	0,1%	Wheat		FRUIT AND TREE NUTS				
	0,1%	NL general	0,03	0,1%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
	0,1%	ES adult	0,02	0,1%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,1%	FR adult	0,02	0,1%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,1%	DE women 14-50 yr	0,02	0,1%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,1%	UK vegetarian	0,02	0,1%	Wheat		FRUIT AND TREE NUTS				
	0,1%	DE general	0,02	0,1%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,1%	UK adult	0,02	0,1%	Wheat		FRUIT AND TREE NUTS				
	0,1%	FI 3 yr	0,01	0,1%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
	0,1%	IE child	0,01	0,1%	Wheat	0,0%	Linseeds				
	0,0%	DK adult	0,01	0,0%	Wheat		FRUIT AND TREE NUTS				
	0,0%	LT adult	0,01	0,0%	Wheat	0,0%	Sunflower seeds				
	0,0%	FI 6 yr	0,01	0,0%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
	0,0%	FR infant	0,01	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,0%	FI adult	0,00	0,0%	Wheat	0,0%	Soyabeans	0,0%	Sunflower seeds		
	0,0%	PL general	0,00	0,0%	Sunflower seeds	0,0%	Soyabeans	0,0%	Poppy seeds		

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 (1,2,4-T) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Triazole alanine (TA) and Triazole Lactic Acid (TLA)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole alanine (TA) and 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:	SANCO/830/	Source of ARfD:	SANCO/830/08 – rev. 3 1
Year of evaluation:	2020	Year of evaluation:	2020

Input values

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

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

Comments: Use

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)	0,6%	GEMS/Food G11	1,88	0,6%	Soyabeans	0,0%	Sunflower seeds	0,0%	Wheat		
	0,6%	GEMS/Food G10	1,85	0,5%	Soyabeans	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
	0,5%	GEMS/Food G08	1,38	0,3%	Soyabeans	0,1%	Sunflower seeds	0,1%	Rapeseeds/canola seeds		
	0,4%	GEMS/Food G07	1,34	0,3%	Soyabeans	0,1%	Rapeseeds/canola seeds	0,1%	Sunflower seeds		
	0,4%	GEMS/Food G15	1,24	0,3%	Soyabeans	0,1%	Sunflower seeds	0,0%	Rapeseeds/canola seeds		
	0,3%	GEMS/Food G06	0,78	0,2%	Soyabeans	0,0%	Sunflower seeds	0,0%	Wheat		
	0,2%	NL toddler	0,71	0,2%	Rapeseeds/canola seeds	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,2%	NL child	0,54	0,1%	Rapeseeds/canola seeds	0,1%	Sunflower seeds	0,0%	Soyabeans		
	0,1%	RO general	0,37	0,1%	Sunflower seeds	0,0%	Wheat				
	0,1%	PT general	0,32	0,0%	Soyabeans	0,0%	Sunflower seeds	0,0%	Wheat		
	0,1%	NL general	0,31	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,1%	IE adult	0,19	0,0%	Sunflower seeds	0,0%	Linseeds	0,0%	Wheat		
	0,1%	FR child 3 15 yr	0,19	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	FR toddler 2 3 yr	0,12	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	DE child	0,12	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	ES child	0,10	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	FR adult	0,09	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	DE women 14-50 yr	0,08	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	IT toddler	0,08	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,0%	ES adult	0,07	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	DE general	0,07	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	FI 3 yr	0,06	0,0%	Rapeseeds/canola seeds	0,0%	Wheat	0,0%	Sunflower seeds		
	0,0%	IT adult	0,05	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
	0,0%	DK child	0,04	0,0%	Wheat	0,0%	Rapeseeds/canola seeds				
	0,0%	FI 6 yr	0,04	0,0%	Rapeseeds/canola seeds	0,0%	Wheat	0,0%	Sunflower seeds		
	0,0%	UK toddler	0,04	0,0%	Wheat		FRUIT AND TREE NUTS				
	0,0%	SE general	0,03	0,0%	Wheat		FRUIT AND TREE NUTS				
	0,0%	LT adult	0,03	0,0%	Sunflower seeds	0,0%	Wheat				
	0,0%	UK infant	0,03	0,0%	Wheat		FRUIT AND TREE NUTS				
	0,0%	FR infant	0,02	0,0%	Sunflower seeds	0,0%	Wheat	0,0%	Soyabeans		
	0,0%	FI adult	0,02	0,0%	Soyabeans	0,0%	Sunflower seeds	0,0%	Wheat		
	0,0%	UK vegetarian	0,02	0,0%	Wheat		FRUIT AND TREE NUTS				
	0,0%	UK adult	0,02	0,0%	Wheat		FRUIT AND TREE NUTS				
	0,0%	IE child	0,01	0,0%	Wheat	0,0%	Linseeds				
	0,0%	DK adult	0,01	0,0%	Wheat		FRUIT AND TREE NUTS				
	0,0%	PL general	0,00	0,0%	Sunflower seeds	0,0%	Soyabeans	0,0%	Poppy seeds		

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

Triazole acetic acid (TAA)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

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:	SANCO/830/08 – rev. 3 1	Source of ARfD:	SANCO/830/08 – rev. 3 1
Year of evaluation:	2020	Year of evaluation:	2020

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: Use hyperlink to sv

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0,0%	GEMS/Food G10	0,11	0,0%	Soyabeans	0,0%	Wheat	0,0%	Rapeseeds/canola seeds		
0,0%	GEMS/Food G11	0,11	0,0%	Soyabeans	0,0%	Wheat	0,0%	Sunflower seeds		
0,0%	GEMS/Food G06	0,10	0,0%	Wheat	0,0%	Soyabeans	0,0%	Sunflower seeds		
0,0%	GEMS/Food G08	0,10	0,0%	Wheat	0,0%	Soyabeans	0,0%	Sunflower seeds		
0,0%	GEMS/Food G07	0,10	0,0%	Wheat	0,0%	Soyabeans	0,0%	Rapeseeds/canola seeds		
0,0%	GEMS/Food G15	0,10	0,0%	Wheat	0,0%	Soyabeans	0,0%	Sunflower seeds		
0,0%	NL toddler	0,07	0,0%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
0,0%	IT toddler	0,07	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	RO general	0,06	0,0%	Wheat	0,0%	Sunflower seeds				
0,0%	NL child	0,06	0,0%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
0,0%	FR child 3 15 yr	0,05	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	PT general	0,05	0,0%	Wheat	0,0%	Soyabeans	0,0%	Sunflower seeds		
0,0%	ES child	0,05	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	DE child	0,05	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	DK child	0,04	0,0%	Wheat	0,0%	Rapeseeds/canola seeds				
0,0%	IT adult	0,04	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	UK toddler	0,04	0,0%	Wheat		FRUIT AND TREE NUTS				
0,0%	FR toddler 2 3 yr	0,03	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	SE general	0,03	0,0%	Wheat		FRUIT AND TREE NUTS				
0,0%	NL general	0,03	0,0%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
0,0%	IE adult	0,03	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Linseeds		
0,0%	UK infant	0,03	0,0%	Wheat		FRUIT AND TREE NUTS				
0,0%	ES adult	0,03	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	FR adult	0,03	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	DE women 14-50 yr	0,02	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	DE general	0,02	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	UK vegetarian	0,02	0,0%	Wheat		FRUIT AND TREE NUTS				
0,0%	UK adult	0,02	0,0%	Wheat		FRUIT AND TREE NUTS				
0,0%	FI 3 yr	0,01	0,0%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
0,0%	IE child	0,01	0,0%	Wheat	0,0%	Linseeds				
0,0%	LT adult	0,01	0,0%	Wheat	0,0%	Sunflower seeds				
0,0%	DK adult	0,01	0,0%	Wheat		FRUIT AND TREE NUTS				
0,0%	FI 6 yr	0,01	0,0%	Wheat	0,0%	Rapeseeds/canola seeds	0,0%	Sunflower seeds		
0,0%	FR infant	0,01	0,0%	Wheat	0,0%	Sunflower seeds	0,0%	Soyabeans		
0,0%	FI adult	0,00	0,0%	Wheat	0,0%	Soyabeans	0,0%	Sunflower seeds		
0,0%	PL general	0,00	0,0%	Sunflower seeds	0,0%	Soyabeans	0,0%	Poppy seeds		

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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IESTI calculations - Raw commodities

Difenoconazole

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

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

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

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

Show results of IESTI calculation only for crops with GAPs under assessment

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)
0,09%	Wheat	0,1 / 0,01	0,14
0,01%	Soyabeans	0,1 / 0,01	0,02
0,01%	Rapeseeds/canola seeds	0,5 / 0,01	0,01
0,01%	Linseeds	0,2 / 0,01	0,01

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%	Wheat	0,1 / 0,01	0,08
0,03%	Soyabeans	0,1 / 0,01	0,06
0,00%	Poppy seeds	0,05 / 0,01	0,01
0,00%	Rapeseeds/canola seeds	0,5 / 0,01	0,01
0,00%	Linseeds	0,2 / 0,01	0,00

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,9%	Wheat	0,1 / 0,1	1,4
0,4%	Rapeseeds/canola seeds	0,5 / 0,5	0,69
0,1%	Soyabeans	0,1 / 0,1	0,23
0,1%	Linseeds	0,2 / 0,2	0,21

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,5%	Wheat	0,1 / 0,1	0,84
0,3%	Soyabeans	0,1 / 0,1	0,55
0,2%	Rapeseeds/canola seeds	0,5 / 0,5	0,26
0,06%	Linseeds	0,2 / 0,2	0,10
0,02%	Poppy seeds	0,05 / 0,05	0,04

1,2,4-triazole (1,2,4-T)

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

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,1%	Wheat	0 / 0,01	0,14
0,03%	Sunflower seeds	0 / 0,01	0,03
0,02%	Soyabeans	0 / 0,01	0,02
0,01%	Rapeseeds/canola seeds	0 / 0,01	0,01
0,01%	Linseeds	0 / 0,01	0,01
0,01%	Mustard seeds	0 / 0,01	0,01

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)
0,08%	Wheat	0 / 0,01	0,08
0,06%	Soyabeans	0 / 0,01	0,06
0,01%	Sunflower seeds	0 / 0,01	0,01
0,01%	Poppy seeds	0 / 0,01	0,01
0,01%	Poppy seeds	0 / 0,01	0,01
0,01%	Rapeseeds/canola seeds	0 / 0,01	0,01
0,00%	Linseeds	0 / 0,01	0,00

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

Triazole alanine (TA) and Triazole lactic acid (TLA)

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

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

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

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

Show results for all crops

Unprocessed commodities

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

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

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,5%	Sunflower seeds	0 / 0,48	1,5
0,4%	Soyabeans	0 / 0,48	1,1
0,2%	Rapeseeds/canola seeds	0 / 0,48	0,66
0,2%	Linseeds	0 / 0,48	0,51
0,2%	Mustard seeds	0 / 0,48	0,49
0,05%	Wheat	0 / 0,01	0,14

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,9%	Soyabeans	0 / 0,48	2,6
0,2%	Sunflower seeds	0 / 0,48	0,48
0,1%	Poppy seeds	0 / 0,48	0,34
0,1%	Poppy seeds	0 / 0,48	0,34
0,08%	Rapeseeds/canola seeds	0 / 0,48	0,25
0,08%	Linseeds	0 / 0,48	0,23
0,03%	Wheat	0 / 0,01	0,08

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

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

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

Triazole acetic acid (TAA)

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

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,01%	Wheat	0 / 0,01	0,14
0,01%	Sunflower seeds	0 / 0,02	0,06
0,00%	Soyabeans	0 / 0,02	0,05
0,00%	Rapeseeds/canola	0 / 0,02	0,03
0,00%	Linseeds	0 / 0,02	0,02
0,00%	Mustard seeds	0 / 0,02	0,02

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)
0,01%	Soyabeans	0 / 0,02	0,11
0,01%	Wheat	0 / 0,01	0,08
0,00%	Sunflower seeds	0 / 0,02	0,02
0,00%	Poppy seeds	0 / 0,02	0,01
0,00%	Poppy seeds	0 / 0,02	0,01
0,00%	Rapeseeds/canola seeds	0 / 0,02	0,01
0,00%	Linseeds	0 / 0,02	0,01

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

A 3.3 IESTI calculations - Processed commodities

Difenoconazole

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,1%	Wheat / milling (flour)	0,1 / 0,01	0,12	0,0%	Wheat / bread/pizza	0,1 / 0,01	0,04	0,8%	Wheat / milling (flour)	0,1 / 0,1	1,2	0,3%	Wheat / bread/pizza	0,1 / 0,1	0,44
0,0%	Wheat / milling (wholemeal)-baking	0,1 / 0,01	0,06	0,02%	Wheat / pasta	0,1 / 0,01	0,04	0,3%	Wheat / milling (wholemeal)-	0,1 / 0,1	0,55	0,2%	Wheat / pasta	0,1 / 0,1	0,38
0,0%	Soyabeans / soya drink	0,1 / 0,01	0,04	0,02%	Wheat / bread (wholemeal)	0,1 / 0,01	0,03	0,3%	Soyabeans / soya drink	0,1 / 0,1	0,42	0,2%	Wheat / bread (wholemeal)	0,1 / 0,1	0,35
0,0%	Soyabeans / boiled	0,1 / 0	0,01	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,2%	Rapeseeds / oils	0,5 / 1	0,29	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Rapeseeds / oils	0,5 / 0,02	0,01	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,09%	Soyabeans / boiled	0,1 / 0,04	0,15	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list															

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

1,2,4-triazole (1,2,4-T)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,1%	Wheat / milling (flour)	0 / 0,01	0,12	0,0%	Wheat / bread/pizza	0 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,1%	Wheat / milling (wholemeal)-baking	0 / 0,01	0,06	0,04%	Wheat / pasta	0 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Soyabeans / soya drink	0 / 0,01	0,04	0,03%	Wheat / bread (wholemeal)	0 / 0,01	0,03	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Sunflower seeds / oils	0 / 0,02	0,02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Soyabeans / boiled	0 / 0	0,01	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Rapeseeds / oils	0 / 0,02	0,01	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list															

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 (1,2,4-T) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Triazole alanine (TA) and Triazole lactic acid (TLA)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,7%	Soyabeans / soya drink	0 / 0,48	2,0	0,0%	Wheat / bread/pizza	0 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,4%	Sunflower seeds / oils	0 / 0,96	1,1	0,01%	Wheat / pasta	0 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,2%	Soyabeans / boiled	0 / 0,19	0,70	0,01%	Wheat / bread	0 / 0,01	0,03	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,1%	Rapeseeds / oils	0 / 0,96	0,28	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Wheat / milling (flour)	0 / 0,01	0,12	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Wheat / milling (wholemeal)-bakir	0 / 0,01	0,06	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list															

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

Triazole acetic acid (TAA)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,0%	Wheat / milling (flour)	0 / 0,01	0,12	0,0%	Wheat / bread/pizza	0 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Soyabeans / soya drink	0 / 0,02	0,08	0,00%	Wheat / pasta	0 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Wheat / milling (wholemea	0 / 0,01	0,06	0,00%	Wheat / bread	0 / 0,01	0,03	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Sunflower seeds / oils	0 / 0,04	0,05	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Soyabeans / boiled	0 / 0,01	0,03	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Rapeseeds / oils	0 / 0,04	0,01	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list															

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.

Appendix 4 Additional information provided by the applicant

Additional information is not required.